# 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, 2019**

**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.)** |
| **650 Townsend Street, Suite 500, 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 3, 2019, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 24,686,878.
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 $.0001 Per Share | IRTC | The NASDAQ Global Select 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:

- 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 financial performance
- 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, 2019 | December 31, 2018 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 28,235 | $ 20,023 |
| Short-term investments | 30,507 | 58,320 |
| Accounts receivable, net | 28,252 | 21,977 |
| Inventory | 2,504 | 2,062 |
| Prepaid expenses and other current assets | 3,810 | 4,100 |
| Total current assets | 93,308 | 106,482 |
| Property and equipment, net | 10,208 | 9,158 |
| Operating lease right-of-use assets | 9,232 | — |
| Goodwill | 862 | 862 |
| Other assets | 3,574 | 3,208 |
| Total assets | $ 117,184 | $ 119,710 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,960 | $ 2,284 |
| Accrued liabilities | 20,099 | 26,570 |
| Deferred revenue | 1,309 | 1,243 |
| Accrued interest, current portion | 129 | 139 |
| Operating lease liabilities, current portion | 5,052 | — |
| Total current liabilities | 28,549 | 30,236 |
| Debt | 34,922 | 34,899 |
| Deferred rent, noncurrent portion | — | 153 |
| Operating lease liabilities, noncurrent portion | 3,990 | — |
| Total liabilities | 67,461 | 65,288 |
| Commitments and contingencies (Note 6) | | |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value – 5,000,000 shares authorized at March 31, 2019 and December 31, 2018; and none issued and outstanding at March 31, 2019 and December 31, 2018 | — | — |
| Common stock, $0.001 par value – 100,000,000 shares authorized at March 31, 2019 and December 31, 2018; 24,628,643 and 24,368,073 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively | 24 | 23 |
| Additional paid-in capital | 261,231 | 257,955 |
| Accumulated other comprehensive income (loss) | 2 | (41) |
| Accumulated deficit | (211,534) | (203,515) |
| Total stockholders' equity | 49,723 | 54,422 |
| Total liabilities and stockholders' equity | $ 117,184 | $ 119,710 |

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, | |
|---|---|---|
| | 2019 | 2018 |
| Revenue | $ 47,214 | $ 30,565 |
| Cost of revenue | 11,730 | 8,611 |
| Gross profit | 35,484 | 21,954 |
| Operating expenses: | | |
| Research and development | 6,756 | 4,019 |
| Selling, general and administrative | 36,705 | 28,577 |
| Total operating expenses | 43,461 | 32,596 |
| Loss from operations | (7,977) | (10,642) |
| Interest expense | (409) | (858) |
| Other income, net | 379 | 383 |
| Loss before income taxes | (8,007) | (11,117) |
| Income tax provision | 12 | — |
| Net loss | $ (8,019) | $ (11,117) |
| Net loss per common share, basic and diluted | $ (0.33) | $ (0.47) |
| Weighted-average shares, basic and diluted | 24,474,308 | 23,479,955 |

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, | |
|---|---|---|
| | 2019 | 2018 |
| Net loss | $ (8,019) | $ (11,117) |
| Other comprehensive income (loss): | | |
| Net change in unrealized losses on available-for-sale securities | 43 | (20) |
| Comprehensive loss | $ (7,976) | $ (11,137) |

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, | |
|---|---|---|
| | **2019** | **2018** |
| **Cash flows from operating activities** | | |
| Net loss | $ (8,019) | $ (11,117) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 621 | 548 |
| Stock-based compensation | 4,415 | 3,247 |
| Amortization of debt discount and issuance costs | 26 | 64 |
| Accretion of discounts on investments, net | (227) | (171) |
| Provision for doubtful accounts and contractual allowances | 4,709 | 2,680 |
| Amortization of operating lease right-of-use assets | 1,183 | — |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (10,984) | (5,536) |
| Inventory | (442) | (174) |
| Prepaid expenses and other current assets | (169) | 790 |
| Other assets | (365) | 409 |
| Accounts payable | (333) | (950) |
| Accrued liabilities | (6,380) | (2,977) |
| Deferred rent | — | 66 |
| Deferred revenue | 66 | (139) |
| Operating lease liabilities | (1,200) | — |
| Net cash used in operating activities | (17,099) | (13,260) |
| **Cash flows from investing activities** | | |
| Purchases of property and equipment | (1,635) | (1,108) |
| Purchases of available-for-sale investments | (9,616) | (5,437) |
| Maturities of available-for-sale investments | 37,700 | 28,004 |
| Net cash provided by investing activities | 26,449 | 21,459 |
| **Cash flows from financing activities** | | |
| Proceeds from issuance of common stock, net | 2,120 | 877 |
| Tax withholding upon vesting of restricted stock awards | (3,258) | (1,274) |
| Net cash used in financing activities | (1,138) | (397) |
| Net increase in cash, cash equivalents, and restricted cash | 8,212 | 7,802 |
| Cash, cash equivalents and restricted cash beginning of period | 20,023 | 8,671 |
| Cash, cash equivalents and restricted cash end of period | $ 28,235 | $ 16,473 |
| **Supplemental disclosures of cash flow information** | | |
| Interest paid | $ 411 | $ 787 |
| **Non-cash investing and financing activities** | | |
| Property, plant and equipment costs included in accounts payable and accrued liabilities | $ 38 | $ 80 |

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)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2019** | **2018** |
| Common stock: | | |
| Beginning balance | $ 23 | $ 23 |
| Issuance of common stock upon exercise of options | 1 | — |
| Ending balance | $ 24 | $ 23 |
| | | |
| Additional paid-in capital: | | |
| Beginning balance | $ 257,955 | $ 236,184 |
| Issuance of common stock upon exercise of options | 2,120 | 877 |
| Stock-based compensation expense | 4,415 | 3,247 |
| Tax withholding upon vesting of restricted stock awards | (3,259) | (1,271) |
| Ending balance | $ 261,231 | $ 239,037 |
| | | |
| Accumulated other comprehensive income (loss): | | |
| Beginning balance | $ (41) | $ (65) |
| Net change in unrealized losses on available for sale securities | 43 | (20) |
| Ending balance | $ 2 | $ (85) |
| | | |
| Accumulated deficit: | | |
| Beginning balance | $ (203,515) | $ (156,589) |
| Net loss | (8,019) | (11,117) |
| Cumulative effect of accounting changes | — | 1,354 |
| Ending balance | $ (211,534) | $ (166,352) |
| | | |
| Total stockholders' equity | $ 49,723 | $ 72,623 |

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

## 1. Organization and Description of Business

iRhythm Technologies, Inc. (the "Company") was incorporated in the state of Delaware in September 2006. The Company is a digital healthcare company redefining the way cardiac arrhythmias are clinically diagnosed by combining wearable biosensing technology with cloud-based data analytics and deep-learning capabilities. The Company commenced commercial introduction of its products 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.

## 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, 2018, and related disclosures, have been derived from the audited consolidated financial statements at that date but does 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. Certain prior period amounts in the accompanying consolidated financial statements have been reclassified to conform to current period presentation. The results of operations for the three months ended March 31, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 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, 2018 included in the Company's annual report on Form 10-K, filed with the SEC on March 4, 2019.

*Revision of Previously Reported Financial Information*

During the preparation of the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2019, the Company identified an error in the presentation of the changes in the allowance for doubtful accounts and contractual allowance disclosures in its Quarterly reports for the periods ended March 31, June 30 and September 30, 2018. During these quarters, a portion of the allowance for contractual adjustments was incorrectly presented as a provision for doubtful accounts. The Company concluded that the amounts were not material to any of its previously issued condensed consolidated financial statements. The error impacted the disclosures but did not impact the Company's condensed consolidated balance sheets, statements of operations or statements of cash flows. The error did not impact the disclosures in the previously issued consolidated financial statements in the Form 10-K for the year ended December 31, 2018.

The following tables presents the impact of the revision on the changes in the contractual allowance and allowance for doubtful accounts balances for the interim periods in the year ended December 31, 2018 (in thousands):

| Allowance for doubtful accounts | Three Months Ended March 31, 2018 | | Six Months Ended June 30, 2018 | | Nine Months Ended September 30, 2018 | |
|---|---|---|---|---|---|---|
| | As reported | As revised (1) | As reported | As revised (2) | As reported | As revised (3) |
| Balance, beginning of period | $ 3,568 | $ 3,568 | $ 3,568 | $ 3,568 | $ 3,568 | $ 3,568 |
| Add: provision for doubtful accounts | 1,691 | 325 | 3,822 | 1,791 | 5,917 | 3,254 |
| Less: write-offs, net of recoveries and other adjustments | 5 | 5 | (2,526) | (2,526) | (2,514) | (2,514) |
| Balance, end of period | $ 5,264 | $ 3,898 | $ 4,864 | $ 2,833 | $ 6,971 | $ 4,308 |

| Contractual Allowance | Three Months Ended March 31, 2018 | | Six Months Ended June 30, 2018 | | Nine Months Ended September 30, 2018 | |
|---|---|---|---|---|---|---|
| | As reported | As revised (1) | As reported | As revised (2) | As reported | As revised (3) |
| Balance, beginning of period | $ 7,444 | $ 7,444 | $ 7,444 | $ 7,444 | $ 7,444 | $ 7,444 |
| Add: allowance for contractual adjustments | 989 | 2,355 | 2,618 | 4,649 | 3,004 | 6,256 |
| Less: contractual adjustments | 18 | 18 | (3,072) | (3,072) | (2,467) | (3,056) |
| Balance, end of period | $ 8,451 | $ 9,817 | $ 6,990 | $ 9,021 | $ 7,981 | $ 10,644 |

Note that the above adjustments did not result in any changes to the Company's total receivables-related reserves for the periods in the table above.

(1) For the three months ended March 31, 2018, the allowance for contractual adjustments was increased by $1.4 million and the provision for doubtful accounts was reduced by the same amount.
(2) For the six months ended June 30, 2018, the allowance for contractual adjustments was increased by $2.0 million and the provision for doubtful accounts was reduced by the same amount.
(3) For the nine months ended September 31, 2018, the allowance for contractual adjustments was increased by $2.7 million and the provision for doubtful accounts was reduced by the same amount. In addition, in the contractual allowances table, contractual adjustments were increased by $0.6 million and the allowance for contractual adjustments was reduced by the same amount.

***Accounts Receivable, Allowance for Doubtful Accounts and Contractual Allowance***

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

The Company establishes an allowance for doubtful accounts for estimated uncollectible receivables based on its historical experience and recognizes the provision as a component of selling, general and administrative expenses. The Company establishes a contractual allowance when it estimates that consideration to be received will be lower than the contracted rate based on its historical experience and recognizes the provision as a reduction to revenue.

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

| | Three Months Ended March 31, 2019 | Year Ended December 31, 2018 |
|---|---|---|
| Balance, beginning of period | $ 4,851 | $ 3,568 |
| Add: provision for doubtful accounts | 828 | 5,826 |
| Less: write-offs, net of recoveries and other adjustments | (1,346) | (4,543) |
| Balance, end of period | $ 4,333 | $ 4,851 |

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

| | Three Months Ended March 31, 2019 | Year Ended December 31, 2018 |
|---|---|---|
| Balance, beginning of period | $ 10,601 | $ 7,444 |
| Add: allowance for contractual adjustments | 3,881 | 9,392 |
| Less: contractual adjustments | (1,435) | (6,235) |
| Balance, end of period | $ 13,047 | $ 10,601 |

The following table presents the impact of allowance for doubtful accounts and contractual allowance on accounts receivable (in thousands):

| | Three Months Ended March 31, 2019 | Year Ended December 31, 2018 |
|---|---|---|
| Gross accounts receivable | $ 45,632 | $ 37,429 |
| Less: allowance for doubtful accounts | (4,333) | (4,851) |
| Less: contractual allowance | (13,047) | (10,601) |
| Net accounts receivable | $ 28,252 | $ 21,977 |

The Company reviews and updates its estimates for the allowances for doubtful accounts and contractual allowance periodically to reflect its experience regarding historical collections. If management were to make different judgments or utilize different estimates in the allowances for doubtful accounts and contractual allowance, differences in the amount of reported selling, general and administrative expenses and revenue could result, respectively.

***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, cash equivalents, and investments 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 when it becomes probable that a receivable will not be collected. Federal government agencies, including Centers for Medicare and Medicaid Services (“CMS”) and the military, accounted for approximately 35% and 37% of the Company’s revenue for the three months ended March 31, 2019 and 2018, respectively. Accounts receivable related to federal government agencies accounted for 19% and 18% at March 31, 2019 and December 31, 2018, 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 accounts for contract revenue with a customer when there is a legally enforceable contract between the Company and the customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. The Company's revenue is measured based on consideration specified in the contract with each customer. A unique aspect of healthcare is the involvement of multiple parties to the service transaction. In addition to the patient, often a third-party, for example a commercial or governmental payor or healthcare institution, like a hospital or clinic, will pay 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 and should be considered in determining collectability and the transaction price for services provided to a patient covered by that third-party payor.

The Company recognizes revenue on an accrual basis based on estimates of the amount that will ultimately be realized. These estimates require significant judgment by management. In determining the amount to recognize for a delivered report, 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.

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 rate 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 is based on factors including an average of the Company’s historical collection experience for 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 Veteran’s Administration and Department of Defense.

The Company is utilizing the portfolio approach practical expedient under ASC 606 for revenue recognition. 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 the healthcare institution, the Company has historical experience of collecting substantially all of the negotiated contractual rates and determined at contract inception that these customers, and or their related third-party payor that pays the Company on their behalf, have the intention and ability to pay the promised consideration. As such, the Company is not providing an implicit price concession but, rather, has chosen to accept the risk of default, and any subsequent impairment of the related receivable are recorded as bad debt expense.

For contracted and CMS portfolios, the Company is providing an implicit price concession because, while the Company has a contract with the underlying payor, the Company expects to accept a lower amount of consideration when claims are adjudicated and allowable claims are determined by the commercial payor. The implicit price concession is recorded as variable consideration to the transaction price and recorded as an adjustment to revenue as a contractual allowance. Historical cash collection indicates that it is probable that substantially all of the allowable claim amount will be received, and hence this amount is recorded as revenue. Any subsequent impairment of the related receivable is recorded as bad debt expense.

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

***Disaggregation of Revenue***

The Company disaggregates revenue from contracts with customers by payor type. The Company believes these categories aggregate the payor types by nature, amount, timing and uncertainty of its revenue streams. Disaggregated revenue by payor type and major service line for the three months ended March 31, 2019 was as follows (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2019 | 2018 |
| Commercial Payors | $ 24,347 | $ 13,491 |
| Centers for Medicare & Medicaid | 12,746 | 8,432 |
| Healthcare Institutions | 10,121 | 8,642 |
| Total | $ 47,214 | $ 30,565 |

***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, or contract liabilities are recorded as deferred revenue on the Condensed Consolidated Balance Sheets and revenue is recognized when reports are delivered to physicians. Total revenue recognized during each of the three months ended March 31, 2019 and March 31, 2018 that was included in the contract liability balance at the beginning of each respective period was $1.2 million.

***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.

***Leases***

*Identifying a lease*

The Company determines whether a contract contains a lease at the inception of a contract. If the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration, the Company considers the contract to contain a lease. The Company determines whether a contract conveys the right to control the use of an identified asset for a period of time if the contract contains both of the following terms:

- The right to obtain substantially all of the economic benefits from use of the identified asset
- The right to direct the use of the identified asset

*Discount Rate for leases*

On January 1, 2019, the rate implicit in the Company's leases was not readily determinable. As such, the Company used its incremental borrowing rate to calculate its right-of-use assets and lease liabilities. The Company determined the appropriate incremental borrowing rate by utilizing the interest rate obtained in connection with the Third Amended and Restated Loan and Security Agreement with Silicon Valley Bank which was finalized on October 23, 2018.

*Lease term*

The lease term is generally the minimum noncancelable period of each lease. The Company does not include option periods in determining the right-of-use asset and right-of-use liability unless it is reasonably certain that the Company will exercise the option at inception or when a triggering event occurs. As of March 31, 2019, the Company did not include any options to renew in the lease terms of its current lease portfolio.

***Recently Adopted Accounting Guidance***

In February 2016, the Financing Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, Leases ("Topic 842"), which requires lessees to recognize lease liabilities and corresponding right-of-use assets on the consolidated balance sheet for all leases. For finance leases, the lessee would recognize interest expense and amortization of the right-of-use asset and, for operating leases, the lessee would recognize a straight-line lease expense. Topic 842 also changes the definition of a lease and expands the disclosure requirements of lease arrangements. The Company has no embedded leases with suppliers. Upon adoption of Topic 842 on January 1, 2019 using the modified retrospective method, the Company recognized right-of-use assets of $10.4 million and lease liabilities of $10.2 million. There was no cumulative-effect adjustment recorded on January 1, 2019. The Company adopted the following practical expedients allowed under Topic 842:

- The package of three practical expedients, which allows entities to make an election that allows them not to reassess (1) whether existing or expired contracts contain embedded leases under Topic 842, (2) lease classification of existing or expiring leases, and (3) indirect costs for existing or expired leases
- Combining lease and non-lease components practical expedient, which allows lessees, as an accounting policy election by class of underlying asset, to choose not to separate non-lease components from lease components and instead to account for each separate lease component and the non-lease components associated with that lease component as a single lease component
- Comparative reporting practical expedient, which allows entities to initially apply Topic 842 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption

For further details, refer to *Note 6. Commitments and Contingencies*.

**3. Cash Equivalents and Investments**

The fair value of securities, not including cash at March 31, 2019 and December 31, 2018, were as follows (in thousands):

| | March 31, 2019 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| Money market funds | $ 23,613 | $ — | $ — | $ 23,613 |
| U.S. government securities | 3,476 | 1 | — | 3,477 |
| Corporate notes | 11,284 | 2 | — | 11,286 |
| Commercial paper | 15,744 | — | — | 15,744 |
| Total available-for-sale marketable debt securities | $ 54,117 | $ 3 | $ — | $ 54,120 |
| Classified as: | | | | |
| Cash equivalents | | | | $ 23,613 |
| Short-term investments | | | | 30,507 |
| Total cash equivalents and investments | | | | $ 54,120 |

| | December 31, 2018 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| Money market funds | $ 10,606 | $ — | $ — | $ 10,606 |
| U.S. government securities | 9,976 | — | (1) | 9,975 |
| Corporate notes | 16,514 | 3 | (18) | 16,499 |
| Commercial paper | 36,331 | — | — | 36,331 |
| Total available-for-sale marketable debt securities | $ 73,427 | $ 3 | $ (19) | $ 73,411 |
| Classified as: | | | | |
| Cash equivalents | | | | $ 15,091 |
| Short-term investments | | | | 58,320 |
| Total cash equivalents and investments | | | | $ 73,411 |

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, 2019 | December 31, 2018 |
|---|---|---|
| Due within one year | $ 54,120 | $ 73,411 |
| Due after one year through three years | — | — |
| Total available-for-sale marketable debt securities | $ 54,120 | $ 73,411 |

The following tables present the Company's available-for-sale securities that were in an unrealized loss position as of March 31, 2019 and December 31, 2018 (in thousands):

| | As of March 31, 2019 | | | | | |
|---|---|---|---|---|---|---|
| | Less than 12 months | | 12 Months or Greater | | Total | |
| Assets | Fair Value | Unrealized Loss | Fair Value | Unrealized Loss | Fair Value | Unrealized Loss |
| Corporate notes | $ 2,498 | $ — | $ — | $ — | $ 2,498 | $ — |
| Total | $ 2,498 | $ — | $ — | $ — | $ 2,498 | $ — |

| | December 31, 2018 | | | | | |
|---|---|---|---|---|---|---|
| | Less than 12 months | | 12 Months or Greater | | Total | |
| Assets | Fair Value | Unrealized Loss | Fair Value | Unrealized Loss | Fair Value | Unrealized Loss |
| U.S. government securities | $ 5,977 | $ (1) | $ — | $ — | $ 5,977 | $ (1) |
| Corporate notes | 11,521 | (10) | 2,993 | (8) | 14,514 | (18) |
| Total | $ 17,498 | $ (11) | $ 2,993 | $ (8) | $ 20,491 | $ (19) |

Available-for-sale securities held as of March 31, 2019 had a weighted average days to maturity of 30 days. As of March 31, 2019, the Company had one investment in an unrealized loss position, and no investment has been in an unrealized loss position for more than 12 months. There have been no material realized gains or realized losses on available-for-sale securities for the periods presented.

**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 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, 2019 are $34.9 million and $34.9 million, respectively. The carrying amount and the estimated fair value of the Company’s outstanding interest-bearing obligations at December 31, 2018 were $34.9 million and $34.9 million, respectively.

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

The following table presents the fair value of the Company's financial assets and liabilities determined using the inputs defined above (amounts in thousands).

| | March 31, 2019 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Assets** | | | | |
| Money market funds | $ 23,613 | $ — | $ — | $ 23,613 |
| U.S. government securities | — | 3,477 | — | 3,477 |
| Corporate notes | — | 11,286 | — | 11,286 |
| Commercial paper | — | 15,744 | — | 15,744 |
| Total | $ 23,613 | $ 30,507 | $ — | $ 54,120 |

| | December 31, 2018 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Assets** | | | | |
| Money market funds | $ 10,606 | $ — | $ — | $ 10,606 |
| U.S. government securities | — | 9,975 | — | 9,975 |
| Corporate notes | — | 16,499 | — | 16,499 |
| Commercial paper | — | 36,331 | — | 36,331 |
| Total | $ 10,606 | $ 62,805 | $ — | $ 73,411 |

## 5. Balance Sheet Components

***Inventory***

Inventory and Printed Circuit Board Assemblies ("PCBAs"), which are recorded as other assets as they are used many times over a period longer than one year on average, consisted of the following (in thousands):

| | March 31, 2019 | December 31, 2018 |
|---|---|---|
| Raw materials | $ 968 | $ 1,028 |
| Finished goods | 4,661 | 3,565 |
| Total | $ 5,629 | $ 4,593 |
| | | |
| Classified as: | | |
| Inventory | $ 2,504 | $ 2,062 |
| Other assets | 3,125 | 2,531 |
| Total | $ 5,629 | $ 4,593 |

Amounts reported as other assets are comprised of the PCBA costs that are included in both raw materials and finished goods totals above.

***Property and Equipment, Net***

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

| | March 31, 2019 | December 31, 2018 |
|---|---|---|
| Laboratory and manufacturing equipment | $ 3,120 | $ 2,750 |
| Computer equipment and software | 1,062 | 1,062 |
| Furniture and fixtures | 925 | 925 |
| Leasehold improvements | 726 | 726 |
| Internal-use software | 10,228 | 8,925 |
| Total property and equipment, gross | 16,061 | 14,388 |
| Less: accumulated depreciation and amortization | (5,853) | (5,230) |
| Total property and equipment, net | $ 10,208 | $ 9,158 |

Depreciation and amortization expense was $0.6 million and $0.5 million for the three months ended March 31, 2019 and 2018, respectively.

***Accrued Liabilities***

Accrued liabilities consisted of the following (in thousands):

| | March 31, 2019 | December 31, 2018 |
|---|---|---|
| Accrued vacation | $ 3,404 | $ 2,825 |
| Accrued payroll and related expenses | 8,443 | 18,188 |
| Accrued ESPP contributions | 1,530 | 352 |
| Accrued professional services fees | 867 | 1,243 |
| Claims payable | 3,420 | 2,374 |
| Other | 2,435 | 1,588 |
| Total accrued liabilities | $ 20,099 | $ 26,570 |

**6. Commitments and Contingencies**

***Lease Arrangements***

The Company leases office, manufacturing, and clinical centers under non-cancelable operating leases which expire on various dates through 2031. These leases generally contain scheduled rent increases or escalation clauses and renewal options. Operating lease right-of-use assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The operating lease right-of-use assets also include any lease payments made to the lessor at or before the commencement date. The Company recognizes operating lease expense on a straight-line basis over the lease period. The total operating lease cost recognized during the three months ended March 31, 2019 was $1.3 million and cash paid for operating leases during the three months ended March 31, 2019 was $1.4 million.

On October 4, 2018, the Company entered into an office lease (“San Francisco Lease”) to rent approximately 117,560 rentable square feet in San Francisco, California, which will become the Company’s new headquarters. The Company’s current headquarters is in the same building as the office space covered by the San Francisco Lease.

The San Francisco lease is expected to commence on or around the second quarter of 2019 and has a twelve-year term, which will expire on August 31, 2031. The Company is entitled to one option to extend the San Francisco Lease for a five-year term, subject to certain requirements. In addition, the landlord will provide a tenant improvement allowance of up to $2.4 million for leasehold improvements in connection with the cost of construction of the initial alterations within the premises.

Annual rental payments will be $10.0 million, with a 3% increase each year and will be accounted for in accordance with Topic 842.

The Company has obtained a standby letter of credit in the amount of $6.9 million, which may be drawn down by the landlord to be applied for certain purposes upon the Company's breach of any provisions under the San Francisco Lease.

As of March 31, 2019, maturities of operating lease liabilities were as follows (in thousands):

| **Period Ending December 31:** | | |
|---|---|---|
| 2019 (remainder of year) | $ | 4,107 |
| 2020 | | 2,092 |
| 2021 | | 1,160 |
| 2022 | | 432 |
| 2023 | | 427 |
| Thereafter | | 1,698 |
| | | 9,916 |
| Less: imputed interest | | (874) |
| Total operating lease liabilities | $ | 9,042 |

Minimum future lease payments previously disclosed in the 2018 10-K and under the previous lease accounting standard, which includes annual rental payments for the San Francisco lease which has not commenced as of the reporting date, for the year ended December 31, 2018 are as follows (in thousands):

| **Period Ending December 31:** | | |
|---|---|---|
| 2019 | $ | 8,135 |
| 2020 | | 10,669 |
| 2021 | | 10,828 |
| 2022 | | 11,150 |
| 2023 | | 11,483 |
| Thereafter | | 98,209 |
| Total | $ | 150,474 |

The weighted average remaining lease term of the Company's operating leases as of March 31, 2019 was 3.95 years. The weighted average discount rate of the Company's operating leases is 4.75% as of March 31, 2019.

***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.

***Indemnifications***

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. 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 California corporate 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**

***Pharmakon Loan Agreement***

In December 2015, the Company entered into a Loan Agreement with Biopharma Secured Investments III Holdings Cayman LP (the "Pharmakon Loan Agreement"). The Pharmakon Loan Agreement provides for up to $55.0 million in term loans split into two tranches as follows: (i) the Tranche A Loans are $30.0 million in term loans, and (ii) the Tranche B Loans are up to $25.0 million in term loans. The Tranche A Loans were drawn on December 4, 2015. The Tranche B Loans were available to be drawn prior to December 4, 2016. No additional draw was taken.

The Tranche A Loans bear interest at a fixed rate equal to 9.50% per annum that is due and payable quarterly in arrears. During the first eight calendar quarters, 50% of the interest due and payable was added to the then outstanding principal.

In December 2015, the Company used the proceeds from the Pharmakon Loan Agreement to repay $4.9 million of bank debt to Silicon Valley Bank ("SVB"). The issuance costs and debt discount have been netted against the borrowed funds on the balance sheet.

On October 23, 2018, the Company repaid the principal amount of the Tranche A Loan of $30.0 million and related accrued interest of $3.3 million. The Company incurred a $3.0 million loss in connection with the early extinguishment of the Pharmakon Loan Agreement which included a prepayment premium fee of $1.0 million and additional consideration related to the prepayment of $1.5 million.

***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 may 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 becomes 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 may borrow up to 80% of its eligible accounts receivable, up to the maximum of $15.0 million.

In August 2016, the Company obtained a $3.1 million standby letter of credit pursuant to the SVB Loan Agreement in connection with a lease for its San Francisco office.

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, 2019, 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, 2019. The obligations under the Third Amended and Restated Loan Agreement are collateralized by substantially all assets of the Company.

***California HealthCare Foundation Note***

In November 2012, the Company entered into a Note Purchase Agreement and Promissory Note with the California HealthCare Foundation (the "CHCF Note"), through which the Company borrowed $1.5 million. The CHCF Note accrued simple interest of 2.0%. The accrued interest and the principal was to mature in November 2016. In partial consideration for the issuance of the CHCF Note, the Company issued warrants to purchase 22,807 shares of the Company's Series D convertible preferred stock.

In June 2015, the Company amended the CHCF Note to extend the maturity date to May 2018. The CHCF Note was subordinate to other debt. In May 2018, the Company repaid the principal amount of $1.5 million and related $0.2 million in accrued interest on the CHCF Note.

**8. Income Taxes**

The Company recorded an immaterial tax provision related to its U.K. entity during the three months ended March 31, 2019. The Company did not record a provision or benefit for income taxes during the three months ended March 31, 2018, as it reported losses in each period which are not more likely than not to be realized. Due to the uncertainties surrounding the realization of deferred tax assets through future taxable income, the Company has provided a full valuation allowance and, therefore, no benefit has been recognized for the net operating loss carryforwards and other deferred tax assets.

## 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, 2019.

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

| | March 31, 2019 | December 31, 2018 |
|---|---|---|
| Options issued and outstanding | 1,885,914 | 2,094,137 |
| Unvested restricted stock units | 896,759 | 547,891 |
| Common stock warrants issued and outstanding | 4,857 | 4,857 |
| Shares available for grant under future stock plans | 6,789,722 | 5,607,014 |
| Total | 9,577,252 | 8,253,899 |

## 10. Stock Incentive Plans

### Equity Incentive Plan Activity

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

| | Awards Available for Grant |
|---|---|
| **Balance at December 31, 2017** | **4,034,152** |
| Additional awards authorized | 1,168,865 |
| Awards granted | (666,913) |
| Awards forfeited | 124,478 |
| Awards withheld for tax purposes | 56,710 |
| **Balance at December 31, 2018** | **4,717,292** |
| Additional options authorized | 1,218,402 |
| Awards granted | (481,366) |
| Awards forfeited | 46,222 |
| Awards withheld for tax purposes | 33,929 |
| **Balance at March 31, 2019** | **5,534,479** |

The following table summarizes stock option activity under the 2006 and 2016 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, 2017** | **2,601,181** | $ 12.24 | 7.17 | $ 113,958 |
| Options granted | 366,928 | $ 68.32 | | |
| Options exercised | (798,424) | $ 7.19 | | |
| Options forfeited | (75,548) | $ 34.30 | | |
| **Balance at December 31, 2018** | **2,094,137** | $ 23.20 | 7.02 | $ 97,976 |
| Options granted | 18,730 | $ 83.54 | | |
| Options exercised | (203,552) | $ 10.42 | | |
| Options forfeited | (23,401) | $ 58.23 | | |
| **Balances at March 31, 2019** | **1,885,914** | $ 24.74 | 6.96 | $ 95,499 |
| Options exercisable – March 31, 2019 | 1,230,759 | $ 13.74 | 6.30 | $ 75,343 |
| Options vested and expected to vest – March 31, 2019 | 1,850,457 | $ 24.18 | 6.93 | $ 94,689 |

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 and 2018, the Company granted options with a weighted-average grant date fair value of $38.65 and $30.70 per share, respectively.

## 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 a Black-Scholes option valuation model with the weighted average assumptions below.

| | Three Months Ended March 31, | |
|---|---|---|
| | 2019 | 2018 |
| Expected term (in years) | 6.1 | 6.1 |
| Expected volatility | 45.0% | 45.9% |
| Risk-free interest rate | 2.40% | 2.72% |
| Dividend yield | 0.0% | 0.0% |

### *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, | |
|---|---|---|
| | 2019 | 2018 |
| Cost of revenue | $ 88 | $ 117 |
| Research and development | 873 | 576 |
| Selling, general and administrative | 3,454 | 2,554 |
| Total stock-based compensation expense | $ 4,415 | $ 3,247 |

As of March 31, 2019, there was total unamortized compensation costs of $13.2 million, net of estimated forfeitures, related to unvested stock options which the Company expects to recognize over a period of approximately 2.2 years, $39.5 million, net of estimated forfeitures, related to unrecognized restricted stock unit ("RSU") expense, which the Company expects to recognize over a period of 2.6 years, and $0.9 million unrecognized ESPP expense, which the Company will recognize over 0.7 years.

***Performance based RSUs ("PRSU")***

During the three months ended March 31, 2019, the Company granted PRSUs to key executives of the Company. The performance equity program has a 2-year performance period measuring target revenue Compound Annual Growth Rate ("CAGR") achievement for fiscal year 2020 compared to fiscal year 2018. There is a minimum performance threshold of 75% to earn 50% of target, and a maximum threshold of 125% achieved to earn 200% of target. The exact number of earned shares will be determined based on linear interpolation using the revenue CAGR as it falls between the minimum and maximum thresholds outlined above. The fair value of the PRSUs granted during the three months ended March 31, 2019 will range from $0 to $19.5 million, depending on the achievement of the performance target. A total of 202,738 PRSUs were granted and the Company did not record any expense for these grants for the three months ended March 31, 2019. In the event that achievement of the performance targets becomes probable, the Company will recognize a cumulative expense amount for prior periods.

**12. Net Loss Per Common Share**

As the Company had net losses for the three months ended March 31, 2019 and 2018, all potential common shares were determined to be anti-dilutive. The following table sets forth the computation of the basic and diluted net loss per share attributable to holders of common stock (in thousands, except share and per share data):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2019 | 2018 |
| Numerator: | | |
| Net loss | $ (8,019) | $ (11,117) |
| Denominator: | | |
| Weighted-average shares used to compute net loss per common share, basic and diluted | 24,474,308 | 23,479,955 |
| Net loss per common share, basic and diluted | $ (0.33) | $ (0.47) |

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, 2019 and 2018, because their inclusion would be anti-dilutive:

| | As of March 31, | |
|---|---|---|
| | 2019 | 2018 |
| Options to purchase common stock | 1,885,914 | 2,695,913 |
| RSUs issued and unvested | 896,759 | 581,127 |
| Warrants to purchase common stock | 4,857 | 4,857 |
| Total | 2,787,530 | 3,281,897 |

## 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
- 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 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 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. Third-party payors accounted for approximately 91%, and 85% of our revenue for the three months ended March 31, 2019 and 2018, respectively. Our revenue in the third-party commercial payor category is primarily contracted, which means we have entered into pricing contracts with these payors. Approximately 35% and 37% of our total revenue for the three months ended March 31, 2019 and 2018, respectively, is received from federal government agencies under established reimbursement codes. Institutions, which are typically hospitals or private physician practices accounted for approximately 9% and 15% of our revenue for the three months ended March 31, 2019 and 2018, respectively. We rely on a third-party billing partner, XIFIN, Inc., to submit patient claims and collect from commercial payors, certain government agencies, and patients.

Since our Zio service was cleared by the U.S. Food and Drug Administration ("FDA"), we have provided the Zio service to over one million patients and have collected approximately 400 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, and quota-carrying sales representatives. 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. We continue to increase the size of our U.S. sales organization to expand the current customer account base and increase utilization of our Zio service. In addition, we will continue exploring sales and marketing expansion opportunities in international geographies.

**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 third-party payors, which include commercial payors and government agencies, such as CMS 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.

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, 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 expect our revenue to increase as we expand our sales and marketing infrastructure, increase awareness of our product offerings, increase the number of covered and contracted lives for our Zio service, expand the range of indications for our Zio service and develop new products and services. 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.

***Cost of Revenue and Gross Margin***

Cost of revenue is expensed as incurred and 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 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 monitor includes a PCBA, 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. Historically, we have increased our average selling price by entering into contracts with third-party commercial payors at rates that were higher than amounts typically collected from payors without contracts or from institutional customers. 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 believe we will be able to continue to achieve pricing increases as more payors contract with us due to the benefits the Zio service provides compared to other available products. 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. We expect further decreases in the cost of service as we spread the fixed portion of our overhead costs over a larger number of units produced, which will result in a decrease in our per unit manufacturing costs.

***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. We expect our sales and marketing expenses to increase in absolute dollars as we hire additional sales personnel and increase our sales support infrastructure in order to further penetrate the U.S. market and expand into international markets.

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 consists of cash and non-cash components. The cash component of 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, 2019 and 2018***

| | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| | 2019 | 2018 | $ Change | % Change |
| Revenue | $ 47,214 | $ 30,565 | $ 16,649 | 54% |
| Cost of revenue | 11,730 | 8,611 | 3,119 | 36% |
| Gross profit | 35,484 | 21,954 | 13,530 | 62% |
| *Gross margin* | 75% | 72% | | |
| Operating expenses: | | | | |
| Research and development | 6,756 | 4,019 | 2,737 | 68% |
| Selling, general and administrative | 36,705 | 28,577 | 8,128 | 28% |
| Total operating expenses | 43,461 | 32,596 | 10,865 | 33% |
| Loss from operations | (7,977) | (10,642) | 2,665 | 25% |
| Interest expense | (409) | (858) | 449 | 52% |
| Other income, net | 379 | 383 | (4) | 1% |
| Loss before income taxes | (8,007) | (11,117) | 3,110 | 28% |
| Income tax provision | 12 | — | 12 | n/a |
| Net loss | $ (8,019) | $ (11,117) | $ 3,098 | 28% |

***Revenue***

Revenue increased $16.6 million, or 54%, to $47.2 million during the three months ended March 31, 2019 from $30.6 million during the three months ended March 31, 2018. The increase in revenue was 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 under contract, increasing physician acceptance and expansion of our sales force as we continue to gain market acceptance for our Zio service.

***Cost of Revenue and Gross Margin***

Cost of revenue increased $3.1 million, or 36%, to $11.7 million during the three months ended March 31, 2019 from $8.6 million during the three months ended March 31, 2018. The increase in cost of revenue was primarily due to increased Zio service volume in 2019. This increase was partially offset by the reduction in costs to provide the Zio service, which was achieved through manufacturing efficiencies in the production of our device and reductions in cardiac technician labor costs through algorithm improvements and software driven workflow enhancements.

Gross margin for the three months ended March 31, 2019 increased to 75%, compared to 72% for the three months ended March 31, 2018. The increase was driven primarily by the reduction in the cost of the Zio service due to our continued efforts to lower manufacturing costs, fixed costs absorption and reduced labor costs per device through our algorithm improvements and software-driven and other workflow enhancements.

***Research and Development Expenses***

Research and development expenses increased $2.7 million, or 68%, to $6.8 million during the three months ended March 31, 2019 from $4.0 million during the three months ended March 31, 2018, which was driven by incremental costs related to Zio AT as well as other product development efforts. The increase was primarily attributable to a $2.0 million increase in payroll and personnel-related expenses as a result of increased headcount, and $0.6 million for allocated facility-related expenses.

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses increased $8.1 million, or 28%, to $36.7 million during the three months ended March 31, 2019 from $28.6 million during the three months ended March 31, 2018. The increase was primarily attributable to a $6.8 million increase in payroll and personnel-related expenses as a result of increased headcount to support the growth in our operations, which included an increase of $2.3 million in commissions and bonus primarily as a result of increased revenues, as well as an additional $1.0 million increase in bad debt expense.

A significant amount of selling, general, and administrative incremental spend can be directly attributed to our continued focus on salesforce expansion and its support infrastructure to support our growth strategy.

***Interest Expense***

Interest expense decreased to $0.4 million for the three months ended March 31, 2019, compared to $0.9 million for the three months ended March 31, 2018 due to the decrease in interest rate as a result of the extinguishment of the loan agreement with Biopharma Secured Investments III Holdings Cayman LP in October 2018 as well as repayment of the loan agreement with California HealthCare Foundation in May 2018.

***Other Income, Net***

Other income, net was $0.4 million for the three months ended March 31, 2019, compared to $0.4 million for the three months ended March 31, 2018. There were no significant changes within other income, net in 2019.

**Liquidity and Capital Expenditures**

***Overview***

As of March 31, 2019, we had cash and cash equivalents of $28.2 million and short-term investments of $30.5 million and an accumulated deficit of $211.5 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, | |
|---|---|---|
| | 2019 | 2018 |
| Net cash (used in) provided by: | | |
| Operating activities | $ (17,099) | $ (13,260) |
| Investing activities | 26,449 | 21,459 |
| Financing activities | (1,138) | (397) |
| Net increase in cash, cash equivalents, and restricted cash | $ 8,212 | $ 7,802 |

**Cash Used in Operating Activities**

During the three months ended March 31, 2019, cash used in operating activities was $17.1 million, which consisted of a net loss of $8.0 million, adjusted by non-cash charges of $10.7 million and a net change of $19.8 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of a change in allowance for doubtful accounts and contractual allowance of $4.7 million and in stock based-based compensation of $4.4 million. The change in our net operating assets and liabilities was primarily due to an increase of $11.0 million in accounts receivable as a result of increased revenues.

During the three months ended March 31, 2018, cash used in operating activities was $13.3 million, which consisted of a net loss of $11.1 million, adjusted by non-cash charges of $6.4 million and a net change of $8.5 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of a change in stock based-based compensation of $3.2 million, in allowance for doubtful accounts and contractual allowance of $2.7 million. The change in our net operating assets and liabilities was primarily due to an increase of $5.5 million in accounts receivable and a decrease of $3.0 million of accrued payroll related expenses.

**Cash Provided by Investing Activities**

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 $1.6 million of capital expenditures to purchase property and equipment.

Cash provided by investing activities during the three months ended March 31, 2018 was $21.5 million, which consisted primarily of $28.0 million in cash received from the maturities of available for sale investments, partially offset by purchases of available for sale investments of $5.4 million, and $1.1 million of capital expenditures to purchase property and equipment.

**Cash Used in Financing Activities**

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

During the three months ended March 31, 2018, cash used in financing activities was $0.4 million, primarily due $1.3 million tax withholding upon the vesting of Restricted Stock Units, partially offset by $0.9 million in proceeds from the issuance of common stock

**Indebtedness**

In December 2015, we entered into a Loan Agreement with Biopharma Secured Investments III Holdings Cayman LP (the “Pharmakon Loan Agreement”). The Pharmakon Loan Agreement provided for up to $55.0 million in term loans split into two tranches as follows: (i) the Tranche A Loans were $30.0 million in term loans, and (ii) the Tranche B Loans were up to $25.0 million in term loans. The Tranche A Loans were drawn on December 4, 2015. The Tranche B Loans were available to be drawn prior to December 4, 2016. No additional draw was taken.

The Tranche A Loans bore interest at a fixed rate equal to 9.50% per annum that was due and payable quarterly in arrears. During the first eight calendar quarters, 50% of the interest due and payable was added to the then outstanding principal.

In December 2015, we used the proceeds from the Pharmakon Loan Agreement to repay $4.9 million of bank debt to SVB. The issuance costs and debt discount were netted against the borrowed funds on the balance sheet.

On October 23, 2018, we repaid the principal amount of the Tranche A Loan of $30.0 million and related accrued interest of $3.3 million. We incurred a $3.0 million loss in connection with the early extinguishment of the Pharmakon Loan Agreement which included a prepayment premium fee of $1.0 million and additional consideration related to prepayment of $1.5 million.

***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 may borrow up to 80% of our eligible accounts receivable, up to the maximum of $15.0 million.

In August 2016, we obtained a $3.1 million standby letter of credit pursuant to the SVB Loan Agreement in connection with a lease for the San Francisco office.

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, 2019 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 December 31, 2018. The obligations under the Third Amended and Restated Loan Agreement are collateralized by substantially all of our assets.

***California HealthCare Foundation Note***

In November 2012, we entered into a Note Purchase Agreement and Promissory Note with the California HealthCare Foundation (the "CHCF Note") through which we borrowed $1.5 million. The CHCF Note accrued simple interest of 2.0%. The accrued interest and the principal was to mature in November 2016. In partial consideration for the issuance of the CHCF Note, we issued warrants to purchase 22,807 shares of the Company's Series D convertible preferred stock.

In June 2015, we amended the CHCF Note to extend the maturity date to May 2018.

The CHCF Note was subordinate to other debt. In May 2018, we repaid the principal amount of $1.5 million and related $0.2 million in accrued interest on the CHCF Note.

**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, 2018 are presented in our Form 10-K filed with the SEC on March 4, 2019. 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, 2018. 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 February 2016, the FASB issued ASU No. 2016-02, Leases ("Topic 842"), which requires lessees to recognize lease liabilities and corresponding right-of-use assets on the consolidated balance sheet for all leases. For finance leases, the lessee would recognize interest expense and amortization of the right-of-use asset and, for operating leases, the lessee would recognize a straight-line lease expense. It also changes the definition of a lease and expands the disclosure requirements of lease arrangements. The Company has no embedded leases with suppliers. Upon adoption of Topic 842 on January 1, 2019 using the modified retrospective method, the Company recognized right-of-use assets of $10.4 million and lease liabilities of $10.2 million. There was no cumulative-effect adjustment recorded on January 1, 2019. The Company adopted the following practical expedients allowed under Topic 842:

- The package of three practical expedients, which allows entities to make an election that allows them not to reassess (1) whether existing or expired contracts contain embedded leases under Topic 842, (2) lease classification of existing or expiring leases, and (3) indirect costs for existing or expired leases
- Combining lease and non-lease components practical expedient, which allows lessees, as an accounting policy election by class of underlying asset, to choose not to separate non-lease components from lease components and instead to account for each separate lease component and the non-lease components associated with that lease component as a single lease component
- Comparative reporting practical expedient, which allows entities to initially apply Topic 842 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption

For further details, refer to *Note 6. Commitments and Contingencies* of the Form 10-Q.

## 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 $58.7 million as of March 31, 2019, 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, 2019. 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, 2019, 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 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) prior to the filing of this quarterly report. 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 at the reasonable assurance level as of March 31, 2019 due to the following material weaknesses, also described in Item 9A of the Company’s annual report on Form 10-K filed with the SEC on March 4, 2019, which continue to be unremediated as of March 31, 2019:

- 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 did not result in any adjustments to our annual or interim financial statements. 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 did not detect errors in a timely manner that could have been 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. This material weakness did not result in any adjustments to our annual or interim financial statements.

- 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 formula errors within the year-end contractual allowance analysis which resulted in an immaterial misstatement to revenue, accounts receivable and bad debt expense.

Notwithstanding these material weaknesses, management has concluded that the condensed consolidated financial statements included in this quarterly report on Form 10-Q present fairly, in all material aspects, our financial position at the end of, and the results of operations and cash flows for, the periods presented in conformity with accounting principles generally accepted in the United States.

**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 2019. 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 2019 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

**Plan for Remediation of Material Weakness**

We are committed to remediating the control deficiencies that gave rise to the material weaknesses described above. We are working to remediate the material weaknesses as quickly and efficiently as possible. However, the material weakness will not be considered remediated until the remediated controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. Management is responsible for implementing changes and improvements to our internal control over financial reporting and for remediating the control deficiencies that gave rise to these material weaknesses. During fiscal 2019, we are enhancing our system of internal control over financial reporting with the following actions:

- Increasing the depth and experience of our Finance organization by increasing the number of staff, expanding our technical experience in accounting, auditing and reporting matters and implementing appropriate training programs for staff, manager and executive levels.
- Hiring an Internal Audit Director that will be focused on the development, maintenance and monitoring of our overall control environment and system of internal control over financial reporting.
- Improving the design and effectiveness of key controls for our order to cash and procure to pay transaction cycles, automated and manual journal entries and the accuracy and completeness of key reports used in the preparation of our consolidated financial statements

**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**

***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, 2019 and 2018, we had a net loss of $8.0 million and $11.1 million, respectively, and we expect to continue to incur additional losses. As of March 31, 2019, we had an accumulated deficit of $211.5 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 limited operating history makes it difficult to evaluate our current business and future prospects***

We first commercialized the Zio service in the first quarter of 2011 and do not have a long history operating as a commercial company. As a result, our operating results are not predictable. Since 2011, our revenue has been derived, and we expect it to continue to be derived, substantially from sales of the Zio service. Because of its recent commercial introduction, the Zio service has limited product and brand recognition. In addition, demand for our services may decline or may not increase as quickly as we expect. Failure of the Zio service to significantly penetrate current or new markets would harm our business, financial condition and results of operations.

***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 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
- 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, 2019, 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. In addition, regional Medicare Administrative Contractors (“MACs”), change from time to time, which may result in changes to our reimbursement rates, increased administrative burden and reimbursement delay.

***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, called Category III CPT codes, used for newly introduced technologies and specific to our category of diagnostic monitoring through 2022. The fees associated with these temporary CPT codes are also temporary and may be modified by CMS. After both use data and published clinical evidence is gathered over time on newly introduced technologies, eventually the temporary CPT code can become a

permanent code – or what is called a Category I CPT code. The process to convert a code from Category III to Category I CPT code is governed by the AMA and CMS. Relative to the CMS applicable fees after 2022, it is incumbent upon us to successfully secure permanent CPT codes from the AMA by 2022, which codes are valued by CMS and remain mostly unchanged for five years after the values are initially determined. Category I CPT codes can have values and associated pricing that are higher or lower compared to the 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 MACs which 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 temporary 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 payers 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.

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 health care 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 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.

***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 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
- advocated by key opinion leaders

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 products. These contracts provide a high degree of certainty to us, physicians and hospitals and clinics with respect to the rate at which our products 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. 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, hospitals and clinics. 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 products.

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 products 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 products because of the administrative work involved in interacting with patients to answer their questions and help them obtain reimbursement for our products. If physicians are unwilling to prescribe our products 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

- 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") for both the manufacture of the Zio monitor and the provision of the Zio service, noncompliance with which could cause an interruption in our manufacturing and services
- to increase our manufacturing output significantly and scale our services, we will have to attract and retain qualified employees for our operations

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 and MDD 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
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's failure to consistently produce quality components
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components
- inability to control the quality of products manufactured by third parties
- delays in delivery by our suppliers due to changes in demand from us or their other customers

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, 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
- 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 get reimbursed by CMS, we must establish an IDTF. IDTFs are defined by CMS as entities 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 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 2019, we recognized approximately four 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
- 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., 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 atrial fibrillation. 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.

***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, 2019, we had $34.9 million outstanding under our credit facility consisting 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, Karim Karti, our Chief Operating 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
- 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.

***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
- 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, 2018, we had federal and state net operating loss carryforwards ("NOLs") of $206.7 million and $107.4 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 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, 2018, 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.

***If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may decrease.***

The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal controls over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. Section 404 of the Sarbanes-Oxley Act ("Section 404") requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm to attest to, the effectiveness of our internal control over financial reporting. Prior to December 31, 2017, we availed ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. As of December 31, 2017, we ceased to be an "emerging growth company." We expect that the cost of our compliance with Section 404 will correspondingly increase as a result of our independent registered public accounting firm being required to undertake an assessment of our internal control over financial reporting. Our compliance with applicable provisions of Section 404 have required and will continue to require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Section 404 also requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal control over financial reporting along with an auditor attestation. If we have material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We have implemented the process and documentation necessary to perform the evaluation needed to comply with Section 404, but we may not be able to complete our evaluation, testing and any required remediation in a timely fashion in any given quarterly period.

During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, our management will be unable to conclude that our internal control over financial reporting is effective and our independent registered public accounting firm will be unable to issue an attestation report on the effectiveness of our internal control over financial reporting. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to conclude that our internal control over financial reporting is effective, or if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Internal control deficiencies could also result in a restatement of our financial results in the future. We could also become subject to stockholder or other third-party litigation as well as investigations by the stock exchange on which our securities are listed, the Securities and Exchange Commission, or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions or other remedies.

**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 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 whom we purchase hardware or software may not indemnify 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 secret.

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 fees and court costs. In addition, if we are found to willfully infringe 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. 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. These risks could be difficult to eliminate or manage, and, if not addressed, could harm our business, 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, 2018, we owned, or retained exclusive license to, eleven issued U.S. patents, the earliest of which will expire in 2028. As of December 31, 2018, we also owned, or retained an exclusive license to, four 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, 2018, we had twenty-two pending patent applications globally, including six 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 include claims 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.

***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, tradenames 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 do not own any registered trademarks for the mark "IRHYTHM" and we are aware of at least one third party that has registered the "IRHYTHM" mark in the United States, the European Union and Taiwan 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 Offices in the United States and the European Union, and those proceedings could impact our ability to register the "IRHYTHM" mark in those jurisdictions. It is possible that the third party could bring suit against us claiming infringement of the "IRHYTHM" mark, and if it did so and if there were a court determination against us, we might then be obligated to pay monetary damages, enter into a license agreement, or cease use of the "IRHYTHM" name and mark, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

***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
- 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 $10,957 to $21,916 per false claim in 2017.

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 and manufacture
- laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution
- premarketing clearance or approval
- record keeping

- product marketing, promotion and advertising, sales and distribution
- 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 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"), both of which cover procedures and documentation of 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 conducted an ISO 13485 surveillance audit of our design, manufacturing and service operations in June 2018 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. 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 attempt broad sweeping 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
- 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.

***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 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 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
- 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
- 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**

Not applicable.

**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 |
| 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.

**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 10, 2019

By: /s/ Kevin M. King
Kevin M. King
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 10, 2019

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 10, 2019

**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 10, 2019

**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, 2019, 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 10, 2019

/s/ Matthew C. Garrett

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

Date: May 10, 2019

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.