



**MRI Interventions, Inc.**

**19,045,808 Shares of Common Stock**

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This prospectus supplement relates to the prospectus dated September 24, 2012, which permits the resale of up to 13,490,434 outstanding shares of our common stock, and 5,555,374 shares of our common stock issuable upon the exercise of outstanding warrants, by the selling securityholders identified in the prospectus, as amended and supplemented from time to time. We will pay the expenses of registering the shares, but we are not selling any shares of common stock in this offering and therefore will not receive any proceeds from this offering. We will, however, receive the exercise price of the warrants if and when the warrants are exercised for cash by the securityholders.

This prospectus supplement is being filed to update, amend, and supplement the information previously included in the prospectus with the information contained in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 (the "10-Q"). Accordingly, we have attached the 10-Q to this prospectus supplement. You should read this prospectus supplement together with the prospectus, which is to be delivered with this prospectus supplement.

Our common stock is traded in the over-the-counter market and is quoted on the OTC Bulletin Board under the symbol MRIC. On November 12, 2012, the last reported sale price of our common stock was \$1.90 per share.

*We are an "emerging growth company" under the federal securities laws and will be subject to reduced public company reporting requirements. Investing in our common stock involves risk. See "Risk Factors" beginning on page 7 of the prospectus, as amended and supplemented by the "Risk Factors" beginning on page 34 of the 10-Q, to read about factors you should consider before buying shares of our common stock.*

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

The date of this prospectus supplement is November 14, 2012.

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

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**

(State or Other Jurisdiction  
of Incorporation or Organization)

**58-2394628**

(IRS Employer  
Identification Number)

**One Commerce Square, Suite 2550**

**Memphis, Tennessee**  
(Address of Principal Executive Offices)

**38103**

(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

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, 2012, there were 48,018,000 shares of common stock outstanding.

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MRI INTERVENTIONS, INC.

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## SAFE-HARBOR STATEMENT

This Quarterly Report on Form 10-Q contains “forward-looking statements” as defined under U.S. federal securities laws. These statements reflect management’s current knowledge, assumptions, beliefs, estimates and expectations and express management’s current views of future performance, results and trends, and may be identified by their use of terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will,” and other similar terms. Forward-looking statements are subject to a number of risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements. Readers should not place undue reliance on forward-looking statements. Such statements are made as of the date of this Quarterly Report, and we undertake no obligation to update such statements after this date.

Risks and uncertainties that could cause our actual results to materially differ from those described in forward-looking statements include those discussed in our filings with the Securities and Exchange Commission (including those described in Item 1A of Part II and elsewhere in this Quarterly Report) and the following:

- demand and market acceptance of our products;
  - our ability to successfully expand our sales and marketing capabilities;
  - product quality or patient safety issues, which could lead to product recalls, withdrawals, launch delays, sanctions, seizures, litigation, or declining sales;
  - our dependence on collaborative relationships and licensing arrangements;
  - our ability to successfully complete the development of, and to obtain regulatory clearance or approval for, future products, including our current product candidates;
  - sufficiency of our cash resources to maintain planned commercialization efforts and research and development programs;
  - the healthcare reform legislation and its implementation, and possible additional legislation, regulation and other governmental pressures in the United States or globally, which may affect pricing, reimbursement, taxation and rebate policies of government agencies and private payors or other elements of our business;
  - our ability to identify business development and growth opportunities for existing or future products;
  - individual, group or class action litigation alleging product liability claims;
  - future actions of the FDA or any other regulatory body or government authority that could delay, limit or suspend product development, manufacturing or sale or result in seizures, injunctions, monetary sanctions or criminal or civil liabilities;
  - our ability to enforce our patent rights or patents of third parties preventing or restricting the manufacture, sale or use of affected products or technology; and
  - any impact of the commercial and credit environment on us and our customers and suppliers.
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**MRI INTERVENTIONS, INC.**  
**Condensed Balance Sheets**  
(Unaudited)

	<u>September 30,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u>
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 3,787,252	\$ 145,478
Accounts receivable	186,054	401,580
Inventory	939,744	968,818
Prepaid expenses and other current assets	<u>129,873</u>	<u>19,773</u>
Total current assets	5,042,923	1,535,649
<b>Property and equipment, net</b>	1,281,730	1,218,830
<b>Software license inventory</b>	1,137,500	-
<b>Deferred costs</b>	-	214,469
<b>Other assets</b>	<u>31,400</u>	<u>61,481</u>
Total assets	<u>\$ 7,493,553</u>	<u>\$ 3,030,429</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 2,535,348	\$ 4,037,168
Accrued compensation	347,947	1,011,413
Accrued interest	-	971,733
Other accrued liabilities	1,305,622	2,015,046
Derivative liability	7,439	-
Related party deferred revenue	2,046,374	2,600,000
Convertible notes payable, net of unamortized discount of \$117,405 at December 31, 2011	<u>-</u>	<u>3,953,595</u>
Total current liabilities	6,242,730	14,588,955
<b>Related party deferred revenue</b>	-	1,396,374
<b>Related party accrued interest</b>	-	799,102
<b>Other accrued liabilities</b>	498,474	209,143
<b>Related party convertible notes payable, net of unamortized discount of \$0 and \$432,706 at September 30, 2012 and December 31, 2011, respectively</b>	4,338,601	4,377,294
<b>Convertible notes payable, net of unamortized discount of \$0 and \$316,610 at September 30, 2012 and December 31, 2011, respectively</b>	2,000,000	3,308,390
<b>Junior secured notes payable, net of unamortized discount of \$2,808,977 and \$2,805,686 at September 30, 2012 and December 31, 2011, respectively</b>	<u>191,023</u>	<u>194,314</u>
Total liabilities	<u>13,270,828</u>	<u>24,873,572</u>
<b>Commitments and contingencies (Notes 5, 8 and 9)</b>	-	-
<b>Stockholders' deficit:</b>		
Series A convertible preferred stock; \$.01 par value; 8,000,000 shares authorized, 7,965,000 shares issued and outstanding at December 31, 2011	-	7,965,000
Common stock, \$.01 par value; at September 30, 2012, 100,000,000, 48,168,760, and 47,842,930 shares authorized, issued, and outstanding, respectively; at December 31, 2011, 70,000,000, 16,410,820, and 16,084,990 shares authorized, issued, and outstanding, respectively	481,687	164,108
Additional paid-in capital	60,357,805	31,495,593
Treasury stock, at cost, 325,830 common shares	(1,679,234)	(1,679,234)
Accumulated deficit	<u>(64,937,533)</u>	<u>(59,788,610)</u>
Total stockholders' deficit	<u>(5,777,275)</u>	<u>(21,843,143)</u>
Total liabilities and stockholders' deficit	<u>\$ 7,493,553</u>	<u>\$ 3,030,429</u>

See accompanying notes.

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2012</u>	<u>2011</u>	<u>2012</u>	<u>2011</u>
<b>Revenues:</b>				
Related party license revenues	\$ 650,000	\$ 650,000	\$ 1,950,000	\$ 1,950,000
Service revenues	163,381	-	414,115	-
Product revenues	318,447	504,902	831,472	703,983
Total revenues	<u>1,131,828</u>	<u>1,154,902</u>	<u>3,195,587</u>	<u>2,653,983</u>
<b>Costs and operating expenses:</b>				
Cost of product revenues	133,371	308,020	391,797	421,357
Research and development:				
Research and development costs	573,562	909,910	1,749,253	3,133,635
Reversal of R&D obligation (see Note 9)	-	-	(882,537)	-
Selling, general, and administrative	1,441,934	1,367,644	4,585,082	3,709,120
Total costs and operating expenses	<u>2,148,867</u>	<u>2,585,574</u>	<u>5,843,595</u>	<u>7,264,112</u>
Operating loss	(1,017,039)	(1,430,672)	(2,648,008)	(4,610,129)
<b>Other income (expense):</b>				
Other income (expense), net	21,112	480	(3,513)	(2,431)
Interest income	7,200	425	10,180	3,218
Interest expense	(85,828)	(705,839)	(2,507,582)	(1,846,164)
<b>Net loss</b>	<u>\$ (1,074,555)</u>	<u>\$ (2,135,606)</u>	<u>\$ (5,148,923)</u>	<u>\$ (6,455,506)</u>
<b>Net loss per share attributable to common stockholders:</b>				
Basic and diluted	<u>\$ (0.02)</u>	<u>\$ (0.13)</u>	<u>\$ (0.14)</u>	<u>\$ (0.41)</u>
<b>Weighted average shares outstanding:</b>				
Basic and diluted	<u>47,531,093</u>	<u>16,041,240</u>	<u>37,807,188</u>	<u>15,919,249</u>

See accompanying notes.

**MRI INTERVENTIONS, INC.**  
**Condensed Statement of Stockholders' Deficit**  
**Nine Months Ended September 30, 2012**  
**(Unaudited)**

	<u>Convertible Preferred Stock Series A</u>		<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Treasury Stock</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
Balances, January 1, 2012	7,965,000	\$ 7,965,000	16,084,990	\$ 164,108	\$31,495,593	\$(1,679,234)	\$ (59,788,610)	\$(21,843,143)
Employee share-based compensation	-	-	-	-	842,644	-	-	842,644
Beneficial conversion feature of convertible notes payable	-	-	-	-	383,204	-	-	383,204
Warrants issued with convertible notes payable	-	-	-	-	383,204	-	-	383,204
Fair value of warrants issued to placement agents and subagents	-	-	-	-	237,299	-	-	237,299
Conversion of convertible notes and accrued interest into common stock	-	-	16,397,727	163,977	11,216,232	-	-	11,380,209
Conversion of Series A preferred stock into common stock	(7,965,000)	(7,965,000)	7,965,000	79,650	7,885,350	-	-	-
Non-employee share based compensation	-	-	-	-	808,636	-	-	808,636
Common stock issued in exchange for settlement of software license obligations	-	-	1,500,000	15,000	1,647,500	-	-	1,662,500
July 2012 unit offering	-	-	5,454,523	54,545	5,461,950	-	-	5,516,495
Exercise of options and warrants	-	-	440,690	4,407	(3,807)	-	-	600
Net loss for the nine months ended September 30, 2012	-	-	-	-	-	-	(5,148,923)	(5,148,923)
Balances, September 30, 2012	-	\$ -	<u>47,842,930</u>	<u>\$ 481,687</u>	<u>\$60,357,805</u>	<u>\$(1,679,234)</u>	<u>\$ (64,937,533)</u>	<u>\$ (5,777,275)</u>

See accompanying notes.

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

	<b>Nine Months Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (5,148,923)	\$ (6,455,506)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and license amortization	309,987	249,203
Share-based compensation	1,651,280	757,200
Loss on change in fair value of derivative liability	7,439	-
Amortization and write-off of debt issuance costs and original issue discounts (see Note 8)	2,056,552	1,042,097
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	215,526	(198,537)
Inventory	(237,057)	40,720
Prepaid expenses and other current assets	(110,100)	9,838
Other assets	16,581	20,000
Accounts payable and accrued expenses	(2,018,300)	1,682,172
Related party deferred revenue	(1,950,000)	(1,950,000)
<b>Net cash flows from operating activities</b>	<b>(5,207,015)</b>	<b>(4,802,813)</b>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(93,256)	(16,655)
<b>Net cash flows from investing activities</b>	<b>(93,256)</b>	<b>(16,655)</b>
<b>Cash flows from financing activities:</b>		
Net proceeds from issuance of convertible notes	3,424,950	3,310,000
Net proceeds from PIPE financing	5,516,495	-
Proceeds from warrant exercise	600	2,250
<b>Net cash flows from financing activities</b>	<b>8,942,045</b>	<b>3,312,250</b>
<b>Net change in cash and cash equivalents</b>	<b>3,641,774</b>	<b>(1,507,218)</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>145,478</b>	<b>1,577,314</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 3,787,252</b>	<b>\$ 70,096</b>
<b>SUPPLEMENTAL CASH FLOW INFORMATION</b>		
<b>Cash paid for:</b>		
Income taxes	\$ -	\$ -
Interest	\$ 26,274	\$ -

See accompanying notes.



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

**NON-CASH TRANSACTIONS:**

- In February 2012, the terms of related party notes payable were modified (see Note 6) 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 (see Note 7). 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 (see Note 7).
- 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 (see Note 7) were recorded as additional paid-in capital and a discount to the convertible notes payable.
- ClearPoint reusable components were transferred from inventory to loaned systems, which is a component of property and equipment, with costs of \$266,131 and \$348,455 during the nine months ended September 30, 2012 and 2011, respectively.
- 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 (see Note 9).

See accompanying notes.

**MRI INTERVENTIONS, INC.**  
**Notes to Condensed Financial Statements**  
**As of and for the Three and Nine Months Ended September 30, 2012**  
**(Unaudited)**

**1. Description of the Business and Management's Plans**

MRI Interventions, Inc. (the "Company") is a medical device company that is 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, or MRI, guidance while performing minimally invasive surgical procedures. The Company was incorporated in the State of Delaware on March 12, 1998.

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 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 (see Note 5) with affiliates of Boston Scientific Corporation ("BSC"), pursuant to which BSC may incorporate certain of the Company's MRI-safety technologies into BSC's implantable leads for cardiac and neurological applications.

*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, 2011 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 the Securities and Exchange Commission (SEC) rules for interim financial information, and, therefore, omit certain information and footnote disclosure necessary to present the statements in accordance with generally accepted accounting principles in the United States ("GAAP"). These condensed financial statements should be read in conjunction with the audited financial statements and notes thereto included in Amendment No. 2 to the Company's Registration Statement on Form 10 ("Form 10") filed with the SEC on February 28, 2012. The accompanying condensed balance sheet as of December 31, 2011 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, 2012 may not be indicative of the results to be expected for the entire year or any future periods.

*Liquidity and Management's Plans*

Since inception, the Company has financed its activities principally from the sale of equity securities, borrowings, and license arrangements. In July 2012, the Company completed a private offering (see Note 8) in which it sold securities for net proceeds of approximately \$5,516,000. The Company intends to fund its future commercialization and development activities and its working capital needs largely from existing cash on hand, borrowings and/or from the sale of equity securities until funds provided by operations are sufficient to meet working capital requirements. Management believes that the Company's existing cash resources together with cash generated from sales of products, will be sufficient to meet anticipated cash requirements through the first quarter of 2013. There can be no assurance that the Company will be successful in meeting its financing requirements on reasonably commercial terms, or at all, or that the Company will generate revenues sufficient to cover its costs.

The accompanying condensed financial statements have been prepared assuming the Company will continue as a going concern. For the nine month period ended September 30, 2012 and for the years ended December 31, 2011 and 2010, the Company incurred net losses of \$5,148,923, \$8,311,410, and \$9,454,235, respectively, and the cumulative net loss since the Company's inception through September 30, 2012 is \$64,937,533. In view of these matters, the ability of the Company to continue as a going concern is dependent upon its ability to generate additional financing sufficient to commercialize its developed products, support its research and development activities and obtain future regulatory clearances or approvals, and ultimately to generate revenues sufficient to cover all costs.

In December 2011, the Company filed a Form 10 with the SEC to register the Company's common stock as a class of equity securities under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). On February 27, 2012, the Form 10 became effective. As such, the Company became a public reporting company subject to the periodic reporting requirements of the Exchange Act.

**MRI INTERVENTIONS, INC.**  
**Notes to Condensed Financial Statements**  
**As of and for the Three and Nine Months Ended September 30, 2012**  
**(Unaudited)**

**2. Summary of Significant Accounting Policies**

*Fair Value Measurements*

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 to quoted prices in active markets for identical assets and liabilities (“Level 1”) and the lowest priority to unobservable inputs (“Level 3”).

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, 2012:

	<u>Carrying Value</u>	<u>Estimated Fair Value</u>
Related party BSC convertible notes payable	\$ 4,338,601	\$ 3,553,042
Convertible note payable	2,000,000	2,000,000
Junior secured notes payable	191,023	1,875,042

The difference between the carrying value of the related party BSC convertible notes payable, which is equal to the face value due to troubled debt restructuring accounting (see Note 6), 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 to an 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.

See Note 6 for fair value information related to the Company’s derivative liability.

*Inventory*

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

*Revenue Recognition*

The Company’s revenues arise from: (1) sales of ClearPoint system reusable components, including associated installation services; (2) sales of ClearPoint disposable products; and (3) license and development arrangements. The Company recognizes revenue, in accordance with Accounting Standards Codification (“ASC”) 605-10-S99, Revenue Recognition, when persuasive evidence of an arrangement exists, the fee is fixed or determinable, collection of the fee is probable and risk of loss has transferred to the customer. For all product sales, the Company requires either a purchase agreement or a purchase order as evidence of an arrangement.

(1) *Sales of ClearPoint system reusable components* - When selling directly to end customers, revenues related to sales of ClearPoint system reusable components 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 system installation. When selling to a distributor, revenues related to sales of ClearPoint system reusable components are recognized at the time risk of loss passes. ClearPoint system reusable components include software. This software is incidental to the utility of the ClearPoint system as a whole, and as such, the provisions of ASC 985-605, Software Revenue Recognition, are not applicable. ClearPoint system reusable component sales were approximately \$118,000 and \$435,000 during the nine months ended September 30, 2012 and 2011, respectively.

**MRI INTERVENTIONS, INC.**  
**Notes to Condensed Financial Statements**  
**As of and for the Three and Nine Months Ended September 30, 2012**  
**(Unaudited)**

(2) *Sales 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, which is generally at shipping point or delivery to the customer's location, based on the specific terms with that customer.

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

- *Related Party Revenue Recognition under BSC Neuro Agreement (Note 5)* - The Company analyzed whether the components of the arrangement represent separate units of accounting as defined by GAAP. Application of these standards requires subjective determinations and requires management to make judgments about the value of the individual elements and whether delivered elements are separable from the other aspects of the contractual relationship. The Company determined it does not have clear and objective evidence of fair value of the various elements of the agreement and, therefore, under GAAP regarding Multiple-Element Arrangements, the deliverables are being treated as one unit of accounting.

This agreement requires the achievement of specified milestones in the development of an MRI-safe implantable lead by December 31, 2012. If the milestones are not achieved by that date and this failure is not the result of BSC Neuro's failure to reasonably cooperate with the Company in pursuing the milestones, the Company will be required to repay BSC Neuro certain amounts, including any development expenses and milestone payments previously made to the Company under this agreement and any patent prosecution costs incurred by BSC Neuro with respect to the intellectual property licensed under this agreement. The existence of this provision indicates the sales price is not fixed or determinable and all monies which have been or will be received prior to December 31, 2012 have and will be deferred until such time. If the repayment obligations are not triggered as of December 31, 2012, the related party deferred revenue related to this agreement will be recognized over the estimated period of continuing involvement. If the repayment obligations are triggered as of December 31, 2012, the related party deferred revenue related to this contract will be repaid to BSC Neuro.

The agreement includes research and development service performance requirements. The Company has recorded deferred research and development services revenue along with the related costs (charged to expense) on a gross basis since the Company is obligated and bears all credit risk with respect to the cost of providing the services.

Future product royalty income related to the agreement will be recognized as the related products are sold and amounts are due to the Company.

- *Related Party Revenue Recognition under BSC Cardiac Agreement (Note 5)* - The Company analyzed whether the components of the arrangement represent separate units of accounting as defined by GAAP. Application of these standards requires management to make subjective judgments about the value of the individual elements and whether delivered elements are separable from the other aspects of the contractual relationship. The Company determined it does not have clear and objective evidence of fair value of the various elements of the agreement and, therefore, under GAAP regarding Multiple-Element Arrangements, the deliverables are being 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 has continuing involvement through research and development services that is required because the Company's know-how and expertise related to the technology are proprietary to the Company, such upfront fees are deferred and recognized over the estimated period of continuing involvement on a straight-line basis.

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

- *Service Revenues* - In September 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, 2012, the Company recorded service revenues of approximately \$404,000 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.

*Net Loss Per Share*

The Company calculates net loss per share in accordance with 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 consideration for 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. For all periods presented, 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:

	<u>As of September 30,</u>	
	<u>2012</u>	<u>2011</u>
Stock options	6,132,127	3,687,477
Warrants	8,945,247	1,520,986
Shares under convertible note agreements	4,371,029	4,529,043
	<u>19,448,403</u>	<u>9,737,506</u>

*Share-Based Compensation*

The Company accounts for compensation for all arrangements under which employees and others receive shares of stock or other equity instruments (including options and warrants) in accordance with ASC 718, Compensation – Stock Compensation. Under ASC 718, the fair value of each award is estimated and amortized as compensation expense over the requisite service period. The fair value of the Company’s share-based options and warrants is estimated on the grant date using the Black-Scholes valuation model. This valuation model requires the input of highly subjective assumptions, including the expected stock volatility, estimated option term and risk-free interest rate during the expected term. To estimate the expected term, the Company utilizes the “simplified” method for “plain vanilla” options as discussed within the SEC’s Staff Accounting Bulletin 107 (“SAB 107”). The Company believes that all factors listed within SAB 107 as pre-requisites for utilizing the simplified method are true for the Company and for the Company’s share-based compensation arrangements. The Company intends to utilize the simplified method for the foreseeable future until more detailed information about exercise behavior becomes available.

The Company utilizes risk-free interest rates based on a zero-coupon U.S. treasury instrument, the term of which is consistent with the expected term of the stock options. The Company has not paid and does not anticipate paying cash dividends on its shares of common stock; therefore, the expected dividend yield is assumed to be zero.

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*Fair Value Determination of Privately-Held Equity Securities*

Determining the fair value of privately held stock requires making complex and subjective judgments. Prior to the time the Company's common stock was publicly traded, the Company used the income approach, the market approach, and the probability weighted expected return method to estimate the value of the enterprise for the dates on which securities were issued/granted and outstanding. The income approach was based on estimated future cash flows that utilized the Company's forecasts of revenue and costs. The assumptions underlying the revenue and cost estimates were consistent with the Company's business plan. The market approach was based on recent sales of the Company's common stock in privately negotiated transactions between stockholders, the once anticipated initial public offering ("IPO") price of the Company's common stock, or conversion terms negotiated with holders of convertible securities issued by the Company. When the Company began the process of preparing for its IPO, it began to utilize the probability weighted expected return method, which was based on identifying the most likely liquidity events for the Company, the probability of each occurring, and the equity values for each after applying different percentages to the likelihood of the different values assigned to each anticipated outcome of those events. Once the Company's planned IPO was withdrawn in the third quarter of 2010, the Company reverted to using the income and market approaches previously discussed. The assumptions used in each of the different valuation methods take into account certain discounts such as selecting the appropriate discount rate and control and lack of marketability discounts. The discount rates used in these valuations ranged from 22% to 35%. The discounts for lack of marketability ranged from 15% to 35% and the discount for lack of control ranged from 20% to 30%. If different discount rates or lack of marketability and control discounts had been used, the valuations would have been different. The enterprise value under each valuation method was allocated to preferred and common shares taking into account the enterprise value available to all stockholders and allocating that value among the various classes of stock based on the rights, privileges, and preferences of the respective classes in order to provide an estimate of the fair value of a share of the Company's common stock. There is inherent uncertainty in these estimates.

Since May 21, 2012, the Company's common stock has been traded in the over-the-counter market and has been quoted on the OTC Bulletin Board under the symbol MRIC. Prior to the time the Company's stock was publicly traded, the fair value of the Company's common stock, as well as the common stock underlying options and warrants, granted as compensation, or issued in connection with the settlement of liabilities ("stock based transactions"), were estimated by management, with input from a third-party valuation specialist from time to time. The Company intends to include the prices of public trading of its common stock as a key input going forward in determining fair value for stock based transactions.

*New Accounting Pronouncements*

In June 2011, the Financial Accounting Standards Board ("FASB") issued new accounting guidance related to the presentation of comprehensive income that increases comparability between GAAP and International Financial Reporting Standards ("IFRS"). This guidance requires companies to present the components of net income and other comprehensive income either as one continuous statement or as two consecutive statements, eliminating the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. Public entities are required to apply this guidance for fiscal years and interim periods within those years, beginning after December 15, 2011. The Company adopted this guidance during the nine months ended September 30, 2012, and the adoption of this guidance had no impact on the Company's results of operations or financial position and is not expected to have an impact on the Company's future results of operations or financial position.

In May 2011, the FASB issued guidance to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between GAAP and International Financial Reporting Standards. This update changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. This guidance was effective for annual periods beginning after December 15, 2011 (the 2012 fiscal year) and should be applied prospectively. As this guidance was only disclosure related, it did not have any effect on the carrying value of the assets or liabilities on the balance sheet as of September 30, 2012.

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**3. Inventory**

Inventory consists of the following as of:

	<b>September 30, 2012</b>	<b>December 31, 2011</b>
Work in process	\$ 437,488	\$ 454,366
Software	397,000	467,000
Finished goods	<u>105,256</u>	<u>47,452</u>
Inventory included in current assets	939,744	968,818
Software license inventory	<u>1,137,500</u>	<u>-</u>
	<u>\$ 2,077,244</u>	<u>\$ 968,818</u>

**4. Property and Equipment**

Property and equipment consist of the following as of:

	<b>September 30, 2012</b>	<b>December 31, 2011</b>
Equipment	1,017,634	\$ 934,253
Furniture and fixtures	105,376	106,054
Leasehold improvements	157,236	157,236
Computer equipment and software	108,285	101,482
Loaned systems	<u>990,106</u>	<u>723,975</u>
	2,378,637	2,023,000
Less accumulated depreciation and amortization	<u>(1,096,907)</u>	<u>(804,170)</u>
Total property and equipment, net	<u>1,281,730</u>	<u>\$ 1,218,830</u>

Depreciation and amortization expense for property and equipment for the nine months ended September 30, 2012 and 2011 was \$296,487 and \$236,536, respectively. The Company may loan the reusable components of a ClearPoint system to a customer to perform procedures using ClearPoint disposable products which are purchased from the Company. Accordingly, the \$990,106 and \$723,975 of loaned systems at September 30, 2012 and December 31, 2011, respectively, represent the historical cost of ClearPoint reusable components transferred from inventory to property and equipment. Depreciation on loaned ClearPoint systems is computed using the straight-line method based on an estimated useful life of five years. At September 30, 2012 and December 31, 2011, accumulated depreciation on loaned systems was \$197,439 and \$73,846, respectively.

**5. Related Party License Agreements**

License and development agreements have been entered into with affiliates of BSC. Because an affiliate of BSC is a stockholder of the Company and such affiliate of BSC has a representative that has been elected to serve on the Company's board of directors, management has deemed all transactions with BSC and its affiliates to be of a related party nature.

*BSC Neuro Agreement*

On December 30, 2005, the Company entered into definitive license and development agreements (collectively, as amended, the "BSC Neuro Agreement") with Advanced Bionics Corporation, an affiliate of BSC. Advanced Bionics Corporation subsequently changed its name to Boston Scientific Neuromodulation Corporation ("BSC Neuro"). Under the BSC Neuro Agreement, the Company granted BSC Neuro an exclusive commercial license with respect to certain of the Company's owned and licensed intellectual property, in the neuromodulation field, to make, use, import, lease and sell neuro-related leads, neuro-related lead extensions, and neuro-related lead-type devices, such as implantable pulse generators.

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In connection with the February 2012 modification of the BSC Notes (see Note 6), the Company and BSC Neuro also amended the terms of the BSC Neuro Agreement. The amended terms included a reduction in the amount BSC Neuro could be required to pay the Company in future milestone-based payments associated with successful development and regulatory approval of the leads, from an original maximum amount of \$1,600,000 to an amended maximum amount of \$800,000. Under the BSC Neuro Agreement, BSC Neuro is obligated to pay royalties to the Company based on BSC Neuro's net sales of licensed products, as defined by the agreement. In addition to the reduction in potential milestone-based payments, the amendment to the BSC Neuro Agreement also reduced by half the royalty rates used in calculating such royalty payments due to the Company. Furthermore, the amended BSC Neuro Agreement requires the Company to meet certain net working capital targets, be current on its payroll obligations, and not suffer an event of default under any indebtedness for borrowed money, in each case while the BSC Notes remain outstanding (see Note 6). If the Company does not meet those requirements while the BSC Notes are outstanding, the Company will be required to assign certain patents and patent applications to BSC Neuro. However, upon any such assignment to BSC Neuro, BSC Neuro will grant to the Company an exclusive, royalty-free, perpetual worldwide license to the same patents and patent applications in all fields of use other than neuromodulation and implantable medical leads for cardiac applications.

The Company did not receive any up-front license payments pursuant to the BSC Neuro Agreement. In addition to other potential payments under the agreement as described above, the Company could receive over \$500,000 in incentive payments for incremental development work, but only if and to the extent BSC Neuro requests the Company to perform such work. The BSC Neuro Agreement requires specified milestones in the development of an MRI-safe implantable lead to be achieved by December 31, 2012. If the milestones are not achieved by that date and this failure is not the result of BSC Neuro's failure to reasonably cooperate with the Company in pursuing the milestones, the Company will be required to repay BSC Neuro certain amounts, including any development expenses and milestone payments previously made to the Company under this agreement and any patent prosecution costs incurred by BSC Neuro with respect to the intellectual property licensed under this agreement. As of September 30, 2012, the Company has received approximately \$750,000 of payments from BSC Neuro which would be subject to the repayment obligation described above. In addition, the Company would be responsible to reimburse BSC Neuro for out-of-pocket costs incurred by BSC Neuro in prosecuting patent applications and maintaining issued patents for the licensed technologies. As discussed in Note 2, Revenue Recognition, all amounts received have been recorded as deferred revenue.

*BSC Cardiac Agreement*

Effective March 19, 2008, the Company entered into definitive license and development agreements (collectively, the "BSC Cardiac Agreement") with Cardiac Pacemakers, Inc. ("BSC Cardiac"), an affiliate of BSC. Under the BSC Cardiac Agreement, the Company granted BSC Cardiac an exclusive commercial license with respect to certain of the Company's owned and licensed intellectual property rights, in the field of implantable medical leads for cardiac applications, to make, have made, use, promote, market, import, distribute, lease, sell, offer for sale and commercialize products in the licensed field of use. The Company is required to continue to investigate the feasibility of its technology and, upon successful completion of feasibility studies, to work with BSC Cardiac to develop this technology for different types of MRI-compatible and MRI-safe implantable cardiac leads.

Pursuant to the BSC Cardiac Agreement, in addition to prospective royalty payments on net sales of licensed products, the Company received non-refundable licensing fees totaling \$13,000,000 in 2008, and the Company could receive up to \$20,000,000 in future milestone-based payments associated with the successful development and regulatory approval of the implantable cardiac leads, subject to certain patents being issued on patent applications licensed to BSC Cardiac. The Company initially recorded the payment of up-front licensing fees as deferred revenue and is recognizing revenue over the five year estimated period of continuing involvement (see Note 2, Revenue Recognition). The Company determined the five-year estimated period of continuing involvement based upon the Company's internal development plan and projected timeline for the different implantable cardiac leads. The Company reevaluates its estimated remaining period of continuing involvement at each reporting period, and any changes will be incorporated into the determination of revenue recognition on a prospective basis.



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Except as set forth below, the licensing provisions of the BSC Cardiac Agreement will terminate upon the expiration of the last issued patent that is licensed under the agreement, and the development provisions of the BSC Cardiac Agreement will expire upon FDA approval of a design for each of the different lead types described in the agreement. BSC Cardiac has the one-time option, within 60 days after successful completion of the first cardiac lead feasibility study, to cease further development work and to terminate the provisions of the BSC Cardiac Agreement. If BSC Cardiac elects to exercise its option under the BSC Cardiac Agreement to terminate further development efforts, the license the Company granted to BSC Cardiac will automatically become non-exclusive with respect to certain of the intellectual property, other intellectual property will be removed from the scope of the license and revert to the Company, and BSC Cardiac will not be obligated to pay the Company any future royalties on net sales of products containing intellectual property that remains subject to the non-exclusive license. Likewise, any unachieved future milestone-based payments will not be due to the Company.

**6. Related Party Notes Payable**

*Related Party BSC Convertible Notes Payable*

In October 2009, the Company entered into a convertible note payable arrangement with BSC. During October, November and December 2009, the Company borrowed an aggregate of \$3,500,000 from BSC under this arrangement pursuant to three convertible notes payable (the "BSC Notes"). These borrowings accrued interest at 10% per year and were scheduled to mature on the second anniversary of the date on which the funds were advanced. Effective February 2, 2012, the Company entered into a loan modification with BSC (also see Note 5) pursuant to which (i) interest accrued under each of the BSC Notes as of February 2, 2012 was added to the principal balance of the note, (ii) beginning February 2, 2012, the interest rate of each of the BSC Notes was reduced from 10% per year to 0%, and (iii) the maturity date of each of the BSC Notes was extended by three years (until October through December 2014). As of February 2, 2012, the outstanding aggregate loan balance, including principal and interest, owed to BSC was \$4,338,601. Pursuant to ASC 470-60, Troubled Debt Restructurings by Debtors, the loan modification was considered a "Troubled Debt Restructuring." However, because the total future cash payments required under the new terms of the BSC Notes were not reduced from what was owed at the time of the loan modification, no gain was recorded under Troubled Debt Restructuring accounting.

The Company will be required to prepay all or a portion of the BSC Notes upon the consummation of any future "qualified financing," which is defined as any equity financing in which shares of the Company's preferred stock are issued in exchange for cash proceeds. Upon consummation of a qualified financing from Medtronic, Inc., St. Jude Medical, Inc., or Johnson & Johnson, or any of their respective subsidiaries or affiliates, up to 100% of the cash proceeds from such qualified financing must be used to prepay the outstanding balance of the BSC Notes. Upon consummation of a qualified financing from any other investor, up to 25% of the cash proceeds from such qualified financing must be applied by the Company to prepay the outstanding balance of the BSC Notes. The Company has not conducted a qualified financing since entering into the loan arrangement with BSC under which the Company issued the BSC Notes. The Company can prepay the BSC Notes at any time. Each of the BSC Notes is convertible, at the option of the holder, at any time prior to the earlier of the maturity date or the consummation of a qualified initial public offering (which is defined as a bona fide first underwritten public offering of the Company's common stock on a firm commitment basis in which the aggregate gross proceeds received by the Company at the public offering price equals or exceeds \$20,000,000), into one share of the Company's preferred stock at a conversion price equal to the lower of \$8.00 per share or the price per share paid by investors in a future qualified financing conducted by the Company. In the event BSC elected to convert the BSC Notes into shares of preferred stock other than in the context of a qualified financing, each such share of preferred stock would initially be convertible into one share of the Company's common stock. The BSC Notes are secured by a first priority security interest in all of the Company's assets.

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The Company analyzed the terms of the conversion feature of the BSC Notes under ASC Topic 815, Derivatives and Hedging, and determined, based upon the conversion price reset provision, that the conversion feature should be accounted for as a derivative liability (see Note 2, Summary of Significant Accounting Policies – Fair Value Measurements). Under this guidance the conversion feature was initially measured at fair value upon the issuance of the BSC Notes and has been adjusted to the current fair value at the end of each reporting period. Changes in fair value are recorded in other income (expense) in the related statements of operations. The Company calculated the fair value of this derivative liability utilizing the Black-Scholes pricing model. The assumptions used in calculating the fair value of the derivative liability using this model were as follows:

	<b>September 30, 2012</b>	<b>December 31, 2011</b>
Dividend yield	0%	0%
Expected volatility	42.47%	46.58%
Risk free interest rate	0.27%	0.25%
Expected remaining term (years)	2.1	0.15
Common stock price	\$ 2.12	\$ 0.60

The Company recognized a loss in its statements of operations of \$7,439 during the three and nine months ended September 30, 2012 as the fair value of the derivative liability was \$7,439 at September 30, 2012, and nil at December 31, 2011. The fair value of the derivative liability was measured using Level 2 inputs at September 30, 2012 and Level 3 inputs for all reporting periods prior to 2012.

*Related Party 2011 Unsecured Convertible Notes Payable*

In June through September 2011, the Company issued unsecured convertible notes (the “Summer 2011 Notes”) in the aggregate amount of \$1,310,000 to six non-employee directors of the Company. The note holders also received warrants to purchase 1,310,000 shares of the Company’s common stock in the aggregate. The Summer 2011 Notes had two-year maturities and accrued interest at 15% per year. The warrants were fully vested upon issuance, have a term of two years, and have an exercise price of \$0.01 per share. The original terms of the Summer 2011 Notes provided for automatic conversion of the notes into shares of the Company’s common stock upon consummation of an initial public offering of shares of the Company’s common stock, based on a conversion price equal to 60% of the public offering price. In addition, the original terms of the Summer 2011 Notes provided for optional conversion of the notes, at the election of the note holder, upon consummation of a reverse merger of the Company into a public shell company, based on a conversion price equal to 60% of the fair market value of the Company’s common stock at the time of the merger. The Summer 2011 Notes were amended in December 2011 to provide for automatic conversion of the principal and all accrued interest into shares of the Company’s common stock upon the effectiveness of a Form 10 filed by the Company with the SEC under the Exchange Act, based on a conversion price of \$0.60 per share. Upon the effectiveness of the Company’s Form 10 on February 27, 2012, all of the Summer 2011 Notes, representing an aggregate of \$1,425,865 in principal and accrued interest, were converted into 2,376,447 shares of the Company’s common stock. In conjunction with the conversion of the Summer 2011 Notes, the Company applied the guidance in ASC 470-20, Debt with Conversion and Other Options (“ASC 470-20”), and wrote-off the unamortized discount of \$405,602 associated with the relative fair value of the warrants, which were issued with the Summer 2011 Notes, against additional paid-in capital.

The table below summarizes related party notes payable at:

	<b>September 30, 2012</b>	<b>December 31, 2011</b>
BSC Notes - principal	\$ 4,338,601	\$ 3,500,000
Summer 2011 Notes - principal	-	1,310,000
Total related party notes payable - principal	<u>4,338,601</u>	<u>4,810,000</u>
BSC Notes - unamortized discount	-	-
Summer 2011 Notes - unamortized discount	-	(432,706)
Total related party notes payable - unamortized discount	-	<u>(432,706)</u>
BSC Notes - net	4,338,601	3,500,000
Summer 2011 Notes - net	-	877,294
Total related party notes payable - net	<u>\$ 4,338,601</u>	<u>\$ 4,377,294</u>

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**7. Convertible Notes Payable**

*2010 Unsecured Convertible Notes Payable*

In March 2010, the Company issued 10% senior unsecured convertible notes (the "March 2010 Notes") in the aggregate principal amount of \$4,071,000. The original terms of the March 2010 Notes provided for a mandatory conversion feature upon the closing of an initial public offering of the Company's common stock that would automatically convert the outstanding principal amount of the notes into shares of the Company's common stock at the lesser of \$8.00 per share or 80% of the public offering price, subject to a minimum \$4.00 per share conversion price. In addition, the original terms of the March 2010 notes permitted note holders to convert the outstanding principal into shares of the Company's common stock at any time, based on a conversion price of \$8.00 per share, subject to certain adjustments. The March 2010 Notes were scheduled to mature in March 2012. All accrued interest was to be paid in cash upon the earlier of maturity or conversion. In late 2011 and early 2012, all of the March 2010 Notes were amended to provide for automatic conversion of the outstanding principal and accrued interest into shares of the Company's common stock on the effective date of a Form 10 filed by the Company with the SEC under the Exchange Act, based on a conversion price of \$1.00 per share. Upon the effectiveness of the Company's Form 10 on February 27, 2012, all of the March 2010 Notes, representing an aggregate of \$4,868,017 in principal and accrued interest, were converted into 4,868,041 shares of the Company's common stock. In conjunction with the conversion of the March 2010 Notes, the Company applied the guidance in ASC 470-20 and charged to interest expense the associated unamortized discount of \$13,500 and the unamortized deferred offering costs of \$13,883.

*2011 Unit Offering Notes*

In October 2011, the Company initiated a private placement of securities in which the Company offered units, each unit consisting of a 10% junior secured convertible note ("2011 Unit Offering Note") in the principal amount of \$100,000 and a warrant to purchase 50,000 shares of the Company's common stock. The 2011 Unit Offering Notes were scheduled to mature three years from the date of issuance and accrued interest at 10% per year. Per the terms of the 2011 Unit Offering Notes, all principal and accrued interest automatically converted into shares of the Company's common stock based on a conversion price of \$0.60 per share on the effective date of the Company's Form 10, which was February 27, 2012. The warrants were fully vested upon issuance, have a term of five years, and have an exercise price of \$0.75 per share. Upon completion of the unit offering in February 2012, the Company had sold 54,305 units resulting in the issuance of convertible notes in the aggregate principal amount of \$5,430,500 and warrants to purchase 2,715,250 shares of common stock under the terms described above. Of the 54,305 units sold, 38,055 units were sold after December 31, 2011. The Company's placement agent for the unit offering, and its sub-placement agents, received an aggregate cash fee equal to 10% of the gross proceeds from the offering, as well as warrants to purchase an aggregate of 941,288 shares of the Company's common stock, which represented 8% of the aggregate number of shares of common stock issuable upon conversion of the 2011 Unit Offering Notes and exercise of the warrants sold in the unit offering, at the time of issuance. The warrants issued to the placement agent and its sub-placement agents have an exercise price of \$0.60 per share. The fair value of these warrants of \$237,299 was calculated using the Black-Scholes pricing model assuming a dividend yield of 0%, an expected volatility of 48%, a risk free interest rate of 0.89% and an expected life of five years. The \$237,299 was recorded as a deferred offering cost to be amortized to interest expense using the effective interest method over the term of the 2011 Unit Offering Notes.

Utilizing guidance in ASC 470-20, the Company initially allocated the proceeds from the sale of the units on a relative fair value basis between the convertible notes and the warrants issued. Using the relative fair value of the notes, an effective conversion price was determined which resulted in a beneficial conversion feature ("BCF"). The fair value of the warrants was calculated using the Black-Scholes pricing model assuming a dividend yield of 0%, an expected volatility of 49%, a risk free interest rate of 0.93% and an expected life of five years. The relative fair value of the warrants issued and the intrinsic value of the BCF, which were \$383,204 each for the units issued in 2012, were recorded as increases to additional paid-in capital and a discount to the carrying value of the 2011 Unit Offering Notes. Management estimated the fair value of the Company's common stock to be \$0.60 per share at the time the 2011 Unit Offering Notes were issued, and management believed the 10% stated interest rate approximated the market interest rate. The effective conversion price of the conversion feature under the 2011 Unit Offering Notes was \$0.54 per share. Upon the effectiveness of the Company's Form 10 on February 27, 2012, all of the 2011 Unit Offering Notes, representing an aggregate of \$5,491,929 in principal and accrued interest, were converted into 9,153,248 shares of the Company's common stock. In conjunction with the conversion of the 2011 Unit Offering Notes, the Company applied the guidance in ASC 470-20 and charged the related aggregate unamortized debt discount of \$1,063,018 and unamortized deferred offering costs of \$785,239 to interest expense.

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*2011 Junior Secured Convertible Note Payable and Strategic Agreement*

In April 2011, the Company issued a \$2,000,000 subordinated secured convertible note (“April 2011 Note”) to a medical device co-development partner (“Strategic Partner”). The April 2011 Note matures in April 2016, unless earlier converted, and it accrues interest at the rate of 10% per year. Interest is payable at maturity if the note is not converted. The April 2011 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 BSC Notes (see Note 6). In the event the Company closes a qualified financing, which is defined as an equity financing in which the Company issues shares of its preferred stock and receives at least \$10,000,000 in net proceeds, the principal and accrued interest of the April 2011 Note will automatically convert into shares of the preferred stock that are issued in the qualified financing if the number of shares to be issued upon conversion represents at least 10% of the Company’s outstanding shares of stock on a fully diluted basis. If the number of shares that would be issued upon conversion represents less than 10% of the Company’s outstanding shares of stock on a fully diluted basis, the conversion will be at the Strategic Partner’s election. Under the original terms, the Strategic Partner had the right to accelerate the maturity date of the April 2011 Note if the Company did not consummate a qualified financing within 180 days following the issue date of the note. The terms of the April 2011 Note were amended in September 2011 to extend the period within which to complete a qualified financing from 180 days to 360 days (April 2012) and to establish a maximum conversion price of \$0.60 per share (again, only in connection with the closing of a qualified financing). The April 2011 Note was further amended in February 2012 to remove the acceleration provision mentioned above related to the consummation of a qualified financing and to provide the Strategic Partner 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, regardless of whether there is a qualified financing within that period of time.

Concurrent with the issuance of the April 2011 Note, the Company and the Strategic Partner entered into a Co-Development and Distribution Agreement pursuant to which the Company appointed the Strategic Partner as the exclusive distributor of the Company’s ClearPoint system products in the MRI-guided neurological drug delivery field and as a non-exclusive distributor of the Company’s ClearPoint system products for other MRI-guided neurological applications. In connection with the Co-Development and Distribution Agreement, the Company is obligated to perform a limited amount of training and support functions. In addition, under the Co-Development and Distribution Agreement, the Company licensed certain ClearPoint system technology to the Strategic Partner, and the Company and the Strategic Partner will work together to potentially integrate the Company’s ClearPoint product line into the Strategic Partner’s interventional MRI product line, particularly for an MRI-guided neurological drug delivery application.

Relying upon guidance in ASC 605-25 Revenue Recognition Multiple Element Arrangements, the Company analyzed whether the deliverables of the arrangement with the Strategic Partner represented separate units of accounting. Application of these standards requires subjective determinations and requires management to make judgments about the value of the individual elements and whether delivered elements are separable from the other aspects of the contractual relationship. The Company determined that the April 2011 Note was the only element of the arrangement that had standalone value to the Strategic Partner separate from the other elements; thus, the Company accounted for the arrangement in two units of accounting. The distribution, license, service and support elements of the arrangement did not have value to the Strategic Partner on an individual basis, but together these elements did have value to the Strategic Partner and, therefore, represent a unit of accounting. The Company applied the relative selling price method to determine the value to associate with each unit of accounting. This method establishes a hierarchy of factors to consider when determining relative selling price: (1) vendor-specific objective evidence, (2) third-party evidence of selling price, or lastly, (3) management’s best estimate of the selling price. Because of the unique nature of the rights conveyed, there was no vendor-specific objective evidence or third-party evidence of relative selling price. Therefore, the Company was required to use its best estimate of the relative selling price of the deliverables comprising each unit of accounting. The Company determined the relative selling price of the unit of accounting associated with the distribution, license, service and support elements to be zero, as the Company would have conveyed these rights and assumed these obligations in exchange for the potential benefits from leveraging the distribution resources of the Strategic Partner (i.e. sales to the Strategic Partner are expected to yield similar net profits to those the Company generates on its direct customer sales). The other unit of accounting is comprised of the April 2011 Note with its junior security interest. Upon the issuance of the note, the note’s conversion feature did not require any accounting adjustment since it was a contingent feature subject to the completion of a qualified financing, which is not considered to be within the Company’s control. Therefore, the full \$2,000,000 in cash proceeds was recorded as a liability related to the April 2011 Note. The Company determined that the February 2012 amendment to the April 2011 Note, which provided the optional conversion feature, represented conventional convertible debt and did not require any additional accounting treatment.

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*Summary of Convertible Notes Payable*

The table below summarizes convertible notes payable by liability classification:

	<u>Current</u>		<u>Long-term</u>	
	<u>September 30, 2012</u>	<u>December 31, 2011</u>	<u>September 30, 2012</u>	<u>December 31, 2011</u>
March 2010 Notes - principal	\$ -	\$ 4,071,000	\$ -	\$ -
2011 Unit Offering Notes - principal	-	-	-	1,625,000
April 2011 Note - principal	-	-	2,000,000	2,000,000
Total convertible notes payable - principal	-	4,071,000	2,000,000	3,625,000
March 2010 Notes - unamortized discount	-	(117,405)	-	-
2011 Unit Offering Notes - unamortized discount	-	-	-	(316,610)
April 2011 Note - unamortized discount	-	-	-	-
Total convertible notes payable - unamortized discount	-	(117,405)	-	(316,610)
March 2010 Notes - net	-	3,953,595	-	-
2011 Unit Offering Notes - net	-	-	-	1,308,390
April 2011 Note - net	-	-	2,000,000	2,000,000
Total convertible notes payable - net	<u>\$ -</u>	<u>\$ 3,953,595</u>	<u>\$ 2,000,000</u>	<u>\$ 3,308,390</u>

**8. Stockholders' Equity**

*July 2012 Private Placement*

In July 2012, the Company entered into securities purchase agreements with certain investors 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 \$1.10 per unit (the "July PIPE Financing"). Each unit consisted of one share of common stock and a warrant to purchase one-half share of common stock. The pricing for the July PIPE Financing was set by the Company on June 25, 2012.

In the July PIPE Financing, the Company sold to the investors 5,454,523 shares of common stock, together with warrants to purchase 2,727,274 shares of common stock, for aggregate gross proceeds of \$6,000,000. Each warrant is exercisable for five years from the date of issuance and has an exercise price of \$1.45 per share, subject to adjustment from time to time for stock splits or combinations, stock dividends, stock distributions, recapitalizations and other similar transactions. In addition, the exercise price of the warrants will be subject to weighted average anti-dilution protection, such that the exercise price will be adjusted downward on a weighted average basis to the extent the Company issues common stock or common stock equivalents in a financing transaction at a price below the then prevailing warrant exercise price. Non-employee directors of the Company invested a total of \$269,980 in the July PIPE Financing. The Company's placement agent for the July PIPE Financing, and its sub-placement agents, earned cash commissions of \$480,000 as well as warrants to purchase 409,093 shares of the Company's common stock. The placement agent warrants have the same terms and conditions as the investor warrants, except that the placement agent warrants have an exercise price of \$1.10 per share.

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In connection with the July PIPE Financing, the Company entered into registration rights agreements with the investors pursuant to which the Company agreed to prepare and file 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 transaction. The Company filed that registration statement on August 13, 2012, and the registration statement became effective on September 21, 2012. In the event the Company fails to continuously maintain the effectiveness of the registration statement (with certain permitted exceptions), the Company will incur certain liquidated damages to investors in the July PIPE Financing, up to a maximum amount of 6% of the investors' investment in that transaction, or \$360,000. The Company will bear the costs, including legal and accounting fees, associated with the registration statement. Management believes that the Company will be able to maintain continuous effectiveness of the registration statement and, as such, no liability has been recorded related to this liquidated damages provision.

*Preferred Stock*

In 2006, the Company issued 7,965,000 shares of Series A Convertible Preferred Stock. The holders of Series A Convertible Preferred Stock had the right to convert such shares, at any time, into shares of common stock at the then applicable conversion rate. In addition, the terms of the Series A Convertible Preferred Stock provided for automatic conversion into common stock at the then applicable conversion rate upon the closing of an initial public offering or the consent of holders of a majority of the outstanding shares of the Series A Convertible Preferred Stock. In connection with any of the foregoing conversion events, every four shares of Series A Convertible Preferred Stock would convert into one share of common stock, subject to adjustment for certain corporate events, including stock splits, stock dividends and recapitalizations. However, on December 15, 2011, the Company's Board of Directors approved an amendment to the terms of the Series A Convertible Preferred Stock providing for the automatic conversion of all outstanding shares of Series A Convertible Preferred Stock into shares of common stock, on a 1-for-1 basis, on the effective date of a Form 10 filed by the Company with the SEC under the Exchange Act. That amendment was approved by the stockholders of the Company on February 10, 2012, and a Certificate of Amendment effecting the change to the terms of the Series A Convertible Preferred Stock was filed with the State of Delaware on that same day. Accordingly, upon the effectiveness of the Company's Form 10 on February 27, 2012, the outstanding shares of Series A Convertible Preferred Stock converted into 7,965,000 shares of the Company's common stock.

On February 10, 2012, the stockholders of the Company also approved an Amended and Restated Certificate of Incorporation to be filed in connection with the effectiveness of the Company's Form 10. The Company filed the Amended and Restated Certificate of Incorporation with the state of Delaware on February 27, 2012, and it became effective upon filing. Under such Amended and Restated Certificate of Incorporation, the Company has the authority to issue up to 25,000,000 shares of preferred stock, and the Board of Directors has the authority, without further action by the stockholders, to issue up to that number of shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. In June 2012, the Board of Directors established the terms of a series of preferred stock known as "Series A Convertible Preferred Stock". The Board of Directors designated the Series A Convertible Preferred Stock solely to provide BSC a series of the Company's preferred stock into which BSC could elect to convert the BSC Notes other than in connection with a qualified financing. The Company has not issued any shares of the Series A Convertible Preferred Stock. Likewise, the Company has not filed a Certificate of Designations with the Secretary of State of the State of Delaware to create the Series A Convertible Preferred Stock. The Company does not intend to file such Certificate of Designations unless and until BSC elects to convert its BSC Notes into shares of the Series A Convertible Preferred Stock.

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*Summary of Conversions to Common Stock Upon Effectiveness of the Form 10*

The table below summarizes the impact to the Company's balance sheet and to shares outstanding of the conversions to common stock that occurred upon the effectiveness of the Company's Form 10, which occurred on February 27, 2012:

	<b>Impact to Balance Sheet</b>			<b>Increase in Common Shares Outstanding</b>
	<b>Before Conversions</b>	<b>Impact of Conversions</b>	<b>After Conversions</b>	
<b>Impact on assets</b>				
Deferred costs	\$ 799,123	\$ (799,123)	\$ -	-
<b>Impact on liabilities and equity</b>				
Accrued interest on converted notes	\$ 974,311	\$ (974,311)	\$ -	1,092,559
Summer 2011 Notes, net	904,397	(904,397)	-	2,183,334
March 2010 Notes, net	4,057,500	(4,057,500)	-	4,071,000
2011 Unit Offering Notes, net	4,367,482	(4,367,482)	-	9,050,834
Total impact on liabilities	<u>10,303,690</u>	<u>(10,303,690)</u>	<u>-</u>	<u>16,397,727</u>
Series A convertible preferred stock	7,965,000	(7,965,000)	-	7,965,000
Additional paid-in capital and common stock	-	19,345,209	19,345,209	-
Accumulated deficit	-	(1,875,642)	(1,875,642)	-
Total impact on equity	<u>7,965,000</u>	<u>9,504,567</u>	<u>17,469,567</u>	<u>7,965,000</u>
Total impact on liabilities and equity	<u>\$ 18,268,690</u>	<u>\$ (799,123)</u>	<u>\$ 17,469,567</u>	<u>24,362,727</u>

The impact to accumulated deficit relates to the write-off of unamortized debt discounts and deferred financing costs.

*Stock Options*

At September 30, 2012, the Company had five share-based compensation plans (a "1998 Plan," a "2007 Plan," two "2010 Plans," and a "2012 Plan," which are referred to collectively herein as the "Plans"). The Plans provide for the granting of share-based awards, such as incentive and non-qualified stock options, to employees, directors, consultants and advisors. One of the 2010 Plans and the 2012 Plan also provide for cash-based awards. Awards may be subject to a vesting schedule as set forth in each individual award agreement. The Company terminated the 1998 Plan, effective June 24, 2008, with respect to future grants such that no new options may be awarded under the 1998 Plan on or after June 24, 2008. Upon adoption of the 2010 Plans, the Company also ceased making awards under its 2007 Plan. The 2012 Plan was adopted by the Company's Board of Directors in January 2012 and approved by the Company's stockholders in February 2012. A total of 3,000,000 shares of the Company's common stock have been reserved for issuance under the 2012 Plan, of which 2,797,400 shares were subject to outstanding options at September 30, 2012. With the adoption of the 2012 Plan, no additional grants under the 2010 Plans have been or will be made subsequent to December 31, 2011.

Activity under the Plans during the nine months ended September 30, 2012 is summarized below:

	<b>Shares</b>	<b>Weighted - Average Exercise Price</b>
Outstanding, January 1, 2012	3,679,977	\$ 2.05
Granted	2,797,400	1.02
Exercised, including 16,000 shares withheld on net settled exercises	(30,000)	1.80
Forfeited	(315,250)	2.16
Outstanding, September 30, 2012	<u>6,132,127</u>	1.58

The estimated grant date fair values of options granted under the 2012 Plan during the nine months ended September 30, 2012 were calculated using the Black-Scholes valuation model, based on the following assumptions:

Dividend yield	0%
Expected Volatility	45.2%
Risk free Interest rates	0.83% - 1.13%
Expected lives (years)	6.0





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

<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
<u>2012</u>	<u>2011</u>	<u>2012</u>	<u>2011</u>
\$ 299,083	\$ 248,540	\$ 842,645	\$ 757,200

As of September 30, 2012, there was unrecognized compensation expense of \$2,061,237 related to outstanding stock options which is expected to be recognized over a weighted average period of approximately 1.9 years.

*Warrants*

In May 2012, the Company issued an aggregate of 1,250,000 common stock warrants to two non-employee directors in recognition of their long-standing support of the Company. The warrants were immediately vested and exercisable upon issuance, have an exercise price of \$1.00 per share, and have a term of five years. The fair value of the 1,250,000 warrants issued was \$514,250, which was calculated using the Black-Scholes valuation model. In addition, during the nine months ended September 30, 2012, the Company issued 366,666 warrants to third parties with an exercise price of \$1.00 and having a fair value of \$293,163. The aggregate fair value of the aforementioned warrants of \$808,636 was recorded as a selling, general and administrative expense during the nine months ended September 30, 2012, of which \$214,637 was recorded as expense during the three months ended September 30, 2012.

Warrants have generally been issued for terms of up to five years. Common stock warrants issued and outstanding during the nine months ended September 30, 2012 are as follows:

	<u>Shares</u>	<u>Weighted - Average Exercise Price</u>
Outstanding, January 1, 2012	1,922,944	\$ 0.43
Issued	7,607,071	1.05
Exercised, including 158,078 shares withheld on net settled exercises	<u>(584,768)</u>	0.69
Outstanding, September 30, 2012	<u>8,945,247</u>	0.94

The assumptions used in calculating the fair value of warrants issued during the nine months ended September 30, 2012, utilizing the Black-Scholes valuation model are as follows:

Dividend yield	0%
Expected Volatility	41.3% - 49.0%
Risk free Interest rates	0.19% - 0.93%
Expected lives (years)	1.7 - 5.0

**9. Changes in Contractual Commitments**

*Software License Agreement*

Effective June 22, 2012, the Company and its ClearPoint system software development partner entered into an amendment (the "Software Amendment") to the master services and licensing agreement (the "Master Software Agreement") between the parties.

The Company entered into the Master Software Agreement in July 2007 for the software development partner to develop on the Company's behalf, based on the Company's detailed specifications, a customized software solution for the Company's ClearPoint system. The software development partner 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, the software development partner utilized certain of its own pre-existing software code. Under the Master Software Agreement, the Company received a non-exclusive, worldwide license to that code as an integrated component of the Company's ClearPoint system software. In return, the Company agreed to pay the software development partner a license fee for each copy of the ClearPoint system software that the Company distributes, subject to certain minimum license purchase commitments by the Company.

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Pursuant to the Software Amendment, the Company agreed to issue the software development partner 1,500,000 shares of the Company's common stock (1) in full payment and satisfaction of license fees owed to the software development partner in the amount of \$612,500 for licenses previously purchased by the Company, (2) in full payment and satisfaction of all of the Company's remaining minimum license purchase commitments from the software development partner in the amount of \$962,500, and (3) in exchange for additional licenses provided by the software development partner to the Company valued at \$87,500 based on the original terms of the Master Software Agreement. The Company applied guidance in ASC 505-50, Equity-Based Payments to Non-Employees, using the contractual value of the amounts owed and of the licenses acquired to measure and record the transaction. The portion of the licenses purchased by the Company that is not expected to be sold or placed in service during the next twelve months, in the amount of \$1,137,500, has been recorded as a non-current asset, software license inventory.

*Key Personnel Incentive Program*

The Company adopted its Key Personnel Incentive Program to provide a key consultant (who is a non-employee director of the Company) and a key employee (collectively, the "Participants") with the opportunity to receive incentive bonus payments based on the performance of future services to the Company or upon a consummation of a transaction involving the sale of the Company. In June 2012, the Participants voluntarily and irrevocably relinquished their rights to receive, and the Participants discharged the Company from its obligations to make, any and all incentive bonus payments under the Key Personnel Incentive Program based on the performance of services.

Pursuant to the Key Personnel Incentive Program, in the event of a sale transaction, each of the Participants will be entitled to receive an incentive bonus payment equal to \$1,000,000. In addition, one of the Participants will also receive an incentive bonus payment equal to 1.4% of net proceeds from the sale transaction in excess of \$50,000,000, but not to exceed \$700,000. If a sale has not occurred by December 31, 2025, the Key Personnel Incentive Program will terminate.

Because the Company was discharged from any obligations to make incentive bonus payments related to performance of services under the Key Personnel Incentive Program, in June 2012 the Company reversed all amounts previously accrued for such service-based payments under the program. This resulted in a credit to reversal of R&D obligation of \$882,537 for the amounts that had been accrued as research and development costs in 2010, 2011 and during the three months ended March 31, 2012 (\$120,895 had been accrued during the three months ended March 31, 2012).

*Employment Agreements*

In June 2012, the Company entered into employment agreements (each, an "Employment Agreement," and collectively, the "Employment Agreements") with four of its executive officers (each, an "Executive," and collectively, the "Executives"). Among other provisions customary for agreements of this nature, the Employment Agreements provide for severance in the event of a termination without cause or if the Executive terminates his employment for good reason, as those terms are defined in each Employment Agreement. Likewise, the Employment Agreements provide for certain payments in connection with a change of control transaction. The initial base salaries set forth in the Employment Agreements are the same as the base salaries for each of the Executives immediately prior to the execution of the Employment Agreements.

*Sponsored Research Agreement*

In September 2012, the Company entered into a research agreement with a university pursuant to which the Company agreed to provide the university funding in the amount of \$317,415 to support certain research activities over the one-year period beginning October 1, 2012. Under the terms of the research agreement, the Company will make four quarterly payments of \$79,354. The first of these payments was made in October 2012.

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**10. Subsequent Events**

*Hiring of Vice President, Global Sales and Marketing*

In November 2012, the Company hired a Vice President, Global Sales and Marketing (the “VP of Sales”). The related employment agreement stipulates that in November 2012, the VP of Sales will be granted stock options to purchase 300,000 shares of the Company’s common stock and that an additional 100,000 options will be granted on both the first and second anniversary dates of his starting date. The employment agreement also provides for certain payments in connection with a change of control transaction. Pursuant to the employment agreement, on November 10, 2012, the Company granted the VP of Sales options to purchase 300,000 shares of the Company’s common stock at an exercise price of \$1.63 per share, such options having a 10 year term.

## **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 our condensed financial statements and related notes appearing elsewhere in this Quarterly Report and in our other public filings with the Securities and Exchange Commission.*

### **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 magnetic resonance imaging, or MRI. We have two product platforms. Our ClearPoint system, which is in commercial use in the United States, 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 February 2011, we also obtained CE marking approval for the ClearPoint system, which enables us to sell the ClearPoint system in the European Union. Substantially all of our product revenues for 2011 and for the nine months ended September 30, 2012 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 and the Boston Scientific licensing fees. Prior to 2008, we were a development stage enterprise. We have incurred significant losses since our inception in 1998 as we have devoted substantially all of our efforts to research and development. As of September 30, 2012, we had an accumulated deficit of \$64.9 million. We may continue to incur significant operating losses as we commercialize our ClearPoint system products, continue to develop our product candidates and expand our business generally. We also expect that our general and administrative expenses will increase due to additional operational and regulatory costs and expenses associated with operating as a public company.

### **Factors Which May Influence Future Results of Operations**

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

### **Revenues**

In June 2010, we received 510(k) clearance from the FDA to market our ClearPoint system in the United States for general neurological procedures. Future revenues from sales of our ClearPoint system products are difficult to predict and may not be sufficient to offset our continuing research and development expenses and our increasing selling, general and administrative expenses for the next several years. 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. With respect to a single hospital, we do not anticipate that sales of the reusable components of our ClearPoint system will generate recurring revenues from the sale of additional reusable components to that customer.

Since inception, our revenues relate primarily to our collaborative agreements with Boston Scientific, principally from recognition of portions of the \$13.0 million of licensing fees which we received in 2008. Revenues associated with these licensing fees are recognized on a straight-line basis over a five-year period ending in the first quarter of 2013, which is our estimated period of continuing involvement in the development activities. Additional payments related to substantive, performance-based milestones that may be received under the agreement regarding implantable cardiac leads will be deferred upon receipt and achievement of the specified milestones and recognized over our estimated period of continuing involvement.

#### ***Cost of Product Revenues***

Cost of product revenues primarily consists of 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, 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.

Product development timelines, likelihood of success and total costs vary widely by product candidate. At this time, due to the risks inherent in the product clearance and approval process and given the stage of development of the ClearTrace system, 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 and taxes, postage, office supplies and meeting costs. Our selling, general and administrative expenses are expected to increase due to costs associated with the commercialization of our ClearPoint system, increased headcount necessary to support our continued growth in operations, and the additional operational and regulatory burdens and costs associated with operating as a public company. In addition, we expect to continue to incur costs associated with protecting our intellectual property rights as necessary to support our product offerings.

#### ***Critical Accounting Policies***

There have been no significant changes in our critical accounting policies during the nine months ended September 30, 2012, from the critical accounting policies described in Amendment No. 2 to our Form 10 registration statement containing our audited financial statements for the year ended December 31, 2011, which we filed with the SEC on February 28, 2012.

## Results of Operations

### Three Months Ended September 30, 2012 Compared to the Three Months Ended September 30, 2011

(\$ in thousands)	Three Months Ended September 30,		Percentage Change
	2012	2011	
<b>Revenues</b>	\$ 1,132	\$ 1,155	(2)%
<b>Cost of product revenues</b>	133	308	(57)%
<b>Research and development costs</b>	574	910	(37)%
<b>Selling, general and administrative expenses</b>	1,442	1,368	5%
<b>Other expense:</b>			
Interest expense, net	(79)	(705)	(89)%
Other income, net	21	-	NM
<b>Net loss</b>	(1,075)	(2,136)	50%

NM= not meaningful

*Revenues.* Revenues were \$1.1 million for the three months ended September 30, 2012, and \$1.2 million for the same three month period in 2011, a decrease of \$23,000, or 2%. License fee revenues related to our license agreements with Boston Scientific were \$650,000 during both periods. During the three months ended September 30, 2012, we recorded development service revenues of \$163,000 related to development services we provided to a third party. We do not expect the development service revenues to be a long-term on-going source of revenues. Product revenues for the three months ended September 30, 2012 and 2011 were \$318,000 and \$505,000, respectively, a decrease of \$186,000 or 37%. Approximately \$31,000 of the product revenues for the three months ended September 30, 2012 relate to the sale of ClearPoint system reusable components, compared with \$344,000 in the same three month period in 2011. We sold two ClearPoint systems during the three months ended September 30, 2011 and we sold select ClearPoint system reusable components to a distributor during the same three month period this year. ClearPoint system disposable component sales for the three months ended September 30, 2012 were \$287,000 compared with \$161,000 for the same three month period in 2011, an increase of \$126,000 or 78%. The increase in disposable product sales reflects an increasing number of ClearPoint procedures being performed as adoption of the ClearPoint system continues to increase.

*Cost of Product Revenues.* Cost of product revenues was \$133,000 for the three months ended September 30, 2012, compared to \$308,000 for the same three month period in 2011, a decrease of \$175,000, or 57%. The decrease in cost of product revenues was due to lower sales of ClearPoint system reusable components during the three months ended September 30, 2012 compared to the same three month period last year, resulting in a decrease of \$253,000. This decrease was partially offset by a \$40,000 increase in cost of sales associated with the increase in ClearPoint system disposable components and a increase in depreciation expense for loaned systems.

*Research and Development Costs.* Research and development costs were \$574,000 for the three months ended September 30, 2012, compared to \$910,000 for the same three month period in 2011, a decrease of \$336,000, or 37%. The primary driver of the decrease was a reduction in sponsored research, mostly related to our ClearTrace system, as we incurred \$230,000 in expenses during the three months ended September 30, 2011, and we funded no sponsored research during the same three month period in 2012. We also experienced a decrease in research and development costs of \$121,000 related to our Key Personnel Incentive Program, since no expense was recorded for the three months ended September 30, 2012 as a result of the program participants' voluntary and irrevocable relinquishment, in June 2012, of their rights to receive 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.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses were \$1.4 million for the three months ended September 30, 2012, compared with \$1.4 million for the same three month period in 2011, an increase of \$74,000, or 5%. The net increase occurred as we recorded \$215,000 in share-based compensation expense associated with warrants we issued to a service provider, and we experienced an increase in expense of approximately \$100,000 related to fees incurred for investor relations services and fees associated with our public company reporting obligations. These increases were mostly offset by a reduction in expense related to the timing of intellectual property related legal expenses.

*Other Income (Expense), Net.* Net interest expense for the three months ended September 30, 2012 was \$79,000, compared with \$705,000 for the same three month period in 2011, a decrease of \$626,000, or 89%. The decrease relates to the conversion of convertible notes payable into shares of our common stock in February 2012, which notes payable were outstanding during the three months ended September 30, 2011. The decrease in net interest expense is also attributable to a February 2012 loan modification pursuant to which the interest rate on related party notes payable was reduced from 10% to 0%.

Other income, net for the three months ended September 30, 2012 was \$21,000. Substantially all the other income reported in the three months ended September 30, 2012 relates to a gain due to the change in the fair value of our derivative liability.

***Nine Months Ended September 30, 2012 Compared to the Nine Months Ended September 30, 2011***

(\$s in thousands)	Nine Months Ended September 30,		Percentage Change
	2012	2011	
<b>Revenues</b>	\$ 3,196	\$ 2,654	20%
<b>Cost of product revenues</b>	392	421	(7)%
<b>Research and development:</b>			
<b>Research and development costs</b>	1,749	3,134	(44)%
<b>Reversal of R&amp;D obligations</b>	(883)	-	NM
<b>Selling, general and administrative expenses</b>	4,585	3,709	24%
<b>Other expense:</b>			
Interest expense, net	(2,496)	(1,842)	36%
Other expense, net	(4)	(3)	33%
<b>Net loss</b>	(5,149)	(6,456)	20%

NM= not meaningful

*Revenues.* Revenues were \$3.2 million for the nine months ended September 30, 2012, compared to \$2.7 million for the same nine month period in 2011, an increase of \$542,000, or 20%. License fee revenues related to our license agreements with Boston Scientific were \$2.0 million during both periods. During the nine months ended September 30, 2012, we recorded development service revenues of \$414,000 related to development services we provided to a third party. No such revenue was recorded during the same period in 2011. Product revenues for the nine months ended September 30, 2012 and 2011 were \$831,000 and \$704,000, respectively, an increase of \$127,000 or 18%. Approximately \$118,000 of the product revenues during the nine months ended September 30, 2012 relate to the sale of ClearPoint system reusable components, compared to \$435,000 for the same nine month period in 2011, a decrease of \$317,000. The decrease occurred as we sold three ClearPoint systems to customers during the nine months ended September 30, 2011, and we sold one ClearPoint system and other select reusable components to a distributor during the same period this year. Substantially all of the remaining product revenues for the nine months ended September 30, 2012 and 2011 of \$713,000 and \$269,000, respectively, relate to sales of ClearPoint disposable products. The 165% increase in disposable product sales reflects an increasing number of ClearPoint procedures being performed as adoption of the ClearPoint system continues to increase.

*Cost of Product Revenues.* Cost of product revenues was \$392,000 for the nine months ended September 30, 2012, compared to \$421,000 for the same nine month period in 2011, a decrease of \$29,000, or 7%. The decrease in cost of product revenues, in spite of the increase in product revenues, resulted from the change in sales mix as ClearPoint disposable sales represented 86% of product sales for the nine months ended September 30, 2012 compared with only 38% for the same nine month period in 2011. Margins on the sale of our ClearPoint system disposable components are typically significantly higher than on the sale of our ClearPoint system's reusable components. The decrease due to the change in sales mix was partially offset by the overall increase in product revenues and an increase of \$94,000 in depreciation expense for loaned systems, which was driven by the higher number of loaned systems in the field for the nine months ended September 30, 2012 compared with the same nine month period in 2011.

*Research and Development Costs.* Research and development costs were \$1.7 million for the nine months ended September 30, 2012, compared to \$3.1 million for the same nine month period in 2011, a decrease of \$1.4 million, or 44%. The primary driver of the decrease was a reduction in sponsored research, mostly related to our ClearTrace system, as we incurred \$691,000 in expenses during the nine months ended September 30, 2011, and we funded no sponsored research during the same nine month period in 2012. In addition, we recorded a credit of (\$97,000) during the nine months ended September 30, 2012 related to sponsored research as we negotiated with a research partner to reduce amounts we were previously invoiced, but which we had not yet paid, in order to reflect an adjustment for work outlined in our agreement with the research partner that was not completed. We experienced a decrease in research and development costs of \$241,000 related to our Key Personnel Incentive Program (see the explanation of reversal of service-based obligation below). The remainder of the decrease relates mostly to scaled back spending associated with our ClearTrace system development program, with consultant expenses decreasing by \$225,000 and the related software development costs declining by \$158,000. We scaled back our ClearTrace development program spending while we were seeking additional funding.

*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 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 \$4.6 million for the nine months ended September 30, 2012, compared with \$3.7 million for the same nine month period in 2011, an increase of \$876,000, or 24%. The increase relates mostly to share-based compensation expense of \$807,000 associated with warrants we issued in May 2012 to two non-employee directors to purchase 1.25 million shares of our common stock and additional warrants we issued to a service provider, two research contributors and a long-time financial adviser to purchase 366,666 shares of our common stock. All of these warrants had an exercise price of \$1.00 per share and were immediately vested upon issuance, and the fair value of these warrants was computed using the Black-Scholes pricing model. The remainder of the increase related mostly to costs incurred in connection with our being a public company.

*Other Income (Expense), Net.* Net interest expense for the nine months ended September 30, 2012, was \$2.5 million, compared with \$1.8 million for the same nine month period in 2011, an increase of \$654,000, or 36%. Accrued interest expense for the nine months ended September 30, 2012 was \$447,000, compared to \$802,000 for the same nine month period in 2011. The reduction in accrued interest was related to the conversion of convertible notes payable into shares of our common stock in February 2012, which notes payable were outstanding for all or part of the nine months ended September 30, 2011. The remainder of the interest expense recorded during the nine months ended September 30, 2012 was mostly related to the \$1.9 million write-off of deferred debt issuance costs and unamortized debt discounts associated with the conversion of convertible notes payable into shares of our common stock in February 2012. The remainder of interest expense recorded during the nine months ended September 30, 2011 related to amortization of debt discounts and deferred debt issuance costs. Interest income was approximately \$7,000 for the nine months ended September 30, 2012, compared with \$3,000 for the same nine month period last year.

## **Liquidity and Capital Resources**

We received \$13.0 million in licensing fees in 2008 under one of our agreements with Boston Scientific. We recognize revenue from these licensing fees over the estimated time period to complete our development work under the agreement. In addition, under the terms of the agreements, we could receive up to \$20.8 million in future milestone-based payments, subject to our achievement of the milestones stipulated in the agreements and the issuance of certain patents licensed to Boston Scientific, of which there can be no assurance. In addition to payments received from Boston Scientific, we have financed our operations and internal growth almost exclusively through private placements of stock and borrowings. We have incurred significant losses since our inception in 1998. As of September 30, 2012, we had an accumulated deficit of \$64.9 million. Our accumulated deficit resulted primarily from research and development activities and the costs to support such efforts as recorded in general and administrative costs.



During 2009, Boston Scientific loaned us \$3.5 million pursuant to the terms of three convertible promissory notes. Each loan accrued interest at the rate of 10% per year, compounded annually, and each loan was scheduled to mature on the second anniversary of the date on which the funds were advanced. Effective February 2, 2012, we entered into a loan amendment with Boston Scientific which extended the maturity dates of each loan by three years and also reduced the interest rate of each loan from 10% to 0%, beginning February 2, 2012. As of February 2, 2012, the outstanding aggregate loan balance owed to Boston Scientific was \$4.3 million. The Boston Scientific loans are secured by a first priority security interest in all of our assets. Under the terms of the loans, we will be required to prepay all or a portion of the loans upon the consummation of a qualified financing, which is any equity financing in which shares of our preferred stock are issued in exchange for cash proceeds. Upon consummation of a qualified financing from Medtronic, Inc., St. Jude Medical, Inc., or Johnson & Johnson, or any of their respective subsidiaries or affiliates, up to 100% of the cash proceeds from such qualified financing must be used to prepay the outstanding amount of the loans. Upon consummation of a qualified financing from any other investor, up to 25% of the cash proceeds from such qualified financing must be applied by us to prepay the outstanding amount of the loans. To date, we have not consummated a qualified financing. We can prepay each loan at any time prior to its respective maturity date. These loans are currently convertible, at the option of Boston Scientific, into 542,325 shares of our preferred stock, based on a current conversion price of \$8.00 per share. Each such share of preferred stock would be convertible initially into one share of our common stock. Alternatively, in the event we consummate a qualified financing, Boston Scientific could elect to convert its loans into shares of the preferred stock we issue in the qualified financing, based on a conversion price of \$8.00 per share or the price per share paid by investors in the qualified financing, whichever is lower.

In March 2010, we issued 10% senior unsecured convertible notes in the aggregate principal amount of \$4.1 million in a private placement. The notes were scheduled to mature two years from the date of issuance, unless earlier converted, and they accrued interest at the rate of 10% per year. When issued, the notes did not provide for conversion into shares of our common stock upon the effectiveness of a registration statement on Form 10. However, all of the note holders amended their notes to provide for the automatic conversion of their notes, including the principal and all accrued interest, into shares of our common stock upon the effectiveness of a registration statement on Form 10, based on a conversion price of \$1.00 per share. We filed a registration statement on Form 10 in December 2011, which registration statement became effective in February 2012. Upon effectiveness of that registration statement, these notes converted into 4,868,041 shares of our common stock.

In November 2010, we closed a private placement in which we sold units to existing stockholders and other existing investors in the company. The offering was structured to allow existing stakeholders to maintain their pro rata interest in the company. Each unit consisted of a junior secured note and one share of our common stock. In the aggregate, we issued 10,714,286 units and received proceeds of \$3.0 million, meaning we issued 10,714,286 shares of common stock and promissory notes in the aggregate principal amount of \$3.0 million. The notes mature in November 2020 and accrue interest at the rate of 3.5% per year. The notes are secured by a subordinated security interest in all our assets. The notes are not convertible into shares of our common stock or any other securities. All outstanding principal and interest on the notes will be due and payable in a single payment upon maturity.

In April 2011, we issued a 10% subordinated secured convertible note in the principal amount of \$2.0 million to Brainlab AG. The note matures in April 2016, unless earlier converted, and it accrues interest at the rate of 10% per year. All outstanding principal and interest on the note will be due and payable in a single payment upon maturity. The note is secured by a security interest in all our assets. In the event we close a financing transaction in which we issue shares of our preferred stock and receive at least \$10.0 million in net proceeds, the principal and accrued interest of Brainlab's note will automatically convert into shares of the preferred stock issued in the financing, based on the lower of the price paid by investors in the financing or \$0.60 per share, if the number of shares to be issued upon conversion represents at least 10% of our outstanding shares of stock on a fully diluted basis. If the number of shares that would be issued upon conversion represents less than 10% of our outstanding shares of stock on a fully diluted basis, the note will convert into the shares of preferred stock that are issued in the financing, based on the lower of the price paid by investors in the financing or \$0.60 per share, only upon Brainlab's election to convert. Brainlab's note was amended as of February 23, 2012, to give Brainlab the option, at any time on or prior to February 23, 2013, to convert the principal and accrued interest under its note into shares of our common stock, based on a conversion price of \$0.60 per share. At that conversion price, Brainlab would have received 3,828,704 shares of our common stock upon conversion of its note as of September 30, 2012.

In June through September 2011, we issued unsecured convertible notes in the aggregate principal amount of \$1.3 million to six of our non-employee directors. The note holders also received common stock warrants to purchase 1,310,000 shares of our common stock. The notes were scheduled to mature two years from the date of issuance, unless earlier converted, and they accrued interest at 15% per year. The warrants were fully vested upon issuance, have a term of five years, and have an exercise price of \$0.01 per share. When issued, the notes provided for conversion into shares of our common stock (i) upon consummation of an initial public offering, based on a conversion price equal to 60% of the public offering price, or (ii) upon consummation of a reverse merger of our company into a publicly held shell company, based on a conversion price equal to 60% of the fair market value of our common stock at the time of the merger. The notes were subsequently amended to provide for automatic conversion of the notes, including the principal and all accrued interest, into shares of our common stock upon the effectiveness of a registration statement on Form 10, based on a conversion price of \$0.60 per share. These notes converted into 2,376,447 shares of our common stock upon the effectiveness of our Form 10 registration statement in February 2012.

In October 2011, we began a private placement of our securities in which we offered units, with each unit consisting of a 10% secured convertible note in the principal amount of \$100,000 and a warrant to purchase 50,000 shares of our common stock. The private placement ended in February 2012. The notes had a three year maturity, unless earlier converted, and they accrued interest at 10% per year. The notes were secured by a security interest in all our assets. The notes provided for automatic conversion, including the principal and all accrued interest, into shares of our common stock upon the effectiveness of a registration statement on Form 10, based on a conversion price of \$0.60 per share. Likewise, a note holder could elect at any time to convert the note into shares of our common stock, based on a conversion price of \$0.60 per share. The warrants were fully vested upon issuance, have a term of five years, and have an exercise price of \$0.75 per share. We received gross proceeds of \$5.4 million in connection with the unit offering. The placement agent and its sub-placement agents for the financing received, in the aggregate, cash fees in the amount of \$543,050, as well as warrants to purchase an aggregate of 941,288 shares of our common stock at an exercise price of \$0.60 per share. The notes issued in the unit offering converted into 9,153,248 shares of our common stock upon the effectiveness of our Form 10 registration statement. The warrants issued in the unit offering are exercisable for 2,715,250 shares of our common stock.

The table below summarizes the impact to our balance sheet and to shares outstanding of the conversions to common stock that occurred upon the effectiveness of our Form 10 registration statement, which occurred on February 27, 2012:

	<b>Impact to Balance Sheet</b>			<b>Increase in Common Shares Outstanding</b>
	<b>Before Conversions</b>	<b>Impact of Conversions</b>	<b>After Conversions</b>	
<i>(in 000s except for share amounts)</i>				
<b>Impact on assets</b>				
Deferred costs	\$ 799	\$ (799)	\$ -	-
<b>Impact on liabilities and equity</b>				
Accrued interest on converted notes	\$ 974	\$ (974)	\$ -	1,092,559
Summer 2011 Notes, net	904	(904)	-	2,183,334
March 2010 Notes, net	4,058	(4,058)	-	4,071,000
2011 Unit Offering Notes, net	4,367	(4,367)	-	9,050,834
Total impact on liabilities	<u>10,304</u>	<u>(10,304)</u>	-	<u>16,397,727</u>
Series A convertible preferred stock *	7,965	(7,965)	-	7,965,000
Additional paid-in capital and common stock	-	19,345	19,345	-
Accumulated deficit	-	(1,876)	(1,876)	-
Total impact on equity	<u>7,965</u>	<u>9,505</u>	<u>17,470</u>	<u>7,965,000</u>
Total impact on liabilities and equity	<u>\$ 18,269</u>	<u>\$ (799)</u>	<u>\$ 17,470</u>	<u>24,362,727</u>

\* See Note 8 to the September 30, 2012 condensed financial statements.

In early July 2012, we entered into securities purchase agreements with certain investors for the sale of shares of our common stock and warrants to purchase shares of our common stock in a private placement (the "July 2012 PIPE Financing"). In the July 2012 PIPE Financing, we sold to the investors 5,454,523 shares of common stock, together with warrants to purchase 2,727,274 shares of common stock, for aggregate gross proceeds of \$6.0 million. The warrants were fully vested upon issuance, expire five years from the date of issuance and have an exercise price of \$1.45 per share, subject to adjustment from time to time for stock splits or combinations, stock dividends, stock distributions, recapitalizations and other similar transactions. In addition, the exercise price of the warrants will be subject to weighted average anti-dilution protection, such that the exercise price will be adjusted downward on a weighted average basis to the extent the Company issues common stock or common stock equivalents in a financing transaction at a price below the then prevailing warrant exercise price. The placement agent and its sub-placement agents for the July 2012 PIPE Financing received, in the aggregate, cash fees in the amount of \$480,000, as well as warrants to purchase an aggregate of 409,093 shares of our common stock, which expire five years from the date of issuance, at an exercise price of \$1.10 per share. We are using the proceeds from the July 2012 PIPE Financing for working capital and general corporate purposes.

## Cash Flows

Cash activity for the nine months ended September 30, 2012 and 2011 is summarized as follows:

(\$ in thousands)	Nine Months Ended September 30,	
	2012	2011
Cash used in operating activities	\$ (5,207)	\$ (4,803)
Cash used in investing activities	(93)	(16)
Cash provided by financing activities	8,942	3,312
Net increase (decrease) in cash and cash equivalents	<u>\$ 3,642</u>	<u>\$ (1,507)</u>

Net cash used in operating activities for both nine month periods primarily reflects the net loss for those periods, which was reduced in part by amortization, depreciation and share-based compensation expense, but which increased by the change in deferred revenue. Net cash used in operating activities for the nine months ended September 30, 2012 also reflects a use of cash related to the \$2.0 million reduction in accounts payable and accrued expenses as we paid down certain outstanding balances with cash from our 2012 financings and cash from accounts receivable. Net cash used in operating activities for the nine months ended September 30, 2011 also reflects a source of cash of \$1.7 million related to an increase in accounts payable and accrued expenses. The losses for both periods resulted mostly from selling, general and administrative expenses and from funding research and development activities.

Net cash provided by financing activities for the nine months ended September 30, 2012 relates to the \$5.5 million of net proceeds generated from our July 2012 PIPE Financing transaction and the \$3.4 million of net proceeds generated in 2012 from our unit offering, which we concluded in February 2012. Net cash provided by financing activities for the nine months ended September 30, 2011 relates mostly to the proceeds from our issuance of a \$2.0 million convertible note payable in April 2011 and \$1.3 million we received in a financing transaction in which we issued both convertible notes payable and warrants to purchase shares of our common stock.

## 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. We believe that our existing cash resources, together with cash generated from sales of our products, will be sufficient to meet our anticipated cash requirements through the first quarter of 2013. We anticipate that we will conduct another offering to sell additional equity or debt securities prior to the end of the first quarter of 2013 in order to meet our short-term cash requirements. The size of this offering will dictate the need and timing for additional financings to meet longer term liquidity requirements. The sale of additional equity and debt securities will likely result in dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We will require additional capital beyond our near term forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned commercialization, research and development activities, which could materially harm our business.

Our forecast of the period of time through which our financial resources will be adequate to support our operations, the costs to commercialize our ClearPoint system products and the costs to complete development of our product candidates are forward-looking statements and involve risks and uncertainties. Actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in Item I.A of Part II in this Quarterly Report. We have based these estimates on assumptions that may prove to be wrong, and we could deplete our available capital resources sooner than we currently expect.

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, marketing and distribution capabilities and other corporate infrastructure;
- the cost of establishing 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.

### **Contractual Obligations**

Significant changes in our contractual obligations during the nine months ended September 30, 2012 from the contractual obligations disclosed in the Amendment No. 2 to Form 10 registration statement, which we filed with the SEC on February 28, 2012, are described below. In addition, as described above in “Management’s Discussion and Analysis of Financial Condition and Results of Operation–Liquidity and Capital Resources,” during the nine months ended September 30, 2012 certain convertible notes payable converted into shares of our common stock upon the effectiveness of the Form 10 registration statement.

#### *Software License Agreement*

Effective June 22, 2012, we entered into an agreement (the “Amendment”) with our software development partner for our ClearPoint system to amend the master services and license agreement between us (the “Master Agreement”).

We entered into the Master Agreement in July 2007 for the software development partner to develop on our behalf, based on our detailed specifications, a customized software solution for our ClearPoint system. The software development partner was in the business of providing software development and engineering services on a contract basis to a number of companies. In developing the ClearPoint system software, the software development partner utilized certain of its own pre-existing software code. Under the Master Agreement, we received a non-exclusive, worldwide license to that code as an integrated component of the ClearPoint system software. In return, we agreed to pay the software development partner a license fee for each copy of the ClearPoint system software distributed, subject to certain minimum license purchase commitments.

Pursuant to the Amendment, we agreed to issue the software development partner 1,500,000 shares of our common stock (1) in full payment and satisfaction of license fees owed to the software development partner in the amount of \$613,000 for licenses we previously purchased, (2) in full payment and satisfaction of all our remaining minimum license purchase commitments under the Master Agreement in the amount of \$963,000, and (3) in exchange for additional licenses provided by the software development partner to us valued at \$88,000 based on the original terms of the Master Agreement.

#### *Key Personnel Incentive Program*

We adopted our Key Personnel Incentive Program to provide a key consultant (who is a non-employee director of the Company) and a key employee (collectively, the “Participants”) with the opportunity to receive incentive bonus payments based on the performance of future services for us or upon a consummation of a transaction involving the sale of the company. In June 2012, the Participants voluntarily and irrevocably relinquished their rights to receive, and the Participants discharged us from our obligations to make, any and all incentive bonus payments related to performance of services under the Key Personnel Incentive Program.

Pursuant to the Key Personnel Incentive Program, in the event of a sale transaction, each of the Participants will be entitled to receive an incentive bonus payment equal to \$1.0 million. In addition, one of the Participants will also receive an incentive bonus payment equal to 1.4% of net proceeds from the sale transaction in excess of \$50.0 million, but the bonus payment will not exceed \$700,000. If a sale has not occurred by December 31, 2025, the Key Personnel Incentive Program will terminate.

#### *Employment Agreements*

In June 2012, we entered into employment agreements (each, an “Employment Agreement,” and collectively, the “Employment Agreements”) with four of our executive officers (each, an “Executive,” and collectively, the “Executives”). Among other provisions customary for agreements of this nature, the Employment Agreements provide for severance in the event of a termination without cause or if the Executive terminates his employment for good reason, as those terms are defined in each Employment Agreement. Likewise, the Employment Agreements provide for certain payments in connection with a change of control transaction. The initial base salaries set forth in the Employment Agreements are the same as the base salaries for each of the Executives that were in effect immediately prior to the execution of the Employment Agreements.

#### *Sponsored Research Agreement*

In September 2012, we entered into a research agreement with a university pursuant to which we agreed to provide the university funding in the amount of \$317,415 to support certain research activities over the one-year period beginning October 1, 2012. Under the terms of the research agreement, we will make four quarterly payments of \$79,354. The first of these payments was made in October 2012.

### **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 United States 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. We believe we have no material exposure to risk from changes in foreign currency exchange rates at this time. We will continue to monitor and evaluate our internal processes relating to foreign currency exchange, including the potential use of hedging strategies.

### **ITEM 4. CONTROLS AND PROCEDURES.**

#### *Disclosure Controls and Procedures*

We have established disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or the Exchange Act. Our disclosure controls and procedures are designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others within our organization. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2012 to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2012.

#### *Changes in Internal Control Over Financial Reporting*

During the quarter ended September 30, 2012, there were no changes in our internal control over financial reporting that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS.

Not applicable.

### ITEM 1A. RISK FACTORS.

*Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and all other information contained in this Quarterly Report on Form 10-Q, including our condensed financial statements and the related notes, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, also may become important factors that affect us. If any of the following risks materialize, our business, financial condition and results of operations could be materially harmed.*

#### **Risks Related to Our Business**

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

As of September 30, 2012, we had an accumulated deficit of approximately \$64,938,000. 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 \$5,149,000 for the nine months ended September 30, 2012, approximately \$8,311,000 for the year ended December 31, 2011, approximately \$9,454,000 for the year ended December 31, 2010, and approximately \$7,159,000 for the year ended December 31, 2009. We may continue to incur significant operating losses as we continue to invest capital in the sales and marketing of our products, development of our product candidates and our business generally. We also expect that our general and administrative expenses may increase due to additional operational and regulatory burdens associated with operating as a public company.

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 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 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 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 new medical devices such as our ClearPoint system. Therefore, our ability to successfully commercialize our ClearPoint system depends significantly on the availability 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.

We do not know if hospitals will consider third-party reimbursement levels adequate to cover the cost of our ClearPoint system. Furthermore, we do not know if physicians will consider third-party reimbursement levels 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 limit our sales growth.

One result of the current Medicare payment system, which is also utilized by most non-governmental third-party payors, is that a patient's treating physician orders a particular service and the hospital (or other facility in which the procedure is performed) bears the cost of delivery of the service. Hospitals have limited ability to align their financial interests with those of the treating physician because Medicare law generally prohibits hospitals from paying physicians to assist in controlling the costs of hospital services, including paying physicians to limit or reduce services to Medicare beneficiaries even if such services are medically unnecessary. As a result, hospitals have traditionally stocked supplies and products requested by physicians and have had limited ability to restrict physician choice of products and services.

The Patient Protection and Affordable Care Act enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 enacted on March 30, 2010, or, together, the Affordable Care Act, includes a number of provisions that will likely result in more coordination between hospitals and physicians resulting in the alignment of financial incentives between hospitals and physicians to control hospital costs. On June 28, 2012, the United States Supreme Court announced its decision upholding the Affordable Care Act, with the exception of the provision that would have forced states that did not comply with Medicaid expansion potentially to forfeit all of their Medicare funding. 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 may limit the acceptance and availability of our products, which could have an adverse effect on our financial results and business.



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

In the United States, we believe that existing billing codes apply to procedures using 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 ClearPoint system or any product that we may market in the future 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 its 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, not cost-effective, or 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 currently 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 delay our ability to manufacture our ClearPoint system in a timely manner or within budget.

***If we are unable to expand our sales and marketing capabilities, we may be unable to generate material product revenues.***

We are dependent on our sales force to obtain new customers for our ClearPoint system and to increase sales of our ClearPoint products to existing customers. We expect to continue building a small, highly focused sales force to market and sell 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 personnel to support our growth. 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 and train sufficient numbers of effective sales personnel, or our sales 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, on a non-exclusive basis, in the United States and Europe. However, there is no assurance that Brainlab will be successful in marketing and selling our ClearPoint system. Under our agreement, Brainlab is not subject to any minimum sales or other performance requirements. Likewise, for ClearPoint products that Brainlab sells, our revenues will be lower than if we sell the ClearPoint products ourselves.

***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 U.S. or foreign governments; and
- negative consequences from changes in tax laws.

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

***The Affordable Care Act and other payment and policy changes may have a material adverse effect on us.***

In addition to the reimbursement changes discussed above, the Affordable Care Act will also impose a 2.3% excise tax on the sale of any taxable human medical device after December 31, 2012, subject to certain exclusions, by the manufacturer, producer or importer of such devices. The total cost to the industry is expected to be approximately \$20 billion over ten years. This new and significant tax burden could have a material negative impact on the results of our operations and the operations of our strategic partners. Further, the Affordable Care Act encourages hospitals and physicians to work collaboratively through shared savings programs, such as accountable care organizations, as well as other bundled payment initiatives, which may ultimately result in the reduction of medical device acquisitions and the consolidation of medical device suppliers used by hospitals. While passage of the Affordable Care Act may ultimately expand the pool of potential patients for our ClearPoint system, the above-discussed changes could adversely affect our financial results and business.

Further, 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 it is unclear how the federal election may ultimately impact the effects of the Affordable Care Act. Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives, if any, 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.

***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, have been, and may continue to be, negatively impacted by our focus on the commercialization of our ClearPoint system.

Under our co-development agreement, we had paid Siemens \$1,120,000 as of September 30, 2012 in connection with Siemens' MRI software development work, and, in addition, we had accrued payables of approximately \$254,000. 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, and, as noted above, our focus currently is on the commercialization of our ClearPoint system. To date, we have conducted only animal studies and other preclinical work with respect to the ClearTrace system. As development efforts are ongoing, we cannot predict a timetable for completion of our development activities. Likewise, 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 Food and Drug Administration, or 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. We may not be able to file for regulatory clearance or approval and may not receive necessary clearance or approval to commercialize a product candidate in any foreign market, either of which would preclude sale of that product candidate in foreign jurisdictions.

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 will 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 may seek to obtain additional, more specific indications for use of our ClearPoint system beyond the general neurological intervention claim. 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 that we may seek may require clinical trials to support regulatory clearance or approval, and we may not successfully complete or have the funds to initiate these clinical trials. The FDA may not clear or approve these future claims or future generations of our ClearPoint system for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or PMA approval. Failure to receive clearance or approval for additional claims for our ClearPoint system could have an adverse effect on our ability to expand our business.

***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 a PMA 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 marketed 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 the 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 royalties in the amounts that we currently anticipate. To our knowledge, our licensed intellectual property has not been incorporated into any of the Boston Scientific's currently commercialized products.

## Risks Related to our Need for Financing

*We may not be able to continue operations as a going concern, and our stockholders may lose their entire investment in us.*

At September 30, 2012 and December 31, 2011, we had cash and cash equivalents of approximately \$3,787,000 and \$145,000, respectively, and stockholders' deficit of approximately \$5,777,000 and \$21,843,000, respectively. In addition, we had a net loss for the nine months ended September 30, 2012 of approximately \$5,149,000, a net loss for the year ended December 31, 2011 of approximately \$8,311,000, a cumulative net loss from inception through September 30, 2012 of approximately \$64,938,000, and a negative working capital position at September 30, 2012 of approximately \$1,200,000. In view of these matters, our ability to continue as a going concern is dependent upon our ability to generate additional financing sufficient to commercialize our products, support our research and development activities and obtain future regulatory clearances or approvals, and ultimately to generate revenues sufficient to cover all costs.

Since our inception, we have financed our activities principally from sales of equity securities, borrowings, and license arrangements. Similarly, we intend to finance our future commercialization and development activities and our working capital needs largely from sales of equity securities or borrowings until funds provided by operations are sufficient to meet our working capital requirements. There can be no assurance that we will be successful in satisfying our financing requirements on reasonable commercial terms, if at all, or that we will generate revenues sufficient to cover our costs. If we cannot continue as a going concern, our stockholders may lose their entire investment in us.

*We will need additional funding to continue to commercialize our ClearPoint system and to bring the ClearTrace system to market, and we may not be able to raise capital when needed, which would force us to delay, reduce or eliminate our commercialization efforts or our product development programs.*

We will require additional capital in order to continue to establish effective marketing and sales capabilities for our ClearPoint system and to conduct the research and development and regulatory clearance and approval activities necessary to bring the ClearTrace system to market. Although our operating plans may change, and we may need additional funds sooner than anticipated to meet our operational needs and capital requirements, we believe our existing cash resources, together with cash generated from sales of our products, will be sufficient to meet our anticipated liquidity requirements through the first quarter of 2013. Prior to the end of the first quarter of 2013, we plan to commence an offering to sell additional equity or debt securities in order to meet our short-term cash requirements. The size of this offering will dictate the need and timing for additional financings to meet longer term liquidity requirements.

Additional funds may not be available when we need them or on terms that are acceptable to us, or at all. If adequate funds are not available on a timely basis, we may take actions that negatively impact the commercialization of our ClearPoint system, or terminate or delay the development of the ClearTrace system.

Our future funding requirements will depend on many factors, including:

- the cost and timing of expanding our sales, 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 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 by issuing securities or through collaborative or licensing arrangements 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.

As of October 31, 2012, our portfolio included 11 wholly-owned issued United States patents (including one design patent), 30 wholly-owned pending United States patent applications (including five provisional applications), eight co-owned issued United States patents, seven co-owned pending United States patent applications, eight wholly-owned issued foreign patents, 34 wholly-owned pending foreign patent applications (including three Patent Cooperation Treaty applications), 14 co-owned issued foreign patents and 15 co-owned pending foreign patent applications. In addition, as of October 31, 2012, we had licensed rights to 17 United States and 15 foreign third-party issued patents, and we had licensed rights to five United States and 11 foreign third-party pending patent applications. 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 assure 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 technical and 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 received a non-exclusive, worldwide license from a third party to certain software code that is integrated into the software component of our ClearPoint system. In return, we agreed to pay the third party a license fee for each copy of the ClearPoint system software that we distribute, subject to certain minimum license purchase commitments which we have satisfied. Our agreement with the third party continues through July 2015. If we do not extend the agreement, we will not be able purchase additional licenses after July 2015, which 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, could 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; (3) we must maintain net working capital, which is defined as our current assets minus our current liabilities other than deferred revenue, of at least \$(6.0) million as of the end of each month from June 2012 through December 2012; (4) we must maintain net working capital of at least \$(2.0) million as of the end of each month from January 2013 through March 2013; and (5) we must have a net working capital ratio, which is defined as our current assets divided by our current liabilities other than deferred revenue, of at least 0.80 as of the end of April 2013 and as of the end of each month thereafter.

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 October 31, 2012, our licensing arrangements with Boston Scientific included six wholly owned issued United States patents, three wholly owned pending United States patent applications, eight wholly owned issued foreign patents, six wholly owned pending foreign patent applications, eight 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.

***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.***

Many of our employees were previously employed at universities or other medical device companies, including competitors or potential competitors. In the future, we could be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending against such claims, a court could order us to pay substantial damages and prohibit us from using technologies or features that are essential to our products and product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. In addition, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain product candidates, which could severely harm our business. Even if we are successful in defending against these claims, such litigation could result in substantial costs and be a distraction to our employees and management.

***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 or in the event we file for bankruptcy. 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 marketed products or refunds;
- recall, detention or seizure of our marketed 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 marketed 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 operations and financial results.***

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.

***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 intervention 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 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 uses of our products that are not cleared or approved, whether on our website, in product brochures or in customer communications. This prohibition means that the FDA could deem it unlawful for us to make claims about the use of our ClearPoint system for specific neurological procedures, or proactively discuss or provide information or training on the use of our ClearPoint system for those specific neurological procedures. 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. This would constitute an off-label use. We expect that physicians will use our ClearPoint system for a variety of specific neurological procedures.

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, in addition to the privacy and security rules normally associated with HIPAA which are discussed below, 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 and analogues 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 imposes certain reporting obligations on manufacturers of drugs, devices and biologics. Specifically, on March 31, 2013, and on the 90th day of each calendar year thereafter, these manufacturers must report all 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 December 19, 2011, CMS issued proposed regulations to implement this so-called "Sunshine" provision of the Affordable Care Act. The proposed regulations suggest that we will be subject to such data collecting, reporting and public disclosure obligation. Data collecting obligations were scheduled to commence on the effective date of final regulations, which were expected in 2012 with reporting obligations beginning on March 31, 2013. However, in response to a letter from Senators Grassley and Kohl, CMS Acting Administrator, Marilyn Tavenner, responded in early May 2012, stating that "while we [CMS] intend to release a final rule later this year, we [CMS] will not require data collection by applicable manufacturers and applicable group purchasing organizations before January 1, 2013." The official CMS blog post dated May 3, 2012, consistently states that "CMS will not require data collection by applicable manufacturers and applicable group purchasing organizations before January 1, 2013." Further, on May 18, 2012, eight members of the U.S. House of Representatives sent a letter to Acting Administrator Tavenner requesting that implementation of the "Sunshine" provisions be delayed until the appropriate congressional committees of jurisdiction are given a chance to review the proposed rule and its anticipated impact. CMS has not yet responded to this letter and as such, it is unclear when the implementation of these provisions will occur. Violations of the reporting requirements are subject to civil monetary penalties, capped at \$150,000 annually for failing to report, and \$1,000,000 for knowingly failing to report. Data reported by manufacturers is currently scheduled to be made publicly available by September 30, 2013.
- 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:

- 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);

- assisting us with the technical evaluation of our methods, processes and devices related to their respective fields;
- advising us with respect to the commercialization of products in their respective fields; and
- providing training and other similar services on the proper use of our products.

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, 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 was enacted in February 2009, 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, or FTC, 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 provisions that became effective in February 2010. Because the final regulatory changes to the HIPAA regulations required as part of HITECH have not yet been released, we are unable to predict what the impact on our business may be. 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, engineering team, sales and marketing team and key research and physician advisors, 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, and Peter G. Piferi, our Chief Operating Officer. The loss of members of our senior management team, engineering team, sales and marketing team and key research and physician advisors, or our inability to attract or retain other qualified personnel or advisors, 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 and Mr. Piferi. Although we have obtained key employee insurance covering Mr. Jenkins and Mr. Piferi in the amount of \$2,000,000, this would not fully compensate us for the loss of Mr. Jenkins' or Mr. Piferi's 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 marketing team. We plan to continue to grow our business and will need to hire additional personnel to support this growth. It is often difficult to hire and retain these persons, and we may be unable to replace key persons if they leave or fill new positions requiring key persons with appropriate experience. If we experience difficulties locating and hiring suitable personnel in the future, our growth may be hindered. Qualified individuals are in high demand, particularly in the medical device industry, and we may incur significant costs to attract and retain them. If we are unable to attract and retain the personnel we need to succeed, our business and growth could be harmed.

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

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

- expanding our sales 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 personnel, systems, controls and infrastructure 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, in which case 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 a 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 on the OTC Bulletin Board, 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 became 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 the rules adopted under the Exchange Act. The SEC has adopted rules 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:

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

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

***Our common stock is quoted on the OTC Bulletin Board, and our stock price could be volatile.***

Our common stock is currently quoted on the OTC Bulletin Board. This market lacks the credibility of established stock markets and is characterized by larger gaps between bid and ask prices. Stocks quoted on the OTC Bulletin Board 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, we filed a registration statement 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. That registration statement became effective in September 2012, and as such all of the shares of our common stock covered by the registration statement are now freely transferable, unless held by an affiliate of ours. In addition to the shares of our common stock covered by that registration statement, as of October 31, 2012, approximately 32.5 million of our outstanding shares are freely transferable or may be publicly resold pursuant to Rule 144 under the Securities Act. Of those shares, approximately 9.9 million shares are held by our affiliates and approximately 22.6 million shares are 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 statement, 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.

In addition, we filed a registration statement on Form S-8 to register the shares issuable upon exercise of outstanding options or reserved for issuance under our stock option plans. That registration statement became effective when filed.

***Our directors, executive officers and principal stockholders and their respective affiliates have substantial control over us and could delay or prevent a change in corporate control.***

As of October 31, 2012, our directors and executive officers, together with their affiliates, beneficially owned, in the aggregate, 27.6% of our common stock. As a result, these stockholders, acting together, have substantial control over the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, have significant influence over the management and affairs of our company. Accordingly, this concentration of ownership may 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 amended and restated bylaws only upon receiving at least 66 2/3% of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

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

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although we could lose that status sooner if our revenues exceed \$1 billion, if we issue more than \$1 billion in non-convertible debt in a three year period, or if the market value of our common stock held by non-affiliates exceeds \$700 million as of any June 30 before that time, in which case we would no longer be an emerging growth company as of the following December 31. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

***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 control, disclosure controls and procedures and financial reporting and accounting systems, including requirements under the Sarbanes-Oxley Act of 2002, as amended, or 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 will 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 to 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.

In addition, the Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, for the fiscal year ending December 31, 2012, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 will require that we incur substantial expense and expend significant management time on compliance-related issues.

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

In May 2012, we entered into a service agreement with a third-party service provider, pursuant to which we agreed to issue the service provider warrants to purchase up to 270,000 shares of our common stock at an exercise price of \$1.00 per share, as partial compensation for services rendered. During the three months ended September 30, 2012, we issued the service provider warrants to purchase 135,000 shares of our common stock. All warrants issued to the service provider under the service agreement expire in May 2014, to the extent such warrants are not earlier exercised.

On July 2, 2012 and July 3, 2012, we entered into securities purchase agreements with certain investors for the private placement of shares of our common stock and warrants to purchase shares of our common stock, at a purchase price of \$1.10 per unit. Each unit consisted of one share of common stock and a warrant to purchase one-half share of common stock. Summer Street Research Partners, and the additional broker-dealers it engaged as sub-agents, served as our placement agents in the financing transaction. In the financing transaction, we sold to the investors approximately 5.5 million shares of common stock, together with warrants to purchase approximately 2.7 million shares of common stock, for aggregate gross proceeds of \$6.0 million. The warrants we issued to investors are exercisable for five years from the date of issuance and have an exercise price of \$1.45 per share, subject to adjustment as provided therein. As a result of the financing transaction, the placement agents earned commissions of approximately \$0.5 million as well as warrants to purchase approximately 0.4 million shares of our common stock. The warrants we issued to the placement agents have the same terms and conditions as the investor warrants, except that the placement agent warrants have an exercise price of \$1.10 per share.

During the three months ended September 30, 2012, holders of warrants to purchase an aggregate of 584,768 shares of our common stock exercised their warrants. Of that aggregate number, warrants to purchase 60,000 shares of our common stock, having an exercise price of \$0.01 per share, were exercised for cash proceeds totaling \$600. The remaining warrants, having a weighted average exercise price of \$0.73 per share, were exercised on a cashless basis, which resulted in the net issuance of 366,690 shares of our common stock. Therefore, we issued a total of 426,690 shares of our common stock upon exercise of warrants during the three months ended September 30, 2012.

We claimed exemption from registration under the Securities Act for the sales and issuances of the securities in 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 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 14, 2012

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 Chief Accounting Officer)*

## EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation (1)
3.2	Amended and Restated Bylaws (1)
3.3	Form of Registration Rights Agreement by and among MRI Interventions, Inc. and the purchasers named therein (2)
3.4	Form of Subscription Agreement for 10% Secured Convertible Promissory Note Due 2014 (3)
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4.
4.2	Specimen of Common Stock Certificate (4)
4.3	Form of 10% Senior Unsecured Convertible Note Due 2012 (3)
4.4	Form of Junior Secured Promissory Note Due 2020, as amended by that certain Omnibus Amendment dated as of April 5, 2011, as further amended by that certain Second Omnibus Amendment dated as of October 14, 2011 (5)
4.5	10% Subordinated Secured Convertible Note Due 2016 issued to Brainlab AG, as amended (5)
4.6	Form of Unsecured Convertible Promissory Note Due 2013, as amended (3)
4.7	Form of 10% Secured Convertible Promissory Note Due 2014 (3)
4.8	Form of Amendment to 10% Senior Unsecured Convertible Note Due 2012 (3)
4.9	Form of Warrant issued to purchasers in the July 2012 private placement to purchase shares of common stock of MRI Interventions, Inc. (2)
10.1+	1998 Stock Option Plan (3)
10.2+	2007 Stock Incentive Plan (3)
10.3+	Amended and Restated Key Personnel Incentive Program (3)
10.4+	2010 Incentive Compensation Plan (3)
10.5+	2010 Non-Qualified Stock Option Plan (3)
10.6	Junior Security Agreement by and between MRI Interventions, Inc. and Landmark Community Bank, in its capacity as collateral agent, dated as of November 5, 2010, as amended by that certain First Amendment dated April 5, 2011, and as further amended by that certain Second Amendment dated October 14, 2011 (3)
10.7	Security Agreement by and between MRI Interventions, Inc. and Landmark Community Bank, in its capacity as collateral agent, dated as of October 14, 2011 (3)
10.8+	Form of Indemnification Agreement (3)
10.9†	License Agreement by and between SurgiVision, Inc. and The Johns Hopkins University entered into on or around June 20, 1998, as amended by that certain Amendment to License Agreement dated as of January 15, 2000, and as further amended by that certain Addendum to License Agreement entered into on or around December 7, 2004 (3)



- 10.10† License Agreement by and between SurgiVision, Inc. and The Johns Hopkins University entered into on or around December 7, 2006 (3)
- 10.11† Technology License Agreement dated as of December 30, 2005 by and between SurgiVision, Inc. and Boston Scientific Neuromodulation Corporation (formerly known as Advanced Bionics Corporation), as amended by that certain Omnibus Amendment dated June 30, 2007, as further amended by that certain Omnibus Amendment #2 dated March 19, 2008 (6)
- 10.12† System and Lead Development and Transfer Agreement dated as of December 30, 2005 by and between SurgiVision, Inc. and Boston Scientific Neuromodulation Corporation (formerly known as Advanced Bionics Corporation), as amended by that certain Amendment No. 1 dated May 31, 2006, as further amended by that certain Omnibus Amendment dated June 30, 2007, as further amended by that certain Omnibus Amendment #2 dated March 19, 2008 (6)
- 10.13† Technology License Agreement dated as of March 19, 2008 by and between SurgiVision, Inc. and Cardiac Pacemakers, Inc. (3)
- 10.14† Development Agreement dated as of March 19, 2008 by and between SurgiVision, Inc. and Cardiac Pacemakers, Inc. (3)
- 10.15† Cooperation and Development Agreement, dated as of May 4, 2009, by and between SurgiVision, Inc. and Siemens Aktiengesellschaft, Healthcare Sector (6)
- 10.16+ Consulting Agreement with Dr. Paul Bottomley (5)
- 10.17† Co-Development and Distribution Agreement dated as of April 5, 2011 by and between SurgiVision, Inc. and Brainlab AG, as amended by that certain First Amendment dated as of July 18, 2011 (6)
- 10.18† Master Security Agreement dated April 5, 2011 by and between SurgiVision, Inc. and Brainlab AG (3)
- 10.19† Patent License Agreement – Nonexclusive entered into on or around April 27, 2009 by and between SurgiVision, Inc. and National Institutes of Health (3)
- 10.20† Master Services and Licensing Agreement dated as of July 20, 2007 by and between SurgiVision, Inc. and Cedara Software Corp., as amended by that certain First Amendment dated January 18, 2011 (6)
- 10.21† Exclusive License Agreement entered into on or around June 30, 2008 by and between SurgiVision, Inc. and The Johns Hopkins University (3)
- 10.22† Exclusive License Agreement entered into on or around June 30, 2008 by and between SurgiVision, Inc. and The Johns Hopkins University (3)
- 10.23† Exclusive License Agreement entered into on or around June 30, 2008 by and between SurgiVision, Inc. and The Johns Hopkins University (3)
- 10.24 Loan Agreement dated as of October 16, 2009 by and between SurgiVision, Inc. and Boston Scientific Corporation (3)
- 10.25† Patent Security Agreement dated as of October 16, 2009 by and between SurgiVision, Inc. and Boston Scientific Corporation (3)

- 10.26† Research Agreement by and between SurgiVision, Inc. and The University of Utah entered into on or around July 2, 2007, as amended by that certain First Amendment to the Research Agreement entered into on or around January 8, 2008, as further amended by that certain Second Amendment to the Research Agreement dated April 24, 2009, as further amended by that certain Third Amendment to the Research Agreement dated May 1, 2009, as further amended by that certain Fourth Amendment to the Research Agreement entered into on or around February 25, 2010, as further amended by that certain Fifth Amendment to the Research Agreement dated December 31, 2010, and as further amended by that certain Sixth Amendment to the Research Agreement dated November 28, 2011 (6)
- 10.27 Lease Agreement, dated as of April 21, 2008, by and between Shaw Investment Company, LLC and Surgi-Vision, Inc., as amended by that certain Amendment to Lease dated January 20, 2011, as further amended by that certain Amendment to Lease dated March 26, 2012 (1)
- 10.29+ SurgiVision, Inc. Cardiac EP Business Participation Plan (3)
- 10.30+ Cardiac EP Business Participation Plan Award Agreement, dated June 3, 2010, by and between SurgiVision, Inc. and Nassir F. Marrouche (3)
- 10.31+ Amended and Restated Key Personnel Incentive Award Agreement, dated June 2, 2010, by and between SurgiVision, Inc. and Paul A. Bottomley (3)
- 10.32+ Key Personnel Incentive Award Agreement, dated June 2, 2010, by and between SurgiVision, Inc. and Paul A. Bottomley (3)
- 10.33+ Amended and Restated Key Personnel Incentive Award Agreement, dated June 2, 2010, by and between SurgiVision, Inc. and Parag V. Karmarkar (3)
- 10.34+ MRI Interventions, Inc. 2012 Incentive Compensation Plan (4)
- 10.35+ MRI Interventions, Inc. 2012 Incentive Compensation Plan Form of Incentive Stock Option Agreement (4)
- 10.36+ MRI Interventions, Inc. 2012 Incentive Compensation Plan Form of Non-Qualified Stock Option Agreement (4)
- 10.37† Amendment No. 1 to Loan Agreement Secured Convertible Promissory Notes and Patent Security Agreement effective February 2, 2012, between MRI Interventions, Inc. and Boston Scientific Corporation (6)
- 10.38† Omnibus Amendment No. 3 to Technology License Agreement and System and Lead Development and Transfer Agreement effective February 2, 2012, between MRI Interventions, Inc. and Boston Scientific Neuromodulation Corporation (6)
- 10.39 Separation Agreement, dated as of May 8, 2012, by and between John Keane and MRI Interventions, Inc. (7)
- 10.40+ Employment Agreement, dated as of June 19, 2012, by and between Kimble L. Jenkins and MRI Interventions, Inc. (8)
- 10.41+ Employment Agreement, dated as of June 19, 2012, by and between Peter G. Piferi and MRI Interventions, Inc. (8)
- 10.42+ Employment Agreement, dated as of June 19, 2012, by and between David W. Carlson and MRI Interventions, Inc. (8)
- 10.43+ Employment Agreement, dated as of June 19, 2012, by and between Oscar L. Thomas and MRI Interventions, Inc. (8)

10.44†	Second Amendment to the Master Services and Licensing Agreement, dated as of June 22, 2012, by and between Merge Healthcare Canada Corp. and MRI Interventions, Inc. (9)
10.45	Form of Securities Purchase Agreement by and among MRI Interventions, Inc. and the purchasers named therein (2)
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 63 of Title 18 of the United States Code.
101.INS***	XBRL Instance
101.SCH***	XBRL Taxonomy Extension Schema
101.CAL***	XBRL Taxonomy Extension Calculation
101.DEF***	XBRL Taxonomy Extension Definition
101.LAB***	XBRL Taxonomy Extension Labels
101.PRE***	XBRL Taxonomy Extension Presentation

\* Filed herewith.

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

\*\*\* Pursuant to Rule 406T of Regulation S-T adopted by the Securities and Exchange Commission, 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.

+ Indicates management contract or compensatory plan.

† 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.

- (1) Incorporated by reference to the Company's Form 10-Q filed with the SEC on May 11, 2012.
- (2) Incorporated by reference to the Company's Form 8-K filed with the SEC on July 6, 2012.
- (3) Incorporated by reference to the Company's registration statement on Form 10 filed with the SEC on December 28, 2011.
- (4) Incorporated by reference to Amendment No. 1 to the Company's registration statement on Form 10 filed with the SEC on February 9, 2012.
- (5) Incorporated by reference to Amendment No. 2 to the Company's registration statement on Form 10 filed with the SEC on February 28, 2012.
- (6) Incorporated by reference to Amendment No. 3 to the Company's registration statement on Form 10 filed with the SEC on March 15, 2012.
- (7) Incorporated by reference to the Company's Form 8-K filed with the SEC on May 14, 2012.
- (8) Incorporated by reference to the Company's Form 8-K filed with the SEC on June 21, 2012.
- (9) Incorporated by reference to the Company's Form 8-K filed with the SEC on June 26, 2012.

