PROSPECTUS SUPPLEMENT NO. 5
(to Prospectus dated January 26, 2015)

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-201471

MRI Interventions, Inc.

22,885,855 Shares of Common Stock

This prospectus supplement relates to the prospectus dated January 26, 2015, as supplemented by prospectus supplement no. 1 dated March 17, 2015, prospectus supplement no. 2 dated March 17, 2015, prospectus supplement no. 3 dated March 31, 2015 and prospectus supplement no. 4 dated April 17, 2015, which permits the resale of up to 15,556,398 outstanding shares of our common stock, and 7,329,457 shares of our common stock issuable upon the exercise of outstanding warrants, by the selling securityholders identified in the prospectus, as amended and supplemented from time to time. We will pay the expenses of registering the shares, but we are not selling any shares of common stock in this offering and therefore will not receive any proceeds from this offering. We will, however, receive the exercise price of the warrants if and when the warrants are exercised for cash by the securityholders.

This prospectus supplement is being filed to update, amend, and supplement the information previously included in the prospectus with the information contained in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 7, 2015 (the "10-Q"). Accordingly, we have attached the 10-Q to this prospectus supplement. You should read this prospectus supplement together with the prospectus, which is to be delivered with this prospectus supplement.

Our common stock is traded in the over-the-counter market and is quoted on the OTC Markets and the OTC Bulletin Board under the symbol MRIC. On May 6, 2015, the last reported sale price of our common stock was $1.03 per share.

We are an "emerging growth company" under the federal securities laws and will be subject to reduced public company reporting requirements. Investing in our common stock involves risk. See "Risk Factors" beginning on page 6 of the prospectus, as amended and supplemented by the "Risk Factors" beginning on page 20 of the 10-Q, to read about factors you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus or this prospectus supplement. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is May 7, 2015.

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, 2015

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 000-54575

MRI Interventions, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**58-2394628**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification Number)
5 Musick **Irvine, California**	**92618**
(Address of Principal Executive Offices)	(Zip Code)

(949) 900-6833
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files.)

☒Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐	Smaller Reporting Company ☒
(Do not check if smaller reporting company)	

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒No

As of May 5, 2015, there were 74,880,011 shares of common stock outstanding.

MRI INTERVENTIONS, INC.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" as defined under United States federal securities laws. The forward-looking statements are contained principally in the sections of this Quarterly Report entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors." These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- future revenues from sales of ClearPoint system products;
- our ability to market, commercialize and achieve broader market acceptance for our ClearPoint system products; and
- estimates regarding the sufficiency of our cash resources.

In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements, although not all forward-looking statements contain these words. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. You should refer to the section of this Quarterly Report entitled "Risk Factors" under Part II, Item 1A below for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We do not undertake to update any of the forward-looking statements after the date of this Quarterly Report, except to the extent required by applicable securities laws.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

MRI INTERVENTIONS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)

	March 31, 2015	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 6,438,329	$ 9,244,006
Accounts receivable	605,718	468,949
Inventory, net	2,096,899	1,965,039
Prepaid expenses and other current assets	36,129	29,220
Total current assets	9,177,075	11,707,214
Property and equipment, net	406,892	482,970
Software license inventory	892,500	910,000
Other assets	268,814	285,498
Total assets	$ 10,745,281	$ 13,385,682
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,142,876	$ 997,090
Accrued compensation	321,060	323,644
Accrued restructuring charges	753,400	-
Other accrued liabilities	328,842	1,297,712
Derivative liabilites	2,980,964	2,198,162
Deferred product and service revenues	97,840	102,710
Total current liabilities	5,624,982	4,919,318
Accrued interest	962,075	876,025
Senior secured note payable, net of unamortized discount of $225,353 and $271,305 at March 31, 2015 and December 31, 2014, respectively	4,064,091	4,018,139
2014 junior secured 12% notes payable, net of unamortized discount of $351,225 and $369,299 at March 31, 2015 and December 31, 2014, respectively	3,373,775	3,355,701
2010 junior secured notes payable, net of unamortized discount of $2,649,533 and $2,683,171 at March 31, 2015 and December 31, 2014, respectively	350,467	316,829
Total liabilities	14,375,390	13,486,012
Commitments and contingencies (Notes 4, 5, 6 and 7)		
Stockholders' deficit:		
Common stock, $0.01 par value; 100,000,000 shares authorized; 74,880,011 shares issued and outstanding at March 31, 2015; and 74,842,428 issued and outstanding at December 31, 2014	748,800	748,424
Additional paid-in capital	76,843,679	76,428,580
Accumulated deficit	(81,222,588)	(77,277,334)
Total stockholders' deficit	(3,630,109)	(100,330)
Total liabilities and stockholders' deficit	$ 10,745,281	$ 13,385,682

See accompanying notes.

MRI INTERVENTIONS, INC.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended March 31,	
	2015	**2014**
Revenues:		
Product revenues	$ 976,871	$ 713,259
Other service revenues	33,532	10,410
Development service revenues	-	98,862
Total revenues	1,010,403	822,531
Cost of product revenues	385,609	350,685
Research and development costs	527,512	817,621
Selling, general, and administrative expenses	2,288,660	1,800,799
Restructuring charges	753,400	-
Gain on sale of intellectual property	-	(4,338,601)
Operating income (loss)	(2,944,778)	2,192,027
Other income (expense):		
Gain (loss) on change in fair value of deriviative liabilities	(782,802)	483,790
Other income, net	82,688	103,386
Interest income	7,451	2,607
Interest expense	(307,813)	(151,408)
Net income (loss)	$ (3,945,254)	$ 2,630,402
Net income (loss) per share attributable to common stockholders:		
Basic	$ (0.05)	$ 0.04
Diluted	$ (0.05)	$ 0.04
Weighted average shares outstanding:		
Basic	74,842,841	58,716,727
Diluted	74,842,841	61,248,630

See accompanying notes.

MRI INTERVENTIONS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31,	
	2015	**2014**
Cash flows from operating activities:		
Net income (loss)	$ (3,945,254)	$ 2,630,402
Adjustments to reconcile net income (loss) to net cash flows from operating activities:		
Depreciation and license amortization	86,680	92,629
Share-based compensation	377,892	179,746
Expenses paid through the issuance of common stock	37,583	299,657
(Gain) loss on change in fair value of derivative liabilities	782,802	(483,790)
Gain on sale of intellectual property	-	(4,338,601)
Amortization of debt issuance costs and and original issue discounts	110,015	56,985
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(136,769)	317,649
Inventory	(109,994)	(147,906)
Prepaid expenses and other current assets	(6,909)	102,833
Other assets	(4,000)	(1,500)
Accounts payable and accrued expenses	13,782	(85,730)
Deferred revenue	(4,870)	18,508
Net cash flows from operating activities	(2,799,042)	(1,359,118)
Cash flows from investing activities:		
Purchases of property and equipment	(6,635)	(2,390)
Net cash flows from investing activities	(6,635)	(2,390)
Cash flows from financing activities:		
Net proceeds from debt private placement	-	3,503,314
Proceeds from stock option exercises	-	143,000
Net cash flows from financing activities	-	3,646,314
Net change in cash and cash equivalents	(2,805,677)	2,284,806
Cash and cash equivalents, beginning of period	9,244,006	3,516,244
Cash and cash equivalents, end of period	$ 6,438,329	$ 5,801,050
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ -	$ -
Interest	$ 223,500	$ 323

See accompanying notes.

MRI INTERVENTIONS, INC.
Condensed Consolidated Statements of Cash Flows (continued)
(Unaudited)

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

- During the three months ended March 31, 2015, a net amount of ClearPoint reusable components with a cost of $8,006 and accumulated depreciation of $3,640 was transferred from loaned systems to inventory at the net carrying cost. During the three months ended March 31, 2014, a net amount of ClearPoint reusable components with a cost of $47,329 and accumulated depreciation of $18,780 was transferred from loaned systems to inventory at the net carrying cost.

- In March 2014, the Company entered into an asset purchase agreement to sell certain intellectual property. The asset purchase price was satisfied through the cancellation of related party convertible notes payable in the aggregate amount of $4,338,601.

- In recording the March 2014 debt private placement transaction, the Company recorded the fair value of the warrants issued to the placement agent, in the amount of $30,210, as a deferred financing cost, and the Company recorded a corresponding amount to additional paid-in capital. In addition, warrants with a relative fair value of $413,057 were issued to investors in the debt private placement transaction. The relative fair value of these warrants was recorded as additional paid-in capital, which resulted in a corresponding debt discount.

MRI INTERVENTIONS, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of the Business and Liquidity

MRI Interventions, Inc. (the "Company") is a medical device company focused on the development and commercialization of technology that enables physicians to see inside the brain and heart using direct, intra-procedural magnetic resonance imaging ("MRI") guidance while performing minimally invasive surgical procedures. The Company was incorporated in the state of Delaware in March 1998. The Company's principal executive office and principal operations are located in Irvine, California. The Company established MRI Interventions (Canada) Inc., a wholly-owned subsidiary incorporated in Canada, in August 2013. This subsidiary was established primarily for the purpose of performing software development, and its activities are reflected in these consolidated financial statements.

The Company's ClearPoint system, an integrated system comprised of reusable and disposable products, is designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. The Company received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") in 2010 to market the ClearPoint system in the United States for general neurological interventional procedures. The Company's ClearTrace system is a product candidate under development that is designed to allow catheter-based minimally invasive procedures in the heart to be performed in an MRI suite.

Liquidity and Management's Plans

The cumulative net loss from the Company's inception through March 31, 2015 was $81,222,588. Net cash used in operations was $2,799,042 for the three months ended March 31, 2015 and $7,250,303 for the year ended December 31, 2014. Since inception, the Company has financed its activities principally from the sale of equity securities, the issuance of notes payable and license arrangements.

The Company's primary financing activities during the three months ended March 31, 2015 and the year ended December 31, 2014 were: (i) a December 2014 equity private placement, which resulted in net proceeds of $9,379,880; and (ii) a March 2014 debt private placement, which resulted in net proceeds of $3,503,314. In addition, in March 2014, the Company completed a transaction with Boston Scientific Corporation and certain of its affiliates (collectively "Boston Scientific") that resulted in the cancellation of $4,338,601 in related party convertible notes payable held by Boston Scientific which were scheduled to mature in 2014 (see Note 5).

While the Company expects to continue to use cash in operations, the Company believes its existing cash and cash equivalents at March 31, 2015 of $6,438,329, combined with cash expected to be generated from product sales, will be sufficient to meet its anticipated cash requirements through at least March 31, 2016.

During 2015, the Company expects to increase revenues from sales of ClearPoint system products as a result of greater utilization at existing installed sites and an increase in the number of installed sites. Certain planned expenditures are discretionary and could be deferred if the Company is required to do so to fund critical operations.

To the extent the Company's available cash and cash equivalents are insufficient to satisfy its long-term operating requirements, the Company will need to seek additional sources of funds from the sale of equity or debt securities or through a credit facility, or the Company will need to modify its current business plan. There can be no assurances that the Company will be able to obtain additional financing on commercially reasonable terms, if at all. The sale of additional equity or convertible debt securities would likely result in dilution to the Company's current stockholders.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

In the opinion of management, the accompanying unaudited condensed consolidated financial statements ("condensed financial statements") have been prepared on a basis consistent with the Company's December 31, 2014 audited consolidated financial statements, and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly state the information set forth therein. The condensed financial statements have been prepared in accordance with United States ("U.S.") Securities and Exchange Commission ("SEC") rules for interim financial information, and, therefore, omit certain information and footnote disclosures necessary to present such statements in accordance with generally accepted accounting principles in the U.S. ("GAAP"). The preparation of the condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and the related disclosures at the date of the financial statements and during the reporting period. Actual results could materially differ from these estimates. These condensed financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, which was filed with the SEC on March 17, 2015. The accompanying unaudited condensed consolidated balance sheet as of December 31, 2014 has been derived from the audited consolidated financial statements at that date, but does not include all information and footnotes required by GAAP for a complete set of financial statements. The results of operations for the three months ended March 31, 2015 may not be indicative of the results to be expected for the entire year or any future periods.

Derivative Liabilities for Warrants to Purchase Common Stock

Derivative liabilities for warrants to purchase common stock represent the fair value of warrants issued in connection with certain private placements of shares of the Company's common stock (see Note 7). The fair values of these warrants are presented as liabilities based on certain net cash settlement and exercise price reset, or "down round," provisions. These derivative liabilities, which are recorded on the accompanying consolidated balance sheets, are calculated utilizing the Monte Carlo simulation valuation method. Changes in the fair values of these warrants are recognized as other income or expense in the related statement of operations.

Fair Value Measurements

The Company measures and records certain financial assets and liabilities at fair value on a recurring basis. GAAP provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority, referred to as Level 1, to quoted prices in active markets for identical assets and liabilities. The next priority, referred to as Level 2, is given to quoted prices for similar assets or liabilities in active markets or quoted prices for identical or similar assets or liabilities in markets that are not active; that is, markets in which there are few transactions for the asset or liability. The lowest priority, referred to as Level 3, is given to unobservable inputs. The table below reflects the level of the inputs used in the Company's fair value calculation for instruments carried at fair value at (see Note 7):

	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value
March 31, 2015				
Derivative liabilities - warrants	$ -	$ -	$ 2,980,964	$ 2,980,964
December 31, 2014				
Derivative liabilities - warrants	$ -	$ -	$ 2,198,162	$ 2,198,162

Carrying amounts of the Company's cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair values due to their short maturities.

The table below reflects the carrying values and the estimated fair values, based on Level 3 inputs, of the Company's outstanding notes payable, including the related accrued interest, at March 31, 2015:

	Carrying Values	Estimated Fair Values
Senior secured note payable, including accrued interest	$ 4,562,416	$ 4,562,416
2014 junior secured notes payable, including accrued interest	3,382,150	3,733,375
2010 junior secured notes payable, including accrued interest	814,217	2,362,324

Inventory

Inventory is carried at the lower of cost (first-in, first-out (FIFO) method) or net realizable value. All items included in inventory relate to the Company's ClearPoint system. Software license inventory that is not expected to be utilized within the next twelve months is classified as a non-current asset. The Company periodically reviews its inventory for obsolete items and provides a reserve upon identification of potential obsolete items.

Revenue Recognition

The Company's revenues are comprised of: (1) product revenues resulting from the sale of ClearPoint system reusable products, disposable products and ClearTrace system components; (2) development service revenues; and (3) other service revenues. The Company recognizes revenue when persuasive evidence of an arrangement exists, the selling price or fee is fixed or determinable, collection is reasonably assured and, for product revenues, risk of loss has transferred to the customer. For all sales, the Company requires either a purchase agreement or a purchase order as evidence of an arrangement. The Company analyzes revenue recognition on an individual arrangement basis. The Company determines whether deliverables under an arrangement represent one or more separate units of accounting as defined by GAAP. Application of GAAP regarding multiple-element arrangements requires management to make subjective judgments about the values of the individual elements and whether delivered elements are separable from the other aspects of the contractual relationship.

(1) Product Revenues

Sales of ClearPoint system reusable products: Generally, revenues related to the sale of ClearPoint system reusable products are recognized upon installation of the system and the completion of training of at least one of the customer's physicians, which typically occurs concurrently with the installation. Reusable products include software which is integral to the utility of the system as a whole. Sales of reusable products that have stand-alone value to the customer are recognized when risk of loss passes to the customer. Sales of ClearPoint reusable products to a distributor that has been trained to perform system installations and to conduct ClearPoint physician training are recognized at the time risk of loss passes to the distributor.

Sales of disposable products: Revenues from the sale of disposable products, including ClearPoint system disposable products, are recognized at the time risk of loss passes to the customer, which is generally at shipping point or upon delivery to the customer's location, depending on the agreed upon terms with the customer.

Sales of ClearTrace components: Revenues from sales of ClearTrace system components to research sites for non-commercial use are recognized at the time risk of loss passes to the customer, which is generally at shipping point or upon delivery to the customer's location, depending on the agreed upon terms with the customer. The Company does not have regulatory clearance or approval to sell ClearTrace system components for commercial use.

(2) Development Service Revenues — The Company entered into an agreement to provide development services to a third party. Under the agreement, the Company earned revenue equal to costs incurred for outside expenses related to the development services provided, plus actual direct internal labor costs (including the cost of employee benefits), plus an overhead markup of the direct internal labor costs incurred. Revenues are recognized in the period in which the Company incurred the related costs.

(3) Other Service Revenues — Other service revenues are comprised of installation fees, training fees, shipping fees and service fees charged in connection with ClearPoint system installations and ClearPoint system service agreements. Typically, the Company bills upfront for service agreements, which have terms ranging from one to three years. These amounts are recognized as revenues ratably over the term of the related service agreement.

Net Income (Loss) Per Share

The Company computes basic net income (loss) per share using the weighted-average number of common shares outstanding during the period. Diluted net income (loss) per share assumes the conversion, exercise or issuance of all potential common stock equivalents, unless the effect of inclusion would be anti-dilutive. For purposes of this calculation, common stock equivalents include the Company's common stock options and common stock warrants. For purposes of computing diluted net income per share, the number of potential common stock equivalents is reduced by the number of shares the Company could have repurchased with the proceeds from issuance of the potentially dilutive shares.

Concentration Risks and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company holds its cash and cash equivalents on deposit with financial institutions in the United States insured by the Federal Deposit Insurance Corporation. At March 31, 2015, the Company had bank balances in excess of the insured limits of approximately $68,000, most of which was held on deposit to satisfy outstanding checks.

Accounts receivable at March 31, 2015 and December 31, 2014, and substantially all product revenues recognized for the three months ended March 31, 2015 and 2014, relate to sales to customers located in the U.S. and to one distributor. At March 31, 2015, three customers represented 24%, 14% and 12% of the Company's accounts receivable balance. At December 31, 2014, two customers represented 20% and 17% of the Company's accounts receivable balance. No other customer represented more than 9% of total accounts receivable at March 31, 2015 or December 31, 2014. For the three months ended March 31, 2015, sales to two customers represented 17% and 14% of product revenues. For the three months ended March 31, 2014, sales to a distributor represented 15% of product revenues and sales to two customers represented 13% and 12% of product revenues. No other single customer represented greater than 8% of product revenues for the three months ended March 31, 2015 or 2014. The Company performs credit evaluations of its customers' financial condition, and generally does not require collateral from its customers. The Company will provide an allowance for doubtful accounts when collections become doubtful, but the Company has not experienced any credit losses or recorded any allowances to date.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers," which creates a new Topic, Accounting Standards Codification ("ASC") Topic 606. The standard is principle-based and provides a five-step model to determine when and how revenue is recognized. The core principle is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This standard is effective for the Company beginning in 2017 and allows for either full retrospective adoption or modified retrospective adoption. The Company is currently evaluating the impact of the adoption of ASC Topic 606 on its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, "Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern," which provides guidance on determining when and how to disclose going-concern uncertainties in financial statements. The new standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued. An entity must provide certain disclosures if conditions or events raise substantial doubt about the entity's ability to continue as a going concern. The ASU applies to all entities and is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The Company is currently evaluating the impact of this update on future disclosures concerning its liquidity position.

In April 2015, the FASB issued ASU 2015-03, "Simplifying the Presentation of Debt Issuance Costs", which requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This ASU requires retrospective adoption and is effective for financial statements issued for fiscal years beginning after December 15, 2015 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact that this guidance will have on its financial statements.

3. Inventory

Inventory consists of the following as of:

	March 31 2015	December 31, 2014
Raw materials and work in process	$ 1,028,258	$ 899,014
Software license inventory	350,000	350,000
Finished goods	718,641	716,025
Inventory included in current assets	2,096,899	1,965,039
Software license inventory	892,500	910,000
	$ 2,989,399	$ 2,875,039

4. Restructuring Charges

In March 2015, the Company announced that it will consolidate all major business functions into its Irvine, California headquarters. In connection with this consolidation, the Company will close its Memphis, Tennessee office in May 2015. The Company will not retain any of its Memphis-based employees. A total of seven employees have been or will be impacted by the consolidation, including three executives of the Company. In connection with this consolidation, the Company recorded restructuring charges of $753,400. Approximately $718,000 of the restructuring charge relates to costs associated with severance and other compensation for the impacted employees. Most of the amount recorded as a restructuring charge is expected to be paid during the quarter ended June 30, 2015.

5. Sale of Intellectual Property in Exchange for Cancellation of the Boston Scientific Notes

In March 2014, the Company entered into an Asset Purchase Agreement (the “BSC Purchase Agreement”) with Boston Scientific. Pursuant to the BSC Purchase Agreement, Boston Scientific purchased from the Company certain MRI-safety technology for implantable medical leads (the “Transferred Intellectual Property”) for an aggregate purchase price of $4,338,601. The Transferred Intellectual Property includes some, but not all, of the intellectual property the Company previously licensed exclusively to Boston Scientific within the fields of neuromodulation and implantable medical leads for cardiac applications. The purchase price was satisfied through the cancellation of three convertible notes payable issued by the Company to Boston Scientific, which were scheduled to mature in 2014, in the aggregate principal amount of $4,338,601 (the “Boston Scientific Notes”). Accordingly, all obligations of the Company under the Boston Scientific Notes were discharged and the liens that secured the Company’s obligations under the Boston Scientific Notes were terminated and released. The Company recorded a gain in its consolidated statement of operations for the three months ended March 31, 2014, equal to the aggregate purchase price for the assets sold under the BSC Purchase Agreement.

In connection with the BSC Purchase Agreement, the parties entered into a license agreement pursuant to which Boston Scientific granted the Company an exclusive, royalty-free, fully paid up, irrevocable, worldwide license to the Transferred Intellectual Property, with the right to sublicense, within fields of use other than neuromodulation and implantable medical leads for cardiac applications.

In addition, Boston Scientific and the Company entered into amendments to their pre-existing development and license agreements (the “Pre-existing Agreements”), in the fields of neuromodulation and implantable medical leads for cardiac applications, to eliminate the milestone-based payments and royalties provided under those agreements. As such, the Company is no longer entitled to receive any potential future milestone-based payments or royalties under its development and license agreements with Boston Scientific.

The transactions contemplated by the BSC Purchase Agreement do not impact the Company's ability to continue to commercialize its ClearPoint system or to continue the development of its ClearTrace system.

6. Notes Payable

Senior Secured Note Payable

The Company has a note payable to Brainlab AG (the "Brainlab Note") in the principal amount of $4,289,444. Interest accrues at 5.5% per year. The Brainlab Note matures in April 2016, and principal and accrued interest is payable in a single installment upon maturity. The Brainlab Note is secured by a senior security interest in the assets of the Company. The original discount associated with the Brainlab Note represented the difference between the fair value and the principal amount of the note at the time the note was modified in March 2013. The unamortized discount at March 31, 2015 and December 31, 2014 was $225,353 and $271,305, respectively. The discount is being amortized to interest expense using the effective interest method over the term of the Brainlab Note.

2014 Junior Secured 12% Notes Payable

In March 2014, the Company entered into securities purchase agreements for the private placement of (i) 12% second-priority secured non-convertible promissory notes maturing in 2019 (the "2014 Secured Notes") and (ii) warrants to purchase 0.3 share of the Company's common stock for each dollar in principal amount of the 2014 Secured Notes sold by the Company. Pursuant to those securities purchase agreements, the Company sold 2014 Secured Notes in a total aggregate principal amount of $3,725,000, together with warrants to purchase up to 1,117,500 shares of common stock, for aggregate gross proceeds of $3,725,000, before placement agent commissions and other expenses.

The 2014 Secured Notes have a five-year term, and they bear interest at a rate of 12% per year, payable semi-annually, in arrears, on each six-month and one-year anniversary of the issuance date. The 2014 Secured Notes are not convertible into shares of the Company's common stock. Following the third anniversary of the issuance date, the 2014 Secured Notes may be prepaid, without penalty or premium, provided that all principal and unpaid accrued interest under all 2014 Secured Notes is prepaid at the same time. Prior to the third anniversary of the issuance date, the Company may prepay all, but not less than all, of the principal and unpaid accrued interest under the 2014 Secured Notes at any time, subject to the Company's payment of the additional prepayment premium stated in the notes. The 2014 Secured Notes are secured by a security interest in the Company's property and assets, which security interest is junior and subordinate to the security interest that secures Brainlab note.

The warrants issued to the investors are exercisable, in full or in part, at any time prior to the fifth anniversary of the issuance date, at an exercise price of $1.75 per share, subject to adjustment from time to time for stock splits or combinations, stock dividends, stock distributions, recapitalizations and other similar transactions. Assumptions used in calculating the fair value of the warrants using the Black-Scholes valuation model were:

Dividend yield	0%
Expected Volatility	47.5% - 47.7%
Risk free Interest rates	1.73% - 1.76%
Expected life (in years)	5.0

Under GAAP, the Company allocated the $3,725,000 in proceeds proportionately between the 2014 Secured Notes and the warrants issued to investors based on their relative fair values, with $413,057 being recorded as equity. The 2014 Secured Notes were recorded at the principal amount less a discount equal to the $413,057 amount recorded as equity. This discount is being amortized to interest expense over the five year term of the notes using the effective interest method.

Non-employee directors of the Company invested a total of $1,100,000, either directly or through a trust. The Company's placement agents earned cash commissions of $145,500 as well as warrants to purchase 72,750 shares of the Company's common stock. The placement agent warrants have the same terms and conditions as the investor warrants. The placement agent cash commissions, the $30,210 fair value of the placement agent warrants, and other offering expenses totaling $76,186 were recorded as deferred financing costs and are classified as other assets. These deferred financing costs are being amortized to interest expense over the term of the 2014 Secured Notes using the effective interest method.

2010 Junior Secured Notes Payable

In November 2010, the Company issued an aggregate of 10,714,286 units and received proceeds of $3,000,000. The units were sold to existing stockholders and other existing security holders of the Company. Each unit consisted of a junior secured note and one share of the Company's common stock. The Company issued 10,714,286 shares of common stock and junior secured notes in the aggregate principal amount of $3,000,000. The notes mature in November 2020 and accrue interest at the rate of 3.5% per year. The notes are secured by a security interest in the assets of the Company, which security interest is junior and subordinate to the security interests that secure the Brainlab Note and the 2014 Secured Notes. All outstanding principal and interest on the junior secured notes will be due and payable in a single payment upon maturity.

Under GAAP, the Company allocated the $3,000,000 in proceeds from the sale of the units between the junior secured notes and the shares of common stock based on their relative fair values, with $2,775,300 being recorded as equity. The junior secured notes were recorded at the principal amount of $3,000,000 less a discount of $2,775,300. This discount is being amortized to interest expense over the 10-year term of the notes using the effective interest method. The fair value of the notes was estimated based on an assumed market interest rate for notes of similar terms and risk. The fair value of the Company's common stock was estimated by management using a market approach, with input from a third-party valuation specialist.

Four officers of the Company purchased an aggregate of 882,726 units in the offering for $247,164. In addition, three non-employee directors of the Company also purchased an aggregate of 567,203 units in the offering for $158,816.

Scheduled Notes Payable Maturities

Scheduled principal payments with respect to notes payable are summarized as follows:

Years ending December 31,	
2015	$ -
2016	4,289,445
2017	-
2018	-
2019	3,725,000
Thereafter	3,000,000
Total scheduled principal payments	11,014,445
Less unamortized discounts at March 31, 2015	(3,226,112)
	$ 7,788,333

7. Stockholders' Equity

Common Stock Warrants Requiring Liability Accounting

The net-cash settlement and down round provisions contained in the warrants issued in a January 2013 financing transaction require derivative liability accounting treatment for the warrants. Likewise, a down round provision contained in the terms of warrants issued by the Company in a July 2012 financing transaction also requires derivative liability accounting treatment for those warrants. The fair value of all such warrants was calculated using the Monte Carlo simulation valuation method.

Assumptions used in calculating the fair value of the warrants at March 31, 2015 are noted below:

Dividend yield	0%
Expected volatility	40.4% - 100.0%
Risk free interest rates	0.56% - 0.70%
Expected remaining term (in years)	2.26 - 2.82

In addition to the assumptions above, the Company also takes into consideration whether it would participate in another round of equity financing and, if so, what that stock price would be for such a financing at that time.

The fair values and the changes in fair values of the warrants accounted for as a derivative liability is reflected below:

Fair value at December 31, 2014	$	2,198,162
Loss on change in fair value		782,802
Fair value at March 31, 2015	$	2,980,964

Stock Incentive Plans

The Company has various share-based compensation plans and share-based compensatory contracts (collectively, the "Plans"). The Plans provide for the granting of share-based awards, such as incentive and non-qualified stock options, to employees, directors, consultants and advisors, and some of the Plans provide for cash-based awards. Awards may be subject to a vesting schedule as set forth in each individual award agreement.

In June 2013, the stockholders of the Company approved the 2013 Incentive Compensation Plan (the "2013 Plan"). A total of 1,250,000 shares of the Company's common stock are reserved for issuance under the 2013 Plan, of which awards as to 1,055,667 shares were outstanding as of March 31, 2015. Thus, awards as to 194,333 shares remained available for grants under the 2013 Plan as of March 31, 2015.

In December 2013, the Company's board of directors approved the 2013 Non-Employee Director Equity Incentive Plan (the "Director Plan"). A total of 570,000 shares of the Company's common stock are reserved for issuance under the Director Plan. The shares reserved for issuance under the Director Plan are intended to be used to cover the stock options granted pursuant to the terms of the Company's Non-Employee Director Compensation Plan. As of March 31, 2015, awards for 295,000 shares had been issued under the Director Plan. Therefore, 275,000 shares remained available for awards under the Director Plan as of March 31, 2015.

Activity under all of the Company's equity compensation plans during the three months ended March 31, 2015 is summarized below:

	Shares		Weighted - Average Exercise Price
Outstanding at December 31, 2014	10,343,309	$	1.36
Granted	502,500		1.01
Forfeited	(35,000)		0.99
Outstanding at March 31, 2015	10,810,809		1.35

The estimated grant date fair values of options granted during the three months ended March 31, 2015 were calculated using the Black-Scholes valuation model, based on the following assumptions:

Dividend yield	0%
Expected Volatility	46.7% to 48.8%
Risk free Interest rates	1.95% to 2.71%
Expected lives (in years)	6.0

The Company records share-based compensation expense on a straight-line basis over the related vesting period. For the periods indicated below, share-based compensation expense related to options was:

Three Months Ended March 31,	
2015	**2014**
$ 367,309	$ 179,746

As of March 31, 2015, there was unrecognized compensation expense of approximately $1,902,000 related to outstanding stock options, which is expected to be recognized over a weighted average period of approximately 2.2 years.

Warrants

Warrants have generally been issued for terms of up to five years. Common stock warrant activity for the three months ended March 31, 2015 was as follows:

	Shares	Weighted - Average Exercise Price
Outstanding at December 31, 2014	20,759,136	$ 0.91
Issued	35,000	1.00
Terminated	(25,444)	8.00
Outstanding at March 31, 2015	20,768,692	0.90

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited condensed financial statements and the notes thereto appearing in Part I, Item 1 of this Quarterly Report. Historical results and trends that might appear in this Quarterly Report should not be interpreted as being indicative of future operations.

Overview

We are a medical device company that develops and commercializes innovative platforms for performing minimally invasive surgical procedures in the brain and heart under direct, intra-procedural MRI guidance. We have two product platforms. Our ClearPoint system, which is in commercial use, is used to perform minimally invasive surgical procedures in the brain. We anticipate that our ClearTrace system, which is still in development, will be used to perform minimally invasive surgical procedures in the heart. Both systems utilize intra-procedural MRI to guide the procedures. Both systems are designed to work in a hospital's existing MRI suite. We believe that our two product platforms, subject to appropriate regulatory clearance and approval, will deliver better patient outcomes, enhance revenue potential for both physicians and hospitals, and reduce costs to the healthcare system.

In 2010, we received regulatory clearance from the FDA to market our ClearPoint system in the United States for general neurological procedures. In 2011, we also obtained CE marking approval for our ClearPoint system, which enables us to sell our ClearPoint system in the European Union. The majority of our product revenues for the three months ended March 31, 2015 and year ended December 31, 2014 relate to sales of our ClearPoint system products. We do not have regulatory clearance or approval to sell our ClearTrace system for commercial use; however, we have had an isolated sale of certain ClearTrace system components to a research site for non-commercial use. We have financed our operations and internal growth primarily through the sale of equity securities, the issuance of convertible and other secured notes, and license arrangements. We have incurred significant losses since our inception in 1998 as we have devoted substantial efforts to research and development. As of March 31, 2015, we had an accumulated deficit of $81.2 million. We may continue to incur operating losses as we commercialize our ClearPoint system products, continue to develop our ClearTrace system, and expand our business.

Factors Which May Influence Future Results of Operations

The following is a description of factors that may influence our future results of operations, and that we believe are important to an understanding of our business and results of operations.

Revenues

In June 2010, we received 510(k) clearance from the FDA to market our ClearPoint system in the United States for general neurological procedures. Future revenues from sales of our ClearPoint system products are difficult to predict and may not be sufficient to offset our continuing research and development expenses and our increasing selling, general and administrative expenses. We cannot sell our ClearTrace system for commercial use until we receive regulatory clearance or approval.

Generating recurring revenues from the sale of disposable products is an important part of our business model for our ClearPoint system. We anticipate that, over time, recurring revenues will constitute an increasing percentage of our total revenues as we leverage each new installation of our ClearPoint system to generate recurring sales of our ClearPoint disposable products. Our product revenues were $977,000 for the three months ended March 31, 2015 and $3.4 million for the year ended December 31, 2014, respectively, and were almost exclusively related to our ClearPoint system.

Our revenue recognition policies are more fully described in Note 2 to the condensed consolidated financial statements appearing in Part I, Item 1 of this Quarterly Report.

Cost of Product Revenues

Cost of product revenues includes the direct costs associated with the assembly and purchase of disposable products and ClearPoint system reusable products which we have sold, and for which we have recognized the revenue in accordance with our revenue recognition policy. Cost of product revenues also includes the allocation of manufacturing overhead costs and depreciation of loaned systems installed under our ClearPoint Placement Program, as well as any provision for obsolete, impaired, or excess inventory. Cost of product revenues also includes similar applicable costs associated with the sale of any ClearTrace system components for non-commercial use.

Research and Development Costs

Our research and development costs consist primarily of costs associated with the conceptualization, design, testing, and prototyping of our ClearPoint system products and our ClearTrace system components. This includes: salaries, travel, and benefits of research and development personnel, including related share-based compensation; materials and laboratory supplies in research and development activities; consultant costs; sponsored research and product development with third parties; and licensing costs related to technology not yet commercialized. We anticipate that, over time, our research and development expenses may increase as we: (1) continue our ClearTrace system product development efforts; (2) continue to develop enhancements to our ClearPoint system; and (3) expand our research to apply our technologies to additional product applications. From our inception through March 31, 2015, we have incurred approximately $44 million in research and development expenses.

Product development timelines, likelihood of success, and total costs can vary widely by product candidate. There are also risks inherent in the regulatory clearance and approval process. At this time, we are unable to estimate with any certainty the costs that we will incur in the continuing development of our ClearTrace system for commercialization.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of: salaries, sales incentive payments, travel and benefits, including related share-based compensation; marketing costs; professional fees, including fees for attorneys and outside accountants; occupancy costs; insurance; medical device excise taxes; and other general and administrative expenses, which include corporate licenses, director fees, hiring costs, taxes, postage, office supplies and meeting costs. Our selling, general and administrative expenses are expected to increase due to costs associated with the commercialization of our ClearPoint system and increased headcount necessary to support our continued growth in operations.

Critical Accounting Policies

There have been no significant changes in our critical accounting policies during the three months ended March 31, 2015 as compared to the critical accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2014, which we filed with the SEC on March 17, 2015.

Results of Operations

Three Months Ended March 31, 2015 Compared to the Three Months Ended March 31, 2014

($s in thousands)	Three Months Ended March 31, 2015	2014	Percentage Change
Product and other service revenues	$ 1,010	$ 724	40%
Development service revenues	-	99	(100)%
Cost of product revenues	386	351	10%
Research and development costs	528	818	(35)%
Selling, general and administrative expenses	2,289	1,801	27%
Restructuring charges	753	-	NM
Gain on sale of intellectual property	-	(4,339)	(100)%
Other income (expense):			
Gain (loss) on change in fair value of derivative liability	(783)	484	(262)%
Other income, net	84	103	(18)%
Interest expense, net	(300)	(149)	101%
Net income (loss)	(3,945)	2,630	(250)%

NM= not meaningful

Product and Other Service Revenues. Product and other service revenues were $1.0 million for the three months ended March 31, 2015, and $724,000 for the same period in 2014, an increase of $286,000, or 40%. Product and other service revenues included disposable product sales for the three months ended March 31, 2015 of $840,000, compared with $565,000 for the same period in 2014, an increase of $275,000, or 49%. The increase reflected customer purchases of disposable products during the three months ended March 31, 2015 for a higher number of performed and anticipated procedures compared with the same period last year. Approximately $137,000 of the product and other service revenues for the three months ended March 31, 2015 related to the sale of ClearPoint system reusable products, compared with $92,000 for same period last year, an increase of $45,000. Product and other service revenues for the three months ended March 31, 2014 also included $56,000 in ClearTrace system components sold to a research site for non-commercial use. Other service revenues, mostly related to ClearPoint system service agreements and installation services, were $33,000 for the three months ended March 31, 2015, and approximately $11,000 for same period last year.

Development Service Revenues. During the three months ended March 31, 2014, we recorded development service revenues of $99,000, and no such revenues were recorded during the three months ended March 31, 2015. The change reflects the completion of a development project we performed on a contract basis. We do not expect development service revenues to be a long-term ongoing source of revenues.

Cost of Product Revenues. Cost of product revenues was $386,000 for the three months ended March 31, 2015, representing gross margin on product revenues of 60%, compared to $351,000 for the same period last year, representing gross margin of 51%. This improvement in gross margin resulted from leverage from higher production volumes and favorable mix.

Research and Development Costs. Research and development costs were $528,000 for the three months ended March 31, 2015, compared to $818,000 for the same period last year, a decrease of $290,000, or 35%. Approximately $181,000 of the decrease related to a reduction in spending on our ClearTrace development program. Reductions in sponsored research of $67,000 and in consulting services of $31,000 also contributed to the overall decrease.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $2.3 million for the three months ended March 31, 2015, compared with $1.8 million for the same period last year, an increase of $488,000, or 27%. The overall increase related to an increase in share-based compensation of $198,000, an increase in salary and related costs of approximately $100,000 associated with having a full-time executive chairman in addition to a chief executive officer, an increase in hiring costs of $98,000, and increases in sales and marketing expenditures of approximately $67,000. The full-time executive chairman position was eliminated in April 2015 in connection with the plan discussed below to close our Memphis, Tennessee office.

Restructuring Charges. In March 2015, we announced that we will consolidate all major business functions into our Irvine, California headquarters. In connection with this consolidation, we will close our Memphis, Tennessee office in May 2015. We will not retain any of our Memphis-based employees. A total of seven employees have been or will be impacted by the consolidation, including three of our executives. In connection with this consolidation, we recorded restructuring charges of $753,400. Approximately $718,000 of the restructuring charge relates to costs associated with severance and other compensation for the impacted employees. Most of the amounts recorded as restructuring charges are expected to be paid during the quarter ending June 30, 2015.

Gain on Sale of Intellectual Property. During the three months ended March 31, 2014, we recorded a gain of $4.3 million related to the sale of certain intellectual property to Boston Scientific. The purchase price was satisfied through the cancellation of related party convertible notes payable we previously issued to Boston Scientific in the aggregate principal amount of $4.3 million. We recorded a gain equal to the purchase price, as the assets sold had not been previously recorded on our balance sheet.

Other Income (Expense). During the three months ended March 31, 2015, we recorded a loss of $783,000, and during the three months ended March 31, 2014, we recorded a gain of $484,000, in each case resulting from changes in the fair value of our derivative liabilities associated with certain warrants we issued in equity private placement transactions.

Net other income was $84,000 and $103,000 for the three months ended March 31, 2015 and 2014, respectively. Most of the other income for the three months ended March 31, 2015 related to grants received to fund research, and the majority of other income for the three months ended March 31, 2014 related to negotiated reductions in amounts payable to service providers.

Net interest expense for the three months ended March 31, 2015 was $300,000, compared with $149,000 for the same period in 2014. The increase relates mostly to interest on notes payable we issued in our March 2014 private debt private placement, as well as the amortization of the related debt discount and deferred financing costs associated with that transaction.

Liquidity and Capital Resources

Our cumulative net loss from inception through March 31, 2015 was $81.2 million. We expect such losses to continue through at least the year ending December 31, 2015 as we continue to commercialize our ClearPoint system and pursue research and development activities related to our ClearTrace system. Net cash used in operating activities was $2.8 million for the three months ended March 31, 2015 and $7.3 million for the year ended December 31, 2014. Since inception, we have financed our activities principally from the sale of equity securities, the issuance of convertible and other secured notes, and license arrangements.

Our primary financing activities during the three months ended March 31, 2015 and the year ended December 31, 2014 were: (i) a December 2014 equity private placement, which resulted in net proceeds of $9.4 million; and (ii) a March 2014 debt private placement, which resulted in net proceeds of $3.5 million. In addition, in March 2014, we completed a transaction with Boston Scientific that resulted in the cancellation of $4.3 million in related party convertible notes payable that were scheduled to mature in 2014.

While we expect to continue to use cash in operations, we believe our cash and cash equivalents at March 31, 2015 of $6.4 million, combined with cash expected to be generated from product sales, will be sufficient to meet our anticipated cash requirements through at least March 31, 2016. During the remainder of 2015, we expect to increase revenues from sales of ClearPoint system products as a result of greater utilization at existing installed sites and an increase in the number of installed sites. Certain planned expenditures are discretionary and could be deferred if we are required to do so to fund critical operations.

To the extent our available cash and cash equivalents are insufficient to satisfy our long-term operating requirements, we will need to seek additional sources of funds from the sale of equity or debt securities or through a credit facility, or we will need to modify our current business plan. There can be no assurances that we will be able to obtain additional financing on commercially reasonable terms, if at all. The sale of additional equity or convertible debt securities would likely result in dilution to our current stockholders.

Cash Flows

Cash activity for the three months ended March 31, 2015 and 2014 is summarized as follows:

	Three Months Ended March 31,	
($s in thousands)	**2015**	**2014**
Cash used in operating activities	$ (2,799)	$ (1,359)
Cash used in investing activities	(7)	(2)
Cash provided by financing activities	-	3,646
Net increase (decrease) in cash and cash equivalents	$ (2,806)	$ 2,285

Net Cash Flows from Operating Activities. We used $2.8 million and $1.4 million of cash for operating activities during the three months ended March 31, 2015 and 2014, respectively. Net cash used in operating activities during the three months ended March 31, 2015 primarily reflected our $2.9 million loss from operations, plus the $137,000 increase in accounts receivable, plus the $110,000 increase in inventory, less $378,000 in share-based compensation. Net cash used in operating activities during the three months ended March 31, 2014 primarily reflected our $2.2 million income from operations, plus $370,000 for expenses paid through the issuance of common stock, plus a $318,000 reduction in accounts receivable, plus $180,000 in share-based compensation, less the gain on the sale of intellectual property of $4.3 million and a $148,000 increase in inventory.

Net Cash Flows from Investing Activities. Net cash flows used in investing activities for the three months ended March 31, 2015 and 2014 were $7,000 and $2,000, respectively.

Net Cash Flows from Financing Activities. Net cash provided by financing activities for the three months ended March 31, 2014 of $3.6 million related primarily to proceeds from our March 2014 debt private placement.

Operating Capital and Capital Expenditure Requirements

To date, we have not achieved profitability. We could continue to incur net losses as we continue our efforts to expand the commercialization of our ClearPoint system products, continue to develop our ClearTrace system, and pursue additional applications for our technology platforms. Our cash balances are typically held in a variety of interest bearing instruments, including interest bearing demand accounts and certificates of deposit. Cash in excess of immediate requirements is invested primarily with a view to liquidity and capital preservation.

Because of the numerous risks and uncertainties associated with the development and commercialization of medical devices, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to successfully commercialize our ClearPoint products and complete the development of our ClearTrace system. Our future capital requirements will depend on many factors, including, but not limited to, the following:

- the timing of broader market acceptance and adoption of our ClearPoint system products;
- the scope, rate of progress and cost of our ongoing product development activities relating to our ClearPoint system;
- the cost and timing of expanding our sales, clinical support, marketing and distribution capabilities, and other corporate infrastructure;
- the cost and timing of establishing inventories at levels sufficient to support our sales;
- the effect of competing technological and market developments;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- the scope, rate of progress and cost of our research and development activities relating to our ClearTrace system;
- the cost and timing of any clinical trials;
- the cost and timing of regulatory filings, clearances and approvals; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Off Balance Sheet Arrangements

We are not party to any off balance sheet arrangements that have, or are reasonably likely to have, a material current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Interest Rate Risk

Our exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, because all of our investments are in short-term bank deposits and institutional money market funds. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure.

Foreign Currency Risk

To date, we have recorded no product sales in currencies other than U.S. dollars. We have only limited business transactions in foreign currencies. We do not currently engage in hedging or similar transactions to reduce our foreign currency risks, which at present, are not material. We believe we have no material exposure to risk from changes in foreign currency exchange rates at this time. We will continue to monitor and evaluate our internal processes relating to foreign currency exchange, including the potential use of hedging strategies.

ITEM 4. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

We have established disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or the Exchange Act. Our disclosure controls and procedures are designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others within our organization. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of March 31, 2015 to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2015.

Changes in Internal Control Over Financial Reporting

During the quarter ended March 31, 2015, there were no changes in our internal control over financial reporting that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

None.

ITEM 1A. RISK FACTORS.

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and the other information in this Quarterly Report before deciding to invest in our common stock. If any of the following risks actually occurs, our business, results of operations and financial condition could be materially adversely affected, the trading price of our common stock could decline significantly, and you might lose all or part of your investment. Additional risks and uncertainties that we are unaware of or that we believe are not material at this time could also materially adversely affect our business, results of operations or financial condition. In any case, the value of our securities could decline, and you could lose all or part of your investment.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from the risks described under Part I, Item 1A "Risk Factors" included in our Annual Report on Form 10-K, which we filed with the SEC on March 17, 2015.

Risks Related to Our Business

We have incurred losses since our inception and we may continue to incur losses. If we fail to generate significant revenue from sales of our products, we may never achieve or sustain profitability.*

As of March 31, 2015, we had an accumulated deficit of approximately $81.2 million. The accumulated deficit has resulted principally from costs incurred in connection with our sales and marketing activities, research and development efforts and manufacturing activities, and other general and administrative expenses associated with our operations. We have incurred losses in each year since our inception in 1998, and we may continue to incur losses as we continue to invest capital in the sales and marketing of our ClearPoint products, development of our ClearTrace system and growth of our business generally.

As a result of the numerous risks and uncertainties associated with developing medical devices, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Our profitability will depend on revenues from the sale of our products. We cannot provide any assurance that we will ever achieve profitability and, even if we achieve profitability, that we will be able to sustain or increase profitability on a quarterly or annual basis. Further, because of our relatively limited commercialization history, we have limited insight into the trends that may emerge and affect our business. We may make errors in predicting and reacting to relevant business trends, which could harm our business and financial condition. Any failure to achieve and maintain profitability would continue to have an adverse effect on our stockholders' deficit and working capital and could result in a decline in our stock price or cause us to cease operations.

Our ClearPoint system may not achieve broad market acceptance or be commercially successful.

We expect that sales of our ClearPoint system products will account for the majority of our revenues for at least the next few years. Our ClearPoint system may not gain broad market acceptance unless we continue to convince physicians, hospitals and patients of its benefits. Moreover, even if physicians and hospitals understand the benefits of our ClearPoint system, they still may elect not to use our ClearPoint system for a variety of reasons, such as:

- the shift in location of the procedure from the operating room to the MRI suite;
- demand for the MRI suite within the hospital, which may result in limited or no MRI scanner availability for procedures in which our ClearPoint system would be used;
- the familiarity of the physician with other devices and surgical approaches;

- the physician's perception that there are insufficient benefits of our ClearPoint system relative to those other devices and surgical approaches;

- budgetary constraints with respect to the purchase of our ClearPoint system hardware and software;

- the price of our ClearPoint system disposable products, which may be higher than devices used with other surgical approaches; and

- the physician's perception that there is a lack of clinical data on the use of our ClearPoint system.

If physicians and hospitals do not perceive our ClearPoint system as an attractive alternative to other products and procedures, we will not achieve significant market penetration or be able to generate significant revenues. To the extent that our ClearPoint system is not commercially successful or is withdrawn from the market for any reason, our revenues will be adversely impacted, and our business, operating results and financial condition will be harmed.

We have relatively limited experience marketing and selling our ClearPoint system, and if we are unable to expand, manage and maintain our marketing and sales capabilities, we may be unable to generate significant growth in our product revenues.

We started selling our ClearPoint system on a limited basis in August 2010, and we did not begin to meaningfully expand our sales and clinical support capabilities until 2013. As a result, we have relatively limited experience marketing and selling our ClearPoint system. Our operating results are directly dependent upon the marketing and sales efforts of our employees. If our team fails to adequately promote, market and sell our products, our sales will suffer.

We expect to continue building our team to market, sell and support our ClearPoint system products in the United States. That effort, though, could take longer than we anticipate, in which case our commercialization efforts would be negatively impacted. Our ability to achieve significant revenue growth will depend, in large part, on our success in recruiting, training, motivating and retaining a sufficient number of qualified personnel. New hires require significant training and, in most cases, take significant time before they achieve full productivity. Our recent hires and planned hires may not become as productive as we expect, and we may be unable to hire or retain sufficient numbers of qualified individuals, in which case our business would be harmed.

We have entered into a co-development and distribution agreement with Brainlab pursuant to which, among other things, we appointed Brainlab as a distributor of our ClearPoint system products in the United States and Europe. However, there is no assurance that Brainlab will be successful in marketing and selling our ClearPoint system products. In addition, under our agreement, Brainlab is not subject to any minimum sales or other performance requirements. Therefore, we may not realize the desired benefits from our agreement with Brainlab. To date, we have not generated significant revenues from our distribution relationship with Brainlab.

The existence of adequate coverage and reimbursement is important for sales of our products. If hospitals and physicians believe coverage and reimbursement from third-party payors for procedures utilizing our ClearPoint system products are inadequate, adoption of our products will be adversely affected and our revenues and prospects for profitability will suffer.

Our ClearPoint system products are purchased primarily by hospitals, which bill various third-party payors, including governmental healthcare programs, such as Medicare, and private insurance plans, for procedures in which our ClearPoint system is used. Reimbursement is a significant factor considered by hospitals in determining whether to acquire and utilize medical devices such as our ClearPoint system products. Therefore, our ability to successfully commercialize our ClearPoint system depends significantly on the adequacy of coverage and reimbursement from these third-party payors. In the United States, coverage and reimbursement varies among payors.

Medicare pays hospitals a prospectively determined amount for inpatient operating costs. The prospective payment for a patient's stay is determined by the patient's condition and other patient data and procedures performed during the inpatient stay using a classification system known as Medicare Severity Diagnosis Related Groups, or MS-DRGs. Medicare pays a fixed amount to the hospital based on the MS-DRG into which the patient's stay is assigned, regardless of the actual cost to the hospital of furnishing the procedures, items and services provided. Therefore, a hospital must absorb the cost of our products as part of the payment it receives for the procedure in which the products are used. In addition, physicians that perform procedures in hospitals are paid a set amount by Medicare for performing such services under the Medicare physician fee schedule. Medicare payment rates for both systems are established annually.

For commercial payors, reimbursement to hospitals and physicians generally is dependent upon the specific contract terms between the provider and the payor. Many commercial payors look to Medicare policies as a guideline in setting their coverage policies and payment amounts. However, the current coverage policies of these commercial payors may differ from the Medicare program, and the payment rates they make may be higher, lower or the same as the Medicare program. If Medicare reimbursement payments for hospitals and physicians are decreased or limited, coverage and reimbursement determinations by many commercial payors may be affected.

Because hospitals are reimbursed for the procedures in which our ClearPoint system products are used and our products are not separately reimbursed, the additional cost associated with the use of our products could impact hospital profit margins. Some hospitals could believe third-party reimbursement levels are not adequate to cover the cost of our ClearPoint system products. Furthermore, some physicians could believe third-party reimbursement levels are not adequate to compensate them for performing the procedures in which our products are used. Failure by hospitals and physicians to receive an amount that they consider to be adequate reimbursement for procedures in which our products are used will deter them from purchasing or using our products and will limit our sales growth.

Federal legislation and other payment and policy changes may have a material adverse effect on our business.*

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, together, the Affordable Care Act, includes a number of provisions that should result in increased coordination between hospitals and physicians and alignment of financial incentives between hospitals and physicians to control hospital costs. Most significantly, the Affordable Care Act provides for a Medicare shared savings program whereby Medicare will share certain savings realized in the delivery of services to Medicare beneficiaries with accountable care organizations, which may be organized through various different legal structures between hospitals and physicians. Other payment reform provisions in the Affordable Care Act include pay-for-performance initiatives, payment bundling and the establishment of an independent payment advisory board. We expect that the overall result of such payment reform efforts and the increased coordination among hospitals and physicians will be voluntary reductions in the array of choices currently available to physicians with respect to diagnostic services, medical supplies and equipment. Such a reduction in physician choices may also result in hospitals reducing the overall number of vendors from which they purchase supplies, equipment and products. The Affordable Care Act could limit the acceptance and availability of our products, which would have an adverse effect on our financial results and business.

Congress recently passed and, on April 16, 2015, President Obama signed into law, the Medicare Access and CHIP Reauthorization Act, or the Medicare Access Act, which removed the sustainable growth rate or SGR, methodology applicable to fees for physician services. The Medicare Access Act provides for a transition from the fee-for-service payment system to a more value-based system. In this process, reimbursements from the Medicare program may be reduced. As noted above, failure by hospitals and physicians to receive an amount that they consider to be adequate reimbursement for procedures in which our products are used will deter them from purchasing or using our products and will limit our sales growth.

Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives will be implemented at the federal or state level, or the effect any recently promulgated or future legislation or regulation will have on us. However, an expansion in government's role in the United States healthcare industry may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business, possibly materially.

If there are changes in coverage or reimbursement from third-party payors, our revenues and prospects for profitability could suffer.*

In the United States, we believe that existing billing codes apply to procedures in which physicians use our ClearPoint system. Reimbursement levels for procedures using our ClearPoint system or any product that we may market in the future could be decreased or eliminated as a result of recent or future legislation, regulation or reimbursement policies of third-party payors. Any such decrease or elimination would adversely affect the demand for our products and our ability to sell our products on a profitable basis. Furthermore, if procedures using our ClearPoint system gain market acceptance and the number of these procedures increases, the Centers for Medicare and Medicaid Services, or CMS, the federal agency that administers the Medicare Program, as well as other public or private payors, may establish new billing codes for those procedures that provide for a lower reimbursement amount than traditional approaches, which would adversely affect our financial results and business.

Among other things, the Affordable Care Act will ultimately increase the overall pool of persons with access to health insurance in the United States, at least in those states that expand their Medicaid programs. Although such an increase in covered lives should ultimately benefit hospitals, the Affordable Care Act also includes a number of cuts in Medicare reimbursement to hospitals that may take effect prior to the time hospitals realize the financial benefit of a larger pool of insured persons. Those cuts in Medicare reimbursement, together with any additional cuts in Medicare reimbursement stemming from the Medicare Access Act, could adversely impact the operations and finances of hospitals, reducing their ability to purchase medical devices, such as our products.

If third-party payors deny coverage or reimbursement for procedures using our ClearPoint system, our revenues and prospects for profitability will suffer.

Notwithstanding the ClearPoint system's regulatory clearance in the United States, third-party payors may deny coverage or reimbursement if the payor determines that the use of our ClearPoint system is unnecessary, inappropriate, experimental or not cost-effective, or that the ClearPoint system is used for a non-cleared indication. In addition, no uniform policy of coverage and reimbursement for medical technology exists among third-party payors. Therefore, coverage and reimbursement for medical technology can differ significantly from payor to payor. Any denial of coverage or reimbursement for procedures using our ClearPoint system could have an adverse effect on our business, financial results and prospects for profitability.

We currently have significant customer concentration, so economic difficulties or changes in the purchasing policies or patterns of our key customers could have a significant impact on our business and operating results.

A small number of our hospital customers account for a substantial portion of our revenues from sales of ClearPoint disposable products. For example, our largest customer, the University of California, San Francisco Medical Center, or UCSF, accounted for 14% of our ClearPoint disposable product revenues for the year ended December 31, 2014. Likewise, Emory University Hospital, or Emory, accounted for 12% of our ClearPoint disposable product revenues for the same period. Sales to almost all of our customers, including UCSF and Emory, are not based on long-term, committed volume purchase contracts, and we may not continue to generate a similar level of revenues from UCSF, Emory or any other customer. Because of our current customer concentration, our revenues could fluctuate, possibly significantly, due to a reduction or delay in orders from any of our significant customers, which could harm our business and results of operations.

We have limited internal manufacturing resources, and if we are unable to provide an adequate supply of our ClearPoint disposable products, our growth could be limited and our business could be harmed.

Final assembly of many of our ClearPoint disposable components occurs at our Irvine, California facility. If our facility experiences a disruption, we would have no other means of assembling those components until we are able to restore the manufacturing capability at our current facility or develop the same capability at an alternative facility.

In connection with the continued commercialization of our ClearPoint system, we expect that we will need to increase, or "scale up," the production process of our disposable components over the current level of production. While we have taken steps in anticipation of growth, manufacturers often encounter difficulties in scaling up production, such as problems involving yields, quality control and assurance, and shortages of qualified personnel. If the scaled-up production process is not efficient or produces a product that does not meet quality and other standards, we may be unable to meet market demand and our revenues, business and financial prospects would be adversely affected.

Our reliance on single-source suppliers could harm our ability to meet demand for our ClearPoint system in a timely manner or within budget.

Many of the components and component assemblies of our ClearPoint system are provided to us by single-source suppliers. We generally purchase components and component assemblies through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of inventory. While alternative suppliers exist and have been identified for substantially all components, the disruption or termination of the supply of components and component assemblies could cause a significant increase in the cost of these components, which could affect our operating results. Our dependence on a limited number of third-party suppliers and the challenges we may face in obtaining adequate supplies involve several risks, including limited control over pricing, availability, quality and delivery schedules. A disruption or termination in the supply of components could also result in our inability to meet demand for our ClearPoint system, which could harm our ability to generate revenues, lead to customer dissatisfaction and damage our reputation. Furthermore, if we are required to change the supplier of a key component or component assembly of our ClearPoint system, we may be required to verify that the new supplier maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new supplier could also adversely affect our ability to meet demand for our ClearPoint system.

Our ClearTrace system remains under development. We cannot be certain that we will be able to successfully complete development of, and obtain regulatory clearances or approvals for, our ClearTrace system in a timely fashion, or at all.*

Our ClearTrace system is still under development, and, to date, we have conducted only animal studies and other preclinical work with respect to that product candidate. Our ClearTrace system will require substantial additional development and testing, and at present we are focusing most of our efforts and resources on the commercialization of our ClearPoint system. There can be no assurance that our development efforts will be successfully completed or that the ClearTrace system will have the capabilities we expect. We may encounter significant difficulties and costs during the course of our development efforts and we may encounter significant delays. Even if we successfully complete development of our ClearTrace system, there can be no assurance that we will obtain the regulatory clearances or approvals to market and commercialize it. If we are unable to obtain regulatory clearances or approvals for our ClearTrace system, or otherwise experience delays in obtaining such regulatory clearances or approvals, the commercialization of the ClearTrace system will be delayed or prevented, which will adversely affect our ability to generate revenues. Even if cleared or approved, the ClearTrace system may not be cleared or approved for the indications that are necessary or desirable for successful commercialization. Delays in developing our ClearTrace system or obtaining regulatory clearances or approvals may also result in the loss of potential competitive advantages that might otherwise be attained by bringing products to market earlier than our competitors. Any of these contingencies could adversely affect our business.

In the United States, unless an exemption applies, we cannot market a new medical device without first receiving either premarket notification, or 510(k) clearance, or approval of a premarket approval application, or PMA, from the Food and Drug Administration, or FDA. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology, safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The 510(k) clearance process generally takes three to twelve months from submission, but can take significantly longer. The process of obtaining PMA approval is much more costly and uncertain than the 510(k) clearance process. The PMA approval process can be lengthy and expensive and requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on data obtained in clinical trials. The PMA process generally takes one to three years, or even longer, from the time the PMA application is submitted to the FDA until an approval is obtained.

Outside the United States, the regulatory approval process varies among jurisdictions and can involve substantial additional testing. Clearance or approval by the FDA does not ensure clearance or approval by regulatory authorities in other jurisdictions, and clearance or approval by one foreign regulatory authority does not ensure clearance or approval by regulatory authorities in other foreign jurisdictions. The foreign regulatory approval process may include all of the risks associated with obtaining FDA clearance or approval in addition to other risks. In addition, the time required to obtain foreign clearance or approval may differ from that required to obtain FDA clearance or approval and we may not obtain foreign regulatory clearances or approvals on a timely basis, if at all.

We anticipate that the initial market for our ClearTrace system will be the European Union and, at the appropriate time, we expect to seek CE marking approval for the ClearTrace system. The ClearTrace system consists of several components, one or more of which may require the submission of a PMA in the United States.

Our business will be subject to economic, political, regulatory and other risks associated with international operations.

At present, our commercialization activities for our ClearPoint system are focused in the United States. However, we do have CE marking approval to market our ClearPoint system in the European Union. In addition, we ultimately intend to market our ClearPoint system in other foreign jurisdictions as well. There are a number of risks associated with conducting business internationally, including:

- differences in treatment protocols and methods across the markets in which we expect to market our ClearPoint system;
- requirements necessary to obtain product reimbursement;
- product reimbursement or price controls imposed by foreign governments;
- difficulties in compliance with foreign laws and regulations;
- changes in foreign regulations and customs;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or foreign governments; and
- negative consequences from changes in tax laws.

Any of these risks could adversely affect our financial results and our ability to operate outside the United States, which could harm our business.

To the extent we seek a new indication for use of, or new claims for, our ClearPoint system, the FDA may not grant 510(k) clearance or PMA approval of such new use or claims, which may affect our ability to grow our business.

We received 510(k) clearance to market our ClearPoint system for use in general neurological interventional procedures. We could seek to obtain additional, more specific indications for use of our ClearPoint system beyond the general neurological intervention claim. To the extent we seek expanded claims for our ClearPoint system, such claims could, depending on their nature, require 510(k) clearance or FDA approval of a PMA. Moreover, some specific ClearPoint system claims could require clinical trials to support regulatory clearance or approval. In the event we seek a new indication for use of, or new claims for, the ClearPoint system that we believe are necessary or desirable for successful commercialization, the FDA may refuse our requests for 510(k) clearance or PMA approval. Likewise, to the extent clinical trials are necessary, we may not successfully complete or have the funds to initiate such clinical trials.

Clinical trials necessary to support 510(k) clearance or PMA approval for our ClearTrace system or any new indications for use for our ClearPoint system would be expensive and could require the enrollment of large numbers of suitable patients, who could be difficult to identify and recruit. Delays or failures in any necessary clinical trials would prevent us from commercializing any modified product or new product candidate and could adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to support 510(k) clearance or PMA approval for our ClearTrace system or any other product candidates that we may develop, or additional safety and efficacy data that the FDA may require for 510(k) clearance or PMA approval for any new specific indications of our ClearPoint system that we may seek, would be time consuming and expensive with an uncertain outcome. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product candidate we advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical trials could require the enrollment of large numbers of patients, and suitable patients could be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators and support staff, the proximity to clinical sites of patients that are able to comply with the eligibility and exclusion criteria for participation in the clinical trial, and patient compliance. For example, patients could be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our product candidates or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to our product candidates.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy will be required and we may not adequately develop such protocols to support clearance or approval. Further, the FDA could require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial could cause an increase in costs and delays in the approval and attempted commercialization of our product candidates or result in the failure of the clinical trial. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

The results of our clinical trials may not support our product candidate claims or any additional claims we may seek for our products and may result in the discovery of adverse side effects.

Even if any clinical trial that we need to undertake is completed as planned, we cannot be certain that its results will support our product candidate claims or any new indications that we may seek for our products or that the FDA or foreign authorities will agree with our conclusions regarding the results of those trials. The clinical trial process may fail to demonstrate that our products or a product candidate is safe and effective for the proposed indicated use, which could cause us to stop seeking additional clearances or approvals for our ClearPoint system, abandon our ClearTrace system or delay development of other product candidates. Any delay or termination of our clinical trials will delay the filing of our regulatory submissions and, ultimately, our ability to commercialize a product candidate. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

The markets for medical devices are highly competitive, and we may not be able to compete effectively against the larger, well-established companies in our markets or emerging and small innovative companies that may seek to obtain or increase their share of the market.

We will face competition from products and techniques already in existence in the marketplace. The markets for the ClearPoint system and the ClearTrace system are intensely competitive, and many of our competitors are much larger and have substantially more financial and human resources than we do. Many have long histories and strong reputations within the industry, and a relatively small number of companies dominate these markets. Examples of such large, well-known companies include Medtronic plc, St. Jude Medical Inc. and Biosense Webster Inc., a division of Johnson & Johnson.

These companies enjoy significant competitive advantages over us, including:

- broad product offerings, which address the needs of physicians and hospitals in a wide range of procedures;
- greater experience in, and resources for, launching, marketing, distributing and selling products, including strong sales forces and established distribution networks;
- existing relationships with physicians and hospitals;

- more extensive intellectual property portfolios and resources for patent protection;
- greater financial and other resources for product research and development;
- greater experience in obtaining and maintaining FDA and other regulatory clearances or approvals for products and product enhancements;
- established manufacturing operations and contract manufacturing relationships; and
- significantly greater name recognition and more recognizable trademarks.

We may not succeed in overcoming the competitive advantages of these large and established companies. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies may introduce products that compete effectively against our products in terms of performance, price or both.

We could become subject to product liability claims that could be expensive, divert management's attention and harm our business.

Our business exposes us to potential product liability risks that are inherent in the manufacturing, marketing and sale of medical devices. We may be held liable if our products cause injury, or death or are found otherwise unsuitable or defective during usage. Our ClearPoint system and our ClearTrace system each incorporates mechanical and electrical parts, complex computer software and other sophisticated components, any of which can have defective or inferior parts or contain defects, errors or failures. Complex computer software is particularly vulnerable to errors and failures, especially when first introduced.

Because our ClearPoint system and our ClearTrace system are each designed to be used to perform complex surgical procedures, defects could result in a number of complications, some of which could be serious and could harm or kill patients. The adverse publicity resulting from any of these events could cause physicians or hospitals to review and potentially terminate their relationships with us.

The medical device industry has historically been subject to extensive litigation over product liability claims. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. Although we maintain product liability insurance that we believe is appropriate, this insurance coverage is subject to deductibles and coverage limitations, and may not be adequate to protect us against any future product liability claims. Additionally, we may be unable to maintain our existing product liability insurance in the future at satisfactory rates or in adequate amounts. A product liability claim, regardless of its merit or eventual outcome, could result in:

- decreased demand for our products;
- injury to our reputation;
- diversion of management's attention;
- significant costs of related litigation;
- payment of substantial monetary awards by us;
- product recalls or market withdrawals;
- a change in the design, manufacturing process or the indications for which our marketed products may be used;
- loss of revenue; and
- an inability to commercialize product candidates.

Risks Related to Funding

In the event we need additional funding for our business, we may not be able to raise capital when needed or on terms that are acceptable to us, which could force us to delay, reduce or eliminate our commercialization efforts or our product development programs.

We have not yet achieved profitability. Accordingly, we have financed our activities principally from sales of equity securities, borrowings and license arrangements. Most recently, in December 2014, we raised $10.2 million, before commissions and offering expenses, from the sale of shares of our common stock and warrants to purchase shares of our common stock in a private placement transaction. Because of the various risks and uncertainties associated with the commercialization of medical devices, there can be no assurance that our cash resources will cover all of our costs until we achieve profitability. Therefore, we could need additional funding. Additional funds, if needed, may not be available on a timely basis or on terms that are acceptable to us, or at all, in which event we could take actions that negatively impact the commercialization of our ClearPoint system, or terminate or delay the development of the ClearTrace system.

The funding requirements for our business will depend on many factors, including:

- the timing of broader market acceptance and adoption of our ClearPoint system products;
- the scope, rate of progress and cost of our ongoing product development activities relating to our ClearPoint system;
- the cost and timing of expanding our sales, clinical support, marketing and distribution capabilities and other corporate infrastructure;
- the cost and timing of establishing inventories at levels sufficient to support our sales;
- the scope, rate of progress and cost of our research and development activities relating to our ClearTrace system;
- the effect of competing technological and market developments;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- the cost and timing of any clinical trials;
- the cost and timing of regulatory filings, clearances and approvals; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Raising additional funds may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we secure additional funds through arrangements with a strategic or other collaboration partner, we may have to relinquish valuable rights to our technologies, products or product candidates or grant licenses on terms that are not favorable to us. Any of these events could adversely affect our ability to achieve our commercialization and/or product development goals and have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to our Intellectual Property

If we, or the third parties from whom we license intellectual property, are unable to secure and maintain patent or other intellectual property protection for the intellectual property covering our marketed products or our product candidates, our ability to compete will be harmed.

Our commercial success depends, in part, on obtaining patent and other intellectual property protection for the technologies contained in our products and product candidates. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. Our patent position is uncertain and complex, in part, because of our dependence on intellectual property that we license from others. If we, or the third parties from whom we license intellectual property, fail to obtain adequate patent or other intellectual property protection for intellectual property covering our products or product candidates, or if any protection is reduced or eliminated, others could use the intellectual property covering our products or product candidates, resulting in harm to our competitive business position. In addition, patent and other intellectual property protection may not provide us with a competitive advantage against competitors that devise ways of making competitive products without infringing any patents that we own or have rights to.

United States patents and patent applications may be subject to interference proceedings and United States patents may be subject to reissue and reexamination proceedings in the United States Patent and Trademark Office. Foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices. Any of these proceedings could result in either loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of the patent or patent application. Changes in either patent laws or in interpretations of patent laws may also diminish the value of our intellectual property or narrow the scope of our protection. Interference, reexamination and opposition proceedings may be costly and time consuming, and we, or the third parties from whom we license intellectual property, may be unsuccessful in such proceedings. Thus, any patents that we own or license may provide limited or no protection against competitors. In addition, our pending patent applications and those we may file in the future may not result in patents being issued or may have claims that do not cover our products or product candidates. Even if any of our pending or future patent applications are issued, they may not provide us with adequate protection or any competitive advantages. Our ability to develop additional patentable technology is also uncertain.

Non-payment or delay in payment of patent fees or annuities, whether intentional or unintentional, may also result in the loss of patents or patent rights important to our business. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States, particularly in the field of medical devices and procedures.

Others may assert that our products infringe their intellectual property rights, which may cause us to engage in costly disputes and, if we are not successful in defending ourselves, could also cause us to pay substantial damages and prohibit us from selling our marketed products.

There may be United States and foreign patents issued to third parties that relate to our business, including MRI-guided intervention systems and the components and methods and processes related to these systems. Some of these patents may be broad enough to cover one or more aspects of our present technologies and/or may cover aspects of our future technologies. We do not know whether any of these patents, if they exist and if asserted, would be held valid, enforceable and infringed. We cannot provide any assurance that a court or administrative body would agree with any arguments or defenses we may have concerning invalidity, unenforceability or non-infringement of any third-party patent. The medical device industry has been characterized by extensive litigation and administrative proceedings regarding patents and other intellectual property rights, and companies have employed such actions to gain a competitive advantage. If third parties assert infringement or other intellectual property claims against us, our management personnel will experience a significant diversion of time and effort and we will incur large expenses defending our company. If third parties in any patent action are successful, our patent portfolio may be damaged, we may have to pay substantial damages and we may be required to stop selling our products or obtain a license which, if available at all, may require us to pay substantial royalties. We cannot be certain that we will have the financial resources or the substantive arguments to defend our products from infringement or our patents from claims of invalidity or unenforceability, or to defend our products against allegations of infringement of third-party patents. In addition, any public announcements related to litigation or administrative proceedings initiated by us, or initiated or threatened against us, could negatively impact our business.

If we lose access to third-party software that is integrated into our ClearPoint system software, our costs could increase and new installations of our ClearPoint system could be delayed, potentially hurting our competitive position.

We have received a non-exclusive, non-transferable, worldwide license from a third party to certain software, in source code form, that is integrated into the software component of our ClearPoint system. In return, we agreed to pay the third party a one-time license fee, as well as a license fee for each copy of the ClearPoint system software that we distribute, subject to certain minimum license purchase commitments which we already have satisfied. The source code license is perpetual, except in the event we breach our agreement with the third party, in which case the third party may terminate the license for cause. A loss of the license could impede our ability to install our ClearPoint system at new sites until equivalent software could be identified, licensed or developed, and integrated into the software component of our ClearPoint system. These delays, if they occur, would harm our business, operating results and financial condition.

If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, our ability to successfully commercialize our marketed products and product candidates will be harmed, and we may not be able to operate our business profitably.

Our success and ability to compete is dependent, in part, upon our ability to maintain the proprietary nature of our technologies. We rely on a combination of patent, copyright, trademark and trade secret law and nondisclosure agreements to protect our intellectual property. However, such methods may not be adequate to protect us or permit us to gain or maintain a competitive advantage. Our patent applications may not issue as patents in a form that will be advantageous to us, or at all. Our issued patents, and those that may issue in the future, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products.

To protect our proprietary rights, we may in the future need to assert claims of infringement against third parties to protect our intellectual property. There can be no assurance that we will be successful on the merits in any enforcement effort. In addition, we may not have sufficient resources to litigate, enforce or defend our intellectual property rights. Litigation to enforce our intellectual property rights in patents, copyrights or trademarks is highly unpredictable, expensive and time consuming and would divert human and monetary resources away from managing our business, all of which could have a material adverse effect on our financial condition and results of operations even if we were to prevail in such litigation. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not infringed, or that they are invalid or unenforceable, and could award attorney fees.

Despite our efforts to safeguard our unpatented and unregistered intellectual property rights, we may not be successful in doing so or the steps taken by us in this regard may not be adequate to detect or deter misappropriation of our technologies or to prevent an unauthorized third party from copying or otherwise obtaining and using our products, technologies or other information that we regard as proprietary. Additionally, third parties may be able to design around our patents. Furthermore, the laws of foreign countries may not protect our proprietary rights to the same extent as the laws of the United States. Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our technologies, which could substantially impair our ability to compete.

We have entered into confidentiality and intellectual property assignment agreements with our employees and consultants as one of the ways we seek to protect our intellectual property and other proprietary technologies. However, these agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements.

Our employees and consultants may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our proprietary know-how is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect know-how than courts in the United States. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain intellectual property protection could adversely affect our competitive business position.

We may be dependent upon one of our licenses from The Johns Hopkins University to develop and commercialize some components of the ClearTrace system.

We have entered into exclusive license agreements with The Johns Hopkins University, or Johns Hopkins, with respect to a number of technologies owned by Johns Hopkins. Under one of those agreements, which we entered into in 1998, we licensed a number of technologies relating to devices, systems and methods for performing MRI-guided interventions, particularly MRI-guided cardiac ablation procedures. Therefore, that license is important to the development of the ClearTrace system. Without that license, we may not be able to commercialize some of the components of the ClearTrace system, when and if developed, subject to regulatory clearance or approval. Johns Hopkins has the right to terminate the license under specified circumstances, including a breach by us and failure to cure such breach. We are obligated to use commercially reasonable efforts to develop and commercialize products based on the licensed patents and patent applications. This obligation could require us to take actions related to the development of the ClearTrace system that we would otherwise not take.

Risks Related to Regulatory Compliance

We operate in a highly-regulated industry and any failure to comply with the extensive government regulations may subject us to fines, injunctions and other penalties that could harm our business.

We are subject to extensive regulation by the FDA and various other federal, state and foreign governmental authorities. Government regulations and foreign requirements specific to medical devices are wide ranging and govern, among other things:

- design, development and manufacturing;
- testing, labeling and storage;
- product safety;
- marketing, sales and distribution;
- premarket clearance or approval;
- recordkeeping procedures;
- advertising and promotions;
- recalls and field corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; and
- product export.

We are subject to ongoing FDA requirements, including: required submissions of safety and other post-market information; manufacturing facility registration and device listing requirements; compliance with the FDA's medical device current Good Manufacturing Practice regulations, as codified in the Quality System Regulation, or QSR; requirements regarding field corrections and removals of our marketed products; reporting of adverse events and certain product malfunctions to the FDA; and numerous recordkeeping requirements. If we or any of our collaborators or suppliers fail to comply with applicable regulatory requirements, a regulatory agency may take action against us, including any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

- customer notifications or orders for the repair or replacement of our products or refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) clearances or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted; or
- refusing to grant export approval for our products.

The FDA's and foreign regulatory agencies' statutes, regulations or policies may change, and additional government regulation or statutes may be enacted, which could increase post-approval regulatory requirements, or delay, suspend or prevent marketing of our products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

If we or our third-party suppliers fail to comply with the FDA's QSR or any applicable state equivalent, our manufacturing operations could be interrupted and our potential product sales and operating results could suffer.

We and some of our third-party suppliers are required to comply with the FDA's QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products and product candidates. We and our suppliers will also be subject to the regulations of foreign jurisdictions regarding the manufacturing process to the extent we market our products in these jurisdictions. The FDA enforces the QSR through periodic and unannounced inspections of manufacturing facilities. Our facilities were last inspected by the FDA for QSR compliance in September 2014. We anticipate that we and certain of our third-party suppliers will be subject to future inspections. The failure by us or one of our third-party suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations, could result in enforcement actions against us, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. If we fail to comply with the FDA's QSR or any applicable state equivalent, we would be required to incur the costs and take the actions necessary to bring our operations into compliance, which may have a negative impact on our future sales and our ability to generate a profit.

Our products may in the future be subject to product recalls that could harm our reputation, business operating results and financial condition. Likewise, products that are manufactured and sold by third parties and that are needed for procedures in which physicians use our products also may be subject to recalls, which could adversely impact our business, operating results and financial condition.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design, manufacture or labeling. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. We may initiate certain voluntary recalls involving our products in the future. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. If we determine that certain of those recalls do not require notification to the FDA, the FDA may disagree with our determinations and require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement actions against us, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. Regulatory investigations or product recalls could also result in our incurring substantial costs, losing revenues and implementing a change in the design, manufacturing process or the indications for which our products may be used, each of which would harm our business.

In addition, products that are manufactured and sold by other companies and that are needed for procedures in which physicians use our ClearPoint system also could become subject to a recall. Our ClearPoint system is designed to enable a range of minimally-invasive procedures in the brain. Those procedures involve insertion of a catheter, probe, electrode or other similar device into a target region of the brain, and most of those devices are manufactured and sold by other companies. Any of those devices may become the subject of a recall, whether required by the FDA or a foreign governmental body or initiated by the third party manufacturer. The shortage or absence of any of those devices in the marketplace could adversely impact the number of procedures performed by physicians using our ClearPoint system, which would adversely impact our financial condition and results of operations.

If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to Medical Device Reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA's Medical Device Reporting regulations, we are required to report to the FDA any incident in which our products may have caused or contributed to a death or serious injury or in which our products malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. In the future, we may experience events that may require reporting to the FDA pursuant to the medical device reporting regulations. In addition, all manufacturers placing medical devices in European Union markets are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the relevant authority in whose jurisdiction the incident occurred. Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results. In addition, failure to report such adverse events to appropriate government authorities on a timely basis, or at all, could result in an enforcement action against us.

We may incur significant liability if it is determined that we are promoting off-label uses of our products in violation of federal and state regulations in the United States or elsewhere.

We obtained 510(k) clearance of our ClearPoint system from the FDA for a general neurological intervention claim. This general neurological intervention indication is the same indication for use that applies to other devices that have traditionally been used in the performance of stereotactic neurological procedures. Unless and until we receive regulatory clearance or approval for use of our ClearPoint system in specific procedures, uses in procedures other than general neurological interventional procedures, such as biopsies and catheter and electrode insertions, may be considered off-label uses of our ClearPoint system.

Under the federal Food, Drug, and Cosmetic Act and other similar laws, we are prohibited from labeling or promoting our ClearPoint system, or training physicians, for such off-label uses. The FDA defines labeling to include not only the physical label attached to the product, but also items accompanying the product. This definition also includes items as diverse as materials that appear on a company's website. As a result, we are not permitted to promote off-label uses of our products, whether on our website, in product brochures or in customer communications. However, although manufacturers are not permitted to promote for off-label uses, in their practice of medicine, physicians may lawfully choose to use medical devices for off-label uses. Therefore, a physician could use our ClearPoint system for uses not covered by the cleared labeling.

The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance or approval has not been obtained. If the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and market adoption of our products would be impaired. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention and result in substantial damage awards against us.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

Although we do not provide healthcare services or receive payments directly from Medicare, Medicaid or other third-party payors for our products or the procedures in which our products may be used, many state and federal healthcare laws and regulations governing financial relationships between medical device companies and healthcare providers apply to our business and we could be subject to enforcement by both the federal government, private whistleblowers and the states in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- The federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or providing any kickback, bribe or other remuneration, directly or indirectly, in exchange for or to induce the purchase, lease or order, or arranging for or recommending of, any item or service for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs.

- Federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid or other federally-funded healthcare programs that are false or fraudulent, or are for items or services not provided as claimed, and which may apply to entities like us to the extent that our interactions with customers may affect their billing or coding practices. Changes to the federal false claims law enacted as part of the Affordable Care Act will likely increase the number of whistleblower cases brought against providers and suppliers of health care items and services.

- The federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, which established new federal crimes for knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services.

- State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, and the Foreign Corrupt Practices Act, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, or when physicians are employees of a foreign government entity.

- The Affordable Care Act, which imposes certain reporting obligations on manufacturers of drugs, devices and biologics. Specifically, such manufacturers are required to report payments or other transfers of value to or on behalf of a physician or teaching hospital by such manufacturers, as well as any ownership or investment interest held by physicians in such manufacturers. Violations of the reporting requirements are subject to civil monetary penalties.

- The Affordable Care Act also grants the Office of Inspector General additional authority to obtain information from any individual or entity to validate claims for payment or to evaluate the economy, efficiency or effectiveness of the Medicare and Medicaid programs, expands the permissible exclusion authority to include any false statements or misrepresentations of material facts, enhances the civil monetary penalties for false statements or misrepresentation of material facts, and enhances the Federal Sentencing Guidelines for those convicted of federal healthcare offenses.

The medical device industry has been under heightened scrutiny as the subject of government investigations and government enforcement or private whistleblower actions under the Anti-Kickback Statute and the False Claims Act involving manufacturers who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business, including specifically arrangements with physician consultants.

We may from time to time have agreements with physicians that could be scrutinized or could be subject to reporting requirements in the future, including consulting contracts in which we compensate physicians for various services, which could include:

- providing training and other similar services on the proper use of our products;
- advising us with respect to the commercialization of products in their respective fields;
- keeping us informed of new developments in their respective fields of practice;
- advising us on our research and development projects related to their respective fields;
- advising us on improvements to methods, processes and devices related to their respective fields (such as advice on the development of prototype devices); and
- assisting us with the technical evaluation of our methods, processes and devices related to their respective fields.

The Affordable Care Act mandates increased transparency of arrangements between physicians and medical device companies, which we expect will increase our overall cost of compliance. We believe that this increased transparency will also result in a heightened level of government scrutiny of the relationships between physicians and medical device companies. While we believe that all of our arrangements with physicians comply with applicable law, the increased level of scrutiny, coupled with the expanded enforcement tools available to the government under the Affordable Care Act, may increase the likelihood of a governmental investigation. If we become subject to such an investigation, our business and operations would be adversely affected even if we ultimately prevail because the cost of defending such investigation would be substantial. Moreover, companies subject to governmental investigations could lose both overall market value and market share during the course of the investigation.

In addition, we may provide customers with information on products that could be deemed to influence their coding or billing practices, and may have sales, marketing or other arrangements with hospitals and other providers that could also be the subject of scrutiny under these laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Any penalties, damages, fines, exclusions, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, 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 the physicians or other providers or entities with whom we do business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

We may be subject to privacy and data protection laws governing the transmission, use, disclosure, security and privacy of health information which may impose restrictions on technologies and subject us to penalties if we are unable to fully comply with such laws.

Numerous federal, state and international laws and regulations govern the collection, use, disclosure, storage and transmission of patient-identifiable health information. These laws include:

- HIPAA and the Privacy and Security Rules promulgated thereunder apply to covered entities, which include most healthcare facilities that purchase and use our products. The HIPAA Privacy and Security Rules set forth minimum standards for safeguarding individually identifiable health information, impose certain requirements relating to the privacy, security and transmission of individually identifiable health information and provide certain rights to individuals with respect to that information. HIPAA also requires covered entities to contractually bind third parties, known as business associates, in the event that they perform an activity or service for or on behalf of the covered entity that involves access to patient identifiable health information.

- The federal Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which strengthens and expands the HIPAA Privacy and Security Rules and its restrictions on use and disclosure of patient identifiable health information, including imposing liability on business associates of covered entities.

- Both HITECH and state data breach laws that necessitate the notification in certain situations of a breach that compromises the privacy or security of personal information.

- Other federal and state laws restricting the use and protecting the privacy and security of patient information may apply, many of which are not preempted by HIPAA.

- Federal and state consumer protection laws are being applied increasingly by the United States Federal Trade Commission and state attorneys general to regulate the collection, use, storage and disclosure of personal or patient information, through websites or otherwise, and to regulate the presentation of website content.

- Other countries also have, or are developing, laws governing the collection, use and transmission of personal or patient information.

- Federal and state laws regulating the conduct of research with human subjects.

We are required to comply with federal and state laws governing the transmission, security and privacy of patient identifiable health information that we may obtain or have access to in connection with manufacture and sale of our products. We do not believe that we are a HIPAA-covered entity because we do not submit electronic claims to third-party payors, but there may be limited circumstances in which we may operate as a business associate to covered entities if we receive patient identifiable data through activities on behalf of a healthcare provider. We may be required to make costly system modifications to comply with the HIPAA privacy and security requirements that will be imposed on us contractually through business associate agreements by covered entities and directly under HITECH or HIPAA regulations. Our failure to comply may result in criminal and civil liability because the potential for enforcement action against business associates is now greater. Enforcement actions can be costly and interrupt regular operations which may adversely affect our business.

In addition, numerous other federal and state laws protect the confidentiality of patient information as well as employee personal information, including state medical privacy laws, state social security number protection laws, state data breach laws and federal and state consumer protection laws. These various laws in many cases are not preempted by the HIPAA rules and may be subject to varying interpretations by the courts and government agencies, creating complex compliance issues for us and our customers and potentially exposing us to additional expense, adverse publicity and liability. In connection with any clinical trials we conduct, we will be subject to state and federal privacy and human subject protection regulations. The HIPAA requirements and other human subjects research laws could create liability for us or increase our cost of doing business because we must depend on our research collaborators to comply with the applicable laws. We may adopt policies and procedures that facilitate our collaborators' compliance, and contractually require compliance, but we cannot ensure that non-employee collaborators or investigators will comply with applicable laws. As a result, unauthorized uses and disclosures of research subject information in violation of the law may occur. Any such violations could lead to sanctions that could adversely affect our business.

Risks Related to Facilities, Employees and Growth

We are dependent on our senior management team, our sales, clinical support and marketing team and our engineering team, and the loss of any of them could harm our business.*

All of our employees, including the members of our senior management team, are at-will employees, and therefore they may terminate employment with us at any time. Accordingly, there are no assurances that the services of any of our employees will be available to us for any specified period of time. The loss of members of our senior management team, our sales, clinical support and marketing team or our engineering team, or our inability to attract or retain other qualified personnel, could have a material adverse effect on our business, financial condition and results of operations. If the need to replace any of our key employees arises, the replacement process likely would involve significant time and costs, and may significantly delay or prevent the achievement of our business objectives.

In March 2015, we announced that we will consolidate all major business functions into our Irvine, California headquarters, and, as a result, we will close our Memphis, Tennessee office in May 2015. We will not retain any of our Memphis-based employees. In connection with the consolidation, we entered into an employment agreement in March 2015 to hire a new Chief Financial Officer.

We need to hire and retain additional qualified personnel to grow and manage our business. If we are unable to attract and retain qualified personnel, our business and growth could be seriously harmed.

Our performance depends on the talents and efforts of our employees. Our future success will depend on our ability to attract, retain and motivate highly skilled personnel in all areas of our organization, but particularly as part of our sales, clinical support and marketing team. We plan to continue to grow our business and will need to hire additional personnel to support this growth. It is often difficult to hire and retain these persons, and we may be unable to replace key persons if they leave or fill new positions requiring key persons with appropriate experience. If we experience difficulties locating and hiring suitable personnel in the future, our growth may be hindered. Qualified individuals are in high demand, particularly in the medical device industry, and we may incur significant costs to attract and retain them. If we are unable to attract and retain the personnel we need to succeed, our business and growth could be harmed.

If we do not effectively manage our growth, we may be unable to successfully market and sell our products or develop our product candidates.

Our future revenue and operating results will depend on our ability to manage the anticipated growth of our business. In order to achieve our business objectives, we must continue to grow. However, continued growth presents numerous challenges, including:

- expanding our sales, clinical support and marketing infrastructure and capabilities;
- expanding our assembly capacity and increasing production;
- implementing appropriate operational and financial systems and controls;
- improving our information systems;
- identifying, attracting and retaining qualified personnel in our areas of activity; and
- hiring, training, managing and supervising our personnel.

We cannot be certain that our systems, controls, infrastructure and personnel will be adequate to support our future operations. Any failure to effectively manage our growth could impede our ability to successfully develop, market and sell our products and our business will be harmed.

Our operations are vulnerable to interruption or loss due to natural disasters, power loss and other events beyond our control, which would adversely affect our business.

We do not have redundant facilities. With the closure of our Memphis, Tennessee office, we will conduct substantially all of our activities, including executive management, research and development, component processing, final assembly, packaging and distribution activities for our ClearPoint system, at our facility located in Irvine, California, which is a seismically active area that has experienced major earthquakes in the past, as well as other natural disasters, including wildfires. We have taken precautions to safeguard our facility, including obtaining business interruption insurance. However, any future natural disaster, such as an earthquake or a wildfire, could significantly disrupt our operations, and delay or prevent product assembly and shipment during the time required to repair, rebuild or replace our facility, which could be lengthy and result in significant expenses. Furthermore, the insurance coverage we maintain may not be adequate to cover our losses in any particular case or continue to be available at commercially reasonable rates and terms. In addition, our facility may be subject to shortages of electrical power, natural gas, water and other energy supplies. Any future shortage or conservation measure could disrupt our operations and cause expense, thus adversely affecting our business and financial results.

Risks Related to Our Shares of Common Stock

Our stock may be traded infrequently and in low volumes, so you may be unable to sell your shares at or near the quoted bid prices if you need to sell your shares.

The shares of our common stock may trade infrequently and in low volumes in the over-the-counter market, meaning that the number of persons interested in purchasing our common shares at or near bid prices at any given time may be relatively small or non-existent. This situation may be attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community who can generate or influence sales volume. Even if we come to the attention of such institutionally oriented persons, they may be risk-averse in the current economic environment and could be reluctant to follow a company such as ours or purchase or recommend the purchase of our shares until such time as we become more seasoned. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give you any assurance that a broader or more active public trading market for our shares will develop or be sustained. Due to these conditions, we can give you no assurance that you will be able to sell your shares at or near bid prices or at all if you need money or otherwise desire to liquidate your shares. As a result, investors could lose all or part of their investment.

Our stock price is below $5.00 per share and is treated as a "penny stock", which places restrictions on broker-dealers recommending the stock for purchase.

Our common stock is defined as "penny stock" under the Securities Exchange Act of 1934, or the Exchange Act, and its rules. The Securities and Exchange Commission, or SEC, has adopted regulations that define "penny stock" to include common stock that has a market price of less than $5.00 per share, subject to certain exceptions. These rules include the following requirements:

- a broker-dealer must deliver, prior to the transaction, a disclosure schedule prepared by the SEC relating to the penny stock market;
- a broker-dealer must disclose the commissions payable to the broker-dealer and its registered representative;
- a broker-dealer must disclose current quotations for the securities; and
- a broker-dealer must furnish its customers with monthly statements disclosing recent price information for all penny stocks held in the customer's account and information on the limited market in penny stocks.

Additional sales practice requirements are imposed on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. If our common stock remains subject to these penny stock rules these disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for our common stock. As a result, fewer broker-dealers may be willing to make a market in our stock, which could affect a stockholder's ability to sell their shares.

Our common stock is traded in the over-the-counter market, and our stock price could be volatile.

Our common stock is currently traded in the over-the-counter market. The over-the-counter market lacks the credibility of established stock markets and is characterized by larger gaps between bid and ask prices. Stocks traded in the over-the-counter market have traditionally experienced significant price and volume fluctuations that often are unrelated or disproportionate to the operating performance of a company traded in such market. Regardless of our actual operating performance, the market price for our common stock may materially decline from time to time. There can be no assurance that you will be able to sell your stock at a time when the market price is greater than what you paid. If a large volume of our shares of common stock is posted for sale, it will likely cause the market price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market, or the perception that they may occur, may depress the market price of our common stock.

As of April 30, 2015, almost all of our outstanding shares were freely transferable or could be publicly resold pursuant to Rule 144 under the Securities Act. In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated) who has beneficially owned restricted securities for at least six months, including our affiliates, would be entitled to sell such securities, subject to the availability of current public information about the company. A person who has not been our affiliate at any time during the three months preceding a sale, and who has beneficially owned his shares for at least one year, would be entitled under Rule 144 to sell such shares without regard to any limitations under Rule 144. Under Rule 144, sales by our affiliates are subject to volume limitations, manner of sale provisions and notice requirements. Any substantial sale of common stock pursuant to a prospectus, Rule 144 or otherwise may have an adverse effect on the market price of our common stock by creating an excessive supply. Likewise, the availability for sale of substantial amounts of our common stock could reduce the prevailing market price.

We have not paid dividends in the past and do not expect to pay dividends in the future.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all future earnings for the operation and expansion of our business and, therefore, do not anticipate declaring or paying cash dividends in the foreseeable future. The payment of dividends will be at the discretion of our Board of Directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payments of dividends present in any of our future debt agreements and other factors our Board of Directors may deem relevant. If we do not pay dividends, a return on your investment will only occur if our stock price appreciates.

Anti-takeover provisions in our certificate of incorporation, bylaws and Delaware law could prevent or delay a change in control of our company.

Provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law, may discourage, delay or prevent a merger, acquisition or change of control. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors and take other corporate actions. These provisions:

- permit our Board of Directors to issue shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control;
- provide that the authorized number of directors may be changed only by resolution of the Board of Directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);

- provide that special meetings of our stockholders may be called only by the chairman of the Board of Directors, our Chief Executive Officer or by the Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and

- provide that stockholders will be permitted to amend our bylaws only upon receiving at least 66 2/3% of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any broad range of business combinations with any stockholder who owns, or at any time in the last three years owned, 15% or more of our outstanding voting stock, for a period of three years following the date on which the stockholder became an interested stockholder. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

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

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including 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 shareholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although we could lose that status sooner if our revenues exceed $1 billion, if we issue more than $1 billion in non-convertible debt in a three year period, or if the market value of our common stock held by non-affiliates exceeds $700 million as of any June 30 before that time, in which case we would no longer be an emerging growth company as of the following December 31. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

None.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

The exhibits listed in the accompanying Exhibit Index are filed, furnished or incorporated by reference as part of 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.

Date: May 7, 2015

MRI INTERVENTIONS, INC.

By: /s/ Francis P. Grillo
Francis P. Grillo
Chief Executive Officer
(Principal Executive Officer)

By: /s/ David W. Carlson
David W. Carlson
Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation	10-Q	000-54575	3.1	May 11, 2012
3.2	Amended and Restated Bylaws	10-Q	000-54575	3.2	May 11, 2012
4.1	Reference is made to Exhibits 3.1 and 3.2				
4.2	Specimen of Common Stock Certificate	10-Q	000-54575	4.2	November 14, 2014
10.1*	Employment Offer Letter between MRI Interventions, Inc. and Harold A. Hurwitz				
10.2*	Non-Competition Agreement between Harold A. Hurwitz and MRI Interventions, Inc.				
10.3*	Non-Disclosure and Proprietary Rights Agreement between Harold A. Hurwitz and MRI Interventions, Inc.				
10.4*	Consulting Agreement dated April 1, 2015 between MRI Interventions, Inc. and Kimble L. Jenkins				
10.5*	Omnibus Amendment dated April 1, 2015 between MRI Interventions, Inc. and Kimble L. Jenkins				
10.6	Second Amendment to Lease Agreement dated as of February 24, 2015, by and between Shaw Investment Company, LLC and MRI Interventions, Inc.	10-K	000-54575	10.24	March 17, 2015
31.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934				
31.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934				
32+	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Rule 13a-14(b) Under the Securities Exchange Act of 1934 and Section 1350 of Chapter 60 of Title 18 of the United States Code				
101.INS*	XBRL Instance				
101.SCH*	XBRL Taxonomy Extension Schema				
101.CAL*	XBRL Taxonomy Extension Calculation				
101.DEF*	XBRL Taxonomy Extension Definition				
101.LAB*	XBRL Taxonomy Extension Labels				
101.PRE*	XBRL Taxonomy Extension Presentation				

* Filed herewith.

\+ This certification is being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, and it is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.