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, 2017

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 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	☒	(Do not check if a smaller reporting company)	Smaller reporting company	☐
Emerging growth company	☒			

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of April 30, 2017, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 22,228,349.

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 expectations regarding the time during which we will be an emerging growth company under the JOBS Act
- 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, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 15,583	$ 51,643
Investments, short-term	77,397	54,407
Accounts receivable, net	10,982	9,406
Inventory	1,156	1,390
Prepaid expenses and other current assets	1,388	1,671
Restricted cash	91	91
Total current assets	106,597	118,608
Investments, long-term	16,429	10,981
Property and equipment, net	5,529	4,653
Goodwill	862	862
Other assets	3,384	3,052
Total assets	$ 132,801	$ 138,156
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,413	$ 2,103
Accrued liabilities	8,284	10,165
Deferred revenue	980	947
Total current liabilities	10,677	13,215
Debt	32,652	32,227
Deferred rent, noncurrent portion	26	26
Accrued interest, net of current portion	134	126
Total liabilities	43,489	45,594
Commitments and contingencies (Note 7)		
Stockholders' deficit:		
Preferred stock, $0.001 par value – 5,000,000 authorized at March 31, 2017 and December 31, 2016, respectively; and none issued and outstanding at March 31, 2017 and December 31, 2016, respectively	—	—
Common stock, $0.001 par value – 100,000,000 shares authorized at March 31, 2017 and December 31, 2016, respectively; 22,153,146 and 22,139,346 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	27	22
Additional paid-in capital	221,776	219,718
Accumulated other comprehensive loss	(19)	(9)
Accumulated deficit	(132,472)	(127,169)
Total stockholders' equity	89,312	92,562
Total liabilities, stockholders' equity	$ 132,801	$ 138,156

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,	
	2017	2016
Revenue	$ 21,437	$ 12,854
Cost of revenue	6,337	4,659
Gross profit	15,100	8,195
Operating expenses:		
Research and development	2,621	1,545
Selling, general and administrative	17,224	11,521
Total operating expenses	19,845	13,066
Loss from operations	(4,745)	(4,871)
Interest expense	(822)	(795)
Other income (expense), net	264	(460)
Net loss	$ (5,303)	$ (6,126)
Net loss per common share, basic and diluted	$ (0.24)	$ (4.34)
Weighted-average shares used to compute net loss per common share, basic and diluted	22,151,926	1,413,052

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,	
	2017	2016
Net Loss	$ (5,303)	$ (6,126)
Other comprehensive loss:		
Unrealized loss on available-for-sale securities	(19)	—
Comprehensive loss	$ (5,322)	$ (6,126)

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,	
	2017	**2016**
Cash flows from operating activities		
Net loss	$ (5,303)	$ (6,126)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	298	227
Stock-based compensation	2,028	408
Amortization of debt discount and issuance costs	64	62
Amortization of premiums (accretion of discounts) on investments, net	(46)	—
Non-cash interest expense	375	361
Change in allowance for doubtful accounts and contractual allowance	1,772	1,038
Change in fair value of preferred stock warrant liabilities	—	462
Changes in operating assets and liabilities:		
Accounts receivable	(3,348)	(3,134)
Inventory	234	(236)
Prepaid expenses and other current assets	403	42
Other assets	(346)	(230)
Accounts payable	(690)	1,009
Accrued liabilities	(1,873)	(3,239)
Deferred revenue	33	(132)
Net cash used in operating activities	(6,399)	(9,488)
Cash flows from investing activities		
Purchases of property and equipment	(1,174)	(659)
Purchases of available-for-sale investments	(31,822)	—
Maturities of available-for-sale investments	3,300	—
Net cash used in investing activities	(29,696)	(659)
Cash flows from financing activities		
Proceeds from issuance of common stock upon exercise of stock options, net of repurchases	35	6
Payments of deferred issuance costs	—	(822)
Net cash provided by (used in) financing activities	35	(816)
Net decrease in cash and cash equivalents	(36,060)	(10,963)
Cash and cash equivalents, beginning of period	51,643	25,208
Cash and cash equivalents, end of period	$ 15,583	$ 14,245
Supplemental disclosures of cash flow information		
Interest paid	$ 375	$ 472
Non-cash investing and financing activities		
Series E Preferred Stock Issuance costs included in accrued liabilities	$ —	$ 52
Deferred offering costs included in accounts payables and accrued liabilities	$ —	$ 923

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 machine-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's headquarters are based in San Francisco, California, and the Company has manufacturing facilities in Cypress, California, and clinical centers in Lincolnshire, Illinois and Houston, Texas. 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, based upon the billing address of the customer.

Reverse Stock Split

On October 4, 2016, the Company's board of directors approved an amendment to the Company's amended and restated certificate of incorporation to effect a reverse split of the Company's issued and outstanding common stock at a 1-for-5.882698 ratio, which was effected on October 5, 2016. The par value and authorized shares of common stock and convertible preferred stock were not adjusted as a result of the reverse split. All issued and outstanding common stock, options to purchase common stock and per share amounts contained in these condensed consolidated financial statements have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Initial Public Offering

The Company's initial public offering ("IPO") of 7,238,235 shares of common stock was effected through a registration statement on Form S-1 (Registration Nos. 333-213773 and 333-214179), which was declared effective on October 19, 2016. The initial public offering closed on October 25, 2016 and resulted in net proceeds of approximately $110.7 million, after deducting underwriting discounts and commissions of $8.6 million and other expenses of $3.7 million.

In October 2016, immediately upon the Company's sale of its common stock in the initial public offering, all outstanding shares of convertible preferred stock converted into 13,375,333 shares of common stock with the related carrying value of $97.6 million reclassified to common stock and additional paid-in capital. In addition, all convertible preferred stock warrants were also thereby converted into common stock warrants.

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, 2016 has 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. The results of operations for the three months ended March 31, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017 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, 2016 included in the Company's Form 10-K, filed with the SEC on March 31, 2017, pursuant to Rule 424(b) under the Securities Act of 1934.

Principles of Consolidation

The accompanying interim unaudited condensed consolidated financial statements are consolidated for the three months ended March 31, 2017 and 2016 and include the accounts of iRhythm Technologies, Inc. and its wholly-owned subsidiary, iRhythm Technologies Ltd., established in March 2016. The financial statements of iRhythm Technologies Ltd. use the U.S. dollar as the functional currency. For all non-functional currency balances, the remeasurement of such balances to functional currency results in a foreign exchange transaction gain or loss, which is recorded in the consolidated statements of operations.

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, contractual allowances for revenue, allowance for doubtful accounts, the useful lives of property and equipment, the recoverability of long-lived assets including the estimated usage of the printed circuit board assemblies (“PCBAs”), the valuation of deferred tax assets, the fair value of the Company’s preferred and common stock and stock-based compensation. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. Actual results may differ from those estimates.

Fair Value of Financial Instruments

The carrying amounts of certain of the Company’s financial instruments, which includes cash equivalents, accounts receivable, accounts payable and accrued liabilities, approximate fair value due to their short maturities.

Cash Equivalents

Cash equivalents consist of short-term, highly liquid investments with original maturities of three months or less from the date of purchase.

Investments

Short-term investments consist of debt securities classified as available-for-sale and have maturities greater than 90 days, but less than 365 days from the date of acquisition. Long-term investments have maturities greater than 365 days as of the balance sheet date. All investments are carried at fair value based upon quoted market prices. Unrealized gains and losses on available-for-sale securities are excluded from earnings and are reported as a component of accumulated other comprehensive loss. The cost of available-for-sale securities sold is based on the specific-identification method. Realized gains and losses are included in earnings, and are derived for specific-identification method for determining the costs of investments sold.

Restricted Cash

Restricted cash consists of certificates of deposit held with a financial institution as security deposits for building leases and is included in short-term assets on the Company's balance sheets.

Accounts Receivable, Allowance for Doubtful Accounts and Contractual Allowance

Accounts receivable consists of amounts due to the Company from institutions, government payors and commercial insurance payors as a result of the Company's normal business activities. Accounts receivable is reported on the balance sheet net of an estimated allowance for doubtful accounts and contractual allowance.

The Company establishes an allowance for doubtful accounts for estimated uncollectible receivables based on its historical experience as a component of selling, general and administrative expenses. The Company establishes a contractual allowance, which is a reduction in revenue, for estimated uncollectible amounts from Centers for Medicare & Medicaid Services (“CMS”), and contracted third-party commercial payors.

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

	March 31, 2017	December 31, 2016
Balance, beginning of period	$ 1,792	$ 1,125
Add: provision for doubtful accounts	561	1,960
Less: write-offs, net of recoveries and other adjustments	(132)	(1,293)
Balance, end of period	$ 2,221	$ 1,792

The following table presents the changes in the contractual allowance:

	March 31, 2017	December 31, 2016
Balance, beginning of period	$ 2,340	$ 338
Add: contractual allowances	1,211	2,726
Less: write-offs, net of recoveries and other adjustments	(86)	(724)
Balance, end of period	$ 3,465	$ 2,340

Management 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 and cash equivalents and investments are deposited with one financial institution in the United States of America. At times, such deposits 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. Government agencies, including CMS and the Veterans Administration, accounted for approximately 37% and 42% of the Company’s revenue for the three months ended March 31, 2017 and 2016 respectively. Accounts receivable related to government agencies accounted for 24% and 27% at March 31, 2017 and December 31, 2016, respectively.

Supply Risk

While the company has not experienced manufacturing supply disruptions to date, the Company relies on single-source vendors for the supply of its reusable printed circuit board assemblies, disposable housings, instruments and other materials used to manufacture the ZIO Patch and the adhesive that binds the ZIO Patch to a patient’s body. These components and materials are critical, and there could be a considerable delay in finding alternative sources of supply.

Inventory

Inventory is stated at the lower of cost or market, cost being determined on a standard cost basis for material costs and on actual cost basis for labor and overhead, which approximates actual cost on a first in, first out ("FIFO)" basis, and market being determined as the lower of cost or net realizable value. The Company records write-downs of inventory that is obsolete or in excess of anticipated demand or market value based on consideration of product lifecycle stage, technology trends, product development plans and assumptions about future demand and market conditions. Actual demand may differ from forecasted demand and such differences may have a material effect on recorded inventory values. Inventory write-downs are charged to cost of revenue and establish a new cost basis for the inventory.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization is computed using the straight-line method over the estimated useful lives of the assets, ranging from three to five years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the assets. Maintenance and repairs are charged to expense as incurred and improvements and betterments are capitalized.

Internal-Use Software

The Company capitalizes costs related to internal-use software during the application development stage. Costs related to planning and post implementation activities are expensed as incurred. Capitalized internal-use software is amortized, and recognized as cost of revenue, on a straight-line basis over the estimated useful life, which is up to five years. The Company evaluates the useful lives of these assets on an annual basis and tests for impairment whenever events or changes in circumstances occur that could impact the recoverability of these assets. Capitalized internal-use software costs are classified as a component of property and equipment.

Goodwill

Goodwill represents the excess of the purchase price paid over the fair value of tangible and identifiable intangible net assets acquired in business combinations. Goodwill is tested for impairment on an annual basis and at any other time if events occur or circumstances indicate that the carrying amount of goodwill may not be recoverable. Such events or circumstances may include significant adverse changes in the general business climate, among other things. The impairment test is performed by determining the enterprise fair value of the Company, which is primarily based on the Company's market capitalization. If the Company's carrying value, as a one reporting unit entity, is less than its fair value, then the fair value is allocated to all of its assets and liabilities (including any unrecognized intangible assets) as if the fair value was the purchase price to acquire the Company. The excess of the fair value over the amounts assigned to the Company's assets and liabilities is the implied fair value of the goodwill. If the carrying amount of goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to that excess. The Company performs its annual evaluation of goodwill during the fourth quarter of each fiscal year. The Company did not record any charges related to goodwill impairment in any of the periods presented in these condensed consolidated financial statements.

Impairment of Long-Lived Assets

The Company annually reviews long-lived assets for impairment or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future net cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. To date there have been no such impairments of long-lived assets.

Other Assets

Included in the other assets are PCBAs totaling $3.1 million and $2.8 million as of March 31, 2017 and December 31, 2016, respectively. The Company uses a PCBA in each wearable device and it is used numerous times and has a useful life beyond one year. Each time the PCBA is used in a wearable device, a portion of the cost of the PCBA is recorded as a cost of revenue. The Company has based its estimates of how many times a PCBA can be used on testing in research and development, loss rates, product obsolescence, and the amount of time it takes the device to go through the manufacturing, shipping, customer shelf and patient wear time and upload process. The Company periodically evaluates the use estimate.

Comprehensive Loss

Comprehensive loss represents all changes in stockholders' equity except those resulting from and distributions to stockholders. The Company's unrealized gains and losses on available-for-sale securities represent the only component of other comprehensive loss that are excluded from the reported net loss and that are presented in the condensed consolidated statements of comprehensive loss.

Revenue Recognition

The Company's devices, cardiac rhythm monitors, have a wear period for up to 14 days for the ZIO Patch Service or 30 days for the ZIO Event Card. The Company's services, consisting of the delivery of reports containing analysis of data captured by the physical device to the prescribing physician, are generally billable at the start of the wear period or when reports are issued to physicians, depending on the service provided. For the ZIO Event Card, the Company recognizes revenue on a straight-line basis over the applicable wear period, as the event monitoring results are delivered to physicians. For the ZIO Patch Service, the Company recognizes the revenue at the time that a report is delivered to a physician. For all services performed, the Company considers whether or not the following revenue recognition criteria are met: persuasive evidence of an arrangement exists and delivery has occurred or services have been rendered. For services performed for customers the Company invoices directly, additional revenue recognition criteria include that the price is fixed and determinable and collectability is reasonably assured; for customers in which the Company submits claims to third party commercial and governmental payors for reimbursement, it recognizes revenue only when a reasonable estimate of reimbursement can be made.

The assessment of whether a reasonable estimate of reimbursement can be made requires significant judgment by management. Where management's judgment indicates a reasonable estimate of reimbursement can be made, revenue is recognized upon delivery of the patient report for the ZIO Patch Service and straight-line for the ZIO Event Card. Some patients have out-of-pocket costs for amounts not covered by their insurance carrier, and the Company may bill the patient directly for these amounts in the form of co-payments and co-insurance in accordance with their insurance carrier and health plans. Some payors may not cover the Company's service as ordered by the prescribing physician under their reimbursement policies. In the absence of an agreement with the patient or other clearly enforceable legal right to demand payment from the patient, the related revenue is recognized upon the earlier of notification of the payor benefits allowed or when payment is received, until the Company has the ability to make a reasonable estimate. Once a reasonable estimate can be made, revenue is recognized upon delivery of the service. During Q1 2017, the Company recognized revenue from certain non-contracted payors as a reasonable estimate was able to be made, primarily based on the consistency of historical payments.

The Company recognizes revenue related to billings for CMS and commercial payors on an accrual basis, net of contractual allowances, when a reasonable estimate of reimbursement can be made. These contractual allowances represent the difference between the list price (the billing rate) and the reimbursement rate for each payor. Upon ultimate collection from CMS and commercial payors, the amount is compared to the previous estimates and the contractual allowance is adjusted accordingly. Until a contract has been negotiated with a commercial payor, the Company's services may or may not be covered by these entities' existing reimbursement policies. In addition, patients do not enter into direct agreements with the Company that commit them to pay any portion of the cost of the service in the event that their insurance declines to reimburse the Company. In the absence of an agreement with the patient or other clearly enforceable legal right to demand payment from the patient, the related revenue is recognized upon the earlier of notification of the payor benefits allowed or when payment is received, until the Company has the ability to make a reasonable estimate. Revenue related to these uncontracted claims was $2.9 million and $1.8 million for the three months ended March 31, 2017 and 2016, respectively. Revenue recognized on an accrual basis was $18.5 million and $11.1 million for the three months ended March 31, 2017 and 2016, respectively.

Certain of the Company's customers pay the Company directly for the ZIO Service upon shipment of devices. Such advance payments are recorded as deferred revenue on the condensed consolidated balance sheets and revenue is recognized when reports are delivered to physicians.

Cost of Revenue

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. Material costs include both the disposable costs of the device and amortization of the PCBAs. Each time the PCBA is used in a wearable device, a portion of the cost of the PCBA is recorded as a cost of revenue.

Research and Development

The Company's research and development costs are expensed as incurred. Research and development costs include, but are not limited to, payroll and personnel-related expenses, laboratory supplies, consulting costs and overhead charges.

Income Taxes

The Company uses the asset and liability method to account for income taxes in accordance with the authoritative guidance for income taxes. Under this method, deferred tax assets and liabilities are determined based on future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and tax loss and credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company records interest and penalties related to unrecognized tax benefits in income tax expense. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Stock-based Compensation

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

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

Net Loss per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per common share is the same as basic net loss per common share for all periods presented since the effect of potentially dilutive securities are anti-dilutive.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB"), issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of Effective Date, which defers the effective date of ASU 2014-09 by one year allowing early adoption as of the original effective date of fiscal years and interim reporting periods beginning after December 15, 2016, at which time companies may adopt the new standard update under the full retrospective method or the modified retrospective method. The deferral results in the new revenue standard being effective for the Company for fiscal years and interim reporting periods beginning after December 15, 2017. In March, April and May 2016, the FASB issued additional updates to the new revenue standard relating to reporting revenue on a gross versus net basis, identifying performance obligations and licensing arrangements, and narrow-scope improvements and practical expedients, respectively. The Company plans on adopting this standard on January 1, 2018 and has not made the decision as to which adoption method it will utilize. The Company's final determination will depend on the significance of the impact of the new standard on the Company's financial results. The Company is in the initial stages of its evaluation of the adoption of the new standard on its accounting policies.

In July 2015, the FASB issued ASU No. 2015-11, Inventory, Simplifying the Measurement of Inventory. Under ASU 2015-11, the measurement principle for inventory will change from lower of cost or market value to lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The ASU is effective for fiscal years and interim periods within those years beginning after December 15, 2016. The Company adopted this guidance effective January 1, 2017, and there was no impact on the condensed consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. Under ASU 2015-17, deferred tax liabilities and assets will be classified as noncurrent on the balance sheet. Previous guidance required deferred tax liabilities and assets to be separated into current and noncurrent amounts on the balance sheet. The guidance is effective for annual periods beginning after December 15, 2016 and for interim periods within those annual periods. Early adoption is permitted. The Company adopted this guidance effective January 1, 2017, and there was no impact on the condensed consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, which addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. ASU 2016-01 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. The Company has not determined the potential effects of this ASU on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which requires a lessee to recognize assets and liabilities on its consolidated balance sheet for leases with accounting lease terms of more than 12 months. ASU 2016-02 will replace most existing lease accounting guidance in U.S. GAAP when it becomes effective. The new standard states that a lessee will recognize a lease liability for the obligation to make lease payments and a right-of-use asset for the right to use the underlying asset for the lease term. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the consolidated statements of operations. ASU 2016-02 will be effective for our first quarter of fiscal 2020 and requires the modified retrospective method of adoption. Early adoption is permitted. Although we are currently evaluating the effect that ASU 2016-02 will have on our consolidated financial statements and related disclosures, we expect that most of our operating lease commitments will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets upon adoption.

In March 2016, the FASB issued ASU No. 2016-09, Compensation—Stock Compensation (Topic 718). This ASU was issued as part of the FASB's simplification initiative and affects all entities that issue share-based payment awards to their employees. This standard covers accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. As a result of adopting ASU No. 2016-09 on January 1, 2017, the Company has made an accounting policy election to continue to estimate forfeitures. The adoption of ASU No. 2016-09 also requires excess tax benefits and tax deficiencies be recorded in the income statement as opposed to additional paid-in capital when the awards vest or are settled, and has been applied on a prospective basis with no impact on the condensed consolidated financial statements as of and for the three months ended March 31, 2017. As a result of the adoption, the Company's increased its total NOLs by $0.1 million on January 1, 2017 related to deferred tax assets that arose directly from tax deductions related to equity compensation greater than compensation recognized for financial reporting purposes. This amount is fully offset by the valuation allowance.

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments – Credit Losses (Topic 326)*, which is intended to provide financial statement users with more useful information about expected credit losses on financial assets held by a reporting entity at each reporting date. The new standard replaces the existing incurred loss impairment methodology with a methodology that requires consideration of a broader range of reasonable and supportable forward-looking information to estimate all expected credit losses. This ASU is effective for fiscal years and interim periods within those years beginning after December 15, 2019 and early adoption is permitted for fiscal years and interim periods within those years beginning after December 15, 2018. The Company is currently evaluating the impact of this new guidance.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230) – Classification of Certain Cash Receipts and Cash Payments*, which clarifies the classification of certain cash receipts and cash payments in the statements of cash flow to eliminate the diversity in practice related to eight specific cash flow issues. This ASU is effective for fiscal years and interim periods within those years beginning after December 15, 2017, with early adoption permitted. The Company is currently evaluating the impact of this new guidance.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230) – Restricted Cash*, which requires the presentation of changes in restricted cash or restricted cash equivalents on the statement of cash flows. This ASU is effective for the fiscal years and interim periods within those years beginning after December 15, 2017, with early adoption permitted. The Company is currently evaluating the impact of this new guidance.

In January 2017, the FASB issued a new accounting standard update to simplify the measurement of goodwill by eliminating the Step 2 impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. The new guidance required an entity to compare the fair value of a reporting unit with its carrying amount and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value. Additionally, an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. The new guidance becomes effective for goodwill impairment tests in fiscal years beginning after December 15, 2019, though early adoption is permitted. The Company is currently assessing the impact of this new guidance.

3. Cash Equivalents and Investments

The fair value of securities, not including cash at March 31, 2017 and December 31, 2016, were as follows (in thousands):

	March 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 14,026	$ 1	$ —	$ 14,027
U.S. government securities	32,921	1	(13)	32,909
Corporate notes	27,608	5	(13)	27,600
Commercial paper	33,317	—	—	33,317
Total available-for-sale securities	$ 107,872	$ 7	$ (26)	$ 107,853
Classified as:				
Cash equivalents				$ 14,027
Short-term investments				77,397
Long-term investments				16,429
Total cash equivalents and investments				$ 107,853

	December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 45,937	$ —	$ —	$ 45,937
U.S. government securities	16,479	11	—	16,490
Corporate notes	23,947	—	(20)	23,927
Commercial paper	24,971	—	—	24,971
Total available-for-sale securities	$ 111,334	$ 11	$ (20)	$ 111,325
Classified as:				
Cash equivalents				$ 45,937
Short-term investments				54,407
Long-term investments				10,981
Total cash equivalents and investments				$ 111,325

Available-for-sale securities held as of March 31, 2017 had a weighted average days to maturity of 174 days. There have been no material realized gains or realized losses on available-for-sale securities for the periods presented.

As the carrying value approximates the fair value for the Company's cash equivalents, short-term and long-term investments shown in the tables above, the following table summarizes the fair value of the Company's cash equivalents, short-term and long-term investments classified by maturity (in thousands):

	March 31, 2017	December 31, 2016
Due within one year	$ 91,424	$ 100,344
Due after one year through three years	16,429	10,981
Total available-for-sale marketable debt securities	$ 107,853	$ 111,325

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 bonds 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.

Based on Level 2 inputs and the borrowing rates currently available to the Company for loans with similar terms and maturities, the carrying value of the Company's debt approximates its 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, 2017			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ 14,027	$ —	$ —	$ 14,027
U.S. government securities	—	32,909	—	32,909
Corporate notes	—	27,600	—	27,600
Commercial paper	—	33,317	—	33,317
Total	$ 14,027	$ 93,826	$ —	$ 107,853

	December 31, 2016			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ 45,937	$ —	$ —	$ 45,937
U.S. government securities	—	$ 16,490	—	16,490
Corporate notes	—	$ 23,927	—	23,927
Commercial paper	—	$ 24,971	—	24,971
Total	$ 45,937	$ 65,388	$ —	$ 111,325

The following table sets forth a summary of the changes in the fair value of the preferred stock warrants which is classified as Level 3 in the fair value hierarchy. There were no transfers into or out of Level 3 during the periods (in thousands):

	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016
Beginning balance	$ —	$ 2,949
Total change in fair value recorded as other expense, net	—	461
Ending balance	$ —	$ 3,410

The valuation of the preferred stock warrant liabilities is discussed in Note 11.

5. Balance Sheet Components

Inventory and PCBAs

Inventory and PCBAs consisted of the following (in thousands):

	March 31, 2017	December 31, 2016
Raw materials	$ 989	$ 839
Finished goods	3,255	3,324
Total	$ 4,244	$ 4,163
Reported on the consolidated balance sheet as:		
Inventory	$ 1,156	$ 1,390
Other assets	3,088	2,773
Total	$ 4,244	$ 4,163

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, 2017	December 31, 2016
Laboratory and manufacturing equipment	$ 1,889	$ 1,509
Computer equipment and software	821	736
Furniture and fixtures	668	657
Leasehold improvements	510	502
Internal-use software	3,590	2,900
Total property and equipment, gross	7,478	6,304
Less: accumulated depreciation and amortization	(1,949)	(1,651)
Total property and equipment, net	$ 5,529	$ 4,653

Depreciation and amortization expense for the three months ended March 31, 2017 and 2016 was $298,000 and $227,000, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2017	December 31, 2016
Accrued vacation	$ 1,868	$ 1,642
Accrued payroll and related expenses	2,912	6,179
Accrued ESPP contributions	1,100	417
Accrued professional services fees	806	636
Other	1,598	1,291
Total accrued liabilities	$ 8,284	$ 10,165

6. Related-Party Transactions

Kaiser Permanente (“Kaiser”) is a common stockholder of the Company, representing 6.1% ownership of the total outstanding shares of the Company as of December 31, 2016. For the three months ended March 30, 2017 and 2016, the Company recognized revenue of $844,000 and $577,000 respectively, for transactions with Kaiser. The amounts receivable from transactions with Kaiser were $665,000, and $449,000 as of March 31, 2017 and December 31, 2016, respectively. Kaiser additionally performs services related to clinical trials and the Company utilizes Kaiser for employee healthcare. The total expense recorded was $111,000 and $117,000 as of March 31, 2017 and 2016, respectively. The amounts outstanding and included in accounts payable and accrued liabilities were $159,000 and $229,000 as of March 31, 2017, and December 31, 2016 respectively.

7. Commitments and Contingencies

Lease Arrangements

The Company leases office and manufacturing space under non-cancelable operating leases which expire on various dates through 2027. These leases generally contain scheduled rent increases or escalation clauses and renewal options. The Company recognizes rent expense on a straight-line basis over the lease period.

As discussed further in Note 15, in May 2017, the Company entered into a commercial building lease agreement which will expire in September 2027.

The following table summarizes the Company's future minimum lease payments as of March 31, 2017 including the lease signed in May 2017 (in thousands):

Year Ending December 31:		
2017 (remainder of year)	$	3,690
2018		5,089
2019		5,108
2020		1,178
2021 and beyond		2,948
Total	$	18,013

The Company's rent expense was $1.1 million and $0.4 million for the three months ended March 31, 2017 and 2016, respectively.

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.

8. Debt

Pharmakon Loan Agreement

In December 2015, the Company entered into the Loan Agreement with Biopharma Secured Investments III Holdings Cayman LP, or Pharmakon (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 made.

During the first full eight quarters, payments are interest only and for the first two years, 50% of the interest will be "paid-in-kind." The Company is subject to a financial covenant related to minimum trailing revenue targets that begins in June 2017, and is tested on a semi-annual basis. The minimum net revenue covenant ranges from $44.7 million for the period ended June 30, 2017 to $102.6 million for the period ended December 31, 2021. The minimum net revenues financial covenant has a 45-day equity cure period following required delivery date of the financial statements. Pursuant to this equity cure provision, the Company may cure a revenue covenant default by raising additional funds from the sale of equity. The loan matures December 2021.

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 shall be added to the then outstanding principal.

The Pharmakon Loan Agreement requires the Company to maintain a minimum consolidated liquidity and minimum net revenue during the term of the loan facility and contains customary affirmative and negative covenants and event of default provisions that could result in the acceleration of the repayment obligations under the loan facility. Upon a change in control of the Company, Pharmakon has the option to demand payment in full of the outstanding loans together with any prepayment premium.

The obligations under the Pharmakon Loan Agreement are secured by a security interest in substantially all of the Company's assets pursuant to the Pharmakon Guaranty and Security Agreement and this security interest is governed by an intercreditor agreement between Pharmakon and Silicon Valley Bank ("SVB").

In December 2015, the Company used the proceeds from the Pharmakon Loan Agreement to repay $4.9 million of bank debt to SVB. The issuance costs and debt discount have been netted against the borrowed funds on the balance sheet. The debt balance as of March 31, 2017 and December 31, 2016 was $31.2 million and $30.8 million, respectively.

Bank Debt

In June 2014, the Company refinanced its debt with SVB by entering into the Second Amendment to the Amended and Restated Loan Security Agreement ("Second Amendment"). Under this amendment, the Company borrowed $4.9 million with an additional advance of $5.0 million available. All the borrowings under the Second Amended Loan Agreement were collateralized by all of the Company's assets, excluding intellectual property. In connection with entering into the Amended Loan Agreement, the Company issued warrants to purchase 20,136 shares of Series D at $7.31 per share that expire in June 2024 (See Note 11).

In December 2015, the Company used the proceeds from the Pharmakon Loan Agreement to repay $4.9 million of bank debt to SVB and entered into a Second Amended and Restated Loan and Security Agreement with SVB, or 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 revolving credit line 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%, are tied to the Company's trailing six-month revenue and subject to certain revenue targets. 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 letter of credit pursuant to the SVB revolving credit facility in connection with a lease for the San Francisco office. As of March 31, 2017 and December 31, 2016, the Company was eligible to borrow up to $ 6.5 million and $2.5 million, respectively, under the SVB revolving credit line.

The SVB Loan Agreement requires the Company to maintain a minimum consolidated liquidity and minimum net sales during the term of the loan facility. In addition, the SVB Loan Agreement contains customary affirmative and negative covenants and events of default. The obligations under the SVB Loan Agreement are collaterialized by substantially all assets of the Company and this security interest is governed by an intercreditor agreement between Pharmakon and SVB.

California HealthCare Foundation Note

In November 2012, the Company entered into a Note Purchase Agreement and Promissory Note with the California HealthCare Foundation, or the CHCF Note, through which the Company borrowed $1.5 million. The CHCF Note accrues simple interest of 2.0%. The accrued interest and the principal matured 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. In partial consideration for the amendment, the Company issued 8,552 warrants at $6.58 exercise price per share of the Company's Series D convertible preferred stock. See Note 11 for further discussion of the warrants. The CHCF note is subordinate to other bank debt. The debt balance, net of debt discount, as of March 31, 2017 and December 31, 2016 was $1.5 million and $1.5 million, respectively.

9. Income Taxes

The Company did not record a provision or benefit for income taxes during the three months ended March 31, 2017 and 2016, respectively, 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.

At December 31, 2016, the Company had $0.6 million of unrecognized tax benefit, none of which, if recognized, would affect the effective tax rate as most of the unrecognized tax benefit is deferred tax assets currently offset by a valuation allowance.

The Company has not recognized any interest and penalties related to uncertain tax positions as part of the income tax provision.

A number of years may elapse before an uncertain tax position is audited and finally resolved. While it is often difficult to predict the final outcome or the timing of resolution of any particular uncertain tax position, the Company believes that its reserves for income taxes reflect the most likely outcome. The Company adjusts these reserves, as well as the related interest, in light of changing facts and circumstances. Settlement of any particular position could require the use of cash. As of March 31, 2017, changes to the Company's uncertain tax positions in the next twelve months that are reasonably possible are not expected to have a material impact on the Company's financial position or results of operations.

10. Stockholders' Equity

Common stock

As of March 31, 2017, the Company's amended and restated certificate of incorporation dated October 2016, authorized 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. No dividends were declared through March 31, 2017.

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

	March 31, 2017	December 31, 2016
Options issued and outstanding	3,315,677	2,977,218
Unvested Restricted Stock Units	332,592	105,529
Common stock warrants issued and outstanding	217,051	217,245
Shares available for grant under future stock plans	5,085,996	4,226,068
	8,951,316	7,526,060

11. Preferred Stock Warrant Liabilities

In November 2012, in connection with borrowings under a convertible note, the Company issued warrants to purchase shares of Series C or New Preferred. The warrants were only exercisable if the Convertible Notes were converted into Series C or New Preferred. The warrants' exercise price is $0.001 per share and they have a seven year term. On March 27, 2013 the Company closed the Series D financing. The warrants were converted into warrants to purchase 207,177 shares of Series D convertible preferred stock. The Company recognized a charge of $294,000 related to change in the fair value of the warrants for the three months ended March 31, 2016. The warrants were exercised on October 3, 2016. Upon the IPO when the Series A preferred stock warrants converted into common stock warrants and were reclassified to additional paid-in-capital in the Company's balance sheet. As a result, the warrants are no longer subject to fair value remeasurement. In January 2017, 194 warrants were exercised.

In June 2014, in connection with borrowings under the Second Amendment (Note 7), the Company issued warrants to purchase 20,136 shares of Series D Preferred Stock at $7.31 per share that expire June 2024. The fair value of the warrant was determined by using an option pricing model prepared by a third-party based on an allocation of the Company's aggregate value to the outstanding equity instruments, applying a 30% discount to the warrant value for lack of marketability. The fair value of the warrant, $98,000, was recorded as a debt discount and is being amortized over the loan repayment period to interest expense. The Company recognized a charge of $27,000 related to change in the fair value of the warrants for the three months ended March 31, 2016. The warrants were converted into warrants to purchase common stock upon the completion of the IPO in 2016, and were reclassified to additional paid-in-capital in the Company's balance sheet. One of the warrants for 10,068 shares was exercised through a cashless exercise on October 26, 2016 resulting in the issuance of a net 7,310 shares of the Company's common stock, and the other warrant for 10,068 shares remains outstanding as of March 31, 2017.

12. Stock Incentive Plans

2006 Plan

In October 2006, the Company adopted the 2006 Equity Incentive Plan, as amended, (the "2006 Plan"). The Plan provides for the granting of stock options to employees and non-employees of the Company. Options granted under the Plan may be either incentive stock options or nonqualified stock options. Incentive stock options ("ISO") may be granted only to employees (including officers and directors who are also employees). Nonqualified stock options ("NSO") may be granted to employees and non-employees. The board of directors has the authority to determine to whom options will be granted, the number of options, the term and the exercise price.

Options under the Plan may be granted for periods of up to ten years and at prices no less than 85% of the estimated fair value of the shares on the date of grant as determined by the board of directors, provided, however, that (i) the exercise price of an ISO and NSO shall not be less than 100% and 85% of the estimated fair value of the shares on the date of grant, respectively, and (ii) the exercise price of an ISO and NSO granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant. In general, options become exercisable at a rate of 25% after the first anniversary of the grant and then monthly vesting for an additional three years from date of grant. The term for options is no longer than five years for ISOs for which the grantee owns greater than 10% of the voting power of all classes of stock and no longer than ten years for all other options. The Company issues new shares upon the exercise of options.

2016 Plan

In October 2016, the Company adopted the 2016 Equity Incentive Plan, (the "2016 Plan"). The 2016 Plan was subsequently approved by the Company's stockholders and became effective on October 19, 2016, immediately before the effective date of the IPO. Following the effectiveness of the 2016 Plan, no additional options will be granted under the 2006 Plan. In addition, to the extent that any awards outstanding or subject to vesting restrictions under the 2006 Plan are subsequently forfeited or terminated for any reason before being exercised or settled, the shares of common stock reserved for issuance pursuant to such awards as of the closing of the IPO will become available for issuance under the 2016 Plan. The remaining shares available for grant under the 2006 Plan became available for issuance under the 2016 Plan upon the closing of the IPO. On the first day of each year beginning with 2017, the 2016 Plan authorizes an annual increase of the least of 3,865,000 shares, 5% of outstanding shares on the last day of the immediately preceding fiscal year or an amount as determined by the Company's Board of Directors. As of March 31, 2017, the Company has reserved 4,270,875 shares of common stock for issuance under the 2016 Stock Incentive Plan.

Pursuant to the 2016 Plan, stock options, restricted shares, stock units, including restricted stock units and stock appreciation rights may be granted to employees, consultants, and outside directors of the Company. Options granted may be either ISOs or NSOs.

Stock options are governed by stock option agreements between the Company and recipients of stock options. ISOs and NSOs may be granted under the 2016 Plan at an exercise price of not less than 100% of the fair market value of the common stock on the date of grant, determined by the Compensation Committee of the Board of Directors. Options become exercisable and expire as determined by the Compensation Committee, provided that the term of ISOs may not exceed ten years from the date of grant.

Employee Stock Purchase Program ("ESPP")

In October 2016, the Company's Board of Directors and stockholders approved the Employee Stock Purchase Plan (the "ESPP"). Under the ESPP, the Company initially reserved 483,031 shares of common stock for issuance as of its effective date of October 19, 2016. On the first day of each calendar year, beginning in 2017, the number of shares in the reserve will increase by the lesser of 966,062 shares, 1.5% of the shares of the Company's common stock outstanding on the last day of the immediately preceding fiscal year, or an amount as determined by the Company's Board of Directors. The ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15% of their eligible compensation, subject to any plan limitations. The ESPP provides for twelve-month offering periods which each contain two six-month purchase periods. At the end of each purchase period, employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the last day of the purchase period.

As of March 31, 2017, no shares of common stock have been issued to employees participating in the ESPP and 815,121 shares were available for issuance under the ESPP.

Equity Incentive Plan Activity

A summary of share-based awards available for grant is as follows:

	Options Available for Grant
Balance at December 31, 2015	331,938
Additional options authorized	3,865,000
Options granted	(466,914)
Options forfeited	13,013
Balance at December 31, 2016	3,743,037
Additional options authorized	1,106,966
Options granted	(582,217)
Options forfeited	3,089
Balance at March 31, 2017	4,270,875

The following table summarizes stock option activity under the 2006 and 2016 Plans, including grants to nonemployees:

	Options Outstanding			
	Options Outstanding	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Balances at December 31, 2015	2,685,913	$ 4.81	7.63	$ 11,589
Options granted	361,385	15.65		
Options exercised	(57,067)	2.33		
Options forfeited	(13,013)	6.92		
Balances at December 31, 2016	**2,977,218**	$ 6.16	6.93	$ 70,979
Options granted	355,154			
Options exercised	(13,606)			
Options forfeited	(3,089)			
Balances at March 31, 2017	**3,315,677**	$ 9.34	7.21	$ 93,706
Options exercisable – March 31, 2017	2,037,090	$ 4.47	6.12	$ 67,490
Options vested and expected to vest – March 31, 2017	3,227,700	$ 9.02	7.15	$ 92,234

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, 2017 and 2016, the estimated weighted-average grant-date fair value of common stock underlying options granted was $18.61 and $5.11 per share, respectively.

13. 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	
	2017	2016
Expected term (in years)	6.1	6.1
Expected volatility	53.2%	60.0%
Risk-free interest rate	2.09%	1.40%
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	
	2017	2016
Cost of revenue	$ 38	$ 3
Research and development	369	36
Selling, general and administrative	1,621	369
Total stock-based compensation expense	$ 2,028	$ 408

As March 31, 2017, there was total unamortized compensation costs of $10.3 million, net of estimated forfeitures, related to unvested stock options which the Company expects to recognize over a period of approximately 2.5 years, $9.2 million, net of estimated forfeitures, related to unrecognized restricted stock unit (“RSU”) expense, which the Company expects to recognize over a period of 3.2 years, and $1.2 million unrecognized ESPP expense, which the company will recognize over 0.75 years.

Non-Employee Stock-Based Compensation

Stock-based compensation expense related to stock options granted to nonemployees is recognized as the stock options are earned. The measurement of stock-based compensation for non-employees is subject to periodic adjustment as the underlying equity instruments vest, and the related compensation expense is based on the estimated fair value of the equity instruments using the Black Scholes option pricing model. The Company believes that the estimated fair value of the stock options is more readily measurable than the fair value of the services received. Such expense was not material for the three months ended March 31, 2017 and 2016.

14. Net Loss Per Common Share

As the Company had net losses for the three months ended March 31, 2017 and 2016, 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 common stockholders (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2017	2016
Numerator:		
Net loss	$ (5,303)	$ (6,126)
Denominator:		
Weighted-average shares used to compute net loss per common share, basic and diluted	22,151,926	1,413,052
Net loss per common share, basic and diluted	$ (0.24)	$ (4.34)

The following outstanding shares of potentially dilutive securities have been excluded from diluted net loss per common share for the three months ended March 31, 2017 and 2016, because their inclusion would be anti-dilutive:

	Three Months Ended March 31,	
	2017	2016
Convertible preferred stock on an as-if converted basis	—	13,343,990
Options to purchase common stock	3,315,677	2,704,439
RSUs issued and unvested	332,592	—
Warrants to purchase convertible preferred stock on an as-if converted basis	—	328,117
Warrants to purchase common stock	217,051	—
Total	3,865,320	16,376,546

15. Subsequent Events

In May, 2017, the Company entered into a commercial building lease agreement. The lease will expire in September 2027 and provides for the lease of 20,276 square feet of office space in Houston, Texas. With the exception of the first four months, which are at a discount, the base rent is approximately $31,000 per month and escalates 2.5% per year. The total base rent payable over the lease period is approximately $4.3 million.

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 machine-learning capabilities. Our goal is to be the leading provider of first-line ambulatory electrocardiogram, or ECG, monitoring for patients at risk for arrhythmias. We have created a unique platform, called the ZIO Service, which combines an easy-to-wear and unobtrusive biosensor that can be worn for up to 14 days, called the ZIO Patch, with powerful proprietary algorithms which distill data from millions of heartbeats into clinically actionable information. The ZIO Service consists of:

- the wearable ZIO Patch biosensor, which continuously records and stores ECG data from every patient heartbeat for up to 14 days
- a cloud-based analysis of the recorded cardiac rhythms using our proprietary machine-learned algorithms
- a final quality assessment review of the data by our certified cardiac technicians
- the 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 two sources: third-party payors and institutions. Third-party payors, which accounted for approximately 79% and 70% of our revenue for the three months ended March 31, 2017 and 2016, respectively, consist of commercial payors and government agencies, such as the Centers for Medicare & Medicaid Services, or CMS, and the Veterans Administration, or the VA. A significant portion of our revenue in the third-party commercial payor category is contracted, which means we have entered into pricing contracts with these payors. Approximately 37% and 42% of our total revenue for the three months ended March 31, 2017 and 2016, respectively, is received from federal government agencies under established reimbursement codes. A small portion of this revenue is received from patients in accordance with their insurance co-payments and deductibles. Institutions, which are typically hospitals, clinics, or private physician practices accounted for approximately 21% and 30% of our revenue for the three months ended March 31, 2017 and 2016, respectively. We bill these organizations directly for our services and they are responsible for paying those invoices and seeking reimbursement from third-party payors where applicable. In addition, a small percentage of patients whose physicians prescribe the ZIO Service pay us directly. Typically, we bill institutional customers and rely on a third-party billing partner, named XIFIN, Inc., to submit patient claims and collect from commercial and certain government agencies.

Since our ZIO Service was cleared by the U.S. Food and Drug Administration, or FDA, in 2009, we have provided the ZIO Service to over 700,000 patients and have collected over 150 million hours of curated heartbeat data. We believe the ZIO Service is well-positioned to disrupt an already-established $1.4 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 ZIO Service in the United States to physicians, hospitals and clinics 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 departments. We expect to continue to increase the size of our U.S. sales organization to expand the current customer account base and increase utilization of our monitoring solution. In addition, we will continue to explore new opportunities to expand our sales and marketing efforts in international geographies using both direct and distribution channels.

Components of Results of Operations

Revenue

Substantially all of our revenue is currently derived from sales of our ZIO Service in the United States. We earn revenue from the provision of our ZIO Service primarily from two sources, third-party payors and institutions; however, a small percentage of our revenue is derived directly from patient payments. For the three months ended March 31, 2017 and 2016, we recognized approximately 88% and 86%, respectively, of our revenue on an accrual basis for instances where we have a predictable history of collections, which consists primarily of revenue from contracted payors and institutions. We recognize revenue based on the billing rate less contractual and other adjustments to arrive at the amount we expect to collect from third-party payors with an established billing rate. We determine the amount we expect to collect based on a per-payor or agreement basis, after analyzing payment history. When we do not have a contract or agreement, or have an insufficient or unpredictable history of collections, we recognize revenue only upon the earlier of notification of payer benefits allowed or when payment is received. We expect our revenue to increase as we increase the number of covered and contracted lives for our ZIO Service, expand our sales and marketing infrastructure, increase awareness of our product offerings, 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 year holidays compared to other times of the year. To date, the effect of these seasonal fluctuations on our quarterly results has been obscured by the growth of our business.

Cost of Revenue and Gross Margin

Cost of revenue is expensed as incurred and includes direct labor, material costs, equipment and infrastructure expenses, allocated overhead, and shipping and handling. Direct labor includes personnel involved in manufacturing and data analysis. Material costs include both the disposable materials costs of the ZIO Patch and amortization of the re-usable printed circuit board assemblies, or PCBAs. Each ZIO Patch 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 workflow enhancements to reduce labor costs. We expect further decreases in the cost of service as we spread the fixed portion of our manufacturing 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 an allocation of 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 compensation 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.

We expect to incur additional general and administrative expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, or SEC, and those of any national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services.

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 and amounts owed under the promissory note issued to California HealthCare Foundation. The non-cash component consists of interest expense recognized from the amortization of debt discounts derived from the issuance of warrants and debt issuance costs capitalized on our balance sheets, and "paid in kind" interest when debt payments are interest only and are added back to the debt balance.

Other Expense, Net

Other expense, net consists primarily of the change in fair value of our convertible preferred stock warrant liabilities and interest income. Our convertible preferred stock warrants were exercisable for shares that were contingently redeemable and as such, were classified as a liability on our balance sheets at their estimated fair value. Upon completion of our IPO, all convertible preferred stock warrants converted into warrants to purchase common stock. Interest income consists primarily of interest received on our cash, cash equivalents and investments balances.

Results of Operations

Comparison of the Three Months Ended March 31, 2017 and 2016

	Three Months Ended March 31,			
	2017	2016	$ Change	% Change
Revenue	$ 21,437	$ 12,854	$ 8,583	67%
Cost of revenue	6,337	4,659	1,678	36%
Gross profit	15,100	8,195	6,905	84%
Gross margin	70%	64%		
Operating expenses:				
Research and development	2,621	1,545	1,076	70%
Selling, general and administrative	17,224	11,521	5,703	50%
Total operating expenses	19,845	13,066	6,779	52%
Loss from operations	(4,745)	(4,871)	126	3%
Interest expense	(822)	(795)	(27)	100%
Other income (expense), net	264	(460)	724	157%
Net loss and comprehensive loss	$ (5,303)	$ (6,126)	$ 823	13%

Revenue

Revenue increased $8.6 million, or 67%, to $21.4 million during the three months ended March 31, 2017 from $12.9 million during the three months ended March 31, 2016. Revenue in the period primarily benefitted from volume increases of the ZIO Service performed, as well as improvements in the overall contracted rate.

Cost of Revenue and Gross Margin

Cost of revenue increased $1.7 million, or 36%, to $6.3 million during the three months ended March 31, 2017 from $4.7 million during the three months ended March 31, 2016. The increase in cost of revenue was primarily due to increased ZIO Service volume in 2017. This increase was partially offset by the reduction in costs to provide the ZIO Service, which was achieved primarily through manufacturing efficiencies in the production of our device and material cost reductions.

Gross margin for the three months ended March 31, 2017 increased to 70%, compared to 64% for the three months ended March 31, 2016. The increase was primarily due to the revenue mix shift driven by the success of our contracting efforts, secondarily by the reduction in the cost of the ZIO Service due to our continued efforts to lower manufacturing costs, and to a lesser extent by fixed costs absorption and reduced labor costs per device through our algorithm improvements and software-driven workflow enhancements.

Research and Development Expenses

Research and development expenses increased $1.1 million, or 70%, to $2.6 million during the three months ended March 31, 2017 from $1.5 million during the three months ended March 31, 2016. The increase was primarily attributable to a $0.7 million increase in payroll and personnel-related expenses as a result of increased headcount and a $0.4 million increase in facility-related expenses offset by $0.1 million decrease in clinical trial expenses.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $5.7 million, or 50%, to $17.2 million during the three months ended March 31, 2017 from $11.5 million during the three months ended March 31, 2016. The increase was primarily attributable to a $2.5 million increase in payroll and personnel-related expenses as a result of increased headcount to support the growth in our operations, a $1.4 million increase in professional services expenses, primarily as a result of an increase in accounting, legal, claims processing and recruiting services expenses, a $0.6 million increase related to travel and a $0.6 million increase in facility-related expenses.

Interest Expense

Interest expense remained consistent at $0.8 million during the three months ended March 31, 2017 and the three months ended March 31, 2016 due to our debt financing in December 2015.

Other Income (Expense), Net

Other income (expense), net increased $0.7 million to income of $0.3 million during the three months ended March 31, 2017 from expense of $0.5 million in other income during the three months ended March 31, 2016. The change was primarily related to an increase of $0.3 million of interest income from our investments and $0.4 million decrease from the fair value re-measurement of preferred warrant liabilities at each balance sheet date, which concluded upon the conversion to common warrants upon the IPO in October 2016.

Liquidity and Capital Expenditures

Overview

As of March 31, 2017, we had cash and cash equivalents of $15.6 million, short-term investments of $77.4 million, long-term investments of $16.4 million and an accumulated deficit of $132.5 million. In connection with our IPO that closed in October 2016, we received net cash proceeds of $110.7 million, net of underwriters' discounts and commissions and expenses paid by us. Prior to the IPO, we financed our operations primarily through sales of our private securities, sales of our products and services and debt financings.

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):

(in thousands)	Three Months Ended March 31, 2017	2016
Net cash (used in) provided by:		
Operating activities	$ (6,399)	$ (9,488)
Investing activities	(29,696)	(659)
Financing activities	35	(816)
Net decrease in cash and cash equivalents	$ (36,060)	$ (10,963)

Cash Used in Operating Activities

During the three months ended March 31, 2017, cash used in operating activities was $6.4 million, which consisted of a net loss of $5.3 million, adjusted by non-cash charges of $4.5 million and a net change of $5.6 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of a change in stock based-based compensation of $2.0 million, in allowance for doubtful accounts and contractual allowance of $1.8 million, non-cash interest expense of $0.4 million and depreciation and amortization of $0.3 million. The change in our net operating assets and liabilities was primarily due to a decrease of $1.9 million in accrued liabilities, primarily related to payments made on accrued payroll and related compensation accruals, a decrease of $3.3 million in accounts receivable as a result of increased revenues, and a decrease of $0.7 million in accounts payable due to timing of vendor payments.

During the three months ended March 31, 2016, cash used in operating activities was $9.5 million, which consisted of a net loss of $6.1 million, adjusted by non-cash charges of $2.6 million and a net negative change of $5.9 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 $1.0 million, a change of $0.5 million in the fair value of preferred warrants, stock-based compensation of $0.4 million and depreciation and amortization of $0.2 million. The change in our net operating assets and liabilities was primarily due to an increase of $3.1 million in accounts receivable as a result of increased revenues, a $3.2 million decrease in accrued liabilities primarily related to decreased accrued compensation accruals and a $1.0 million decrease in accounts payable due to timing of payments.

Cash Used in Investing Activities

Cash used in investing activities during the three months ended March 31, 2017 was $29.7 million, which consisted of $31.8 million in purchases of investments, $1.2 million of capital expenditures to purchase property and equipment, which were partially offset by $3.3 million of maturities of investments.

Cash used in investing activities during the three months ended March 31, 2016 was $0.7 million, which consisted of capital expenditures to purchase property and equipment.

Cash Provided by Financing Activities

During the three months ended March 31, 2017, cash provided by financing activities was $35,000 from the exercise of stock options.

During the three months ended March 31, 2016, cash provided by financing activities was $0.8 million, primarily consisting of primarily consisting of payments of deferred issuance costs related IPO.

Indebtedness

Pharmakon Loan Agreement

In December 2015, we entered into a Loan Agreement with Pharmakon. The Pharmakon Loan Agreement provides for up to $55.0 million in term loans split into two tranches as follows: (i) Tranche A Loans of $30.0 million in term loans, and (ii) 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.

During the first four years, payments are interest only, and for the first two years, 50% of the interest will be "paid-in-kind." We are subject to a financial covenant related to minimum trailing revenue targets that begins in June 2017, and is tested on a semi-annual basis. The minimum net revenue covenant ranges from $44.7 million for the period ended June 30, 2017 to $102.6 million for the period ended December 31, 2021. The minimum net revenue financial covenant has a 45-day equity cure period following required delivery date of the financial statements. Pursuant to this equity cure provision, we may cure a revenue covenant default by raising additional funds from the sale of equity. The loan matures in December 2021. As of March 31, 2016, $32.0 million in principal and interest was outstanding under the Pharmakon Loan Agreement.

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

The Pharmakon Loan Agreement requires us to maintain a minimum liquidity and minimum net sales during the term of the loan facility and contains customary affirmative and negative covenants and event of default provisions that could result in the acceleration of the repayment obligations under the loan facility. Upon a change in control of our company, Pharmakon has the option to demand payment in full of the outstanding loans together with the prepayment premium. The obligations under the Pharmakon Loan Agreement are secured by a security interest in substantially all of our assets pursuant to the Pharmakon Guaranty and Security Agreement, and this security interest is governed by an intercreditor agreement between Pharmakon and Silicon Valley Bank, or SVB.

SVB Loan and Security Agreement

In June 2014, we refinanced our debt with SVB by entering into a Second Amendment to the Amended and Restated Loan Security Agreement, or Second Amendment. Under the Second Amendment, we borrowed $4.9 million.

In December 2015, we used the proceeds from the Pharmakon Loan Agreement to repay $4.9 million of bank debt to SVB and entered into a Second Amended and Restated Loan and Security Agreement with SVB, or the SVB Loan Agreement. Under the SVB Loan Agreement we 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 revolving credit line bears 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 credit line is subject to financial covenants tied to our trailing twelve-month net sales. 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 letter of credit pursuant to the SVB revolving credit facility in connection with a new lease. As of March 31, 2017, we were eligible to borrow up to approximately $6.5 million and no amount was outstanding under the SVB revolving credit line.

The SVB Loan Agreement requires us to maintain a minimum consolidated liquidity and minimum net sales during the term of the loan facility. In addition, the SVB Loan Agreement contains customary affirmative and negative covenants and events of default. The obligations under the SVB Loan Agreement are secured by a security interest in substantially all of our assets, and this security interest is governed by an intercreditor agreement between Pharmakon and SVB.

CHCF Note

In November 2012, we entered into a Note Purchase Agreement and Promissory Note with the California HealthCare Foundation, or the CHCF Note, through which we borrowed $1.5 million. The CHCF Note accrues simple interest of 2.0%. The accrued interest and the principal was set to mature in November 2016. In June 2015, we amended the CHCF Note to extend the maturity date to May 2018. The CHCF Note is subordinate to other debt.

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, 2016 are presented in our 10-K filed with the SEC on March 31, 2017 pursuant to Rule 424(b) of the Securities Act of 1934. With the exception of the following, there have been no material changes:

On May 1, 2017, the Company entered into a commercial building lease agreement. The lease will expire in September 2027 and provides for the lease of 20,276 square feet of office space in Houston, Texas. With the exception of the first four months, which are at a discount, the base annual rent is approximately $31,000 per month and escalates 2.5% per year. The total base rent payable over the lease period is approximately $4.3 million.

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 $109.4 million as of March 31, 2017, which consisted of bank deposits, money market funds and 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 $32.7 million, which is net of debt discount and debt issuance costs, as of March 31, 2017. The interest rates on our outstanding debt carry fixed 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.

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. 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 effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recently completed fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 advertising, 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.

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, 2017 and 2016, we had a net loss of $5.3 million and $6.1 million, respectively, and we expect to continue to incur additional losses. As of March 31, 2017, we had an accumulated deficit of $132.5 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 and to develop additional arrhythmic 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. In addition, as a public company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. 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 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 a first-line 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, or CMS, for the professional services they provide in applying the ZIO Patch 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 through at least 2017. 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 and its predecessor products. 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 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
- our revenue recognition policy, which generally provides that we recognize revenue only upon the earlier of notification of payor benefits allowed or when payment is received
- 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 filed against us or by 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.

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, 2017, we received approximately 27% of our revenue from reimbursement for our ZIO Service by CMS. CMS imposes extensive and detailed requirements on manufacturers of medical devices and providers of medical services, 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, or 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. For example, government and other third-party payors require us to identify the service for which we are seeking reimbursement by using a Current Procedural Terminology, or CPT, code set maintained by the American Medical Association. We have secured CPT codes specific to our category of diagnostic monitoring through 2022. In addition, third-party payors often reimburse based on CMS reimbursement rates. To the extent CMS reduces its reimbursement rates for the ZIO Service, 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, or an NCD, by CMS, or at the local level through a local coverage determination, or an LCD, by one or more of the regional Medicare Administrative Contractors, or 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 the ZIO Service, 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 within the region, and regional LCDs may not always be consistent in their determinations. 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.

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 are expected to attempt to make sweeping changes to the current health care laws. It is uncertain how modification or repeal of any of the provisions of the ACA, 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 ACA 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 Patch and the interpretation of results which may inform a diagnosis. Additionally, certain payors may require that physicians prescribe a Holter monitor as the first-line monitoring option. 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, 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 product.

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., or 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 significant 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 upon the earlier of notification of payor benefits allowed or when payment is received. 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 Patch, 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 our ZIO Reports and disruptions to our 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 cardiac 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. We recently installed a new Enterprise Resource Planning, or ERP, platform, which is critical to our ability to track our claims processing and the delivery of our ZIO Reports to physicians, as well as to support our financial reporting systems. The time and resources required to optimize these systems are uncertain, and failure to complete optimization in a timely and efficient manner could adversely affect our operations. 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 cardiac technicians and other personnel to process higher volumes of data. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented 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 have limited experience manufacturing the ZIO Patch in commercial quantities and providing services on a broad scale, which could harm our business.

Because we have only limited experience in manufacturing the ZIO Patch in commercial quantities and providing services on a broad scale, 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 Patch 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
- we may experience a delay in completing validation and verification testing for new controlled environment rooms at our manufacturing facilities
- we are subject to state and federal regulations, including the FDA's Quality System Regulation, or the QSR, for both the manufacture of the ZIO Patch 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

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. Our inability to successfully manufacture the ZIO Patch 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 and state regulatory inspections for compliance with the QSR. Developing and maintaining a compliant quality system is time consuming and expensive. 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 Patch. 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 reusable printed circuit board assemblies, disposable housings, instruments and other materials that we use to manufacture our ZIO Patch and the adhesive that binds the ZIO Patch to a patient's body. 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 Patch 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 a facility, we may be unable to manufacture the ZIO Patch 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 Patch 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 manufacture products for some period of time. If our Cypress facility is inoperable for even a short period of time, the inability to manufacture the ZIO Patch, 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 independent diagnostic testing facility, or 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 cardiac 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 cardiac 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 2017, we have recognized approximately twelve percent of our revenue on a non-accrual basis, and as a result, our quarterly operating results are difficult to predict.

If we do not have a contracted rate with a payor, we recognize revenue only upon the earlier of notification of payor benefits allowed or when payment is received. 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. There is currently no predictable payment history for direct-billed non-contracted payors, and thus because a reasonable estimate of reimbursement cannot be made, we recognize revenue from such accounts only when we are notified of payment or it is received. 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. When management's judgement indicates a reasonable estimate of reimbursement can be made we will begin recognizing the revenue on an accrual basis upon delivery. 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, Inc. 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 who offer Holter and event monitors, and also function as service providers, include BioTelemetry, Inc., LifeWatch AG and Medtronic plc. These companies have also developed other patch-based mobile cardiac monitors that have recently received FDA and foreign regulatory clearances. For example, LifeWatch AG received FDA clearance and CE mark for its mobile cardiac telemetry monitoring patch in January 2016 and December 2015, respectively. In addition, in July 2016, BioTelemetry, Inc. announced FDA clearance for its patch-based mobile cardiac telemetry monitor. 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. Two examples of this are Medtronic plc's 2014 acquisition of Corventis, Inc. and Boston Scientific Corporation's 2015 equity investment and sales cooperation agreement with Preventice Solutions, Inc., which was formerly named eCardio Diagnostics, LLC. In addition, in April 2017, BioTelemetry, Inc. launched a tender offer to acquire LifeWatch AG. Future competition could come from makers of wearable fitness products or large information technology companies focused on improving healthcare. 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, or 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, or OIG, the Department of Justice, or 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, 2017, we had $33.6 million in principal and interest outstanding under our credit facilities consisting of our loan agreements with Pharmakon and SVB and a promissory note issued to California HealthCare Foundation. We must make significant annual debt payments under the loan agreements and the promissory note, which will divert resources from other activities. Our debt with Pharmakon and 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 these loan agreements, the promissory note and the note purchase agreement pursuant to which the promissory note was issued, 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 agreements, the promissory note and the note purchase agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the loan agreements and the promissory note to become immediately due and payable and terminate commitments to extend further credit. If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

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

Our success depends largely on the continued services of key members of our executive management team and others in key management positions. For example, the services of Kevin M. King, our Chief Executive Officer, and Matthew C. Garrett, our Chief Financial Officer, are essential to formulating and executing on corporate strategy and to ensuring the continued operations and integrity of financial reporting within our company. In addition, the services provided by David A. Vort, our Executive Vice President of Sales, are critical to the growth that we have experienced in the sales of our ZIO Service. Our employees may terminate their employment with us at any time. If we lose one or more key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy. We do not currently maintain key person life insurance policies on these or any of our employees.

In addition, our research and development programs and clinical operations depend on our ability to attract and retain highly skilled engineers and certified cardiac technicians. We may not be able to attract or retain qualified engineers and certified cardiac 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, either because we are a public company or otherwise, 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 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 ZIO Patches 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, or FCPA, U.K. Bribery Act of 2010 and comparable laws and regulations in other countries

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 U.S. Foreign Corrupt Practices Act, or 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 the ZIO Patch 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 machine-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. 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 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.

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 and store sensitive data, including legally-protected personally identifiable health information about patients in the United States and the United Kingdom. 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, 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. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of XIFIN, may be vulnerable to attacks by hackers or viruses or breaches due to employee error, malfeasance or other disruptions. 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, or PHI, is transmitted to us by third parties, who may not implement adequate security and privacy measures.

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, our operations could be disrupted, we may be unable to provide the ZIO Service and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm.

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, or HIPAA, and the European Union Data Protection Directive, and regulatory penalties. 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.

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 Patch 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 Patch 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, 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.

To date, the growth of our operations has been largely organic, and we have limited experience in acquiring other businesses or technologies. We may not be able to successfully integrate acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions 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 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 recent 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, 2016, we had federal and state net operating loss carryforwards, or NOLs, of $104.6 million and $58.6 million, respectively, which if not utilized will begin to expire in 2027 for federal purposes and 2017 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 of 1986, 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. 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.

Prior to our IPO, our Chief Financial Officer had not been the chief financial officer of a publicly traded company and although our Chief Executive Officer had been the chief executive officer of another public company, he had never been involved in the transition of a private company to a public company through an initial public offering.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act, requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our annual report for the year ending December 31, 2017, provide a management report on our internal control over financial reporting. 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 are implementing the process and documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act, but we may not be able to complete our evaluation, testing and any required remediation in a timely fashion.

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. Moreover, when we are no longer an emerging growth company, our independent registered public accounting firm will be required 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 when we are no longer an emerging growth company 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 Patch 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, or 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 Patch 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 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 March 31, 2017, we owned, or retained exclusive license to, nine issued U.S. patents, the earliest of which will expire in 2028. As of March 31, 2017, we also owned, or retained an exclusive license to, two issued patents from each of the patent offices in Japan and Australia, and one issued patent from the patent offices in each of Canada, the European Union and Korea. The earliest expiration date of these international patents is 2027. As of March 31, 2017, we had fifteen pending patent applications globally, including four in the United States, two in Canada, four in the European Union, three in Japan, one in Korea and one in the PCT phase. Our patents and patent applications include claims covering key aspects of the design, manufacture and use of the ZIO Patch 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. 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, or the 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. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. 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. 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 (as defined below), 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, or HHS, 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 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or 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, currently set at $5,500 to $11,000 per false claim.

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 Patch 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 Patch and ZIO Service are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries where we do business. 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 Patch and 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, including reports required by the medical device reporting regulations, or 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.

The FDA and the Federal Trade Commission, or 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 authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, 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 510(k) clearance or premarket approval of new products or services, new intended uses or modifications to existing products or services
- withdrawal of 510(k) 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 Patch, labelling of the ZIO Patch, 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 Patch 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 Patch 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 Patch 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 Patch 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, or QSR and the EU's Medical Device Directive, or MDD, both of which cover procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of ZIO Patches. We are also subject to similar state requirements and licenses, and to ongoing ISO 13485 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, or 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. For our design facilities in San Francisco, California, the CDPH completed a routine audit in December 2008, while the FDA completed routine audits in December 2010, February 2013 and June 2016, and no formal observations resulted from these audits. The CDPH also completed a routine audit of our previous manufacturing facility in Huntington Beach, California in June 2010 with no observations noted, while the FDA audited the same facility in May 2013, and issued one Form 483 observation requiring a change to documentation procedures. Remedial action was completed within the 45-day timeline that was agreed to at the close of the audit. No additional follow up with the FDA was required and we believe that we are in substantial compliance 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, or NSAI, our European Notified Body. The NSAI first inspected our facilities for ISO 13485 compliance in May and June of 2014 and found two non-conformities of Minor (Category 2) characterization, one in each of our manufacturing and service operation centers. The NSAI conducted a six-month follow-up of the same facilities in January 2015, and no nonconformities were found. Immediately following the move of our manufacturing facility to Cypress, California, in August 2015, the NSAI conducted a site audit of the new facility and no nonconformities were found. Most recently, the NSAI conducted a routine ISO 13485 surveillance audit of our design, manufacturing and service operations in February and March of 2016 and continued certification was achieved. The audit noted eight non-conformities of Minor (Category 2) characterization, primarily related to documentation processes, the integration of MDD technology and workflow standards within our standard operating procedures, and climate control improvements. Effective implementation of corrective actions for each nonconformance will be evaluated at the next ISO compliance audit in 2017.

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 Patches, which would harm our business.

ZIO Patches 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 Patches 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 that could harm our future revenue and profitability. 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. For example, 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, imposes an excise tax of 2.3% on the sale of most medical devices, including ours. Although this excise tax has temporarily been suspended for two years beginning on January 1, 2016, any failure to pay this amount if it becomes due in the future could result in an injunction on the sale of our products, fines and penalties.

We cannot assure you that the Affordable Care Act, as currently enacted or as amended, repealed or replaced in the future, will not harm our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business. There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. 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 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.

Risks Related to Our Common Stock

Our common stock has only recently become publicly traded, and we expect that the price of our common stock will fluctuate substantially.

Our common stock has only recently become publicly traded, and we cannot be certain that an active trading market for our common stock will be sustained. The lack of an active market may impair the value of our common stock, or your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital to continue to fund operations by selling common stock and may impair our ability to acquire other companies or products by using our common stock as consideration. Although our common stock is listed on the NASDAQ Global Market, if we fail to satisfy the continued listing standards of the NASDAQ Global Market, we could be de-listed, which would negatively impact the price of our common stock.

The market price of our common stock is likely to be highly volatile and 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. 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.

Sales of a substantial number of shares of our common stock in the public market, including by our existing stockholders, could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that these sales and others may have on the prevailing market price of our common stock.

In addition, certain of our stockholders can require us to register shares of our capital stock owned by them for public sale in the United States. We have also filed a registration statement to register shares of our common stock reserved for future issuance under our equity compensation plans. Subject to the satisfaction of applicable exercise periods and applicable volume and restrictions that apply to affiliates, the shares of our common stock issued upon exercise of outstanding options will become available for immediate resale in the public market upon issuance.

Future sales of our common stock may make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. These sales also could cause the market price of our common stock to decline and make it more difficult for you to sell shares of our common stock.

Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of March 31, 2017, our directors, officers and each stockholder holding 5% or more of our outstanding common stock and their respective affiliates beneficially owned approximately 59% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to exert significant influence over the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

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, particularly after we no longer qualify as an "emerging growth company," under the JOBS Act. 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, management's attention may be diverted from other business concerns and our costs and expenses will increase, which could harm our business and operating results. We will likely need to hire more employees in the future or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

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.

We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We currently qualify as an "emerging growth company" under the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from reporting requirements that are applicable to other public companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive to the extent we rely on available exemptions. If some investors do find our common stock less attractive, there may be a less active trading market for our common stock and our stock price may be more volatile or may decline.

We will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates is at least $700 million as of the last business day of our most recently completed second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenue of $1 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three year period or (iv) the end of the fiscal year in which the fifth anniversary of the date of our IPO.

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

Unregistered Sales of Equity Securities

None.

Use of Proceeds

Our initial public offering of 7,238,235 shares of common stock was effected through a registration statement on Form S-1 (Registration Nos. 333-213773 and 333-214179), which was declared effective on October 19, 2016. Our initial public offering closed on October 25, 2016 and resulted in net proceeds of approximately $110.9 million, after deducting underwriting discounts and commissions of approximately $8.6 million and other expenses of approximately $3.5 million. No payments for such expenses were made directly or indirectly to any of our officers or directors.

J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, Canaccord Genuity Inc. and BTIG, LLC acted as the underwriters. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on October 20, 2016 pursuant to Rule 424(b) of the Securities Act.

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.

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 12, 2017

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

Date: May 12, 2017

By: /s/ Matthew C. Garrett
Matthew C. Garrett
Chief Financial Officer
(Principal Financial Officer and Chief Accounting Officer)

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

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 12, 2017

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 12, 2017

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, 2017, 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 12, 2017

/s/ Matthew C. Garrett

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

Date: May 12, 2017

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.