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

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2020

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 May 1, 2020, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 27,039,808.
Securities registered pursuant to Section 12(b) of the Act:

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

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
- 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)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 56,514	$ 20,462
Short-term investments	65,256	120,089
Accounts receivable, net of allowances for doubtful accounts of $11,840 and $9,049 as of March 31, 2020 and December 31, 2019, respectively	24,211	23,867
Inventory	4,227	4,037
Prepaid expenses and other current assets	4,223	4,337
Total current assets	154,431	172,792
Long-term investments	—	8,030
Property and equipment, net	28,454	26,464
Operating lease right-of-use assets	89,249	90,124
Goodwill	862	862
Other assets	9,944	7,940
Total assets	$ 282,940	$ 306,212
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,544	$ 8,243
Accrued liabilities	23,247	32,714
Deferred revenue	1,115	1,251
Debt, current portion	4,861	1,944
Operating lease liabilities, current portion	8,078	7,914
Total current liabilities	42,845	52,066
Debt, noncurrent portion	30,076	32,989
Operating lease liabilities, noncurrent portion	85,042	85,748
Total liabilities	157,963	170,803
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value – 5,000,000 shares authorized at March 31, 2020 and December 31, 2019; and none issued and outstanding at March 31, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value – 100,000,000 shares authorized at March 31, 2020 and December 31, 2019; 27,026,975 and 26,682,720 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	25	25
Additional paid-in capital	394,507	395,695
Accumulated other comprehensive income	364	82
Accumulated deficit	(269,919)	(260,393)
Total stockholders' equity	124,977	135,409
Total liabilities and stockholders' equity	$ 282,940	$ 306,212

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 March 31,	
	2020	**2019**
Revenue, net	$ 63,535	$ 48,334
Cost of revenue	16,063	11,773
Gross profit	47,472	36,561
Operating expenses:		
Research and development	8,415	6,699
Selling, general and administrative	48,230	38,066
Total operating expenses	56,645	44,765
Loss from operations	(9,173)	(8,204)
Interest expense	(380)	(409)
Other income, net	505	375
Loss before income taxes	(9,048)	(8,238)
Income tax provision	17	12
Net loss	$ (9,065)	$ (8,250)
Net loss per common share, basic and diluted	$ (0.34)	$ (0.34)
Weighted-average shares, basic and diluted	26,839,870	24,474,308

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 March 31,	
	2020	2019
Net loss	$ (9,065)	$ (8,250)
Other comprehensive income:		
Net change in unrealized gains on available-for-sale securities	282	43
Comprehensive loss	$ (8,783)	$ (8,207)

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)

	Three Months Ended March 31,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (9,065)	$ (8,250)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,551	621
Stock-based compensation	305	4,856
Amortization of debt discount and issuance costs	4	26
Accretion of discounts on investments, net of premium amortization	(171)	(227)
Provision for doubtful accounts and contractual allowances	9,184	5,411
Amortization of operating lease right-of-use assets	1,495	1,183
Changes in operating assets and liabilities:		
Accounts receivable	(9,989)	(12,392)
Inventory	(191)	(442)
Prepaid expenses and other current assets	114	(29)
Other assets	(2,002)	(365)
Accounts payable	(2,835)	(333)
Accrued liabilities	(9,467)	(6,061)
Deferred revenue	(136)	39
Operating lease liabilities	(1,163)	(1,200)
Net cash used in operating activities	(22,366)	(17,163)
Cash flows from investing activities		
Purchases of property and equipment	(3,405)	(1,705)
Purchases of available-for-sale investments	(8,009)	(9,616)
Sales of available-for-sale investments	14,525	—
Maturities of available-for-sale investments	56,800	37,700
Net cash provided by investing activities	59,911	26,379
Cash flows from financing activities		
Proceeds from issuance of common stock	2,969	2,120
Tax withholding upon vesting of restricted stock awards	(4,462)	(3,258)
Net cash used in financing activities	(1,493)	(1,138)
Net increase in cash and cash equivalents	36,052	8,078
Cash and cash equivalents beginning of period	20,462	20,023
Cash and cash equivalents end of period	$ 56,514	$ 28,101
Supplemental disclosures of cash flow information		
Interest paid	$ 394	$ 411
Non-cash investing and financing activities		
Property and equipment costs included in accounts payable and accrued liabilities	$ 136	$ 38
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 621	$ —

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				Accumulated Other	Total
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Comprehensive Income (Loss)	Stockholders' Equity
Balances at December 31, 2018	**24,368,073**	**$ 23**	**$ 257,955**	**$ (205,825)**	**$ (16)**	**$ 52,137**
Issuance of common stock in connection with employee equity incentive plans, net	260,570	1	2,120	—	—	2,121
Tax withholding upon vesting of restricted stock awards	—	—	(3,259)	—	—	(3,259)
Stock-based compensation expense	—	—	4,856	—	—	4,856
Net loss	—	—	—	(8,250)	—	(8,250)
Net change in unrealized gain on investments	—	—	—	—	43	43
Balances at March 31, 2019	**24,628,643**	**$ 24**	**$ 261,672**	**$ (214,075)**	**$ 27**	**$ 47,648**

	Common Stock				Accumulated Other	Total
	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Comprehensive Income (Loss)	Stockholders' Equity
Balances at December 31, 2019	**26,682,720**	**$ 25**	**$ 395,695**	**$ (260,393)**	**$ 82**	**$ 135,409**
Issuance of common stock in connection with employee equity incentive plans, net	344,255	—	2,969	—	—	2,969
Tax withholding upon vesting of restricted stock awards	—	—	(4,462)	—	—	(4,462)
Stock-based compensation expense	—	—	305	—	—	305
Accounting Standards Codification 326 cumulative effect adjustment upon adoption	—	—	—	(461)	—	(461)
Net loss	—	—	—	(9,065)	—	(9,065)
Net change in unrealized gain on investments	—	—	—	—	282	282
Balances at March 31, 2020	**27,026,975**	**$ 25**	**$ 394,507**	**$ (269,919)**	**$ 364**	**$ 124,977**

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 cardiac arrhythmias are clinically diagnosed by combining wearable biosensing technology with cloud-based data analytics and deep-learning capabilities. The Company began commercial operations in the United States in 2009 following clearance 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 Lincolnshire, Illinois and Houston, Texas and a manufacturing facility in Cypress, California. In March 2016, the Company formed a wholly-owned subsidiary in the United Kingdom. The Company manages its operations as a single operating segment. Substantially all of the Company's assets are maintained in the United States. The Company derives substantially all of its revenue from sales to customers in the United States.

On September 10, 2019, the Company issued and sold an aggregate of 1,575,342 shares (the "Shares") of common stock, in a public offering at a price of $73.00 per share. The Shares included the full exercise of the underwriters' option to purchase an additional 205,479 shares of common stock. Total proceeds received from the offering were $107.3 million, after deducting discounts and issuance costs.

Revision of Prior Period Financial Statements

In 2019, and as previously disclosed in the Company's Quarterly Report on Form 10-Q for the three and nine-months ended September 30, 2019, the Company identified errors in its historical accounting for revenues, contractual allowances, allowance for doubtful accounts and certain other items. The identified errors impacted the Company's accompanying 2017 annual financial statements, 2018 unaudited quarterly and audited annual financial statements and its 2019 unaudited first and second quarter financial statements. In accordance with SEC Staff Accounting Bulletin No. 99, "Materiality," and SEC Staff Accounting Bulletin No. 108,"Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements;" the Company evaluated the errors and determined that the related impacts were not material to any prior annual or interim period, but that correcting the cumulative impact of such errors would be significant to its results of operations for the three and nine months ended September 30, 2019 and the year-ended December 31, 2019. Accordingly, the Company has revised its previously issued financial statements to correct for such immaterial errors. A summary of the impact of the revisions to our previously issued interim financial statements for the three months ended March 31, 2019 is included in Note 13, Revision of Prior Period Financial Statements. The affected balances in the accompanying footnotes to these consolidated financial statements have also been revised accordingly.

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, or U.S. GAAP, and applicable rules and regulations of the Securities and Exchange Commission, or 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, 2019, 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 months ended March 31, 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2020, 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, 2019, included in the Company's annual report on Form 10-K, filed with the SEC on March 2, 2020.

Risks and Uncertainties

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, the fair value of the Company's common stock and 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.

As a result of the COVID-19 outbreak, the Company has experienced significant business disruptions, including restrictions on its ability to travel, reduction in access to customers due to diverted resources at hospitals, and shortened business hours as governments institute prolonged shelter-in-place and/or self-quarantine mandates.

Following recommendations from federal and local government and healthcare agencies, the Company transitioned employees to a remote work environment beginning in early March. For a small number of employees who continue to support essential operations at manufacturing facilities, the Company has instituted social distancing and other measures to ensure the safety of its employees.

While hospital systems and healthcare facilities shift their focus and resources to treating COVID-19 patients and combating the spread of the coronavirus, the Company has adapted its service to meet the immediate needs of physicians, customers, and patients and significantly increased the utilization of its home enrollment service which allows patients to receive and wear the single-use Zio device without going to a healthcare facility.

The Company is continuously reviewing its liquidity and anticipated capital requirements in light of the significant uncertainty created by the COVID-19 global 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 March 31, 2020, the Company is in compliance with its financial covenants in its debt agreement.

On March 27, 2020, the U.S. government enacted the Coronavirus Aid Relief, and Economic Security Act (the CARES Act") to support businesses during the COVID-19 pandemic, including deferment of the employer portion of certain payroll taxes, refundable payroll tax credits, and technical amendments to tax depreciation methods for qualified improvement property. The Company is currently evaluating the impact of the CARES Act on its condensed consolidated financial statements.

Furthermore, capital markets and economies worldwide have been negatively impacted by the COVID-19 pandemic, which may result in a period of regional, national, and global economic slowdown or regional, national, or global recessions that could curtail or delay demand for the Zio service as well as increase the risk of customer defaults or delays in payments. COVID-19 and the current financial, economic, and capital markets environment, and future developments in these and other areas present material uncertainty and risk with respect to the Company's performance, financial condition, volume of business, results of operations, and cash flows. For further information refer to *Note 14. Subsequent Events*.

Investments

Short-term investments consist of debt securities classified as available-for-sale and have maturities greater than 90 days, but less than one year as of the balance sheet date. Long-term investments have maturities greater than one year as of the balance sheet date. All investments are carried at fair value based upon quoted market prices.

The Company periodically assesses its portfolio of debt investments for impairment. For debt securities in an unrealized loss position, this assessment first takes into account the intent to sell, or whether it is more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis. If either of these criteria are met, the debt security's amortized cost basis is written down to fair value through interest and other, net. For debt securities in an unrealized loss position that do not meet the aforementioned criteria, the Company assesses whether the decline in fair value has resulted from credit losses or other factors.

The Company evaluates expected credit losses by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. Expected credit losses on available-for-sale debt securities are recognized in other income, net in the condensed consolidated statements of operations, and any remaining unrealized losses, net of taxes, are reported as a component of accumulated other comprehensive loss. The Company did not recognize any credit losses on its available-for-sale securities during the three months ended March 31, 2020 and there were no impairment charges for unrealized losses in the periods presented.

The cost of available-for-sale securities sold is based on the specific-identification method. Realized gains and losses are included in earnings, and are derived for specific-identification method for determining the costs of investments sold. Amortization of premiums and accretion of discounts are reported as a component of other income, net.

Accounts Receivable, Allowance for Doubtful Accounts and Contractual Allowances

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

The Company establishes an allowance for doubtful accounts for estimated uncollectible receivables based on its assessment of the collectability of customer accounts and recognizes the provision as a component of selling, general and administrative expenses.

The Company records a provision for contractual allowances based on the estimated differences between contracted amounts and expected collection rates. Such provisions are based on the Company's historical experience and are reported as a reduction of revenue.

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

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

	Three Months Ended March 31, 2020	Year Ended December 31, 2019	Three Months Ended March 31, 2019
Balance, beginning of period	$ 9,049	$ 7,296	$ 7,296
Add: provision for doubtful accounts	4,592	9,129	2,015
Add: adoption of ASC 326	461	—	—
Less: write-offs, net of recoveries and other adjustments	(2,262)	(7,376)	(1,346)
Balance, end of period	$ 11,840	$ 9,049	$ 7,965

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

	Three Months Ended March 31, 2020	Year Ended December 31, 2019	Three Months Ended March 31, 2019
Balance, beginning of period	$ 15,433	$ 9,205	$ 9,205
Add: provision for contractual allowances	4,592	15,518	3,396
Less: realized contractual adjustments	(3,477)	(9,290)	(1,435)
Balance, end of period	$ 16,548	$ 15,433	$ 11,166

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, United States Government securities, corporate notes, commercial paper and, by policy, limits the amount of credit exposure with any one financial institution or commercial issuer. The Company has not experienced any material losses on its deposits of cash and cash equivalents or investments.

Concentrations of credit risk with respect to accounts receivable are limited due to the large number of customers comprising the Company's customer base and their dispersion across many geographies. The Company does not require collateral. The Company records an allowance for doubtful accounts based on the assessment of the collectability of customer accounts, considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. Centers for Medicare and Medicaid Services ("CMS"), accounted for approximately 27% and 26% of the Company's revenue for the three months ended March 31, 2020, and 2019, respectively. CMS accounted for 22% and 18% of accounts receivable at March 31, 2020 and March 31, 2019, respectively.

Revenue Recognition

The Company's revenue is generated primarily from the provision of its cardiac rhythm monitoring service, the Zio XT service. The Zio XT is a 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 20 days. The Company has concluded that the Zio XT service is one 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 mobile cardiac telemetry monitor, a wearable patch-based biosensor, offers what the Zio XT offers plus the additional capability of transmissions during the wear period to assist physicians in diagnosing and treating the small percentage of the population requiring more timely action. During the wear period, physicians will receive notifications if there are significant events that meet predetermined arrhythmia detection criteria. The Zio AT service revenue is recognized over the prescription period and delivery of an electronic Zio Report with two performance obligations.

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

A small part of the Company's transactions are covered by third-party payors with whom there is no contractual agreement or not an established amount the third-party payor will pay. In determining the collectability and transaction price for its service, the Company considers factors such as insurance claims which are adjudicated as allowable under the applicable policy and payment history from both payors and patient out-of-pocket costs, payor coverage, whether there is a contract between the payor or healthcare institution and the Company, historical amount received for the service, and any current developments or changes that could impact reimbursement and healthcare institution payments. Certain of these factors are forms of variable consideration which are only included in the transaction price to the extent it is probable that a significant reversal of cumulative revenue will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

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

- Contracted third-party payors – The Company has contracts with negotiated prices for services provided for patients with commercial healthcare insurance carriers.
- CMS – The Company has received independent diagnostic testing facility approval from regional Medicare Administrative Contractors and will receive reimbursement per the relevant Current Procedural Terminology ("CPT") code rates for the services rendered to the patient covered by CMS.
- 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 judgement includes the historical period utilized. The Company monitors the estimated denied claims against the latest available information, and subsequent changes to the estimated denied claims are recorded as an adjustment to revenue in the periods during which such changes occur. 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 we bill patient co-payments and deductibles and from time to time we 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.

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 months ended March 31, 2020 were as follows (in thousands):

	Three Months Ended March 31,	
	2020	2019
Contracted third-party payors	$ 31,710	$ 22,719
Non-contracted third-party payors	3,376	2,819
Centers for Medicare & Medicaid	17,316	12,648
Healthcare Institutions	11,133	10,148
Total	$ 63,535	$ 48,334

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 three months ended March 31, 2020, $1.2 million relating to the contract liability balance at the beginning of 2020 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.

Recently Adopted Accounting Guidance

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost, including trade receivables. ASU No. 2016-13 replaces the existing incurred loss impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. The Company adopted ASC 326 on January 1, 2020, using the modified retrospective transition method through a non-cash $0.5 million cumulative-effect increase to accumulated deficit and the allowance for doubtful accounts. The Company considered the current and expected future economic and market conditions surrounding the novel COVID-19 pandemic and recorded additional reserves that were not individually material to the estimate. Actual results may differ from these estimates.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract, which amended its guidance for costs of implementing a cloud computing service arrangement to align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. This new standard also requires customers to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. The Company adopted ASU No. 2018-15 on January 1, 2020, using the prospective transition method. The impact of adoption on the Company's consolidated financial statements was not material.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which simplifies the accounting for income taxes by removing certain exceptions to the general principles for income taxes. The Company elected to early adopt ASU 2019-12 effective as of January 1, 2020, and the impact of adoption on the Company's condensed consolidated financial statements was not material.

3. Cash Equivalents and Investments

The fair value of cash equivalents and available-for-sale investments at March 31, 2020 and December 31, 2019, were as follows (in thousands):

	March 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 34,541	$ —	$ —	$ 34,541
U.S. government securities	56,032	371	—	56,403
Corporate notes	8,860	1	(8)	8,853
Total cash equivalents and available-for-sale investments	$ 99,433	$ 372	$ (8)	$ 99,797
Classified as:				
Cash equivalents				$ 34,541
Short-term investments				65,256
Total cash equivalents and available-for-sale investments				$ 99,797

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 13,897	$ —	$ —	$ 13,897
U.S. government securities	77,329	72	(1)	77,400
Corporate notes	14,955	11	—	14,966
Commercial paper	35,753	—	—	35,753
Total cash equivalents and available-for-sale investments	$ 141,934	$ 83	$ (1)	$ 142,016
Classified as:				
Cash equivalents				$ 13,897
Short-term investments				120,089
Long-term investments				8,030
Total cash equivalents and available-for-sale investments				$ 142,016

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):

	March 31, 2020	December 31, 2019
Due within one year	$ 99,797	$ 133,986
Due after one year through three years	—	8,030
Total cash equivalents and available-for-sale investments	$ 99,797	$ 142,016

The following tables present the Company's available-for-sale securities that were in an unrealized loss position as of March 31, 2020 (in thousands):

	March 31, 2020			
	Less than 12 months		Total	
Assets	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate notes	$ 7,849	$ (8)	$ 7,849	$ (8)
Total	$ 7,849	$ (8)	$ 7,849	$ (8)

Unrealized losses as of December 31, 2019 were not material. Available-for-sale securities held as of March 31, 2020 had a weighted average maturity of 90 days. At March 31, 2020, three investments were in an unrealized loss position and no investments have been in an unrealized loss position for more than one year.

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 March 31, 2020 are $34.9 million and $36.4 million, respectively. The carrying amount and the estimated fair value of the Company's outstanding interest-bearing obligations at December 31, 2019 were $34.9 million and $35.2 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).

	March 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ 34,541	$ —	$ —	$ 34,541
U.S. government securities	—	56,403	—	56,403
Corporate notes	—	8,853	—	8,853
Total	$ 34,541	$ 65,256	$ —	$ 99,797

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ 13,897	$ —	$ —	$ 13,897
U.S. government securities	—	77,400	—	77,400
Corporate notes	—	14,966	—	14,966
Commercial paper	—	35,753	—	35,753
Total	$ 13,897	$ 128,119	$ —	$ 142,016

5. Balance Sheet Components

Inventory and Other Assets

Inventory consisted of the following (in thousands):

	March 31, 2020	December 31, 2019
Raw materials	$ 1,666	$ 1,574
Finished goods	2,561	2,463
Total	$ 4,227	$ 4,037

The Company uses Printed Circuit Board Assemblies ("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 Zio AT monitor, a portion of the cost of the PCBA is recorded as a cost of revenue. Each time a wireless gateway is used with a Zio AT monitor, a portion of the gateway is recorded as a cost of revenue. PCBAs which are recorded as other assets, were $9.5 million and $7.4 million as of March 31, 2020, and December 31, 2019, respectively.

Property and Equipment, Net

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

	March 31, 2020	December 31, 2019
Laboratory and manufacturing equipment	$ 4,409	$ 4,238
Computer equipment and software	2,379	2,315
Furniture and fixtures	3,803	3,669
Leasehold improvements	8,136	7,597
Internal-use software	18,885	16,277
Total property and equipment, gross	37,612	34,096
Less: accumulated depreciation and amortization	(9,158)	(7,632)
Total property and equipment, net	$ 28,454	$ 26,464

Depreciation and amortization expense was $1.6 million and $0.6 million for the three months ended March 31, 2020, and March 31, 2019, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2020	December 31, 2019
Accrued vacation	$ 4,480	$ 3,809
Accrued payroll and related expenses	8,375	19,156
Accrued ESPP contribution	1,776	417
Accrued professional services fees	181	2,846
Accrued interest	128	128
Claims payable	3,159	2,802
Other	5,148	3,556
Total accrued liabilities	$ 23,247	$ 32,714

6. Commitments and Contingencies

Legal Proceedings

From time to time, the Company may become involved in legal proceedings arising from the ordinary course of its business. Management is currently not aware of any matters that could have a material adverse effect on the financial position, results of operations or cash flows of the Company.

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, which is over a 24 month term, 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 has agreed to make additional payments to Verily up to an aggregate of $12.75 million in milestone payments upon achievement of various development and regulatory milestones over the 24 months of the Development Agreement, which payments will be made in cash to Verily. During the year ended December 31, 2019 the Company achieved a milestone resulting in additional expense of $1.0 million which was included in accounts payable as of December 31, 2019 and paid in the first quarter of 2020. No additional milestones were achieved during the three months ended March 31, 2020.

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 us, 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.

7. Debt

Bank Debt

In December 2015, the Company entered into a Second Amended and Restated Loan and Security Agreement with SVB, (the "SVB Loan Agreement"). Under the SVB Loan Agreement, the Company could borrow, repay and reborrow under a revolving credit line, but not in excess of the maximum loan amount of $15.0 million, until December 4, 2018, when all outstanding principal and accrued interest became due and payable. Any principal amount outstanding under the SVB Loan Agreement shall bear interest at a floating rate per annum equal to the rate published by The Wall Street Journal as the "Prime Rate" plus 0.25%. The Company could borrow up to 80% of its eligible accounts receivable, up to the maximum of $15.0 million.

In October 2018, the Company entered into the Third Amended and Restated Loan and Security Agreement with SVB ("Third Amended and Restated SVB Loan Agreement"). This Agreement amends and restates the Second Amended and Restated Loan and Security Agreement between the Company and SVB dated December 4, 2015, as amended by the First Loan Modification Agreement between the Company and SVB dated August 22, 2016.

Pursuant to the Third Amended and Restated SVB Loan Agreement, the Company obtained a term loan ("SVB Term Loan") for $35.0 million. Total proceeds from the SVB Term Loan were used to pay off the loan agreement with Biopharma Secured Investments III Holdings Cayman LP ("Pharmakon"), totaling $35.8 million. The Company will make interest-only payments through October 31, 2020, followed by 36 monthly payments of principal plus interest on the SVB Term Loan. Interest charged on the SVB Term Loan will be the greater of (a) a floating rate based on the "Prime Rate" published by The Wall Street Journal minus 0.75%, or (b) 4.25%.

Under the Third Amended and Restated SVB Loan Agreement, the Company may borrow, repay, and reborrow under a revolving credit line, but not in excess of the maximum loan amount of $25.0 million, which includes an $11.0 million standby letter of credit sublimit availability. In October 2018, a $6.9 million standby letter of credit was obtained in connection with a lease for the Company's San Francisco headquarters. Any principal amount outstanding under the Third Amended and Restated SVB Loan Agreement revolving credit line shall bear interest at an amount that is the greater of (a) a floating rate per annum equal to the rate published by The Wall Street Journal as the "Prime Rate" or (b) 5.00%. The Company may borrow up to 75% of eligible accounts receivable, up to the maximum of $25.0 million. As of March 31, 2020, no amount was outstanding under the revolving credit line.

The Third Amended and Restated Loan Agreement requires the Company to maintain a minimum consolidated liquidity ratio or minimum adjusted Earnings Before Interest, Tax, Depreciation, and Amortization during the term of the loan facility. In addition, the SVB Loan Agreement contains customary affirmative and negative covenants and events of default. The Company was in compliance with loan covenants as of March 31, 2020. The obligations under the Third Amended and Restated Loan Agreement are collateralized by substantially all assets of the Company.

8. Income Taxes

The Company recorded a tax provision related to its U.K. entity during the three months ended March 31, 2020 and March 31, 2019. 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.

9. Stockholders' Equity

Common stock

The Company's amended and restated certificate of incorporation dated October 25, 2016, authorizes the Company to issue 100,000,000 shares of common stock with a par value of $0.001 per share and 5,000,000 shares of preferred stock with a par value of $0.001 per share. The holders of common stock are entitled to receive dividends whenever funds and assets are legally available and when declared by the board of directors, subject to the prior rights of holders of all series of convertible preferred stock outstanding. No dividends were declared through March 31, 2020.

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

	March 31, 2020	December 31, 2019
Options issued and outstanding	1,221,621	1,503,247
Unvested restricted stock units	947,101	886,030
Shares available for grant under future stock plans	8,319,642	6,709,235
Shares available for future issuance	10,488,364	9,098,512

10. 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, 2018	**4,717,292**
Additional awards authorized	1,218,402
Awards granted	(649,911)
Awards forfeited	181,513
Awards withheld for tax purposes	60,836
Balance at December 31, 2019	**5,528,132**
Additional awards authorized	1,333,928
Awards granted	(286,155)
Awards forfeited	110,981
Awards withheld for tax purposes	51,475
Balance at March 31, 2020	**6,738,361**

During the three months ended March 31, 2020, 286,155 restricted stock units ("RSUs") were granted, 130,920 RSUs vested, and 94,155 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, 2018	**2,094,137**	$ 23.20	7.02	$ 97,976
Options granted	20,010	$ 82.77		
Options exercised	(540,307)	$ 9.59		
Options forfeited	(70,593)	$ 54.54		
Balance at December 31, 2019	**1,503,247**	$ 27.40	6.43	$ 62,401
Options exercised	(264,800)	$ 11.21		
Options forfeited	(16,826)	$ 68.32		
Balances at March 31, 2020	**1,221,621**	$ 30.35	6.39	$ 62,595
Options exercisable – March 31, 2020	941,215	$ 23.59	6.05	$ 54,482
Options vested and expected to vest – March 31, 2020	1,210,815	$ 30.07	6.38	$ 62,368

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.

During the three months ended March 31, 2019, the Company granted options with a weighted-average grant date fair value of $38.65 per share. The Company did not grant any options during the three months ended March 31, 2020.

11. Stock-Based Compensation

Employee Stock Options Valuation

The fair value of employee and director stock options was estimated at the date of grant using the Black-Scholes option pricing model with the weighted average assumptions below.

	Three Months Ended March 31,
	2019
Expected term (in years)	6.1
Expected volatility	45.0 %
Risk-free interest rate	2.40 %
Dividend yield	— %

The Company did not grant stock options during the three months ended March 31, 2020.

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 March 31,	
	2020	2019
Cost of revenue	$ —	$ 88
Research and development	741	873
Selling, general and administrative	(436)	3,895
Total stock-based compensation expense	$ 305	$ 4,856

As of March 31, 2020, there was total unamortized compensation costs of $7.6 million, net of estimated forfeitures, related to unvested stock options which the Company expects to recognize over a period of approximately 1.5 years, $58.1 million, net of estimated forfeitures, related to unrecognized restricted stock unit (“RSU”) expense, which the Company expects to recognize over a period of 2.4 years, and $0.5 million unrecognized ESPP expense, which the Company will recognize over 0.7 years.

Performance based RSUs (“PRSU”)

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

In February 2019, the company granted PRSU's that are earned based on the compound annual growth rate ("CAGR") of fiscal year 2020's revenue compared to fiscal year 2018's revenue, measuring a minimum performance threshold of 75% to earn 50% of target, and a maximum threshold of 125% achieved to earn 200% of target.

In February 2020, the company granted PRSU's 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.

The exact number of earned shares for both grants will be determined based on linear interpolation using the actual results as they fall between the minimum and maximum thresholds outlined above.

Due to the impact of the COVID-19 pandemic, management has determined that as of March 31, 2020, the Company’s achievement of its performance targets described above, is not probable. PRSU expense of $4.8 million recognized in fiscal year 2019 has been reversed and no PRSU expense has been recognized in the first quarter of 2020.

The following table presents key terms of outstanding PRSU awards (in thousands except for share amounts and percentages):

Grant Year	PRSU Performance Period	Performance %	PRSU Shares Granted	Fair Value of PRSU Shares Granted	Cumulative Expense Recognized for PRSUs
2019	2018 - 2020	—%	159,314	$ 15,160	$ —
2020	2019 - 2022	—%	133,834	10,993	—
			293,148	$ 26,153	$ —

12. Net Loss Per Common Share

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 March 31,	
	2020	2019
Numerator:		
Net loss	$ (9,065)	$ (8,250)
Denominator:		
Weighted-average shares used to compute net loss per common share, basic and diluted	26,839,870	24,474,308
Net loss per common share, basic and diluted	$ (0.34)	$ (0.34)

The following outstanding shares of potentially dilutive securities have been excluded from diluted net loss per common share for the three months ended March 31, 2020 and 2019, because their inclusion would be anti-dilutive:

	Three Months Ended March 31,	
	2020	2019
Options to purchase common stock	1,221,621	1,885,914
PRSUs and RSUs unvested	947,101	896,759
Warrants to purchase common stock	—	4,857
Total	2,168,722	2,787,530

13. Revision of Prior Period Financial Statements

As discussed in Note 1, the Company has revised certain prior period financial statements to correct errors in its accounting for revenues, contractual allowances, allowance for doubtful accounts and certain other items as presented below (in thousands, except share data):

Revised Consolidated Balance Sheets

	As of March 31, 2019		
	As Reported	Adjustment	As Revised
Assets			
Cash and cash equivalents	$ 28,235	$ (134)	$ 28,101
Accounts receivable, net	28,252	(1,481)	26,771
Prepaid expenses and other current assets	3,810	(140)	3,670
Total current assets	93,308	(1,755)	91,553
Property and equipment, net	10,208	70	10,278
Operating lease right-of-use assets	9,232	(270)	8,962
Total assets	117,184	(1,955)	115,229
Liabilities and Stockholders' Equity			
Accrued liabilities	20,099	437	20,536
Deferred revenue	1,309	(47)	1,262
Operating lease liabilities, current portion	5,052	(211)	4,841
Total current liabilities	28,549	179	28,728
Operating lease liabilities, noncurrent portion	3,990	(59)	3,931
Total liabilities	67,461	120	67,581
Additional paid-in capital	261,231	441	261,672
Accumulated other comprehensive income	2	25	27
Accumulated deficit	(211,534)	(2,541)	(214,075)
Total stockholders' equity	49,723	(2,075)	47,648
Total liabilities and stockholders' equity	117,184	(1,955)	115,229

Revised Consolidated Statements of Operations

	Three months ended March 31, 2019		
	As Reported	Adjustment	As Revised
Revenue	$ 47,214	$ 1,120	$ 48,334
Cost of revenue	11,730	43	11,773
Gross profit	35,484	1,077	36,561
Research and development	6,756	(57)	6,699
Selling, general and administrative	36,705	1,361	38,066
Total operating expenses	43,461	1,304	44,765
Loss from operations	(7,977)	(227)	(8,204)
Other income, net	379	(4)	375
Loss before income taxes	(8,007)	(231)	(8,238)
Net loss	(8,019)	(231)	(8,250)
Net loss per common share, basic and diluted	(0.33)	(0.01)	(0.34)

Revised Consolidated Statements of Comprehensive Loss

	Three months ended March 31, 2019		
	As Reported	Adjustment	As Revised
Net loss	$ (8,019)	$ (231)	$ (8,250)
Comprehensive loss	(7,976)	(231)	(8,207)

Revised Consolidated Statements of Cash Flows

	Three months ended March 31, 2019		
	As Reported	Adjustment	As Revised
Cash flows from operating activities			
Net loss	$ (8,019)	$ (231)	$ (8,250)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	4,415	441	4,856
Provision for doubtful accounts and contractual allowances	4,709	702	5,411
Changes in operating assets and liabilities:			
Accounts receivable	(10,984)	(1,408)	(12,392)
Prepaid expenses and other current assets	(169)	140	(29)
Accrued liabilities	(6,380)	319	(6,061)
Deferred revenue	66	(27)	39
Net cash used in operating activities	(17,099)	(64)	(17,163)
Cash flows from investing activities			
Purchases of property and equipment	(1,635)	(70)	(1,705)
Net cash provided by investing activities	26,449	(70)	26,379
Net increase in cash, cash equivalents, and restricted cash	8,212	(134)	8,078
Cash and cash equivalents end of period	28,235	(134)	28,101

Revised Consolidated Statements of Shareholder's Equity

	Three months ended March 31, 2019		
	As Reported	Adjustment	As Revised
Stock-based compensation expense	$ 4,415	$ 441	$ 4,856
Additional-paid-in-capital ending balance	261,231	441	261,672
Accumulated other comprehensive loss beginning balance	(41)	25	(16)
Accumulated other comprehensive loss ending balance	2	25	27
Accumulated deficit beginning balance	(203,515)	(2,310)	(205,825)
Net loss	(8,019)	(231)	(8,250)
Accumulated deficit ending balance	(211,534)	(2,541)	(214,075)
Total stockholders' equity	49,723	(2,075)	47,648

14. Subsequent Events

During the three months ended March 31, 2020, the Company experienced a decline in revenue as a result of the COVID-19 pandemic. As part of the its response, the Company took the following cost reduction measures beginning in April 2020: temporary salary reductions for all salaried employees, unpaid furloughs for some hourly employees, and layoffs. The Company is also temporarily reducing the base salary of the Company’s Chief Executive Officer, Board of Director retainer fees, executive officers, and vice presidents. In addition, the Company has proactively taken initial steps to reduce spend, including eliminating or delaying project spend for non-essential programs, reducing spend on travel and consulting, and

implementing a hiring freeze. The Company is still developing this plan, and therefore, it cannot reasonably estimate costs related to termination benefits at this time. The Company continues to analyze its cost structure and may implement additional cost reduction measures as may be necessary due to the on-going economic challenges resulting from the COVID-19 pandemic.

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, Zio XT and Zio AT monitors, which continuously record and store ECG data from every patient heartbeat for up to 14 consecutive days; Zio AT offers the option of timely transmission of data during the prescribed wear period;
- 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 government agencies, such as CMS, Veterans Administration, and the military. In addition, a small percentage of institutions, which are typically hospitals or private physician practices, 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 50% and 47% of our revenue for the three months ended March 31, 2020 and 2019, respectively. Approximately, 27% and 26% of our total revenue for the three months ended March 31, 2020 and 2019 is received from Centers for Medicare and Medicaid Services ("CMS"), which is under established reimbursement codes. Healthcare institutions, which are typically hospitals or private physician practices accounted for approximately 18% and 21% of our revenue for the three months ended March 31, 2020 and 2019, respectively. Non-contracted third party payors and self-pay accounted for 5% and 6% of our total revenue for the three months ended March 31, 2020 and March 31, 2019. We rely on a third-party billing partner, XIFIN, Inc., to submit patient claims and collect from commercial payors, certain government agencies, and patients.

Since our Zio service was cleared by the U.S. Food and Drug Administration ("FDA"), we have provided the Zio service to over two million patients and have collected over 600 million hours of curated heartbeat data. We believe the Zio service is well-positioned to disrupt an already-established $1.8 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 and hospital administrators and other clinical departments. In addition, we will continue exploring sales and marketing expansion opportunities in international geographies.

As further explained in *Note 1. Organization and Description of Business* and *Note 13. Revision of Prior Period Financial Statements* in the notes to the accompanying condensed consolidated financial statements, the Company has revised its previously issued interim financial statements as of and for the three months ended March 31, 2019. This Management's Discussion and Analysis has been revised to reflect the correction of these prior period errors.

COVID-19 Impact

The Company cannot currently predict the extent or duration of the ongoing impact to its financial statements and has suspended guidance. Although the Company cannot currently predict the extent or duration of the COVID-19 related impact to its financial results, the Company does expect the impact of COVID-19 to be more significant in the near-term.

We are taking a variety of measures to promote the safety and security of our employees and customers. Our response to COVID-19 is focused on:

- ***Protecting and supporting the health and well-being of our employees, our communities and our customers by limiting the transmission of COVID-19.*** Following recommendations from federal and local government and healthcare agencies, the Company transitioned employees to a remote work environment beginning in early March 2020. For a small number of our employees who continue to support essential operations at our facilities, we have instituted social distancing and other measures to ensure the safety of our employees. We rapidly implemented business continuity protocols and have been able to transition to a remote operating environment while continuing to deliver our Zio service. We will continue to follow local and national guidelines to determine the appropriate time to resume in-office functions.

- ***Delivering uninterrupted patient care for both Zio XT and Zio AT and supporting efforts to monitor COVID-19 patients.*** While hospital systems and healthcare facilities shift their focus and resources to treating COVID-19 patients and combating the spread of COVID-19, we have adapted our service to meet the immediate needs of our physician customers and patients. Our digital service platform enables physician ordering, results reporting, data curation and patient support independent of location, across virtual or in-office care models. As an example, we have 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. Home enrollment also eliminates clinical staff exposure to cleaning or reusing traditional Holter and event monitors that may have been exposed to viruses or other pathogens. In addition, health systems with acute needs to facilitate a reduction in healthcare provider contact and the additional need for monitoring capacity are looking to deploy Zio AT for in-patient monitoring. The FDA informed the Company that Zio AT usage for this application is consistent with the FDA COVID-19 Remote Monitoring guidance.

- Adjusting our operating plan as appropriate to ensure continued financial strength. The Company continues to maintain a strong cash position and has taken initiatives to adjust our operating plan to ensure the Company maintains appropriate liquidity during these uncertain times. The Company has proactively taken initial steps to reduce spend, including eliminating or delaying project spend for non-essential programs, reducing spend on travel and consulting, implementing a hiring freeze, and reducing payroll costs through employee furloughs and pay cuts.

Components of Results of Operations

Revenue

Substantially all of our revenue is derived from sales of our Zio service in the United States. We earn revenue from the provision of our Zio service primarily from contracted third-party payors, CMS, and healthcare institutions. In addition, a small percentage of institutions, which are typically hospitals or private physician practices, purchase the Zio service from us directly, and a very small percentage of commercial non-contracted 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, the Company considers factors such as claim payment history from both payors and patient out-of-pocket costs, payor coverage, whether there is a contract between the payor or healthcare institution and the Company, historical amount received for the service, and 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. During the three months ended March 31, 2020, the Company experienced a decline in revenue as a result of the COVID-19 pandemic.

Cost of Revenue and Gross Margin

Cost of revenue includes direct labor, material costs, equipment and infrastructure expenses, amortization of internal-use software, allocated overhead, and shipping and handling. Direct labor includes payroll and personnel-related costs including stock-based compensation involved in manufacturing, data analysis, and customer service. Material costs include both the disposable materials costs of the Zio monitors and amortization of the re-usable 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 cost of revenue to increase in absolute dollars to the extent our revenue grows.

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 service per device by obtaining volume purchase discounts for our material costs and implementing scan-time algorithm improvements and software-driven and other workflow enhancements to reduce labor costs. Gross margin for the first quarter of 2020 was negatively impacted due to the COVID-19 pandemic and the Company expects this impact to continue in the near term.

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 and product enhancements.

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.

Interest Expense

Interest expense is attributable to borrowings under our loan agreements. Refer to *Note 7. 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, cash equivalents and investments balances.

Results of Operations

Comparison of the Three Months Ended March 31, 2020 and 2019

	Three Months Ended March 31,			
	2020	2019	$ Change	% Change
Revenue	$ 63,535	$ 48,334	$ 15,201	31 %
Cost of revenue	16,063	11,773	4,290	36 %
Gross profit	47,472	36,561	10,911	30 %
Gross margin	75 %	76 %		
Operating expenses:				
Research and development	8,415	6,699	1,716	26 %
Selling, general and administrative	48,230	38,066	10,164	27 %
Total operating expenses	56,645	44,765	11,880	27 %
Loss from operations	(9,173)	(8,204)	(969)	12 %
Interest expense	(380)	(409)	29	7 %
Other income, net	505	375	130	35 %
Loss before income taxes	(9,048)	(8,238)	(810)	10 %
Income tax provision	17	12	5	42 %
Net loss	$ (9,065)	$ (8,250)	$ (815)	10 %

Revenue

Revenue increased $15.2 million, or 31%, to $63.5 million during the three months ended March 31, 2020 from $48.3 million during the three months ended March 31, 2019. The increase in revenue was primarily attributable to the increase in volume of the Zio services performed as a result of the expansion of coverage and the increase in the number of payors. In the second half of March 2020, the Company experienced a decline in revenues as a result of the COVID-19 pandemic.

Cost of Revenue and Gross Margin

Cost of revenue increased $4.3 million, or 36%, to $16.1 million during the three months ended March 31, 2020 from $11.8 million during the three months ended March 31, 2019. The increase in cost of revenue was primarily due to increased Zio service volume in 2019.

Gross margin for the three months ended March 31, 2020 decreased to 75%, compared to 76% for the three months ended March 31, 2019.

Research and Development Expenses

Research and development expenses increased $1.7 million, or 26%, to $8.4 million during the three months ended March 31, 2020 from $6.7 million during the three months ended March 31, 2019. The increase was primarily attributable to a $2.0 million increase in employee related costs and a $1.1 million increase in allocated facility costs, partially offset by $1.2 million reduction of expense due to an increase in costs capitalized to internal use software.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $10.2 million, or 27%, to $48.2 million during the three months ended March 31, 2020 from $38.1 million during the three months ended March 31, 2019. The increase was primarily attributable to a $3.3 million increase in payroll and stock-based compensation as a result of increased headcount, $2.6 million in bad debt expense, and $1.9 million in rent expense due to expansion of San Francisco headquarters.

Interest Expense

Interest expense was $0.4 million for the three months ended March 31, 2020, compared to $0.4 million for the three months ended March 31, 2019. There were no significant changes in interest expense during the three months ended March 31, 2020 compared with the three months ended March 31, 2019.

Other Income, Net

Other income, net was $0.5 million for the three months ended March 31, 2020, compared to $0.4 million for the three months ended March 31, 2019. There were no significant changes in other income, net expense during the three months ended March 31, 2020 compared with the three months ended March 31, 2019.

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 March 31, 2020, we had cash and cash equivalents of $56.5 million, short-term investments of $65.3 million, an accumulated deficit of $269.9 million, and an unused availability under our credit facility of $4.4 million.

Our expected future capital requirements may depend on many factors including expanding our customer base, the expansion of our salesforce, 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. 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):

	Three Months Ended March 31,	
	2020	2019
Net cash (used in) provided by:		
Operating activities	$ (22,366)	$ (17,163)
Investing activities	59,911	26,379
Financing activities	(1,493)	(1,138)
Net increase in cash and cash equivalents	$ 36,052	$ 8,078

Cash Used in Operating Activities

During the three months ended March 31, 2020, cash used in operating activities was $22.4 million, which consisted of a net loss of $9.1 million, adjusted by non-cash charges of $12.4 million and a net change of $25.7 million in our net operating assets and liabilities. The non-cash charges were primarily comprised of a change in the allowance for doubtful accounts and contractual allowances of $9.2 million and depreciation and amortization of $1.6 million. The change in our net operating assets and liabilities was primarily due to an increase of $10.0 million in accounts receivable as a result of increased revenues and an increase of $9.5 million in accrued liabilities.

During the three months ended March 31, 2019, cash used in operating activities was $17.2 million, which consisted of a net loss of $8.3 million, adjusted by non-cash charges of $11.9 million and a net change of $20.8 million in our net operating assets and liabilities. The non-cash charges were primarily comprised of a change in allowance for doubtful accounts and contractual allowance of $5.4 million, and in stock-based compensation of $4.9 million. The change in our net operating assets and liabilities was primarily due to an increase of $12.4 million in accounts receivable as a result of increased revenues.

Cash Provided by Investing Activities

Cash provided by investing activities during the three months ended March 31, 2020 was $59.9 million, which consisted of cash received from the maturities of available for sale investments of $56.8 million and sales of available for sale investments of $14.5 million. This was partially offset by $8.0 million in purchases of available for sale investments and $3.4 million of capital expenditures associated with leasehold improvements and internal use software.

Cash provided by investing activities during the three months ended March 31, 2019 was $26.4 million, which consisted primarily of $37.7 million in cash received from the maturities of available for sale investments, partially offset by purchases of available for sale investments of $9.6 million, and $1.7 million of capital expenditures to purchase property and equipment.

Cash Used in Financing Activities

During the three months ended March 31, 2020, cash used in financing activities was $1.5 million, primarily due to $4.5 million in tax withholding upon the vesting of RSUs, partially offset by $3.0 million in proceeds from the issuance of common stock in connection with employee options exercises and our Employee Stock Purchase Program.

During the three months ended March 31, 2019, cash used by financing activities was $1.1 million, primarily due to $3.3 million in tax withholding upon the vesting of RSUs, partially offset by $2.1 million in proceeds from the issuance of common stock.

Bank Debt

In December 2015, we entered into a Second Amended and Restated Loan and Security Agreement with SVB, (the "SVB Loan Agreement"). Under the SVB Loan Agreement, we could borrow, repay and reborrow under a revolving credit line, but not in excess of the maximum loan amount of $15.0 million, until December 4, 2018, when all outstanding principal and accrued interest became due and payable. Any principal amount outstanding under the SVB Loan Agreement shall bear interest at a floating rate per annum equal to the rate published by The Wall Street Journal as the "Prime Rate" plus 0.25%. We could borrow up to 80% of our eligible accounts receivable, up to the maximum of $15.0 million.

In October 2018, we entered into the Third Amended and Restated Loan and Security Agreement with SVB ("Third Amended and Restated SVB Loan Agreement"). This Agreement amends and restates the Second Amended and Restated Loan and Security Agreement between the Company and SVB dated December 4, 2015, as amended by the First Loan Modification Agreement between the Company and SVB dated August 22, 2016.

Pursuant to the Third Amended and Restated SVB Loan Agreement, we obtained a term loan ("SVB Term Loan") for $35.0 million. Total proceeds from the SVB Term Loan were used to pay off the loan agreement with Biopharma Secured Investments III Holdings Cayman LP ("Pharmakon"), totaling $35.8 million. We will make interest-only payments through October 31, 2020, followed by 36 monthly payments of principal plus interest on the SVB Term Loan. Interest charged on the SVB Term Loan will be the greater of (a) a floating rate based on the "Prime Rate" published by The Wall Street Journal minus 0.75%, or (b) 4.25%.

Under the Third Amended and Restated SVB Loan Agreement, we may borrow, repay, and reborrow under a revolving credit line, but not in excess of the maximum loan amount of $25.0 million, which includes an $11.0 million standby letter of credit sublimit availability. In October 2018, a $6.9 million standby letter of credit was obtained in connection with a lease for our San Francisco headquarters. Any principal amount outstanding under the Third Amended and Restated SVB Loan Agreement revolving credit line shall bear interest at an amount that is the greater of (a) a floating rate per annum equal to the rate published by The Wall Street Journal as the "Prime Rate" or (b) 5.00%. We may borrow up to 75% of eligible accounts receivable, up to the maximum of $25.0 million. As of March 31, 2020 no amount was outstanding under the revolving credit line.

The Third Amended and Restated Loan Agreement requires us to maintain a minimum consolidated liquidity ratio or minimum adjusted Earnings Before Interest, Tax, Depreciation, and Amortization during the term of the loan facility. In addition, the SVB Loan Agreement contains customary affirmative and negative covenants and events of default. We were in compliance with loan covenants as of March 31, 2020. The obligations under the Third Amended and Restated Loan Agreement are collateralized by substantially all of our assets.

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, 2019 are presented in our Form 10-K filed with the SEC on March 2, 2020. 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, 2019. 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 as well as the lease accounting policy updated upon the adoption of ASC 842 as of January 1, 2019.

Recently Adopted Accounting Guidance

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost, including trade receivables. ASU No. 2016-13 replaces the existing incurred loss impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. We adopted ASC 326 on January 1, 2020, using the modified retrospective transition method through a non-cash $0.5 million cumulative-effect increase to accumulated deficit and the allowance for doubtful accounts. We considered the current and expected future economic and market conditions surrounding the novel COVID-19 pandemic and recorded additional reserves that were not individually material to the estimate. Actual results may differ from these estimates.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract, which amended its guidance for costs of implementing a cloud computing service arrangement to align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. This new standard also requires customers to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. We adopted ASU No. 2018-15 on January 1, 2020, using the prospective transition method. The impact of adoption on our consolidated financial statements was not material.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which simplifies the accounting for income taxes by removing certain exceptions to the general principles for income taxes. We elected to early adopt ASU 2019-12 effective as of January 1, 2020, and the impact of adoption on our condensed consolidated financial statements was not material.

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 $121.8 million as of March 31, 2020, which consisted of bank deposits, money market funds, U.S. government securities, corporate notes, and commercial paper. 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 discount and debt issuance costs, as of March 31, 2020. 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 March 31, 2020 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

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of March 31, 2020. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer 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 March 31, 2020 due to the following material weaknesses, which continue to exist as of March 31, 2020:

- 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 the additional material weaknesses below.

- We did not effectively execute our controls over our financial statement close process, to ensure the prevention or detection of a misstatement that could be material. Specifically, we concluded we did not have an effective business performance review control used to monitor the completeness and accuracy of the financial results and to identify potential failures in lower level controls. This control may not detect errors in a timely manner that could be material to our interim or annual financial statements. Additionally, we did not have appropriate control over the review of journal entries to ensure that they were properly supported and recorded completely and accurately.

- We did not maintain effective controls with respect to the review of the accounting for revenue and related accounts receivable, including maintaining effective controls to prevent or detect errors in the assessment of bad debt and revenue reserves. Specifically, we did not detect errors within the contractual allowance and bad debt expense analyses which resulted in immaterial misstatements to revenue, accounts receivable and bad debt expense.

These material weaknesses resulted in 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, and June 30, 2019. Additionally, these material weaknesses 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.

Notwithstanding these material weaknesses, management has concluded that the condensed consolidated financial statements included in this quarterly report on Form 10-Q state fairly, in all material aspects, our financial position at the end of, and the results of operations and cash flows for, the periods stated in conformity with accounting principles generally accepted in the United States. Refer to Note 13. Revision of Prior Period Financial Statements for further details on adjustments made to our interim and annual financial statements.

Changes in Internal Control Over Financial Reporting

Under the supervision and with the participation of our management, including our President and Chief Executive Officer and Chief Financial Officer, we evaluated whether there were any changes in our internal control over financial

reporting during the first quarter of fiscal 2020. There were no changes in our internal control over financial reporting identified in connection with the above evaluation that occurred during the first quarter of fiscal 2020 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

Plan for Remediation of Material Weaknesses

Management continues to build on the momentum and progress we have made in our remediation efforts. In particular, we continue to focus on:

1) the successful onboarding of recent hires in the Finance organization;

2) internal control and accounting education and awareness efforts for those with roles that impact internal control over financial reporting; and

3) consistent execution of all controls, particularly those in the financial statement close and order to cash cycles.

The material weaknesses will not be considered remediated until the applicable controls operate for a sufficient period of time for management to conclude, through testing, that such controls are operating effectively. We expect that control environment improvements will be implemented in 2020 in response to the material weaknesses.

Limitations on Effectiveness of Controls and Procedures

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. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time we may be involved in legal proceedings or investigations by governmental agencies. For example, we could become involved in litigation related to product liability, unfair competition or intellectual property litigation with our competitors. The defense of these and other 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, all of which could have an adverse impact on our results of operations, financial position or cash flows.

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

Risks Related to Our Business

The COVID-19 pandemic and efforts to reduce its spread has impacted, and may in the future periods negatively impact, our business and operations.

The COVID-19 pandemic has had, and may continue to have, an adverse impact on our operations, as a result of preventive and precautionary measures that we, other businesses, and governments are taking. The spread of COVID-19 in the United States has resulted in travel restrictions impacting our sales representatives and customer service team who support them. Some hospitals have also limited access for non-patients, including our sales professionals, which has negatively impacted our access to physicians and their patients. New hospital sanitization and social distancing protocols, as well as increased competition for resources within hospitals that have dedicated certain resources only to COVID patients, may impact our business and operations. Additionally, we anticipate that an increase in the unemployment rate due to the impact of COVID-19 will decrease the number of potential patients with access to health insurance, which may result in fewer diagnostic procedures. As hospitals cancel and defer diagnostic and elective procedures, it reduces their revenue and impacts their financial results, which could result in pricing pressure on our services as they seek cost savings. Prolonged restrictions relating to COVID-19 could adversely affect our sales and the revenue we derive as a result.

We expect these challenges of the COVID-19 outbreak to continue to impact our number of Zio services provided through the second quarter of 2020, and perhaps for the remainder of 2020 and into 2021, but its extent cannot be quantified at this time. Our customers' patients are also experiencing the economic impact of the current epidemic. Even an important diagnostic procedure like the Zio service 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. 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 open, staffed adequately or open the entire day. Even where physicians continue to treat symptomatic patients, treatment of asymptomatic patients is being deferred in many cases. 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 prescribed.

Governmental mandates related to COVID-19 or other infectious diseases have impacted, and we expect them to continue to impact, our personnel and personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain and/or reduce our margins. For instance, on March 16, 2020, the Department of Public Health of the City and County of San Francisco, where our headquarters is located, issued a mandatory shelter-in-place order through April 7, 2020 that was later extended through May 31, 2020; similarly, the Department of Public Health for Orange County, where are manufacturing facilities are located, has generally followed the State of California's indefinite stay-at-home orders (collectively, the "Government Mandate"). While we have continued to operate with remote employees and essential employees on site, an extended implementation of this Governmental Mandate could impact our ability to operate effectively and conduct ongoing manufacturing or research and development.

While we expect COVID-19 pandemic to impact our business over the short term as some procedures are temporarily deferred, we have taken swift and proactive measures to minimize business disruptions and preserve financial flexibility. In assessing our own cash conservation options, we have taken preemptive steps to curtail near-term spending, including temporary salary reductions for all salaried employees, unpaid furloughs for some hourly employees, and layoffs. We are also temporarily reducing the base salary of the Company's Chief Executive Officer, executive officers, and vice presidents, as well as reducing our Board of Director retainer fees. Our ongoing operations may be impacted as a result of employees assuming additional roles and responsibilities within our organization and we would have fewer resources available to run our operations, which would reduce our expenses, but could also negatively impact our business operations and revenue as a result. We may also encounter voluntary departures of key employees due to any of the foregoing actions that we undertake. If key personnel or large groups of our employees contract the virus, that may also impact our business and operations. In the meantime, we have taken steps to support our employees, including providing the ability for employees to work remotely and implementing strategies to support appropriate social distancing techniques for future interactions. We are also assessing our business continuity plans in the context of this pandemic.

Finally, we anticipate that COVID-19 pandemic may impact clinical and regulatory matters. While we do not have any clinical trials currently in process, COVID-19 is delaying enrollment in new clinical trials across the medical device industry and may affect any new trials we decide to pursue.

Any of these occurrences may significantly harm our business, financial condition and prospects. The ultimate impact of COVID-19 is highly uncertain and subject to change. This impact could have a material, adverse impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely. The extent to which COVID-19 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 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 and results of operations. As a result, we have withdrawn our full year 2020 financial guidance. Additionally, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of COVID-19 on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity and our ability to operate.

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 or reductions in business 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 manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. 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. For the three months ended March 31, 2020, and 2019 we had net losses of $9.1 million and $8.3 million, respectively, and expect to continue to incur additional losses. As of March 31, 2020, we had an accumulated deficit of $269.9 million. 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 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 brand and educate physicians regarding the benefits of our Zio service over existing products and services, such as Holter monitors and event monitors, and to persuade them to prescribe the Zio service as the diagnostic product 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 data demonstrating the efficacy of our service compared to alternative technologies. Any studies we, or third parties which we sponsor, may conduct comparing our Zio service with alternative technologies will be expensive, time consuming and may not yield positive results. Additionally, adoption will be directly influenced by a number of financial factors, including the ability of providers to obtain sufficient reimbursement from third-party commercial payors, and the Centers for Medicare & Medicaid Services ("CMS"), for the professional services they provide in applying the Zio monitor and analyzing the Zio report. The efficacy, safety, performance and cost-effectiveness of our Zio service, on a stand-alone basis and relative to competing services, will determine the availability and level of reimbursement received by us and providers. Some payors do not have pricing contracts with us setting forth the Zio service reimbursement rates for us and providers. Physicians may be reluctant to prescribe the Zio service to patients covered by such non-contracted insurance policies because of the uncertainty surrounding reimbursement rates and the administrative burden of interfacing with patients to answer their questions and support their efforts to obtain adequate reimbursement for the Zio service. If physicians do not adopt and prescribe our Zio service, our revenue will not increase and our financial condition will suffer as a result.

Our revenue relies substantially on the Zio service, which is currently our only product 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 prescriptions of the Zio service, and we expect that sales of 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 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 may require a different type of selling effort. If we are unable to increase prescriptions of 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 through government programs;
- our ability to attract new customers and improve our business with existing customers;
- results of our clinical trials and publication of studies by us, competitors or third parties;
- the timing and success of new product introductions 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 outbreak on our operations and financial results;

- the regulatory environment;
- expenses associated with unforeseen product quality issues;
- timing of physician prescriptions 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 prescribing physician;
- the hiring, training and retention of key employees, including our ability to expand our sales team;
- 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 season, we have observed that the use of our Zio service decreases, which reduces our revenue during those periods. We believe that the decrease in demand may result from physicians or their patients taking vacations. Severe weather conditions or natural disasters also may hamper or otherwise restrict when patients seeking diagnostic services, such as the Zio service, visit prescribing physicians. 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 three months ended March 31, 2020, we received approximately 27% 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 independent diagnostic treatment facility (“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 solutions. 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 the CMS programs.

Changes in public health insurance coverage and CMS reimbursement rates for the Zio service could affect the adoption of the Zio service and our future revenue.

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, or CPT, code-set maintained by the American Medical Association (“AMA”). For Zio XT, we have secured temporary CPT codes (or Category III CPT codes) used for newly introduced technologies and specific to our category of diagnostic monitoring through 2022. The fees associated with these Category III CPT codes are also temporary and may be modified by CMS. Category III CPT codes may be renewed for another five years or converted to permanent codes (or Category I CPT codes) based on specific requirements, including national use data and published clinical evidence, as established by the AMA and CMS. The process to convert Category III CPT codes to Category I CPT codes is governed by the AMA and CMS. On October 25, 2019, the AMA’s CPT Editorial Panel established two new Category I CPT codes which are applicable to the Zio service and will take effect on January 1, 2021. At this point in the process of reviewing new codes, CMS will determine the appropriate level of reimbursement for the services, which will be first published as a proposed rule in July 2020, with a 60 day comment period following and then a final rule published in November 2020. Once Category I CPT codes are valued by CMS the values typically remain unchanged for five years after the values are initially determined. Category I CPT codes can have values and associated pricing that are higher, lower or equal to their associated Category III CPT codes. We can provide no assurance that any Category I CPT code secured for the reimbursement of our Zio service will contain

values and pricing that are the same as or greater than the existing Category III CPT codes. In addition, to the extent CMS reduces its reimbursement rates for the Zio service, regardless of the Category of CPT code, third-party payors may reduce the rates at which they reimburse the Zio service, which could adversely affect our revenue.

Determinations of which products or services will be reimbursed under Medicare can be developed at the national level through a national coverage determination (“NCD”) by CMS, or at the local level through a local coverage determination, or an LCD, 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 regions. In the absence of an NCD, as is the case with Zio XT, the MAC with jurisdiction over a specific geographic region will have the discretion to make an LCD and determine the fee schedule and reimbursement rate associated with Category III CPT codes, and regional LCDs may not always be consistent among all MACs or regions within the United States. We have in the past been, and in the future may be, required to respond to potential changes in reimbursement rates for our products. Reductions in reimbursement rates, if enacted, could have a material adverse effect on our business. 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. Given the evolving nature of the healthcare industry and on-going healthcare cost reforms, we are and will continue to be subject to changes in the level of Medicare coverage for our products, and unfavorable coverage determinations at the national or local level could adversely affect our business and results of operations.

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 product prescriptions, 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 which is 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, or 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 recognized as a Medicaid provider by the state in which the Medicaid recipient receiving the services 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. In addition, and as noted above, each state’s Medicaid program has its own coverage determinations related to our Zio service, and many state Medicaid programs do not provide their recipients with coverage for our Zio service. 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 and 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 prescribed by physicians. If more healthcare cost controls are broadly instituted throughout the healthcare industry, the volume of cardiac monitoring solutions prescribed 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.

The current presidential administration and Congress may attempt to make sweeping changes to the current healthcare laws and their implementing regulations. It is uncertain how modification or repeal of any of the provisions of the Affordable Care Act or its implementing regulations, including as a result of current and future executive orders and legislative actions, will impact us and the medical device industry as a whole. 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, rescind or modify their reimbursement policies or delay payments for our products, including the 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 products, including the Zio service, at inadequate rates, suspend or discontinue reimbursement at any time or require or increase co-payments from patients. Any such actions could have a negative effect on our revenue and the revenue of providers prescribing our products. Physicians may not prescribe our products unless payors reimburse a substantial portion of the submitted costs, including the physician's, hospital's 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 prescribe another arrhythmia diagnostic monitoring option prior to prescribing 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 prescribed 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 continue to validate the clinical value of Zio services 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 contracted payors, 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 billing partner, XIFIN, Inc. ("XIFIN"), must appeal the denial. The appeals process is time-consuming and expensive, and may not result in full or any payment. 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 only 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 rates that are favorable to us. 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. If we fail to establish contracts with more third-party payors it may adversely affect our ability to increase our revenue. In addition, a failure to enter into contracts could affect a physician's willingness to prescribe 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 prescribe 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 and manufacturing operations and general and administrative infrastructure. In addition to the need to scale our clinical operations 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 mean that less experienced people manufacture our Zio monitors, market and sell our Zio service and analyze the data to produce Zio reports, which could result in inefficiencies and unanticipated costs, reduced quality in either our Zio reports or manufactured devices, and disruptions to our service operations. 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 compromise the quality 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 additional 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 on a timely basis 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 most recently 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. 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 sales 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.

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 prescribe our competitors' products and 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:

- we intend to continue to expand our manufacturing capacity, and our production processes may have to change to accommodate this growth;
- 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 in effect in California and elsewhere due to the COVID-19 outbreak;
- 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, including the FDA's Quality System Regulation ("QSR"), the EU's Medical Device Directive ("MDD") and, as of May 2021, the EU's Medical Device Regulation ("MDR") 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; and
- to increase our manufacturing output significantly and scale our services, we will have to attract and retain qualified employees for our operations.

Our inability to successfully manufacture our Zio monitors in sufficient quantities, or provide the Zio service in a timely manner, would materially harm our business.

Our 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 the QSR, MDD and, in the near future, MDR requirements. Developing and maintaining a compliant quality system is time consuming and investment intensive. 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.

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 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 resulting from modifications to, or discontinuation of, a supplier's operations;
- 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 the QSR and state regulatory authorities;
- miscommunication of design specifications due to errors/omissions by either the vendor or our company, resulting delayed delivery of acceptable product;
- delays in product shipments resulting from uncorrected 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 should the slowdown in China persist;

- 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; and
- delays in delivery by our suppliers due to changes in demand from us or their other customers.

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.

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 substrate, disposable plastic housings, instruments and other materials that we use to manufacture and label our Zio monitors. These components and materials are critical and 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 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 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 only one location. Our products are comprised 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, pandemics, flooding and power outages. Any of these may render it difficult or impossible for us to both manufacture new products and 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 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.

We plan to continue to expand and optimize our sales and marketing infrastructure in order to increase our prescribing physician base and our business. Identifying and recruiting qualified personnel and training them in the application of the Zio service, on applicable federal and state laws and regulations and on our 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.

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, institutions and patients, which may have different billing requirements procedures or expectations. We also must bill patient co-payments, co-insurance and deductibles. 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 deductibles;
- differences in information and billing requirements among payors; and
- incorrect or missing patient history, indications or billing information.

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 a participating provider in the Medicare program, and to be reimbursed by CMS under the program, we established an independent diagnostic treatment facility (or "IDTF"). An IDTF is a "provider-type" designation under Medicare, defined by CMS as an entity(ies) independent of a hospital or physician's office in which diagnostic tests are performed by licensed or certified nonphysician personnel under appropriate physician supervision. Our IDTFs are staffed by certified cardiographic technicians, who are overseen by a medical director who reviews the accuracy of the data we curate and from which we prepare reports. 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 defined rates. Certification as an IDTF requires that we follow strict regulations governing how the center operates, such as requirements regarding the experience and certifications of the certified cardiographic technicians. 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. 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 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.

In the first quarter of 2020, we recognized approximately five 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 delay 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 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 claims for our Zio service are not submitted to payors on a timely basis, 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 Holter monitors and mobile cardiac telemetry 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 prescribing 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 efficacy;
- acute and long term outcomes;
- ease of use;
- price;
- physician, hospital and clinic acceptance; and
- third-party reimbursement.

Large competitors in the ambulatory cardiac market include companies that sell standard Holter monitor equipment such as GE Healthcare, Philips Healthcare, Mortara Instrument, Inc., Spacelabs Healthcare, Inc. and Welch Allyn Holdings, Inc., which was acquired by Hill-Rom Holdings, Inc. Additional competitors, such as BioTelemetry, Inc. and Preventice Solutions, Inc., offer Holter and event, and mobile telemetry monitors, and also function as service providers. These companies have also developed other patch-based cardiac monitors that have received FDA and foreign regulatory clearances such as ePatch and MCOT Patch. There are also several small start-up companies trying to compete in the patch-based cardiac monitoring 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. recently 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 that compete with our Zio service. 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.

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. There are few barriers that would prevent new entrants or existing competitors from developing products that compete directly with ours. 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 monetizing our electrocardiogram ("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 have agreed to make additional payments over the term of the Development Agreement up to an aggregate of $12.75 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 approve the developed products or may require additional product testing and clinical trials before approving the developed products, which would result in product launch delays and additional expense. If approved by the FDA, the developed products may not be accepted in the marketplace.

After the initial term of the Development Agreement, 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.

The development, marketing, and sale 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, marketing and sale of our products. 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.

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 March 31, 2020, 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 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 Kevin M. King, our Chief Executive Officer, and Matthew C. Garrett, our Chief Financial Officer, are essential to formulating and executing on corporate strategy and to ensuring the continued operations and integrity of financial reporting within our company. In addition, the services provided by David A. Vort, our Executive Vice President of Sales, are critical to the growth that we have experienced in the sales of our Zio service. 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, our research and development programs and clinical operations depend on our ability to attract and retain highly skilled engineers and certified cardiographic technicians. We may not be able to attract or retain qualified 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 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; and
- compliance risks associated with General Data Protection Regulation ("GDPR") enacted to protect the privacy of all individuals in the European Union and addresses export of the data outside of 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 and the ongoing investigation, and outcome of the investigation, by government agencies of possible violations by us of the FCPA 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 prescribing physician for 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 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 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, 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, payment account information, age, gender, and heart rate 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. Our patient information is encrypted but not de-identified. 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 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. 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 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 access can be difficult to detect, and any delay in identifying them may lead to increased harm. 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 authorize or 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 the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the General Data Protection Regulation, and the European Union Data Protection Directive, and regulatory penalties. 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 user 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 user data. In addition, the interpretation and application of consumer, health-related and data protection laws, rules and regulations in the United States, Europe 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 recently enacted the California Consumer Privacy Act (“CCPA”), which became effective on January 1, 2020, and will, among other things, require new disclosures to California consumers and afford such consumers new abilities to opt out of certain sales of personal information. It remains unclear how various provisions of the CCPA will be interpreted and enforced. The effects of the CCPA 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 prescriptions 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; and
- possible write-offs or impairment charges relating to acquired businesses.

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, 2019, we had federal and state net operating loss carryforwards ("NOLs") of $259.9 million and $153.8 million, respectively, which if not utilized will begin to expire in 2027 for federal purposes and 2019 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. As of December 31, 2019, a Section 382 study has not been performed. 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 material weaknesses 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 below in Item 9A of our Form 10-K filed with the SEC on March 4, 2019, we identified material weaknesses 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 these material weaknesses, 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 Form 10-K filed with the SEC on March 4, 2019, we may need to commit additional resources, hire additional staff, and provide 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 these material weaknesses 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 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 and 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 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, 2019, we owned, or retained exclusive license to, seventeen issued U.S. patents, the earliest of which will expire in 2028. As of December 31, 2019, we also owned, or retained an exclusive license to, six issued patents from the Japanese Patent Office, two issued patents from each of the Australian, Canadian and European Patent Offices, and one issued patent from the Korean Patent Office. The earliest expiration date of these international patents is 2027. As of December 31, 2019, we had nineteen pending patent applications globally, including three in the United States, five in the European Patent Office, four in Japan, two in each of Korea and Canada, and one in each of Australia, 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 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 test requisitions, 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. 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 and clinics 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 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 teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information; HIPAA also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the GDPR, which replaces the 1995 Data Protection Directive known as Directive 95/46/EC;
- the federal physician self-referral prohibition, commonly known as the Stark Law; and
- state law equivalents of each of the above 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 $11,181 to $22,363 per false claim in 2018.

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 and 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 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 and Zio service are subject to extensive regulation by the FDA in the United States and by our Notified Body in the European Union. Government regulations specific to medical devices 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
- record keeping;
- product marketing, promotion and advertising, sales and distribution; and
- post-marketing surveillance, including reporting of deaths or serious injuries and recalls and 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 or premarketing 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, our clearance can be revoked if safety or efficacy problems develop.

In addition, we are required to file various reports with the FDA, and European regulators, including reports required by the medical device reporting regulations ("MDRs") that require that we report to the regulatory authorities if our Zio 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.

If we initiate a correction or removal 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. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our Zio service. Furthermore, the submission of these reports could be used by competitors against us and cause physicians to delay or cancel prescriptions, which could harm our reputation.

If we assess a potential quality issue or complaint 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, regulatory agencies may impose sanctions and we may be subject to regulatory enforcement actions, including warning letters, all of which could harm our business.

The FDA and the Federal Trade Commission ("FTC") also regulate the advertising and promotion of our products and services to ensure that the claims we make are consistent with our regulatory clearances, that there is adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading. 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.

The FDA 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 penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- 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 of regulatory clearance or premarket approvals that have already been granted;
- criminal prosecution.

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

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

Material modifications to the intended use or technological characteristics of the Zio monitors or Zio service will require new 510(k) clearances, premarket approvals or CE Mark grants, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. 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 approval, supplement or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA cleared device or service that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a premarket approval. We may not be able to obtain additional 510(k) clearances 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 an EU 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, 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 Medical Device Regulation ("MDR") will be required. All of these regulations cover procedures and documentation requirements for the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of Zio monitors. We are also subject to similar state requirements and licenses, and to ongoing ISO compliance in all operations, including design, manufacturing, and service, 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 unannounced inspections by governmental agencies, including the FDA, state authorities, EU Notified Bodies and comparable agencies in other countries. If we fail a regulatory inspection, our operations could be disrupted and our manufacturing interrupted. 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 recalls of our device, operating restrictions 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. The FDA has broad post-market and regulatory enforcement powers. We are subject to 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. Our design facilities in San Francisco, California were most recently audited by the FDA in June 2016 and no formal observations resulted. The most recent FDA audit of our manufacturing facility occurred in October 2018 and no formal observations resulted. No additional follow up with the FDA was required and we believe that we are in compliance, in all material respects, with the QSR.

We are also registered with the EU as a medical device developer, manufacturer and service operator through the National Standard Authority of Ireland ("NSAI") our European Notified Body. Most recently, the NSAI completed an ISO 13485 surveillance audit of our design, manufacturing and service operations in June 2019 and we believe that we are in compliance, in all material respects, with the MDD.

We can provide no assurance that we will continue to remain in compliance with the QSR or MDD, or to the European Union's new MDRs, which will be required to comply with by May 2021. If the FDA, CDPH or NSAI 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 defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design or labeling defects. Recalls of Zio monitors 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. The Affordable Care Act, among other things, imposed an excise tax of 2.3% on the sale of most medical devices, including ours, and any failure to pay this amount could result in the imposition of an injunction on the sale of our products, fines and penalties. Although this tax has been suspended through 2019, it is expected to apply to sales of our products in 2020 and thereafter. The current presidential administration and Congress may continue to pursue significant changes to the current health care laws. 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, which has commonly become to be known 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 (the “Withdrawal Agreement”). The Withdrawal Agreement provides that the U.K.’s withdrawal is followed by a “transition period”, during which, in summary, the U.K. is not a member of the E.U. but most E.U. rules and regulations continue to apply to the U.K. During the transition period, the U.K. and the E.U. will seek to negotiate the terms of a long-term trading relationship between the U.K. and the E.U. based on a “Political Declaration” agreed between the U.K. and the E.U. in October 2019. The transition period provided for in the Withdrawal Agreement will expire on December 31, 2020 (unless both the U.K. and the E.U. agree to extend the period of transition by one or two years). The political negotiation surrounding the terms of the U.K.’s withdrawal from the E.U. has created significant uncertainty about the future relationship between the U.K. and the E.U., including with respect to the laws and regulations that will apply. This is because, once the “transition period” expires then, subject to the terms of any long-term trading relationship agreed between the U.K. and the E.U., the U.K. will determine which E.U.-derived laws to replace or replicate. If no long-term trading relationship is agreed between the U.K. and the E.U. by the end of the transition period provided for in the Withdrawal Agreement, the U.K.’s membership of the E.U. could ultimately terminate under a so-called “hard Brexit.” The full effect of Brexit is uncertain and depends on any agreements the U.K. may make to retain access to E.U. markets. Consequently, no assurance can be given about the impact of the outcome and our business, including operational and tax policies, may be seriously harmed or require reassessment if our European operations or presence become a significant part of our business.

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 salesforce, 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 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;
- 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;
- changes in reimbursement 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 of 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.

In addition, the market prices of the stock of many new issuers in the medical device industry and of other companies with smaller market capitalizations like us have been volatile and from time to time have experienced significant share price and trading volume changes unrelated or disproportionate to the operating performance of those companies. Fluctuations in our stock price, volume of shares traded, and changes in our market valuations may make our stock less attractive to certain investors. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it 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 publish negative reports about our business, our share price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our shares or change their opinion of our business, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share 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 will incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404, which has increased now that we will no longer be an emerging growth company under the JOBS Act. 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.

We will incur additional compensation costs in the event that we decide to pay our executive officers cash compensation closer to that of executive officers of other public medical device companies, which would increase our general and administrative expense and could harm our profitability. Any future equity awards will also increase our compensation expense. We also expect that being a public company and compliance with applicable rules and regulations will make it 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.

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:

- a classified board of directors;
- 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 provides that the Court of Chancery of the State 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 provides that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State 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 arising pursuant to the Delaware General Corporation Law or 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 governed by the internal affairs doctrine. 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 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 cash dividends and do not anticipate paying cash 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 agreements limit our ability to, among other things, pay dividends or make other distributions or payments on account of our common stock, in each case 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 you sell our common stock after our stock price appreciates.

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

Not applicable.

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
31.1	Certification of Principal 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
31.2	Certification of Principal 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
32.1*	Certification 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.
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
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* 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.

+ Portions omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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: May 8, 2020

By: /s/ Kevin M. King

Kevin M. King
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 8, 2020

By: /s/ Matthew C. Garrett

Matthew C. Garrett
Chief Financial Officer
(Principal Financial Officer and Chief 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, Kevin M. King, 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)) for the registrant and we 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. 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

    c. 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 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/ Kevin M. King

Kevin M. King
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 8, 2020

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, Matthew C. Garrett, 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)) for the registrant and we 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. 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

    c. 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 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/ Matthew C. Garrett

Matthew C. Garrett
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: May 8, 2020

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 March 31, 2020, as filed with the Securities and Exchange Commission (the "Report"), Kevin M. King, as Chief Executive Officer of the Company, and Matthew Garrett, 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/ Kevin M. King

Kevin M. King
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 8, 2020

/s/ Matthew C. Garrett

Matthew C. Garrett
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: May 8, 2020

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.