UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 September 30, 2013

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)
One Commerce Square, Suite 2550 Memphis, Tennessee	**38103**
(Address of Principal Executive Offices)	(Zip Code)

(901) 522-9300
(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 ☐ (Do not check if smaller reporting company)	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 November 8, 2013, there were 58,488,262 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, performances or achievements, expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our ability to market, commercialize and achieve market acceptance for our products;
- our ability to successfully expand our sales and clinical support capabilities;
- our ability to successfully complete the development of, and obtain regulatory clearance or approval for, our current product candidates; and
- the 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 Balance Sheets
(Unaudited)

	September 30, 2013	December 31, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 5,031,199	$ 1,620,005
Accounts receivable	787,706	445,432
Inventory	1,242,368	899,702
Prepaid expenses and other current assets	164,999	110,873
Total current assets	7,226,272	3,076,012
Property and equipment, net	1,237,453	1,287,115
Software license inventory	945,000	1,137,500
Other assets	111,692	51,119
Total assets	$ 9,520,417	$ 5,551,746
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,543,114	$ 1,961,195
Accrued compensation	178,904	278,124
Other accrued liabilities	373,635	1,177,142
Derivative liabilites	4,106,224	2,129,091
Related party deferred revenues	-	650,000
Deferred product and service revenues	110,265	112,725
Total current liabilities	6,312,142	6,308,277
Other accrued liabilities	445,781	574,722
Related party convertible notes payable	4,338,601	4,338,601
Note payable, net of unamortized discount of $471,103 and $0 at September 30, 2013 and December 31, 2012, respectively	3,818,342	2,000,000
Junior secured notes payable, net of unamortized discounts of $2,782,440 and $2,804,451 at September 30, 2013 and December 31, 2012, respectively	217,560	195,549
Total liabilities	15,132,426	13,417,149
Commitments and contingencies (Notes 5 and 6)		
Stockholders' deficit:		
Common stock, $.01 par value; 100,000,000 shares authorized; 58,807,144 and 58,481,314 shares issued and outstanding, respectively, at September 30, 2013; and 48,418,830 and 48,093,000 issued and outstanding, respectively, at Decembet 31, 2012	588,070	484,187
Additional paid-in capital	66,515,975	58,995,972
Treasury stock, at cost, 325,830 common shares	(1,679,234)	(1,679,234)
Accumulated deficit	(71,036,820)	(65,666,328)
Total stockholders' deficit	(5,612,009)	(7,865,403)
Total liabilities and stockholders' deficit	$ 9,520,417	$ 5,551,746

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	**2012**	**2013**	**2012**
Revenues:				
Product revenues	$ 850,027	$ 318,447	$ 1,807,653	$ 831,472
Development service revenues	49,052	163,381	268,114	414,115
Other service revenues	28,378	-	28,378	-
Related party license revenues	-	650,000	650,000	1,950,000
Total revenues	927,457	1,131,828	2,754,145	3,195,587
Costs and operating expenses:				
Cost of product revenues	365,497	133,371	887,605	391,797
Research and development:				
Research and development costs	725,304	573,562	2,238,574	1,749,253
Reversal of R&D obligation	-	-	-	(882,537)
Selling, general, and administrative	1,697,876	1,441,934	5,034,514	4,585,082
Total costs and operating expenses	2,788,677	2,148,867	8,160,693	5,843,595
Operating loss	(1,861,220)	(1,017,039)	(5,406,548)	(2,648,008)
Other income (expense):				
Gain (loss) on change in fair value of deriviative liabilities	(1,250,857)	(1,667,632)	1,328,112	(1,694,177)
Loss on note payable modification	-	-	(1,356,177)	-
Other income (expense), net	39,160	2,006	406,548	3,926
Interest income	5,798	7,200	20,688	10,180
Interest expense	(127,693)	(85,828)	(363,115)	(2,507,582)
Net loss	$ (3,194,812)	$ (2,761,293)	$ (5,370,492)	$ (6,835,661)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.05)	$ (0.06)	$ (0.09)	$ (0.18)
Weighted average shares outstanding:				
Basic and diluted	58,254,039	47,531,093	56,845,732	37,807,188

See accompanying notes.

MRI INTERVENTIONS, INC.
Condensed Statement of Stockholders' Deficit
Nine Months Ended September 30, 2013
(Unaudited)

	Common Stock		Additional Paid-in	Treasury	Accumulated	
	Shares	Amount	Capital	Stock	Deficit	Total
Balances, January 1, 2013	48,093,000	$ 484,187	$ 58,995,972	$ (1,679,234)	$ (65,666,328)	$ (7,865,403)
January 2013 Private Placement (see Note 5)	9,201,684	92,017	6,407,533	-	-	6,499,550
Share-based compensation	-	-	1,003,028	-	-	1,003,028
Warrant exercises	1,101,177	11,012	8,613	-	-	19,625
Issuance of common stock in payment of director fees	85,453	854	100,829	-	-	101,683
Net loss for the nine months ended September 30, 2013	-	-	-	-	(5,370,492)	(5,370,492)
Balances, September 30, 2013	58,481,314	$ 588,070	$ 66,515,975	$ (1,679,234)	$ (71,036,820)	$ (5,612,009)

See accompanying notes.

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

	Nine Months Ended September 30,	
	2013	**2012**
Cash flows from operating activities:		
Net loss	$ (5,370,492)	$ (6,835,661)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and license amortization	346,183	309,987
Share-based compensation	1,003,028	1,651,280
Expenses paid through the issuance of common stock	101,683	-
(Gain) loss on change in fair value of derivative liability	(1,328,112)	1,694,177
Gain on negotiated reductions in accounts payable and other accrued expenses	(382,263)	-
Loss on loan modification	1,356,177	-
Amortization and write-off of debt issuance costs and original issue discounts	94,732	2,056,552
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(342,274)	215,526
Inventory	(355,709)	(237,057)
Prepaid expenses and other current assets	(54,126)	(110,100)
Other assets	(2,125)	16,581
Accounts payable and accrued expenses	(678,042)	(2,018,300)
Deferred revenue	(652,460)	(1,950,000)
Net cash flows from operating activities	(6,263,800)	(5,207,015)
Cash flows from investing activities:		
Purchases of property and equipment	(73,645)	(93,256)
Acquisition of license	(100,000)	-
Net cash flows from investing activities	(173,645)	(93,256)
Cash flows from financing activities:		
Proceeds from issuance of convertible notes payable, net of issuance costs	-	3,424,950
Proceeds from private placement, net of issuance costs	9,829,014	5,516,495
Proceeds from warrant exercise	19,625	600
Net cash flows from financing activities	9,848,639	8,942,045
Net change in cash and cash equivalents	3,411,194	3,641,774
Cash and cash equivalents, beginning of period	1,620,005	145,478
Cash and cash equivalents, end of period	$ 5,031,199	$ 3,787,252
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ -	$ -
Interest	$ 10,709	$ 26,274

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

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

- In February 2012, the terms of related party notes payable were modified and accrued interest of $838,601 was added to the principal balances of the original notes.

- Upon the effectiveness of the Company's Form 10 registration statement in February 2012, the principal balance of convertible notes payable totaling $10,811,500 and the related accrued interest of $974,311 were converted into shares of the Company's common stock. In addition, unamortized debt discounts totaling $405,602 at the conversion date related to the relative fair value of warrants issued in connection with the issuance of the convertible notes (originally accounted for as equity) were offset against additional paid-in capital.

- In February 2012, warrants with a fair value of $237,299 (recorded as deferred financing costs and additional paid-in capital) were issued to the placement agent and its sub-placement agents in connection with the Company's sale of units consisting of secured convertible notes and common stock warrants.

- In January and February 2012, both the $383,204 relative fair value of warrants and the $383,204 intrinsic value of the beneficial conversion feature associated with notes issued by the Company in an offering of units were recorded as additional paid-in capital and a discount to the convertible notes payable.

- In June 2012, the Company issued 1,500,000 shares of its common stock in exchange for settlement of accounts payable of $612,500 and the purchase of software licenses in the amount of $1,050,000.

- ClearPoint reusable components were transferred from inventory to loaned systems, which is a component of property and equipment, with net costs of $163,553 and $266,131 during the nine months ended September 30, 2013 and 2012, respectively.

- In March 2013, the Company entered into a loan modification in which accrued interest of $389,444 was added to the principal balance of a note payable and the principal balance of the note payable was also increased by an additional $1,900,000 (see Note 4).

- In recording the January 2013 private placement transaction, deferred financing costs of $24,219 were netted against the proceeds recorded to additional paid-in capital.

MRI INTERVENTIONS, INC.
Notes to Condensed 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 on March 12, 1998. In August 2013, the Company formed a subsidiary, MRI Interventions (Canada) Inc. ("MRII Canada"). As of September 30, 2013, there had been no activity in MRII Canada.

The Company's ClearPoint system, an integrated system comprised of reusable components and disposable products, is designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. In 2010, the Company received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") 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. The Company has also entered into exclusive licensing and development agreements with affiliates of Boston Scientific Corporation ("Boston Scientific"), pursuant to which Boston Scientific may incorporate certain of the Company's MRI-safety technologies into Boston Scientific's implantable leads for cardiac and neurological applications.

Liquidity and Management's Plans

For the nine months ended September 30, 2013 and for the year ended December 31, 2012, the Company incurred net losses of $5,370,492 and $5,877,718, respectively, and the cumulative net loss from the Company's inception through September 30, 2013 was $71,036,820. Net cash used in operations was $6,263,800 for the nine months ended September 30, 2013 and $7,433,816 for the year ended December 31, 2012. Since inception, the Company has financed its activities principally from the sale of equity securities, the issuance of convertible notes and license arrangements.

The Company's primary financing activities during the nine months ended September 30, 2013 and the year ended December 31, 2012 were:

- the January 2013 equity private placement (see Note 5), which resulted in net proceeds of $9,829,014;
- the July 2012 equity private placement (the "July 2012 Financing Transaction"), which resulted in net proceeds of $5,516,495; and
- the unit offering the Company completed in February 2012, which resulted in net proceeds of $4,946,560, $3,424,950 of which were received in 2012 and $1,521,610 of which were received in 2011.

While the Company expects to continue to use cash in operations, the Company believes its existing cash and cash equivalents at September 30, 2013 of $5,031,199, combined with cash generated from product and service revenues, will be sufficient to meet the Company's anticipated cash requirements through at least March 2014. During the remainder of 2013, the Company plans to increase its spending on sales and marketing activities as it continues the commercial rollout of its ClearPoint system, from which the Company expects to increase ClearPoint system product revenues. Certain planned expenditures are discretionary and could be deferred if the Company is required to do so to fund critical operations. The sale of additional equity or convertible debt securities will likely result in dilution to the Company's current stockholders. 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 additional equity, debt or other securities or through a credit facility, or 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.

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 financial statements ("condensed financial statements") have been prepared on a basis consistent with the Company's December 31, 2012 audited 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 U.S. Securities and Exchange Commission ("SEC") rules for interim financial information, and, therefore, omit certain information and footnote disclosures necessary to present the statements in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of the 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 financial statements and notes thereto included in the Company's Annual Report on Form 10-K/A for the year ended December 31, 2012, which was filed with the SEC on August 19, 2013. The accompanying condensed balance sheet as of December 31, 2012 has been derived from the audited financial statements at that date, but does not include all information and footnotes required by GAAP for complete financial statements. The results of operations for the three and nine month periods ended September 30, 2013 may not be indicative of the results to be expected for the entire year or any future periods.

Fair Value Measurements

Carrying amounts of the Company's cash and cash equivalents, accounts receivable and 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 of the Company's outstanding notes payable at September 30, 2013:

	Carrying Values	Estimated Fair Value
Related party Boston Scientific convertible notes payable	$ 4,338,601	$ 3,906,979
Note payable	3,818,342	3,818,342
Junior secured notes payable	217,560	2,062,546

The difference between the carrying value of the related party Boston Scientific convertible notes payable, which is equal to the face value due to troubled debt restructuring accounting, and the estimated fair value is attributable to the fact that no interest is charged per the terms of the convertible notes payable, which is below market. The difference between the carrying value and the fair value of the junior secured notes payable relates primarily to the unamortized debt discount. This discount resulted from the relative fair value assigned to the junior secured notes payable at the time of issuance, as the notes were issued in connection with a unit offering, with the units consisting of a note payable and shares of the Company's common stock.

The Company measures 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. See Note 5 for fair value information related to the Company's derivative liabilities, which are the only assets or liabilities carried at fair value by the Company on a recurring basis at September 30, 2013. The table below reflects the level of the inputs used in the Company's fair value calculation for instruments carried at fair value.

	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value
Derivative liability - warrants	$ -	$ -	$ 4,106,224	$ 4,106,224
Derivative liability - conversion option	-	-	-	-

Derivative Liability for Warrants to Purchase Common Stock

The derivative liability for warrants represents the fair value of warrants issued in connection with private placements of shares of the Company's common stock (see Note 5). These warrants are presented as liabilities based on certain exercise price reset and net cash settlement provisions. The liability, which is recorded at fair value on the accompanying balance sheets, is calculated utilizing the Monte Carlo simulation valuation method. The change in fair value of these warrants is recognized as other income or expense in the statements of operations.

Inventory

Inventory is carried at the lower of cost (first-in, first-out 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 arise from: (1) the sale of ClearPoint system reusable components; (2) sales of ClearPoint disposable products; and (3) license, development and other service arrangements. The Company recognizes revenue, in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 605-10-S99, "Revenue Recognition," when persuasive evidence of an arrangement exists, the selling price or fee is fixed or determinable, collection is probable and 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.

(1) *Sale of ClearPoint system reusable components* – Generally, revenues related to ClearPoint system sales 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 ClearPoint system installation. ClearPoint system reusable components include software. This software is integral to the utility of the ClearPoint system as a whole, and as such, the provisions of FASB ASC 985-605, "Software Revenue Recognition," are not applicable. Sales of reusable components that have stand-alone value to the customer are recognized when risk of loss passes to the customer. Sales of reusable components to a distributor that has been trained to perform ClearPoint system installations are recognized at the time risk of loss passes to the distributor.

(2) *Sale of ClearPoint disposable products* – Revenues from the sale of ClearPoint disposable products utilized in procedures performed using the ClearPoint system 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 upon the specific terms agreed upon with the customer.

(3) *License, development other service arrangements* - The Company analyzes revenue recognition on an agreement-by-agreement basis as discussed below.

- *Related Party Revenue Recognition under Boston Scientific Cardiac Agreement* – The Company analyzed whether the deliverables under the arrangement represent 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. The Company determined it did not and does not have clear and objective evidence of fair value of the various elements of the agreement and, therefore, under these standards, the deliverables were treated as one unit of accounting.

  The Company defers recognition of non-refundable upfront license fees if there are continuing performance obligations without which the technology, know-how, rights, products or services conveyed in conjunction with the non-refundable fees have no utility to the licensee that could be considered separate and independent of the Company's performance under other elements of the arrangement. Since the Company had continuing involvement through research and development services that were required because the Company's know-how and expertise related to the technology were proprietary, such upfront fees were deferred and recognized over the estimated period of continuing involvement on a straight-line basis.

During the nine months ended September 30, 2013 and 2012, the Company recognized $650,000 and $1,950,000, respectively, in related party license fee revenues. There were no remaining amounts recorded as deferred related party license revenues subsequent to March 31, 2013 as the Company's period of continuing involvement ended on that date.

Amounts the Company may receive, if any, related to substantive, performance-based milestones in research and development arrangements under the agreement will be recognized upon receipt. Future product royalty income related to the agreement, if any, will be recognized as the related products are sold and amounts are payable to the Company.

- *Development service revenues* – In 2011, the Company entered into an agreement to provide development services to a third party. Under this agreement, the Company earns 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. Revenue is recognized in the period in which the Company incurs the related costs. During the nine months ended September 30, 2013 and 2012, the Company recorded development service revenues of $268,114 and $404,115, respectively, related to this agreement. From time to time, the Company may also perform development services for other third parties evidenced by either a development agreement or a purchase order. During the nine months ended September 30, 2012, the Company recorded revenues totaling $10,000 for such services.

- *Other service revenues* – Other service revenues are comprised primarily of installation fees charged in connection with ClearPoint system installations and service agreement revenues. Typically, the Company will bill upfront for service agreements that have terms ranging from one to three years. These amounts are recognized as revenues ratably over the term of the related service agreement.

Net Loss Per Share

The Company calculates net loss per share in accordance with FASB ASC 260, "Earnings per Share." Basic earnings per share ("EPS") is calculated by dividing the net income or loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without giving consideration to common stock equivalents. Diluted EPS is computed by dividing the net income or loss attributable to common stockholders by the weighted average number of common shares outstanding for the period plus the weighted average number of dilutive common stock equivalents outstanding for the period determined using the treasury stock method when net income is reported. For all periods presented, since such periods resulted in net losses, diluted net loss per share is the same as basic net loss per share. The following table sets forth potential shares of common stock that are not included in the calculation of diluted net loss per share because to do so would be anti-dilutive as of the end of each period presented:

	As of September 30,	
	2013	**2012**
Stock options	6,739,877	6,132,127
Warrants	12,203,489	8,945,247
Shares under convertible note agreements	542,325	4,371,029
	19,485,691	19,448,403

New Accounting Pronouncements

In February 2013, the FASB issued guidance that requires an entity to disclose information showing the effect of items reclassified from accumulated other comprehensive income on the line items of net income. The provisions of this new guidance were effective prospectively as of the beginning of the Company's 2013 fiscal year. The adoption of this standard update did not have an impact on the Company's financial statements for the three or nine months ended September 30, 2013.

3. Inventory

Inventory consists of the following as of:

	September 30, 2013	December 31, 2012
Work in process	$ 564,741	$ 494,290
Software license inventory	397,000	344,500
Finished goods	280,627	60,912
Inventory included in current assets	1,242,368	899,702
Software license inventory	945,000	1,137,500
	$ 2,187,368	$ 2,037,202

4. Note Payable Modification

In April 2011, the Company issued a $2,000,000 subordinated secured convertible note ("April 2011 Note") to Brainlab AG ("Brainlab"). Upon issuance, the April 2011 Note was scheduled to mature in April 2016, unless earlier converted, and it accrued interest at the rate of 10% per year. The April 2011 Note was amended in February 2012, to among other things, provide Brainlab the option to convert the April 2011 Note into shares of the Company's common stock at a conversion price of $0.60 per share at any time on or before February 23, 2013.

On February 21, 2013, Brainlab delivered notice to the Company of its election to convert the April 2011 Note into shares of the Company's common stock at the conversion price of $0.60 per share. However, prior to the issuance of those conversion shares, on March 6, 2013, the Company and Brainlab entered into a loan modification. As a result of that loan modification, Brainlab revoked its election to convert the April 2011 Note into shares of common stock. Under the loan modification, the Company issued an amended and restated subordinated secured convertible note to Brainlab (the "Amended and Restated Note"), which amended the April 2011 Note (i) to remove the equity conversion feature, such that the Amended and Restated Note is not convertible into any shares of the Company's capital stock, (ii) to reduce the interest rate, beginning March 6, 2013, from 10% per year to 5.5% per year, (iii) to ease certain restrictive loan covenants, and (iv) to reflect a new note principal balance of $4,289,444, which represents the sum of (A) the original principal balance of the April 2011 Note in the amount of $2,000,000, plus (B) interest accrued under the April 2011 Note through March 6, 2013 in the amount of $389,444, plus (C) $1,900,000. The Amended and Restated Note completely replaced and superseded the April 2011 Note. The Amended and Restated Note matures in April 2016, and principal and accrued interest under the Amended and Restated Note is payable in a single installment upon maturity. Like the April 2011 Note, the Amended and Restated Note is secured by a security interest in the assets of the Company, which security interest is junior and subordinate to the security interest that secures the related party convertible notes payable issued by the Company to Boston Scientific.

The Company has applied guidance in FASB ASC 470-50, "Debt Modifications and Extinguishments," which requires calculating the fair value of the Amended and Restated Note, as of the loan modification date, based on the amended terms. At the time of the loan modification, the fair value of the Amended and Restated Note, with its principal balance of $4,289,444, was $3,745,621. The difference between the fair value of the Amended and Restated Note immediately following the loan modification and the carrying value of the April 2011 Note and related accrued interest immediately prior to the loan modification, resulted in a charge to other expense of $1,356,177 in the statement of operations during the nine months ended September 30, 2013. The $543,823 difference between the principal amount of the Amended and Restated Note and the fair value of the Amended and Restated Note on the date of the loan modification was recorded as a debt discount and is being amortized to interest expense using the effective interest method over the term of the Amended and Restated Note.

5. Stockholders' Equity

January 2013 Private Placement

In January 2013, the Company entered into a securities purchase agreement for the private placement of shares of the Company's common stock and warrants to purchase shares of the Company's common stock, at a purchase price of $1.20 per unit (the "January 2013 Financing Transaction"). Each unit consisted of one share of common stock and a warrant to purchase one-half share of common stock.

In the January 2013 Financing Transaction, the Company sold to the investors 9,201,684 shares of common stock, together with warrants to purchase 4,600,842 shares of common stock, for aggregate gross proceeds of $11,042,021, before commissions and offering expenses. Non-employee directors of the Company invested a total of $402,000 in the January 2013 Financing Transaction. Each warrant is exercisable for five years from the date of issuance and has 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. In the event the Company issues shares of its common stock or common stock equivalents in a subsequent financing transaction at a price below the then prevailing warrant exercise price, the exercise price of the warrants will be adjusted downward (commonly referred to as a "down round" provision) to the price at which the Company issues the common stock or common stock equivalents.

In addition, the warrants contain a net-cash settlement feature that gives the warrant holder the right to net-cash settlement in the event certain transactions occur. Pursuant to the net-cash settlement provision of the warrants, if such a transaction occurs, the warrant holder will be entitled to receive cash equal to the value calculated under the Black-Scholes valuation model using (i) an expected volatility equal to the greater of 100% and the 100-day volatility obtained from the HVT function on Bloomberg, (ii) an expected term equal to the remaining term of the warrant, and (iii) an interest rate equal to the United States Treasury risk-free rate for the term of the lesser of the remaining term of the warrant or twenty-four months.

The Company's placement agents earned commissions of $1,104,202 and the Company incurred other transaction costs of $133,024 related to the January 2013 Financing Transaction.

In connection with the January 2013 Financing Transaction, the Company entered into a registration rights agreement with the investors pursuant to which the Company filed a registration statement with the SEC covering the resale of the shares of common stock and the shares of common stock underlying the warrants issued in the financing. The Company must bear the costs, including legal and accounting fees, associated with the registration of those shares. If the Company fails to continuously maintain the effectiveness of the registration statement (with certain permitted exceptions), the Company will incur certain damages to the investors, up to a maximum amount of 12% of the investors' investments in the January 2013 Financing Transaction, or approximately $1,300,000.

Common Stock Warrants Requiring Liability Accounting

Under guidance in FASB ASC 815-40, "Contracts in Entity's Own Equity," the net-cash settlement and down round provisions contained in the warrants issued in the January 2013 Financing Transaction require derivative liability accounting treatment for the warrants. Likewise, under ASC 815-40, the down round provision contained in the warrants issued in the July 2012 Financing Transaction also requires derivative liability accounting treatment for the warrants. As of September 30, 2013 and December 31, 2012, the aggregate fair value of these warrants was $4,106,224 and $2,128,302, respectively. The fair value of these warrants was calculated using the Monte Carlo simulation valuation method.

Assumptions used in calculating the fair value of these warrants are noted below (including assumptions used in calculating the transaction date fair value for the warrants issued in the January 2013 Financing Transaction):

	January 2013 Financing Transaction Date	September 30, 2013
Dividend yield	0%	0%
Expected volatility	47.08% - 100.00%	45.96% - 100.00%
Risk free interest rates	0.91%	0.93% - 1.14%
Expected remaining term (years)	5	3.76 to 4.32

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

The change in the fair value of the warrants accounted for as derivative liabilities is reflected below:

Balance at January 1, 2013	$ 2,128,302
Fair value of warrants issued in January 2013 Financing Transaction at transaction date	3,305,245
Decrease in fair value resulting in gain	(1,327,323)
Fair value at September 30, 2013	$ 4,106,224

The Company will continue to adjust the derivative liability for changes in fair value until the earlier of the expiration or exercise of the warrants, at which time the liability will be reclassified to stockholders' equity.

Stock Options

In June 2013, the stockholders of the Company approved the creation of a new share-based incentive plan (the “2013 Plan”). Following stockholder approval of the 2013 Plan, no new grants under the Company’s prior stock plans were made. 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 382,500 shares had been made as of September 30, 2013. Thus, 867,500 shares remained available for award grants as of September 30, 2013 under the 2013 Plan. On November 5, 2013, awards as to 567,000 shares were granted to employees under the 2013 Plan.

Activity under all of the Company’s equity compensation plans during the nine months ended September 30, 2013 is summarized below:

	Shares	Weighted - Average Exercise Price
Outstanding at January 1, 2013	6,432,127	$ 1.58
Granted	452,500	1.20
Forfeited	(144,750)	2.18
Outstanding at September 30, 2013	6,739,877	1.54

The estimated grant date fair values of options granted during the nine months ended September 30, 2013 were calculated using the Black-Scholes valuation model, based on the following assumptions:

Dividend yield	0%
Expected Volatility	45.33% to 45.96%
Risk free Interest rates	0.92% to 1.96%
Expected lives (years)	5.5 to 6.0

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

Three Months Ended September 30,		Nine Months Ended September 30,	
2013	2012	2013	2012
$ 345,632	$ 300,304	$ 988,223	$ 843,866

As of September 30, 2013, there was unrecognized compensation expense of $1,117,909 related to outstanding stock options which is expected to be recognized over a weighted average period of approximately 1.5 years.

Warrants

Warrants have generally been issued for terms of up to five years. Common stock warrant activity for the nine months ended September 30, 2013 was as follows:

	Shares	Weighted - Average Exercise Price
Outstanding at January 1, 2013	8,763,836	$ 0.95
Issued	4,643,842	1.75
Forfeited	(41,666)	1.00
Exercised	(1,162,523)	0.10
Outstanding at September 30, 2013	12,203,489	1.33

In August 2013, warrants were issued to a service provider to purchase 43,000 shares of the Company's common stock at $1.75 per share. The fair value of these warrants of $14,805, which was calculated using the Black-Scholes valuation model, was recorded as share-based compensation expense. Assumptions used in calculating the fair value of these warrants included a dividend yield of 0%, expected volatility of 46.49%, a risk free interest rate of 1.38%, and an expected life of 5 years.

During the nine months ended September 30, 2013, certain warrants were exercised on a net settlement basis which resulted in the Company withholding 61,346 shares out of the common stock warrants exercised.

6. Legal Proceeding

In June 2013, Custom Equity Research, Inc. d/b/a Summer Street Research Partners ("Summer Street") commenced an arbitration proceeding alleging breach of contract and quantum meruit claims against the Company. Summer Street claims, among other things, that the Company owes Summer Street $480,000 in cash commissions, as well as warrants to purchase 460,338 shares of the Company's common stock, in connection with the Company's engagement of Summer Street to serve as its financial advisor and placement agent for two financing transactions undertaken by the Company in 2011 and 2012, respectively. As required under the Company's engagement agreements with Summer Street, the arbitration has been brought before JAMS, The Resolution Experts, an alternative dispute resolution provider. In the arbitration, the Company has filed counter-claims against Summer Street alleging fraud and misrepresentation, abuse of process and malicious prosecution, and the Company is seeking unspecified monetary damages from Summer Street in connection with the counter-claims. The arbitration proceeding is at a preliminary stage. The Company intends to vigorously defend itself and pursue its counter-claims against Summer Street in the arbitration.

Due to the uncertainty surrounding the arbitration process, the Company is unable to reasonably estimate the ultimate outcome of the foregoing matter at this time. Based on currently available information, the Company believes that it has meritorious defenses to Summer Street's claims and that the likelihood is remote that the resolution of this matter will have a material adverse effect on the Company's business, financial condition or future results of operations. As such, no liability associated with this matter has been recorded in the Company's financial statements.

7. Amendment to Agreement with Merge Healthcare

Effective July 28, 2013, the Company and Merge Healthcare Canada Corp. ("Merge") entered into a Third Amendment to the Master Services and Licensing Agreement between the parties (the "Third Amendment").

The Company entered into the Master Services and Licensing Agreement (the "Master Software Agreement") in July 2007 for Merge to develop on the Company's behalf, based on the Company's detailed specifications, a customized software solution for the Company's ClearPoint system. Merge was in the business of providing software development and engineering services on a contract basis to a number of companies. In developing the Company's ClearPoint system software, Merge utilized certain of its own pre-existing software code. Under the Master Software Agreement, the Company received a non-exclusive, worldwide license to the pre-existing software code, in object code form, as an integrated component of the Company's ClearPoint system software. In return, the Company agreed to pay Merge a license fee for each copy of the ClearPoint system software that the Company distributes. In addition, under the Master Software Agreement, Merge has been performing ongoing custom engineering, maintenance and support services with respect to the Company's ClearPoint system software, for which services the Company has been compensating Merge.

At the Company's request, the parties entered into the Third Amendment to enable the Company to internally handle development, maintenance and support of its ClearPoint system software going forward. As a result, the services which the Company was outsourcing to the Merge will now be performed by the Company itself. Under the Third Amendment, Merge granted the Company a non-exclusive, non-transferable, worldwide license to the source code for the pre-existing software to use in the Company's further development and commercialization of its ClearPoint system software. In return, the Company agreed to pay Merge a one-time license fee. Merge may terminate the source code license only for cause. The Company will continue to pay Merge a license fee for each copy of the ClearPoint system software that the Company distributes, but only for licenses in excess of those licenses already purchased or otherwise acquired by the Company prior to the Third Amendment. The Company had already satisfied its minimum license purchase commitments from the Master Software Agreement.

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 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 in the United States and Europe, is used to perform minimally invasive surgical procedures in the brain. We anticipate that the 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 the ClearPoint system, which enables us to market the ClearPoint system in the European Union. Substantially all of our product revenues for 2012 and the nine months ended September 30, 2013 relate to sales of our ClearPoint system products. We do not have regulatory clearance or approval to sell our ClearTrace system, and, therefore, we have not generated revenues from sales of that product candidate. In 2008, we received licensing fees totaling $13.0 million from Boston Scientific for our MRI-safety technologies, which we used to finance our operations and internal growth. We have also financed our operations and internal growth through private placements of securities, borrowings and interest earned on the net proceeds from our private placements. Prior to 2008, we were a development stage enterprise. We have incurred significant losses since our inception in 1998 as we devoted substantial efforts to research and development. As of September 30, 2013, we had an accumulated deficit of $71.0 million. We expect to incur losses through at least December 31, 2013, and we may continue to incur losses thereafter, as we commercialize our ClearPoint system products, continue to develop our product candidates and expand our business generally.

Factors Which May Influence Future Results of Operations

The following is a description of factors which may influence our future results of operations, and which 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 any of our product candidates until we receive regulatory clearance or approval.

The generation of recurring revenues through sales of our disposable components is an important part of our business model for our ClearPoint system. We first generated revenues through the sale of ClearPoint system disposable components in the third quarter of 2010. We anticipate that 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 these disposable components.

Since inception, the most significant source of our revenues has been related to our collaborative agreements with Boston Scientific, principally from recognition of the $13.0 million of licensing fees we received in 2008. Revenues associated with these licensing fees were recognized on a straight-line basis over a five year period, which represented our estimated period of continuing involvement in the development activities, and which ended at March 31, 2013. Any additional payments related to substantive, performance-based milestones that we may receive under the agreement regarding implantable cardiac leads will be recognized upon receipt. These revenue recognition policies are more fully described in the section entitled *"Management's Discussion and Analysis of Financial Condition and Results of Operations–Critical Accounting Policies and Significant Judgments and Estimates"* in our Annual Report on Form 10-K/A for the year ended December 31, 2012 which we filed with the SEC on August 19, 2013.

Cost of Product Revenues

Cost of product revenues includes the direct costs associated with the assembly and purchase of disposable and reusable components of our ClearPoint system 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 write-offs of obsolete, impaired or excess inventory.

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 product candidates. This includes: the salaries, travel and benefits of research and development personnel; materials and laboratory supplies used by our research personnel; consultant costs; sponsored contract research and product development with third parties; and licensing costs. We anticipate that, over time, our research and development expenses may increase as we: (1) continue our product development efforts for the ClearTrace system; (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 September 30, 2013, we have incurred approximately $39 million in research and development expenses.

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

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of: salaries, sales incentive payments, travel and benefits; share-based compensation; professional fees, including fees for attorneys and outside accountants; occupancy costs; insurance; marketing costs; and other general and administrative expenses, which include corporate licenses, director fees, hiring costs, taxes, postage, office supplies and meeting costs. We expect our selling, general and administrative expenses 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 nine months ended September 30, 2013 as compared to the critical accounting policies described in our Annual Report on Form 10-K/A for the year ended December 31, 2012, which we filed with the SEC on August 19, 2013

Results of Operations

Three Months Ended September 30, 2013 Compared to the Three Months Ended September 30, 2012

($s in thousands)	Three Months Ended September 30, 2013	2012	Percentage Change
Product and service revenues	$ 927	$ 482	92%
License revenues	-	650	(100)%
Cost of product revenues	365	133	174%
Research and development costs	725	574	26%
Selling, general and administrative expenses	1,698	1,442	18%
Other expense:			
Other expense, net	(1,212)	(1,665)	(27)%
Interest expense, net	(122)	(79)	54%
Net loss	(3,195)	(2,761)	16%

Product and service revenues. Product and service revenues were $927,000 for the three months ended September 30, 2013, and $482,000 for the same three month period in 2012, an increase of $445,000, or 92%. Product revenues for the three months ended September 30, 2013 were $850,000 compared to $318,000, for the same period in 2012, an increase of $532,000, or 167%. Product revenues included ClearPoint system disposable product sales for the three months ended September 30, 2013 of $470,000 compared with $287,000 for the same three month period in 2012, an increase of $183,000, or 64%. That increase in disposable product sales resulted from the higher number of ClearPoint procedures that were performed during the three months ended September 30, 2013. Approximately $380,000 of the product revenues for the three months ended September 30, 2013 related to the sale of ClearPoint system reusable components, compared with $31,000 for the same three month period in 2012. During the three months ended September 30, 2013 and 2012, we recorded development service revenues of $49,000 and $163,000, respectively, a decrease of 70%. We do not expect the development service revenues to be a long-term ongoing source of revenues. Other service revenues, mostly related to installation services and a service agreement, were $28,000 for the three months ended September 30, 2013. No such revenues were recorded during the same period in 2012.

License revenues. License revenues of $650,000 recorded during the three months ended September 30, 2012 related to license fees we received in 2008 from Boston Scientific that were deferred and recognized over the period of our continued involvement with Boston Scientific's development program for the licensed technology. The period of our continued involvement ended on March 31, 2013, thus, all revenues related to the license fees we received in 2008 were recognized as of March 31, 2013.

Cost of Product Revenues. Cost of product revenues was $365,000 for the three months ended September 30, 2013, compared to $133,000 for the same three month period in 2012, an increase of 174%. The increase in cost of product revenues was primarily attributable to the 167% increase in product revenues for the same period. Gross margin on product revenues was relatively consistent for both periods.

Research and Development Costs. Research and development costs were $725,000 for the three months ended September 30, 2013, compared to $574,000 for the same three month period in 2012, an increase of $151,000, or 26%. A portion of the increase was attributable to research that we sponsored. For the three months ended September 30, 2013, we incurred sponsored research costs of $79,000, while we did not incur any such costs for the three months ended September 30, 2012. The remainder of the increase was attributable to license fee expenses incurred in the three months ended September 30, 2013 related to technologies still in the development phase.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $1.7 million for the three months ended September 30, 2013, compared with $1.4 million for the same three month period in 2012, an increase of $231,000, or 16%. The overall increase was driven by a $410,000 increase in sales and marketing expenses, which was partially offset by a $157,000 decrease in share-based compensation expense. The increase in sales and marketing expenses related mostly to costs associated with personnel additions to our sales and clinical support team. The decrease in share-based compensation reflects a lower number of common stock warrants issued to service providers in the three months ended September 30, 2013 compared with the same period in 2012.

Other Expense. During the three months ended September 30, 2013, net other expense was $1.2 million compared with $1.7 million for the same period in 2012. Substantially all of the net other expense for both periods relates to losses resulting from the change in the fair value of the derivative liability associated with the warrants we issued in equity private placement transactions. In both periods, the fair value of the warrant liability increased, primarily as a result of increases in our stock price during the related period, which resulted in our recording a loss.

Net interest expense for the three months ended September 30, 2013 was $122,000, compared with $79,000 for the same three month period in 2012. The increase relates mostly to amortization of the debt discount arising from the Brainlab loan modification we effected in March 2013.

Nine Months Ended September 30, 2013 Compared to the Nine Months Ended September 30, 2012

($s in thousands)	Nine Months Ended September 30, 2013	2012	Percentage Change
Product and service revenues	$ 2,104	$ 1,246	69%
License revenues	650	1,950	(67)%
Cost of product revenues	888	392	127%
Research and development:			
Research and development costs	2,239	1,749	28%
Reversal of R&D obligations	-	(883)	(100)%
Selling, general and administrative expenses	5,035	4,585	10%
Other income (expense):			
Gain (loss) on change in fair value of derivative liability	1,328	(1,694)	NM
Loss on loan modification	(1,356)	-	NM
Other income, net	408	3	13500%
Interest expense, net	(342)	(2,498)	(86)%
Net loss	(5,370)	(6,836)	(21)%

NM= not meaningful

Product and service revenues. Product and service revenues were $2.1 million for the nine months ended September 30, 2013, and $1.2 million for the same period in 2012, an increase of $858,000, or 69%. Product revenues for the nine months ended September 30, 2013 were $1.8 million compared to $831,000, for the same period in 2012, an increase of $973,000, or 117%. Product revenues included ClearPoint system disposable product sales for the nine months ended September 30, 2013 of $1.2 million, compared with $713,000 for the same period in 2012, an increase of $508,000, or 71%. That increase in disposable product sales resulted from the higher number of ClearPoint procedures that were performed during the nine months ended September 30, 2013. Approximately $586,000 of the product revenues for the nine months ended September 30, 2013 related to the sale of ClearPoint system reusable components compared with $118,000 for the same nine month period in 2012, representing an increase of $467,000 or 394%. During the nine months ended September 30, 2013 and 2012, we recorded development service revenues of $268,000 and $414,000, respectively, a decrease of 35%. We do not expect the development service revenues to be a long-term ongoing source of revenues. Other service revenues, mostly related to installation services and a service agreement, were $28,000 for the nine months ended September 30, 2013. No such revenues were recorded during the same period in 2012.

License revenues. License revenues of $650,000 and $2.0 million for the nine months ended September 30, 2013, and 2012, respectively, related to license fees we received in 2008 from Boston Scientific that were deferred and recognized over the period of our continued involvement with Boston Scientific's development program for the licensed technology. The period of our continued involvement ended on March 31, 2013, thus, all revenues related to the license fees we received in 2008 were recognized as of March 31, 2013.

Cost of Product Revenues. Cost of product revenues was $888,000 for the nine months ended September 30, 2013, compared to $392,000 for the same period in 2012, an increase of 127%. The increase in cost of product revenues was primarily attributable to the 117% increase in product revenues for the same period. Gross margin on product revenues was relatively consistent for both periods.

Research and Development Costs. Research and development costs were $2.2 million for the nine months ended September 30, 2013, compared to $1.7 million for the same nine month period in 2012, an increase of $489,000, or 28%. The primary driver for the increase was costs for research that we sponsored, which increased by $340,000. Sponsored research costs were approximately $243,000 for the nine months ended September 30, 2013 compared with a credit of $97,000 recorded during the same period last year as we negotiated with a research partner to reduce amounts previously invoiced to us, but not yet paid, in order to reflect an adjustment for work outlined in our agreement with the research partner that was not completed. Spending on development related to ClearPoint system software enhancements was approximately $200,000 during the nine months ended September 30, 2013 and no software development costs were incurred during the same period last year. These increases were partially offset by a decrease of $121,000 related to our Key Personnel Incentive Program.

Reversal of R&D Obligation. For the nine months ended September 30, 2012, we recorded a credit to expense of $883,000. This credit was recorded to reverse expenses previously accrued as research and development costs under our Key Personnel Incentive Program. The reversal occurred as a result of the program participants' voluntary and irrevocable relinquishment, in June 2012, of their rights to receive any incentive bonus payments related to performance of services under the program, and our corresponding discharge from our obligations to make any and all such service-based payments. Of the amount reversed, $121,000 of the expense had been recorded during the three months ended March 31, 2012, and the remaining amounts had been accrued as research and development costs in 2010 and 2011.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $5.0 million for the nine months ended September 30, 2013, compared with $4.6 million for the same nine month period in 2012, an increase of $424,000, or 9%. The increase was mostly related to higher sales and marketing expenses, which increased by approximately $880,000, and an increase in professional services of $183,000. These increases were mostly offset by a decrease of $673,000 related to lower share-based compensation expense. The lower share-based compensation expense was primarily due to the common stock warrants we issued during the nine months ended September 30, 2012 to two non-employee directors, two research contributors, a service provider and a long-time financial adviser, compared to the lower number of common stock warrants we issued to a single service provider during the nine months ended September 30, 2013.

Other Income (Expense). We recorded a $1.3 million gain and a $1.7 million loss during the nine months ended September 30, 2013 and 2012, respectively. The gain and the loss resulted from changes in the fair value of the derivative liability associated with the warrants we issued in equity private placement transactions.

During the nine months ended September 30, 2013 we recorded a loss of $1.4 million related to the March 2013 Brainlab loan modification, which included a $1.9 million increase to the principal balance of the note, a decrease in the interest rate from 10% to 5.5%, and the elimination of the note's equity conversion feature. The $1.4 million loss we recorded represented the difference between the carrying amount of the note and related accrued interest immediately prior to the loan modification and the fair value of the note immediately following the loan modification.

Net other income was $383,000 for the nine months ended September 30, 2013, compared with $3,000 for the same period in 2012. Essentially all of the net other income for the nine months ended September 30, 2013 related to negotiated reductions in amounts payable to service providers.

Net interest expense for the nine months ended September 30, 2013 was $342,000, compared with $2.5 million for the same period in 2012. Approximately $2.0 million of the interest expense during the nine months ended September 30, 2012 related to the write-off of debt discounts and deferred financing costs associated with convertible notes that converted into shares of our common stock upon the effectiveness of our Form 10 registration statement in February 2012. The remainder of the decrease related primarily to the conversion of convertible notes payable into shares of our common stock in February 2012, which notes payable were outstanding during a portion of the nine month period ended September 30, 2012. The decrease in net interest expense was also attributable to a February 2012 loan modification pursuant to which the interest rate on our related party notes payable to Boston Scientific was reduced from 10% to 0%.

Liquidity and Capital Resources

For the nine months ended September 30, 2013 and the year ended December 31, 2012, we incurred net losses of $5.4 million and $5.9 million, respectively, and the cumulative net loss from our inception through September 30, 2013 was $71.0 million. We expect such losses to continue through at least the year ended December 31, 2013 as we continue to commercialize our ClearPoint system and pursue research and development activities. Net cash used in operations was $6.3 million and $7.4 million for the nine months ended September 30, 2013 and year ended December 31, 2012, respectively. Since inception, we have financed our activities principally from the sale of equity securities, the issuance of convertible notes and license arrangements.

Our primary financing activities during the nine months ended September 30, 2013 and the year ended December 31, 2012 were:

- our January 2013 equity private placement, which resulted in net proceeds of $9.8 million;
- our July 2012 equity private placement, which resulted in net proceeds of $5.5 million; and
- the unit offering we completed in February 2012, which resulted in net proceeds of $4.9 million, $3.4 million of which we received in 2012 and $1.5 million of which we received in 2011.

While we expect to continue to use cash in operations, we believe our existing cash and cash equivalents at September 30, 2013 of $5.0 million, combined with cash generated from product and service revenues, will be sufficient to meet our anticipated cash requirements through at least March 2014. During the remainder of 2013, we plan to continue to increase our spending on sales and marketing activities as we continue the commercial rollout of our ClearPoint system, from which we expect to increase ClearPoint product revenues. Certain planned expenditures are discretionary and could be deferred if required to do so to fund critical operations. The sale of additional equity or convertible debt securities will likely result in dilution to our current stockholders. 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 additional equity, debt or other securities or through a credit facility, or modify our current business plan. There can be no assurance that we will be able to obtain additional financing on commercially reasonable terms, if at all.

Cash Flows

Cash activity for the nine months ended September 30, 2013 and 2012 is summarized as follows:

	Nine Months Ended September 30,	
($s in thousands)	**2013**	**2012**
Cash used in operating activities	$ (6,264)	$ (5,207)
Cash used in investing activities	$ (174)	$ (93)
Cash provided by financing activities	$ 9,849	$ 8,942
Net increase in cash and cash equivalents	$ 3,411	$ 3,642

We used $6.3 million and $5.2 million of cash for operating activities during the nine months ended September 30, 2013 and 2012, respectively. Net cash used in operating activities during the nine months ended September 30, 2013 primarily reflected our $5.4 million loss from operations, reduced by $988,000 in share-based compensation and $304,000 in depreciation and amortization, but increased by the $652,000 change from year end in deferred revenue and the $1.3 million reduction in accounts payable and accrued expenses. The reductions in accounts payable and accrued expenses occurred as we paid down certain previously existing outstanding balances. Net cash used in operating activities in the nine months ended September 30, 2012 primarily reflected our $2.6 million loss from operations, reduced by $1.7 million in share-based compensation and $309,000 in depreciation and amortization, but increased by the $2.0 million change from year end in deferred revenue, the $2.0 million reduction in accounts payable and accrued expenses, and the $883,000 reversal of an R&D obligation.

Net cash provided by financing activities for the nine months ended September 30, 2013 related to the $9.8 million of net proceeds generated from our January 2013 private placement. Net cash provided by financing activities for the nine months ended September 30, 2012 related to $3.4 million in net proceeds from the unit offering we concluded in February 2012 and the $5.5 million of net proceeds from our July 2012 private placement.

Operating Capital and Capital Expenditure Requirements

To date, we have not achieved profitability. We could continue to incur net losses as we commercialize our ClearPoint system products, continue to develop the ClearTrace system, expand our corporate infrastructure 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 products and complete the development of our product candidates. Our future capital requirements will depend on many factors, including, but not limited to, the following:

- 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 scope, rate of progress and cost of our research and development activities;
- the achievement of milestone events under, and other matters related to, our agreements with Boston Scientific and Siemens Aktiengellseschaft, Healthcare Sector, or Siemens;
- 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.

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 received 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 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 information required to be disclosed by us in the reports that we file or submit under the Exchange Act 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 September 30, 2013 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 at September 30, 2013.

Changes in Internal Control Over Financial Reporting

Except as noted below, there were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

In connection with the preparation of our financial statements as of June 30, 2013, and for the three and six months then ended, we determined that we should have used derivative liability accounting to account for the warrants we issued in our July 2012 equity private placement in recording the net proceeds received, due to the down round provision associated with the exercise price of the warrants. We previously recorded all of the net proceeds from our July 2012 equity private placement as equity. In addition, in accounting for the warrants we issued in our January 2013 equity private placement, we did apply derivative liability accounting; however, the valuation model we used to determine the fair value of the warrants only considered the net cash settlement feature which gives the warrant holder the right to net cash settlement in the event certain transactions occur. In determining fair value, we should have included other scenarios that did not result in application of the net cash settlement feature and should have also considered the down round provision in determining the fair value of the warrants.

We have changed our internal control procedures to include the engagement of a third-party specialist, in connection with any significant financing transaction that includes complex instruments, for advice and consultation in determining the appropriate accounting. In addition, we have implemented a procedure requiring key financial personnel to undergo additional training in the areas of accounting for derivatives and financing transactions.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

As we previously reported in our Quarterly Report on Form 10-Q that was filed with the SEC on August 14, 2013, in June 2013, Custom Equity Research, Inc. d/b/a Summer Street Research Partners, or Summer Street, commenced an arbitration proceeding alleging breach of contract and quantum meruit claims against us. Summer Street claims, among other things, that we owe Summer Street $480,000 in cash commissions, as well as warrants to purchase 460,338 shares of our common stock, in connection with our engagement of Summer Street to serve as our financial advisor and placement agent for two financing transactions we undertook in 2011 and 2012, respectively. As required under our engagement agreements with Summer Street, the arbitration has been brought before JAMS, The Resolution Experts, which is an alternative dispute resolution provider. In the arbitration, we have filed counter-claims against Summer Street alleging fraud and misrepresentation, abuse of process and malicious prosecution, and we are seeking unspecified monetary damages from Summer Street in connection with our counter-claims. The arbitration proceeding is at a preliminary stage. We intend to vigorously defend ourselves and pursue our counter-claims against Summer Street in the arbitration.

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 11, 2013. In addition, the risks described under, and the caption entitled, "We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets or other proprietary information of their former employers." included under Part 1, Item 1A "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 11, 2013 have been removed.

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 revenues from sales of our products, we may never achieve or sustain profitability.*

As of September 30, 2013, we had an accumulated deficit of approximately $71.0 million. The accumulated deficit has resulted principally from costs incurred in our research and development efforts and general operating expenses. We have incurred significant losses in each year since our inception in 1998. Net losses were approximately $5.4 million for the nine months ended September 30, 2013, approximately $5.9 million for the year ended December 31, 2012, approximately $8.3 million for the year ended December 31, 2011, and approximately $9.5 million for the year ended December 31, 2010. We may continue to incur operating losses as we continue to invest capital in the sales and marketing of our products, development of our product candidates and development 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 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' equity (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 vast majority of our revenues for at least the next several 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, increased demand for the MRI suite, and the familiarity of the physician with other devices and approaches.

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.

If we are unable to expand our sales and clinical support capabilities, we may be unable to generate significant product revenues.*

We are dependent on our sales personnel to obtain new customers for our ClearPoint system, and we are dependent on both our sales and clinical support personnel to increase sales of our ClearPoint products to existing customers. We expect to continue building our sales and clinical support team to market and sell our ClearPoint system products, and to provide clinical support for customer use of 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 delayed. Our ability to achieve significant revenue growth will depend, in large part, on our success in recruiting, training and retaining a sufficient number of qualified sales and clinical support 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. If we are unable to hire, train and retain sufficient numbers of effective personnel, or our personnel are not successful in obtaining new customers or increasing sales to our existing customer base, our business will be harmed.

We have entered into a co-development and distribution agreement with Brainlab pursuant to which 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.

If hospitals and physicians are unable to obtain adequate coverage and reimbursement from third-party payors for procedures utilizing our ClearPoint system, our revenues and prospects for profitability will suffer.*

Our ClearPoint system components 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 medical devices such as our ClearPoint system. Therefore, our ability to successfully commercialize our ClearPoint system depends significantly on the adequacy of coverage and reimbursement from these third-party 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 product is 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. Some hospitals could believe third-party reimbursement levels are not adequate to cover the cost of our ClearPoint system. 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.

The Affordable Care Act 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 will likely result in increased coordination between hospitals and physicians resulting in the alignment of financial incentives between hospitals and physicians to control hospital costs. Most significantly, the Affordable Care Act provides for the establishment of a Medicare shared savings program, which went into effect in 2012, 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.

The Affordable Care Act will ultimately increase the overall pool of persons with access to health insurance in the United States. However, with the increase in demand for healthcare services, we expect both a strain on the capacity of the healthcare system and more proposals by legislators, regulators and third-party payors to keep healthcare costs down. Certain proposals, if passed, could impose limitations on the prices we will be able to charge for our ClearPoint system, or the amounts of reimbursement available from governmental agencies or third-party payors. These limitations could have a material adverse effect on our financial position and results of operations.

Federal healthcare reform continues to be a political issue, and 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 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 ClearPoint system, 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 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, 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 could adversely impact the operations and finances of hospitals, reducing their ability to purchase medical devices, such as our products. Further, Congress has not yet addressed in a comprehensive and permanent manner the pending reduction in Medicare payments to physicians under the sustainable growth rate formula, which if not resolved will likely result in an overall reduction in physicians willing to participate in Medicare.

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

We have CE marking approval to market our ClearPoint system in the European Union, which subjects us to rules and regulations in the European Union relating to our products. As part of our product development and regulatory strategy, we also intend to market our ClearPoint system in other foreign jurisdictions. 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 foreign currency exchange rates and currency controls;
- 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 United States 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.

We may not realize the anticipated benefits from our collaborative agreement with Siemens regarding the ClearTrace system.*

In May 2009 we entered into a co-development agreement with Siemens with respect to the development of the hardware and MRI software necessary for the ClearTrace system. Development efforts are ongoing, and there can be no assurance that development efforts will be successful or that development of the ClearTrace system hardware and MRI software will be completed. The progress of the development efforts for the ClearTrace system, including both the hardware and the MRI software, has been, and may continue to be, negatively impacted by our focus on the commercialization of our ClearPoint system.

Under our co-development agreement, through September 30, 2013 we had paid Siemens approximately $1.4 million in connection with Siemens' MRI software development work. The co-development agreement provides that, once the software for the ClearTrace system is commercially available, Siemens will pay us a fixed amount for each software license sold by Siemens until we recoup our investment in the software. However, if our agreement with Siemens is terminated, or if Siemens does not commercialize the software, we will not recover our investment in the software.

Our future success may depend on our ability to obtain regulatory clearances or approvals for the ClearTrace system. We cannot be certain that we will be able to do so in a timely fashion, or at all.

The ClearTrace system is still under development. To date, we have conducted only animal studies and other preclinical work with respect to the ClearTrace system. We cannot predict a timetable for completion of our development activities, and there can be no assurance that the development efforts will be successfully completed. Accordingly, we are not able to estimate when we will make a filing seeking regulatory approval or clearance to market the ClearTrace system in the United States or in any foreign market.

In the United States, without clearance or approval from the FDA we cannot market a new medical device, or a new use of, or claim for, or significant modification to, an existing product, unless an exemption applies. To obtain FDA clearance or approval, we must first receive either premarket clearance under Section 510(k) of the federal Food, Drug, and Cosmetic Act or approval of a premarket approval application, or PMA, from the 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.

The FDA or any applicable foreign authority may not act favorably or quickly in its review of any regulatory submission that we may file. Additionally, we may encounter significant difficulties and costs in obtaining clearances or approvals. If we are unable to obtain regulatory clearances or approvals for the ClearTrace system, or otherwise experience delays in obtaining regulatory clearances or approvals, the commercialization of the ClearTrace system will be delayed or prevented, which will adversely affect our ability to generate revenues. Such delay may also result in the loss of potential competitive advantages that might otherwise be attained by bringing products to market earlier than competitors. Any of these contingencies could adversely affect our business. 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.

Assuming successful completion of development activities, we anticipate that the initial market for the ClearTrace system would be the European Union and, at the appropriate time, we would expect to seek CE marking approval for the ClearTrace system. The ClearTrace system consists of several components, including an ablation catheter. The FDA has determined that ablation catheters specifically indicated to treat atrial fibrillation require the submission of a PMA. Therefore, in the United States, we would be required to pursue the PMA process in order to specifically indicate our ablation catheter for the treatment of atrial fibrillation.

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. In the future, we could seek to obtain additional, more specific indications for use of our ClearPoint system beyond the general neurological intervention claim, although we have no present plan to do so. Some of these expanded claims could require FDA 510(k) clearance. Other claims could require 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 the ClearTrace system or any new indications for use for our ClearPoint system will be expensive and may require the enrollment of large numbers of suitable patients, who may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new product candidates and will adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to support 510(k) clearance or PMA approval for the 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, will 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 may require the enrollment of large numbers of patients, and suitable patients may 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 may 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 may 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 may 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 the 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, Inc., 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 the ClearTrace system incorporate 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 the ClearTrace system are 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, the coverage is subject to deductibles and limitations, and may not be adequate to cover future 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 products may be used;
- loss of revenue; and
- an inability to commercialize product candidates.

We may not realize the anticipated benefits from our license and development agreements with Boston Scientific.

We entered into license and development agreements with Boston Scientific with respect to our MRI-safety technologies, pursuant to which Boston Scientific could incorporate our MRI-safety technologies into Boston Scientific's implantable medical leads for cardiac and neuromodulation applications. There is no assurance that Boston Scientific will advance development efforts to incorporate our technologies into its product candidates, that any such development efforts will be successful or that patents will issue on any patent applications we licensed to Boston Scientific, in which case we would not receive future milestone payments or royalties provided for under our agreements with Boston Scientific. Further, Boston Scientific has no obligation to include our licensed intellectual property in its products or product candidates. Even if Boston Scientific incorporates our licensed intellectual property into its product candidates, Boston Scientific may be unable to obtain regulatory clearance or approval or successfully commercialize the related products, in which case we would not receive product royalties. To our knowledge, our licensed intellectual property has not been incorporated into any of Boston Scientific's currently commercialized products.

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 January 2013, we raised $11.0 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 cost and timing of expanding our sales, clinical support, marketing and distribution capabilities and other corporate infrastructure;
- the cost of establishing product inventories;
- the effect of competing technological and market developments;
- the scope, rate of progress and cost of our research and development activities;
- the achievement of milestone events under, and other matters related to, our agreements with Boston Scientific and Siemens;
- 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 capital may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that 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 raise additional funds through collaboration or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or products or grant licenses on terms that are not favorable to us. Any of these events could adversely affect our ability to achieve our product development and commercialization goals and have a material adverse effect on our business, financial condition and results of operations.

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 marketed 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 marketed products or product candidates, or if any protection is reduced or eliminated, others could use the intellectual property covering our marketed 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 critical third-party software that is integrated into our ClearPoint system software, our costs could increase and sales 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 commercialize our ClearPoint system 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.

We will be required to assign some of our intellectual property to Boston Scientific if we fail to satisfy certain financial requirements.*

During 2009, Boston Scientific loaned us $3.5 million pursuant to the terms of three convertible promissory notes. Those loans mature in October, November and December 2014, respectively. While those loans remain outstanding, we must comply with the following requirements: (1) we must pay when due all of our payroll obligations; (2) we must not suffer an event of default under any indebtedness for borrowed money; and (3) we must have a net working capital ratio, which is defined as our current assets divided by our current liabilities other than deferred revenue and derivative liabilities, of at least 0.80 as of the end of each month.

If we fail to meet any of those requirements while our loans from Boston Scientific are outstanding, we will be required to assign Boston Scientific title to the patents and patent applications that we own and that we license to Boston Scientific. However, upon any such assignment to Boston Scientific, Boston Scientific will grant us an exclusive, royalty-free, perpetual worldwide license to the same patents and patent applications in all fields of use outside neuromodulation and implantable medical leads for cardiac applications. As of September 30, 2013, our licensing arrangements with Boston Scientific included seven wholly-owned issued United States patents, two wholly-owned pending United States patent applications, 10 wholly-owned issued foreign patents, four wholly-owned pending foreign patent applications, 10 co-owned issued United States patents, seven co-owned pending United States patent applications, 14 co-owned issued foreign patents and 15 co-owned pending foreign patent applications.

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 FDA 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 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 have not been inspected by the FDA for QSR compliance. 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, or HIPAA, which, in addition to the privacy and security rules normally associated with HIPAA, 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. On February 1, 2013, CMS issued the final rule to implement this so-called "Sunshine" provision of the Affordable Care Act. Under the final rule, we are subject to the data collecting, reporting and public disclosure obligation. Data collecting obligations began August 1, 2013, and the initial reporting obligations must be satisfied by March 31, 2014. Reported data will be made publicly available by September 30, 2014. 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 its implementing regulations, known as the HIPAA Privacy and Security Rules, 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, 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 most states have 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. These violations may lead to sanctions that will adversely affect our business.

Risks Related to Facilities, Employees and Growth

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

We are highly dependent on members of our senior management, in particular Kimble L. Jenkins, our President, Chief Executive Officer and Chairman of the Board of Directors. The loss of members of our senior management team, sales and clinical support team or 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. We do not maintain key employee life insurance on any of our personnel other than for Mr. Jenkins. Although we have obtained key employee insurance covering Mr. Jenkins in the amount of $2,000,000, this would not fully compensate us for the loss of Mr. Jenkins' services.

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 and clinical support 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 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 will conduct a significant portion of our activities, including 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 common 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 Exchange Act and its rules. The 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;
- a broker-dealer must furnish its customer 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.*

In August 2012 and February 2013, we filed registration statements with the SEC covering certain outstanding shares of our common stock and shares of our common stock underlying certain warrants held by some of our existing securityholders. Those registration statements initially became effective in September 2012 and March 2013, respectively, and amendments to those registration statements became effective in April 2013 and October 2013, respectively. As such, all of the shares of our common stock currently covered by those registration statements are freely transferable, unless held by an affiliate of ours. In addition to the shares of our common stock currently covered by those registration statements, as of October 31, 2013, approximately 37.7 million of our outstanding shares were freely transferable or could be publicly resold pursuant to Rule 144 under the Securities Act. Of those shares, approximately 7.1 million shares were held by our affiliates and approximately 30.6 million shares were held by non-affiliates of the company. 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 the registration statements, 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.

Our directors, executive officers and their respective affiliates have significant influence over our affairs and could delay or prevent a change in corporate control.*

As of October 31, 2013, our directors and executive officers, together with their affiliates, beneficially owned, in the aggregate, 20.3% of our common stock. As a result, these stockholders, acting together, have significant influence over the management and affairs of our company. Accordingly, this concentration of ownership could have the effect of:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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 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 of 2002, as amended, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We 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.

We will incur significant costs as a result of operating as a public company, and our management will be required to divert attention from product commercialization and development and to devote substantial resources and time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We are working with our independent legal and accounting advisors to identify those areas in which changes should be made to our financial and management control systems to manage our growth and our obligations as a public company. These areas include corporate controls and financial reporting and accounting systems, including requirements under the Sarbanes-Oxley Act. Despite recent reforms as a result of the enactment of the JOBS Act, we will incur costs associated with our public company reporting requirements and corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and any securities exchange on which our stock trades, particularly after we are no longer an emerging growth company. We may need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees or as executive officers.

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

During the three months ended September 30, 2013, holders of warrants to purchase an aggregate of 699,023 shares of our common stock exercised their warrants. Of that aggregate number, warrants to purchase 625,000 shares, having an exercise price of $0.01 per share, were exercised for cash proceeds totaling $6,250, which we intend to use for general corporate purposes. The remaining warrants, having an exercise price of $0.60 per share, were exercised on a cashless basis, which resulted in the net issuance of 37,914 shares of our common stock. Therefore, we issued a total of 662,914 shares of our common stock upon exercise of warrants during the three months ended September 30, 2013.

In September 2013, we issued an aggregate of 24,760 shares of common stock to eight non-employee directors under our Non-Employee Director Compensation Plan. These shares were issued in payment of compensation owed to the non-employee directors under that plan. The shares were issued at a price equal to the volume-weighted average price of our common stock for the five-trading day period ended September 30, 2013. These shares were subsequently registered on Form S-8 filed with the SEC on October 25, 2013.

We claimed exemption from registration under the Securities Act for the sales and issuances of the securities in the transactions described above by virtue of Section 4(a)(2) of the Securities Act and/or Rule 506 of Regulation D adopted thereunder. Such sales and issuances did not involve any public offering, were made without general solicitation or advertising and each purchaser was a sophisticated investor with access to all relevant information necessary to evaluate the investment. In addition, for cashless exercise of warrants as described above, we also claimed exemption from registration pursuant to Section 3(a)(9) of the Securities Act.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

Not applicable.

ITEM 6. EXHIBITS.

The exhibits listed in the accompanying Exhibit Index are filed, 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: November 13, 2013

MRI INTERVENTIONS, INC.

By: /s/ Kimble L. Jenkins
Kimble L. Jenkins
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	000-54575	4.2	February 9, 2012
10.1†	Third Amendment to the Master Services and Licensing Agreement, dated as of July 28, 2013, by and between Merge Healthcare Canada Corp. and MRI Interventions, Inc.	10-Q	000-54575	10.56	August 14, 2013
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.

** Pursuant to Rule 406T of Regulation S-T adopted by the SEC, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act of 1933, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, and otherwise are not subject to liability under these sections.

\+ 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.

† Confidential treatment granted under Rule 24b-2 under the Securities Exchange Act of 1934. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been filed separately with the Securities and Exchange Commission pursuant to the confidential treatment request.

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934

I, Kimble L. Jenkins, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended September 30, 2013, of MRI Interventions, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2013

/s/ Kimble L. Jenkins
Kimble L. Jenkins
Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934

I, David W. Carlson, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended September 30, 2013, of MRI Interventions, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2013

/s/ David W. Carlson
David W. Carlson
Chief Financial Officer

Exhibit 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 63 OF TITLE 18 OF THE UNITED STATES CODE

Each of the undersigned, Kimble L. Jenkins and David W. Carlson, certifies pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and Section 1350 of Chapter 63 of Title 18 of the United States Code, that (1) this quarterly report on Form 10-Q for the quarter ended September 30, 2013, of MRI Interventions, Inc. (the "Company") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, and (2) the information contained in this report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2013

/s/ Kimble L. Jenkins
Kimble L. Jenkins
Chief Executive Officer

/s/ David W. Carlson
David W. Carlson
Chief Financial Officer