As filed with the Securities and Exchange Commission on October 7, 2013

Registration No. 333-186573

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

Post-Effective Amendment No. 1
to
FORM S–1
on
FORM S-3

REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

MRI INTERVENTIONS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**3841**	**58-2394628**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification No.)*

One Commerce Square, Suite 2550
Memphis, TN 38103
(901) 522-9300
(Address, including zip code, and telephone number, including area code, of registrant's principal executive office)

Oscar L. Thomas
Vice President, Business Affairs
MRI Interventions, Inc.
One Commerce Square, Suite 2550
Memphis, TN 38103
(901) 522-9300
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:
Richard F. Mattern, Esq.
Baker, Donelson, Bearman, Caldwell & Berkowitz, PC
165 Madison Avenue, Suite 2000
Memphis, TN 38103
(901) 577-2343

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ☐

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ☐

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ☐

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. (check one)

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

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to Section 8(a), may determine.

EXPLANATORY NOTE

Pursuant to Rule 401 adopted under the Securities Act of 1933, this Post-Effective Amendment No. 1 to Form S-1 on Form S-3 is being filed to our registration statement on Form S-1 (Registration No. 333-186573), or the Registration Statement, which was initially declared effective by the Securities and Exchange Commission on March 21, 2013, to: (i) convert the Registration Statement from Form S-1 to Form S-3; and (ii) make certain updating revisions to the information contained herein. This amended Registration Statement relates to the registration of 11,938,285 shares of our common stock for resale by certain selling securityholders named herein. All applicable filing fees were paid at the time of the original filing of the Registration Statement.

The information contained in this prospectus is not complete and may be changed. The selling securityholders named in this prospectus may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell securities, and the selling securityholder is not soliciting offers to buy these securities, in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS **SUBJECT TO COMPLETION, DATED OCTOBER 7, 2013**

MRI Interventions, Inc.

11,938,285 Shares of Common Stock

This prospectus relates to 7,437,443 outstanding shares of our common stock, and 4,500,842 shares of our common stock issuable upon the exercise of outstanding warrants, held by some of our securityholders which are named in this prospectus. The securities we are registering are to be offered for the account of the securityholders. 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.

Our common stock is traded in the over-the-counter market and is quoted on the OTC Bulletin Board and OTC Markets under the symbol MRIC. On October 4, 2013, the last reported sale price of our common stock was $1.51 per share.

The shares included in this prospectus may be offered and sold directly by the securityholders in accordance with one or more of the methods described in the "Plan of Distribution," which begins on page 32 of this prospectus. To the extent the securityholders decide to sell their shares, we will not control or determine the price at which the shares are sold. Brokers or dealers effecting transactions in these shares should confirm that the shares are registered under applicable state law or that an exemption from registration is available.

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" on page 6 to read about factors you should consider before buying shares of our common stock.

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

Prospectus dated , 2013

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No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

Trademarks, Trade Names and Service Marks

ClearConnect™ , *ClearPoint*®, *ClearTrace*®, *MRI Interventions*®, *SmartFlow*®, *SmartFrame*® and *SmartGrid*® are trademarks of MRI Interventions, Inc. Any other trademarks, trade names or service marks referred to in this prospectus are the property of their respective owners. As used in this registration statement, Siemens refers to Siemens Aktiengesellschaft, Healthcare Sector, Boston Scientific refers to Boston Scientific Corporation and its affiliates, and Brainlab refers to Brainlab AG.

Industry and Market Data

Market data and other statistical information contained in this prospectus are based on independent industry publications, government publications, reports by market research firms and other published independent sources. Some data is also based on our good faith estimates, which are derived from other relevant statistical information, as well as the independent sources listed above. Although we believe these sources are reliable, we have not independently verified the information.

About This Prospectus

This prospectus is part of a registration statement that we filed on behalf of the selling securityholders with the Securities and Exchange Commission, or SEC, to permit the selling securityholders to sell the shares described in this prospectus in one or more transactions. The selling securityholders and the plan of distribution of the share being offered by them are described in this prospectus under the heading “Selling Securityholders For Whose Accounts We Are Registering Shares” and “Plan of Distribution.”

As permitted by the rules and regulations of the SEC, the registration statement filed by us includes additional information not contained in this prospectus. You may read the registration statement and the other reports we file with the SEC at the SEC’s web site or its offices described below under the heading “Where You Can Find More Information.”

You should rely only on the information that is contained in this prospectus or that is incorporated by reference into this prospectus. We have not authorized anyone to provide you with information that is in addition to or different from that contained in, or incorporated by reference into, this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it.

The shares of common stock offered by this prospectus are not being offered in any jurisdiction where the offer or sale of such common stock is not permitted. You should not assume that the information contained in, or incorporated by reference into, this prospectus is accurate as of any date other than the date of this prospectus or, in the case of the documents incorporated by reference, the date of such documents, regardless of the date of delivery of this prospectus or any sale of the common stock offered by this prospectus. Our business, financial condition, liquidity, results of operations and prospects may have changed since those dates.

PROSPECTUS SUMMARY

This summary highlights the information contained elsewhere in this prospectus. Because this is only a summary, it does not contain all of the information that may be important to you. You should read this summary together with the entire prospectus, including our financial statements, the notes to those financial statements and the other documents identified under the headings "Where You Can Find More Information" and "Incorporation of Certain Information by Reference" in this prospectus, before making an investment decision.

Unless the context otherwise requires, references in this prospectus to "MRI Interventions," "we," "our," "us" and the "company" refer to MRI Interventions, Inc. The historical financial statements and financial data incorporated by reference into this prospectus are those of MRI Interventions, Inc. and its consolidated subsidiary, which was merged into MRI Interventions, Inc. on June 11, 2010.

Our Business

We are a medical device company that develops and commercializes innovative platforms for performing minimally invasive procedures in the brain and heart under direct, intra-procedural magnetic resonance imaging, or MRI, guidance. For the six months ended June 30, 2013 and for the year ended December 31, 2012, we recorded revenues of approximately $1,827,000 and $5,058,000, respectively, and incurred net losses of approximately $2,176,000 and $5,878,000, respectively.

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 magnetic resonance imaging to guide the procedures. Both systems are designed to work in a hospital's existing MRI suite.

Our products are designed to provide a new, minimally invasive surgical approach to address large patient populations for whom we believe current surgical techniques are deficient. Our ClearPoint system is designed to deliver therapies to treat certain neurological diseases. Our ClearTrace system is designed to deliver therapies to treat certain cardiac diseases. We believe that our two product platforms, subject to appropriate regulatory clearance and approval, will provide better patient outcomes, enhance revenue potential for both physicians and hospitals and reduce costs to the healthcare system.

Our ClearPoint system is in commercial use. In June 2010, we received 510(k) clearance from the Food and Drug Administration, or FDA, to market our ClearPoint system in the United States for general neurological interventional 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. In April 2011, we entered into a co-development and distribution agreement with Brainlab, a leader in the image-guided surgery field, under which Brainlab serves as our distribution partner for the ClearPoint system. ClearPoint systems are in clinical use with MRI scanners from the three major manufacturers, Siemens, GE Healthcare and Philips Healthcare, as well as the two major interventional MR/OR platforms that are manufactured by IMRIS and Brainlab.

The ClearTrace system, a product candidate still in development, is designed to allow catheter-based minimally invasive procedures in the heart to be performed using continuous, intra-procedural MRI guidance. In May 2009, we entered into a co-development agreement with Siemens for the development of hardware and MRI software necessary for the ClearTrace system. Our development activities on the ClearTrace system are ongoing. We have not made any filings seeking regulatory clearance or approval for the ClearTrace system. We anticipate that the initial market for the ClearTrace system will be the European Union.

Our Business Model and Strategy

Our key objective is to commercialize medical systems to enable minimally invasive surgical procedures to be performed under

direct, intra-procedural MRI guidance. Key elements to achieve this objective are:

- growing the installed base for our ClearPoint system;
- increasing utilization of our ClearPoint system; and
- building upon our core technologies to continue to develop MRI-based products, including the ClearTrace system.

Our business model for the ClearPoint system is focused on producing high margin revenue from sales of the disposable components. Given that focus on disposable product sales, we sell our reusable components at lower margins in order to secure installations of our system within hospitals. In addition, we may make the reusable ClearPoint components available to a hospital by loaning the equipment. Our disposable and reusable ClearPoint products are tightly integrated, which allows us to leverage each new installation of a system to generate recurring sales of our disposable products. As of June 30, 2013, a total of 25 ClearPoint systems were installed, 23 in the United States and two in Europe, which includes 15 systems we installed under our ClearPoint Placement Program, eight systems we sold, either directly to the customer or to Brainlab as our distributor, and two systems we installed at hospitals pursuant to the terms of research or clinical trial agreements.

Licenses and Collaborative Relationships

In addition to our internally-developed technology and devices, we have established and intend to continue to pursue licenses and collaborative relationships with medical device companies and academic institutions to further the development and commercialization of our core technologies and product platforms. Our most significant licensing and collaborative relationships are summarized below:

- *Brainlab*. We have entered into a co-development and distribution agreement with Brainlab. Under that agreement, we appointed Brainlab as a distributor of our ClearPoint system products, on a non-exclusive basis, in the United States and Europe. We also agreed to collaborate on the potential integration of our ClearPoint system technologies with Brainlab's own interventional MRI technologies, with particular focus on direct delivery of drugs and other therapeutic agents to targets in the brain under MRI guidance, which we call the MRI-guided neurological drug delivery field of use. For that reason, we appointed Brainlab as our exclusive distributor of ClearPoint system products within the MRI-guided neurological drug delivery field of use.

- *Boston Scientific*. We have entered into a series of agreements with Boston Scientific with respect to our MRI-safety technologies. Under these agreements, Boston Scientific has the exclusive, worldwide right, but not the obligation, to use the licensed technologies in Boston Scientific's implantable cardiac and neurological leads. Boston Scientific is currently assessing the potential use of our MRI-safety technologies in its lead designs.

- *Siemens*. In May 2009, we entered into an agreement with Siemens regarding the development of the hardware and MRI software systems for MRI-guided, catheter-based cardiac ablation to treat atrial fibrillation and other cardiac arrhythmias. Under the agreement, Siemens would develop the software and we would develop the catheters and other hardware, other than the MRI scanner and workstation.

- *Johns Hopkins*. We have several license agreements with The Johns Hopkins University under which we have obtained exclusive licenses for various technologies relating to devices, systems and methods for performing MRI-guided interventions and MRI-safety.

Risks Related to Our Business

We are subject to a number of risks of which you should be aware before you decide to buy our common stock. These risks are discussed more fully in the "Risk Factors" section of this prospectus beginning on page 6 and should be read in their entirety. In general, we face risks associated with the following:

- demand and market acceptance of our products;
- our ability to successfully expand our sales and clinical support 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 collaboration 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 alleging products 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;
- retention of our sales representatives and clinical support staff and our independent distributor; and
- any impact of the commercial and credit environment on us and our customers and suppliers.

Recent Developments

Modification of our Agreement with our ClearPoint Software Partner

Effective July 28, 2013, we entered into an amendment to the Master Services and Licensing Agreement, or Master Agreement, with Merge Healthcare Canada Corp., or Merge Healthcare. We entered into the Master Agreement in July 2007 for Merge Healthcare to develop on our behalf, based on our detailed specifications, a customized software solution for our ClearPoint system. Merge Healthcare was in the business of providing software development and engineering services on a contract basis to a number of companies. In developing our ClearPoint system software, Merge Healthcare utilized certain of its own pre-existing software code, or the Merge Software. Under the Master Agreement, we received a non-exclusive, worldwide license to the Merge Software, in object code form, as an integrated component of our ClearPoint system software. In return, we agreed to pay Merge Healthcare a license fee for each copy of the ClearPoint system software that we distribute. In addition, under the Master Agreement, Merge Healthcare has been performing ongoing custom engineering, maintenance and support services with respect to our ClearPoint system software, for which services we have been compensating Merge Healthcare.

At our request, we entered into the amendment to the Master Agreement to enable us to internally handle development, maintenance and support of our ClearPoint system software going forward. As a result, the services which we were outsourcing to Merge Healthcare will now be performed us. Under the amendment, Merge Healthcare granted us a non-exclusive, non-transferable, worldwide license to the source code for the Merge Software to use in our further development and commercialization of our ClearPoint system software. In return, we agreed to pay Merge Healthcare a one-time license fee. Merge Healthcare may terminate the source code license only for cause. We will continue to pay Merge Healthcare a license fee for each copy of the ClearPoint system software that we distribute, but only for licenses in excess of those licenses already purchased or otherwise acquired by us prior to the amendment to the Master Agreement. We have already satisfied our minimum license purchase commitments from Merge Healthcare under the Master Agreement.

Corporate Information

We were incorporated in Delaware in 1998 under the name Surgi-Vision, Inc. On November 12, 2008, we changed our name to SurgiVision, Inc. On May 13, 2011, we changed our name to MRI Interventions, Inc. We operate in only one business segment. Our principal executive office is located at One Commerce Square, Suite 2550, Memphis, TN 38103, and our telephone number is (901) 522-9300. Our principal operations are located in Irvine, California. Our website address is www.mriinterventions.com. We do not incorporate the information on our website into this prospectus, and you should not consider it part of this prospectus.

Summary of the Offering

This offering involves 11,938,285 shares of our common stock issued or issuable to the selling securityholders, consisting of 7,437,443 shares of our common stock and 4,500,842 shares of our common stock issuable upon exercise of warrants to purchase shares of our common stock.

Common stock offered by the selling securityholders	11,938,285 shares (1)
Common stock outstanding prior to this offering	58,481,314 shares (2)
Common stock to be outstanding after the offering, assuming the exercise of all warrants for the shares covered by this prospectus	62,982,156 shares (3)
Trading symbol	MRIC
Risk Factors	An investment in our common stock involves significant risks. See "Risk Factors" beginning on page 6.

(1) Includes 4,500,842 shares of common stock issuable upon exercise of outstanding warrants, at an exercise price of $1.75 per share.

(2) Based on the number of shares outstanding as of September 30, 2013, and excluding:

- 6,523,225 shares of common stock issuable upon exercise of options issued under our stock option plans, at a weighted average exercise price of $1.46 per share;
- 216,652 shares of common stock issuable upon the exercise of options not issued under our stock option plans, at a weighted average exercise price of $4.09 per share;
- 12,203,489 shares of common stock issuable upon exercise of warrants, at a weighted average exercise price of $1.33 per share, which includes the warrants for the shares covered by this prospectus;
- 542,325 shares of common stock issuable upon the conversion of $4,338,601 in principal amount of a convertible promissory note, at a conversion price of $8.00 per share; and
- 867,500 shares of common stock reserved for future issuance under our 2013 Incentive Compensation Plan.

(3) Based on the number of shares outstanding as of September 30, 2013 and excluding:

- 6,523,225 shares of common stock issuable upon exercise of options issued under our stock option plans, at a weighted average exercise price of $1.46 per share;
- 216,652 shares of common stock issuable upon the exercise of options not issued under our stock option plans, at a weighted average exercise price of $4.09 per share;
- 7,702,647 shares of common stock issuable upon exercise of warrants, at a weighted average exercise price of $1.08 per share;
- 542,325 shares of common stock issuable upon the conversion of $4,338,601 in principal amount of a convertible promissory note, at a conversion price of $8.00 per share; and
- 867,500 shares of common stock reserved for future issuance under our 2013 Incentive Compensation Plan.

RISK FACTORS

An investment in our common stock is speculative and involves a high degree of risk. You should carefully consider the risks under the heading "Risk Factors" beginning on page 28 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed with the SEC on March 11, 2013, which information is incorporated by reference in this prospectus, the additional risks described below and other information in this prospectus and the documents incorporated by reference before deciding to invest in our common stock. If any of the risks actually occur, our business, results of operations, financial condition and cash flows could be materially adversely affected, the trading price of our common stock could decline significantly, and you might lose all or part of your investment. Additional risks and uncertainties that we are unaware of or that we believe are not material at this time could also materially adversely affect our business, financial condition or results of operations. In any case, the value of our securities could decline, and you could lose all or part of your investment. You should also refer to our financial statements and the notes to those statements, which are incorporated by reference in this prospectus. For more information, see "Where You Can Find More Information" and "Incorporation of Certain Information by Reference."

Risks Related to Our Business

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

As of June 30, 2013, we had an accumulated deficit of approximately $67.8 million. The accumulated deficit has resulted principally from costs incurred in our research and development efforts and general operating expenses. We have incurred significant losses in each year since our inception in 1998. Net losses were approximately $2.2 million for the six months ended June 30, 2013, approximately $5.9 million for the year ended December 31, 2012, approximately $8.3 million for the year ended December 31, 2011, and approximately $9.5 million for the year ended December 31, 2010. We may continue to incur operating losses as we continue to invest capital in the sales and marketing of our products, development of our product candidates and development of our business generally.

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

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

We expect that sales of our ClearPoint system products will account for the vast majority of our revenues for at least the next several years. Our ClearPoint system may not gain broad market acceptance unless we continue to convince physicians, hospitals and patients of its benefits. Moreover, even if physicians and hospitals understand the benefits of our ClearPoint system, they still may elect not to use our ClearPoint system for a variety of reasons, such as the shift in location of the procedure from the operating room to the MRI suite, increased demand for the MRI suite, and the familiarity of the physician with other devices and approaches.

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

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

We are dependent on our sales team 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, and to provide clinical support for customer use of our ClearPoint system products, in the United States. That effort, though, could take longer than we anticipate, in which case our commercialization efforts would be delayed. Our ability to achieve significant revenue growth will depend, in large part, on our success in recruiting, training and retaining a sufficient number of qualified sales and clinical support personnel. New hires require significant training and, in most cases, take significant time before they achieve full productivity. Our recent hires and planned hires may not become as productive as we expect, and we may be unable to hire or retain sufficient numbers of qualified individuals. If we are unable to hire, train and retain sufficient numbers of effective personnel, or our personnel are not successful in obtaining new customers or increasing sales to our existing customer base, our business will be harmed.

We have entered into a co-development and distribution agreement with Brainlab pursuant to which we appointed Brainlab as a distributor of our ClearPoint system products in the United States and Europe. However, there is no assurance that Brainlab will be successful in marketing and selling our ClearPoint system products. Under our agreement, Brainlab is not subject to any minimum sales or other performance requirements.

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

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

Medicare pays hospitals a prospectively determined amount for inpatient operating costs. The prospective payment for a patient's stay is determined by the patient's condition and other patient data and procedures performed during the inpatient stay using a classification system known as Medicare Severity Diagnosis Related Groups, or MS-DRGs. Medicare pays a fixed amount to the hospital based on the MS-DRG into which the patient's stay is assigned, regardless of the actual cost to the hospital of furnishing the procedures, items and services provided. Therefore, a hospital must absorb the cost of our products as part of the payment it receives for the procedure in which the product is used. In addition, physicians that perform procedures in hospitals are paid a set amount by Medicare for performing such services under the Medicare physician fee schedule. Medicare payment rates for both systems are established annually. Some hospitals could believe third-party reimbursement levels are not adequate to cover the cost of our ClearPoint system. Furthermore, some physicians could believe third-party reimbursement levels are not adequate to compensate them for performing the procedures in which our products are used. Failure by hospitals and physicians to receive an amount that they consider to be adequate reimbursement for procedures in which our products are used will deter them from purchasing or using our products and will limit our sales growth.

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 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, as amended by the Health Care and Education Reconciliation Act of 2010, or, together, the Affordable Care Act, includes a number of provisions that will likely result in more coordination between hospitals and physicians resulting in the alignment of financial incentives between hospitals and physicians to control hospital costs. Most significantly, the Affordable Care Act provides for the establishment of a Medicare shared savings program, which went into effect in 2012, whereby Medicare will share certain savings realized in the delivery of services to Medicare beneficiaries with accountable care organizations, which may be organized through various different legal structures between hospitals and physicians. Other payment reform provisions in the Affordable Care Act include pay-for-performance initiatives, payment bundling and the establishment of an independent payment advisory board. We expect that the overall result of such payment reform efforts and the increased coordination among hospitals and physicians will be voluntary reductions in the array of choices currently available to physicians with respect to diagnostic services, medical supplies and equipment. Such a reduction in physician choices may also result in hospitals reducing the overall number of vendors from which they purchase supplies, equipment and products. The Affordable Care Act could limit the acceptance and availability of our products, which would have an adverse effect on our financial results and business.

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

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

Among other things, the Affordable Care Act will ultimately increase the overall pool of persons with access to health insurance in the United States, at least in those states that expand their Medicaid programs. Although such an increase in covered lives should ultimately benefit hospitals, the Affordable Care Act also includes a number of cuts in Medicare reimbursement to hospitals that may take effect prior to the time hospitals realize the financial benefit of a larger pool of insured persons. Those cuts in Medicare reimbursement could adversely impact the operations and finances of hospitals, reducing their ability to purchase medical devices, such as our products. Further, Congress has not yet addressed in a comprehensive and permanent manner the pending reduction in Medicare payments to physicians under the sustainable growth rate formula, which if not resolved will likely result in an overall reduction in physicians willing to participate in Medicare.

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

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

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

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

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

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

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

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

We have CE marking approval to market our ClearPoint system in the European Union, which subjects us to rules and regulations in the European Union relating to our products. As part of our product development and regulatory strategy, we also intend to market our ClearPoint system in other foreign jurisdictions. There are a number of risks associated with conducting business internationally, including:

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

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

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

In addition to the changes discussed above, the Affordable Care Act imposes 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 device. The total cost to the industry is expected to be approximately $30 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 various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, an expansion in government's role in the United States healthcare industry may lower reimbursements for our ClearPoint system, reduce medical procedure volumes and adversely affect our business, possibly materially.

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

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

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

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

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

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

In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology, safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The 510(k) clearance process generally takes three to twelve months from submission, but can take significantly longer.

The process of obtaining PMA approval is much more costly and uncertain than the 510(k) clearance process. The PMA approval process can be lengthy and expensive and requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on data obtained in clinical trials. The PMA process generally takes one to three years, or even longer, from the time the PMA application is submitted to the FDA until an approval is obtained.

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

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

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

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

We received 510(k) clearance to market our ClearPoint system for use in general neurological interventional procedures. In the future, we could seek to obtain additional, more specific indications for use of our ClearPoint system beyond the general neurological intervention claim, although we have no present plan to do so. Some of these expanded claims could require FDA 510(k) clearance. Other claims could require FDA approval of a PMA. Moreover, some specific ClearPoint system claims could require clinical trials to support regulatory clearance or approval. In the event we seek a new indication for use of, or new claims for, the ClearPoint system that we believe are necessary or desirable for successful commercialization, the FDA may refuse our requests for 510(k) clearance or PMA approval. Likewise, to the extent clinical trials are necessary, we may not successfully complete or have the funds to initiate such clinical trials.

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

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

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

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

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

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

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

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

These companies enjoy significant competitive advantages over us, including:

- broad product offerings, which address the needs of physicians and hospitals in a wide range of procedures;
- greater experience in, and resources for, launching, marketing, distributing and selling products, including strong sales forces and established distribution networks;
- existing relationships with physicians and hospitals;
- more extensive intellectual property portfolios and resources for patent protection;
- greater financial and other resources for product research and development;
- greater experience in obtaining and maintaining FDA and other regulatory clearances or approvals for products and product enhancements;
- established manufacturing operations and contract manufacturing relationships; and
- significantly greater name recognition and more recognizable trademarks.

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

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

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

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

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

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

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

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

Risks Related to Funding

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

We have not yet achieved profitability. Accordingly, we have financed our activities principally from sales of equity securities, borrowings and license arrangements. Most recently, in January 2013, we raised $11.0 million, before commissions and offering expenses, from the sale of shares of our common stock and warrants to purchase shares of our common stock in a private placement transaction. Because of the various risks and uncertainties associated with the commercialization of medical devices, there can be no assurance that our cash resources will cover all of our costs until we achieve profitability. Therefore, we could need additional funding. Additional funds, if needed, may not be available on a timely basis or on terms that are acceptable to us, or at all, in which event we could take actions that negatively impact the commercialization of our ClearPoint system, or terminate or delay the development of the ClearTrace system.

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

- the cost and timing of expanding our sales, clinical support, marketing and distribution capabilities and other corporate infrastructure;
- the cost of establishing product inventories;
- the effect of competing technological and market developments;
- the scope, rate of progress and cost of our research and development activities;
- the achievement of milestone events under, and other matters related to, our agreements with Boston Scientific and Siemens;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;

- the cost and timing of any clinical trials;
- the cost and timing of regulatory filings, clearances and approvals; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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

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

Risks Related to our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Regulatory Compliance

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

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

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

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

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or orders for the repair or replacement of our products or refunds;

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

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

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

We and some of our third-party suppliers are required to comply with the FDA's QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products and product candidates. We and our suppliers will also be subject to the regulations of foreign jurisdictions regarding the manufacturing process to the extent we market our products in these jurisdictions. The FDA enforces the QSR through periodic and unannounced inspections of manufacturing facilities. Our facilities have not been inspected by the FDA for QSR compliance. We anticipate that we and certain of our third-party suppliers will be subject to future inspections. The failure by us or one of our third-party suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations, could result in enforcement actions against us, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. If we fail to comply with the FDA's QSR or any applicable state equivalent, we would be required to incur the costs and take the actions necessary to bring our operations into compliance, which may have a negative impact on our future sales and our ability to generate a profit.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- The Affordable Care Act, which imposes certain reporting obligations on manufacturers of drugs, devices and biologics. Specifically, such manufacturers are required to report payments or other transfers of value to or on behalf of a physician or teaching hospital by such manufacturers, as well as any ownership or investment interest held by physicians in such manufacturers. On February 1, 2013, CMS issued the final rule to implement this so-called "Sunshine" provision of the Affordable Care Act. Under the final rule, we are subject to the data collecting, reporting and public disclosure obligation. Data collecting obligations began August 1, 2013, and the initial reporting obligations must be satisfied by March 31, 2014. Reported data will be made publicly available by September 30, 2014. Violations of the reporting requirements are subject to civil monetary penalties.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Facilities, Employees and Growth

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

We are highly dependent on members of our senior management, in particular Kimble L. Jenkins, our President, Chief Executive Officer and Chairman of the Board of Directors. The loss of members of our senior management team, sales and marketing team or engineering team, or our inability to attract or retain other qualified personnel, could have a material adverse effect on our business, financial condition and results of operations. We do not maintain key employee life insurance on any of our personnel other than for Mr. Jenkins. Although we have obtained key employee insurance covering Mr. Jenkins in the amount of $2,000,000, this would not fully compensate us for the loss of Mr. Jenkins' services.

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

Our performance depends on the talents and efforts of our employees. Our future success will depend on our ability to attract, retain and motivate highly skilled personnel in all areas of our organization, but particularly as part of our sales and 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 systems, controls, infrastructure and personnel will be adequate to support our future operations. Any failure to effectively manage our growth could impede our ability to successfully develop, market and sell our products and our business will be harmed.

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

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

Risks Related to Our Shares of Common Stock

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

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

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

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

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

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

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

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

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

In August 2012, 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 freely transferable, unless held by an affiliate of ours. Likewise, the registration statement of which this prospectus is a part registers approximately 7.4 million shares of our common stock and approximately 4.5 million shares of common stock issuable upon the exercise of warrants. In addition to the shares of our common stock covered by those registration statements, as of September 30, 2013, approximately 36.4 million of our outstanding shares were freely transferable or could be publicly resold pursuant to Rule 144 under the Securities Act. Of those shares, approximately 7.1 million shares were held by our affiliates and approximately 29.3 million shares were held by non-affiliates of the company. In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated) who has beneficially owned restricted securities for at least six months, including our affiliates, would be entitled to sell such securities, subject to the availability of current public information about the company. A person who has not been our affiliate at any time during the three months preceding a sale, and who has beneficially owned his shares for at least one year, would be entitled under Rule 144 to sell such shares without regard to any limitations under Rule 144. Under Rule 144, sales by our affiliates are subject to volume limitations, manner of sale provisions and notice requirements. Any substantial sale of common stock pursuant to the registration statements, Rule 144 or otherwise may have an adverse effect on the market price of our common stock by creating an excessive supply. Likewise, the availability for sale of substantial amounts of our common stock could reduce the prevailing market price.

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

As of September 30, 2013, our directors and executive officers, together with their affiliates, beneficially owned, in the aggregate, 19.3% of our common stock. As a result, these stockholders, acting together, have significant influence over the management and affairs of our company. Accordingly, this concentration of ownership could have the effect of:

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

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

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

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

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

- permit our Board of Directors to issue shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control;
- provide that the authorized number of directors may be changed only by resolution of the Board of Directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairman of the Board of Directors, our Chief Executive Officer or by the Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provide that stockholders will be permitted to amend our bylaws only upon receiving at least 66 2/3% of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

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

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although we could lose that status sooner if our revenues exceed $1 billion, if we issue more than $1 billion in non-convertible debt in a three year period, or if the market value of our common stock held by non-affiliates exceeds $700 million as of any June 30 before that time, in which case we would no longer be an emerging growth company as of the following December 31. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. The forward-looking statements are contained principally in the section entitled “Risk Factors.” These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements, expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our ability to market, commercialize and achieve market acceptance for our products;
- our ability to successfully expand our sales and clinical support capabilities;
- the anticipated progress of our research and product development activities;
- our ability to successfully complete the development of, and obtain regulatory clearance or approval for, our current product candidates; and
- the estimates regarding the sufficiency of our cash resources.

In some cases, you can identify forward-looking statements by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” and similar expressions intended to identify forward-looking statements, although not all forward-looking statements contain these words. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain.

You should refer to the section of this prospectus entitled "Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We do not undertake to update any of the forward-looking statements after the date of this prospectus, except to the extent required by applicable securities laws.

USE OF PROCEEDS

We will not receive any proceeds from the sale of the common stock by selling securityholders pursuant to this prospectus. All proceeds from the sale of the shares will be for the account of the selling securityholders. We could receive up to approximately $7.9 million in proceeds from the exercise of all of the warrants held by the securityholders and covered by this prospectus, when and if such warrants are exercised for cash. However, the warrants are exercisable on a cashless basis under certain circumstances, and, to the extent the warrants are exercised, we expect that most securityholders would utilize the cashless exercise feature. To the extent we receive any cash proceeds from the exercise of the warrants, we intend to use the proceeds for working capital and general corporate purposes. We will pay the expenses of registration of the shares of our common stock covered by this prospectus, including legal and accounting fees.

SELLING SECURITYHOLDERS FOR WHOSE ACCOUNTS WE ARE REGISTERING SHARES

The shares to be offered by the securityholders named in this prospectus are "restricted" securities under applicable federal and state securities laws and are being registered under the Securities Act to give those securityholders the opportunity to publicly sell these shares, if they elect to do so. The registration of these shares does not require that any of the shares be offered or sold by the securityholders. The securityholders may from time to time offer and sell all or a portion of their shares in the over-the-counter market, in negotiated transactions, or otherwise, at prices then prevailing or related to the then current market price or at negotiated prices.

The registered shares may be sold directly or through brokers or dealers, or in a distribution by one or more underwriters on a firm commitment or best efforts basis. To the extent required, the names of any agent or broker-dealer and applicable commissions or discounts and any other required information with respect to any particular offer will be set forth in a prospectus supplement. Please see "Plan of Distribution." The securityholders and any agents or broker-dealers that participate with the securityholders in the distribution of registered shares may be deemed to be "underwriters" within the meaning of the Securities Act, and any commissions received by them and any profit on the resale of the registered shares may be deemed to be underwriting commissions or discounts under the Securities Act.

The following table sets forth the name of each securityholder, the number of shares of our common stock known by us to be beneficially owned by such securityholder as of July 31, 2013, the number of shares of our common stock that may be offered for resale for the account of such securityholder pursuant to this prospectus and the number of shares of our common stock to be held by such securityholder subsequent to the offering. The information is based upon our review of our stockholder, optionholder and warrantholder registers and information furnished by the securityholders. No estimate can be given as to the amount or percentage of our common stock that will be held by the named securityholders subsequent to the offering because the securityholders are not required to sell any of the shares being registered under this prospectus. Therefore, the following table includes two columns with respect to the number of shares of our common stock to be held by the securityholders following the offering. One column assumes that the securityholders will not sell any of the shares listed in this prospectus, while the other column assumes that the securityholders will sell all of the shares listed in this prospectus.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options, warrants and convertible securities currently exercisable or convertible, or exercisable or convertible within 60 days are deemed outstanding, including for purposes of computing the percentage ownership of the person holding the option, warrant or convertible security, but not for purposes of computing the percentage of any other holder. Percentage ownership is based on 58,318,640 shares of common stock outstanding as of July 31, 2013.

Securityholder	Shares Beneficially Owned Prior to the Offering(1)(2)	Shares Offered by this Prospectus(3)	Shares Beneficially Owned Subsequent to the Offering(1)(2)(4)		Shares Beneficially Owned Subsequent to the Offering(5)(6)	
			Shares	Percent	Shares	Percent
Alice Ann Corporation[7]	75,000	75,000	75,000	*	-	-
Robert G. Allison[7]	212,499	212,499	212,499	*	-	-
William H. Baxter Trustee FBO William H. Baxter Rev Trust u/a dtd 7/3/96[7]	87,501	87,501	87,501	*	-	-
Gary A. Bergren[7]	75,000	75,000	75,000	*	-	-
James E. Besser	615,689	312,501	615,689	1.1%	303,188	*
Hill Blalock, Jr.	885,453	62,502	885,453	1.5%	822,951	1.4%
Steven E. Bram	275,000	150,000	275,000	*	125,000	*
BTR Partners, LP[8]	596,765	249,996	596,765	1.0%	346,769	*
David and Carol Brown Trustees FBO David & Carol Brown Rev Trust u/a dtd 10/23/97[7]	43,749	43,749	43,749	*	-	-
Hartwell Davis Jr.	483,228	312,501	483,228	*	170,727	*
Mario Dell'Aera	434,052	125,004	434,052	*	309,048	*
E Terry Skone TTEE E Terry Skone rev Trust u/a dtd 11/30/2005[7]	43,752	43,752	43,752	*	-	-
Empery Asset Master, LTD[9]	62,500	62,500	62,500	*	-	-
Alberto D. Fernandez	150,000	75,000	150,000	*	75,000	*
Gary L. Ginsberg	43,752	43,752	43,752	*	-	-
Dennis D. Gonyea[7]	62,499	62,499	62,499	*	-	-
Harbor Watch Partners, LP[10]	741,364	162,501	741,364	1.3%	578,863	*
Hartz Capital Investments, LLC[11]	145,834	145,834	145,834	*	-	-
Samuel Herschkowitz	322,751	31,251	322,751	*	291,500	*
Dorothy J. Hoel[7]	62,502	62,502	62,502	*	-	-
Richard A. Hoel[7]	43,749	43,749	43,749	*	-	-
Janet & Donald Voight Trustees FBO Janet M. Voight Trust u/a dtd 8/28/96[7]	31,248	31,248	31,248	*	-	-
Brandon L. Jones	125,001	125,001	125,001	*	-	-
Klaus Kretschmer	629,068	187,500	629,068	1.1%	441,568	*
LBB Capital Partners, LP[12]	450,000	450,000	450,000	*	-	-
Manchester Explorer, L.P.[13]	994,319	312,501	994,319	1.7%	681,818	1.2%
Mary McCall ROM Trust[14]	150,000	150,000	150,000	*	-	-
O'Connor Global Multi-Strategy Alpha Master Limited[15]	602,884	602,884	602,884	1.0%	-	-
Opus Point Healthcare Innovations Fund, LP[16]	752,273	525,000	752,273	1.3%	227,273	*
Opus Point Healthcare (Low Net) Fund, LP[17]	271,025	43,752	271,025	*	227,273	*
Opus Point Healthcare Value Fund, LP[18]	283,523	56,250	283,523	*	227,273	*
Parallax Biomedical Fund LP[19]	104,167	104,167	104,167	*	-	-
John Paulson	62,500	25,000	62,500	*	37,500	*
Michael Pietrangelo[20]	532,130	187,500	532,130	*	344,630	*
Preventive Cardiovascular Nurses Association[7]	113,234	113,234	113,234	*	-	-
PRK Partners, LP[21]	141,623	125,001	141,623	*	16,622	*

Lindsay A. Rosenwald	2,206,921	625,002	2,206,921	3.7%	1,581,919	2.7%
Amory L. Ross	425,806	150,000	425,806	*	275,806	*

Securityholder	Shares Beneficially Owned Prior to the Offering(1)(2)	Shares Offered by this Prospectus(3)	Shares Beneficially Owned Subsequent to the Offering(1)(2)(4)		Shares Beneficially Owned Subsequent to the Offering(5)(6)	
			Shares	Percent	Shares	Percent
Sabby Healthcare Volatility Master Fund, Ltd.(22)	3,331,667	3,125,001	3,331,667	5.6%	206,666	*
Sabby Volatility Warrant Master Fund, Ltd.(22)	416,667	416,667	416,667	*	-	-
Stephen Sander	84,092	75,000	84,092	*	9,092	*
Paul and Nancy Seel(7)	62,499	62,499	62,499	*	-	-
Lucy Shurtleff	522,088	62,502	522,088	*	459,586	*
John N. Spencer, Jr. and Carol P. Spencer(23)	127,582	15,000	127,582	*	112,582	*
Starlight Investment Holdings Limited(24)	283,286	62,502	283,286	*	220,784	*
Wolverine Flagship Fund Trading Limited(25)	1,865,481	1,865,481	1,865,481	3.2%	-	-

* Represents beneficial ownership of less than 1% of our outstanding common stock.

(1) Includes an aggregate of 6,522,515 shares issuable upon exercise of warrants and an aggregate of 96,668 shares issuable upon exercise of options, and assumes a cash exercise of such warrants and options.

(2) Does not take into account any limitations on exercise contained in any warrants.

(3) Includes an aggregate of 4,500,842 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.

(4) Assumes the securityholder does not sell any of the shares of common stock included in this prospectus.

(5) Assumes the securityholder sells all of the shares of common stock included in this prospectus.

(6) Includes an aggregate of 2,021,673 shares issuable upon exercise of warrants and an aggregate of 96,668 shares issuable upon exercise of options, and assumes a cash exercise of such warrants and options.

(7) This securityholder has granted Perkins Capital Management Inc. voting and investment power with respect to the shares owned by the securityholder. Richard C. Perkins, in his capacity as portfolio manager at Perkins Capital Management Inc., may also be deemed to have voting and investment power with respect to the shares owned by the securityholder. Mr. Perkins disclaims any beneficial ownership of the shares.

(8) Benson T. Ross has voting and investment power with respect to the shares owned by BTR Partners LP.

(9) Empery Asset Management LP, the authorized agent of Empery Asset Master Ltd ("EAM"), has discretionary authority to vote and dispose of the shares held by EAM and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by EAM. Mr. Hoe and Mr. Lane disclaim any beneficial ownership of these shares.

(10) Anita Siegel has voting and investment power with respect to the shares owned by Harbor Watch Partners LP.

(11) Empery Asset Management LP, the authorized agent of Hartz Capital Investments, LLC ("HCI"), has discretionary authority to vote and dispose of the shares held by HCI and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by HCI. Mr. Hoe and Mr. Lane disclaim any beneficial ownership of these shares.

(12) Thomas H. Sharpe has voting and investment power with respect to the shares owned by LBB Capital Partners, LP.

(13) Mr. James E. Besser has voting and investment power with respect to the shares owned by Manchester Explorer, L.P.

(14) Richard O. McCall has voting and investment power with respect to the shares owned by the Mary McCall ROM Trust.

(15) UBS O'Connor LLC is the investment manager of O'Connor Global Multi-Strategy Alpha Master Limited and consequently has voting control and investment power over securities held by O'Connor Global Multi-Strategy Alpha Master Limited. Jeffrey Putman is Executive Director of UBS O'Connor LLC. Mr. Putman disclaims beneficial ownership of the shares held by UBS O'Connor LLC FBO O'Connor Global Multi-Strategy Alpha Master Limited. UBS O'Connor LLC is a wholly-owned subsidiary of UBS AG, a company whose securities are listed on the New York Stock Exchange.

(16) Lindsay A. Rosenwald and Michael S. Weiss share voting and investment power with respect to the shares owned by Opus Point Healthcare Innovations Fund, LP.

(17) Lindsay A. Rosenwald and Michael S. Weiss share voting and investment power with respect to the shares owned by Opus Point Healthcare (Low Net) Fund, LP.

(18) Lindsay A. Rosenwald and Michael S. Weiss share voting and investment power with respect to the shares owned by Opus Point Healthcare Value Fund, LP.
(19) Kellie Seringer has voting and investment power with respect to the shares owned by Parallax Biomedical Fund LP.
(20) Mr. Pietrangelo is one of our directors. Mr. Pietrangelo joined our Board of Directors in March 2010.
(21) Parthenia R. Kiersted has voting and investment power with respect to the shares owned by PRK Partners, LP.
(22) Each of Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (collectively, the "Sabby Funds") has indicated that Hal Mintz has voting and investment power over the shares held by it. Each of the Sabby Funds has also indicated that Sabby Management, LLC serves as its investment manager, that Hal Mintz is the manager of Sabby Management, LLC and that each of Sabby Management, LLC and Hal Mintz disclaim beneficial ownership over these shares except to the extent of any pecuniary interest therein.
(23) Mr. Spencer is one of our directors. Mr. Spencer joined our Board of Directors in March 2010.
(24) Jonathan Watson has voting and investment power with respect to the shares owned by Starlight Investment Holdings Limited.
(25) Wolverine Asset Management, LLC ("WAM"), the investment manager of Wolverine Flagship Fund Trading Limited, and John Ziegelman, in his capacity as portfolio manager of WAM, each have voting and investment power over these securities. WAM and Mr. Ziegelman each disclaim beneficial ownership over these securities.

Relationships with Selling Securityholders

Except as disclosed in the table above, to our knowledge, none of the selling securityholders had any position, office, or other material relationship with us or any of our affiliates within the past three years.

PLAN OF DISTRIBUTION

The selling securityholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling securityholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling securityholders may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

- broker-dealers may agree with the selling securityholders to sell a specified number of such shares at a stipulated price per share;

- a combination of any such methods of sale; and

- any other method permitted by applicable law.

The selling securityholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling securityholders to include the pledgee, transferee or other successors-in-interest as selling securityholders under this prospectus. The selling securityholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our common stock or interests therein, the selling securityholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling securityholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling securityholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling securityholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling securityholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the warrants by payment of cash, however, we will receive the exercise price of the warrants.

The selling securityholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule.

The selling securityholders and any underwriters, broker-dealers or agents that participate in the sale of the common stock or interests therein may be “underwriters” within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. Selling securityholders who are “underwriters” within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

To the extent required, the shares of our common stock to be sold, the names of the selling securityholders, the respective purchase prices and public offering prices, the names of any agent, dealer or underwriter, and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling securityholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling securityholders and their affiliates. In addition, to the extent applicable, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling securityholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling securityholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling securityholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We have agreed with the selling securityholders to keep the registration statement of which this prospectus constitutes a part effective until the earlier of (1) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement or (2) the date on which all of the shares may be sold without restriction pursuant to Rule 144 of the Securities Act.

DESCRIPTION OF CAPITAL STOCK

Common Stock

Under our certificate of incorporation, we have 100,000,000 authorized shares of common stock, $0.01 par value per share. As of September 30, 2013, we had 58,481,314 shares of common stock outstanding and no shares of preferred stock outstanding. As of September 30, 2013, we had approximately 600 stockholders of record. In addition, as of September 30, 2013, options and warrants to purchase 18,943,366 shares of common stock were outstanding, as were convertible notes held by Boston Scientific in the aggregate principal amount of approximately $4,300,000. Shares of our common stock have been traded on the over-the-counter market since May 21, 2012, under the symbol “MRIC.”

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our certificate of incorporation and bylaws, our stockholders do not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the Board of Directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are fully paid and nonassessable.

Preferred Stock

Under our certificate of incorporation, we have 25,000,000 authorized shares of preferred stock, $0.01 par value per share. 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 wholly unissued 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. The Board of Directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of the company and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock.

In June 2012, our Board of Directors established the terms of a series of preferred stock known as "Series A Convertible Preferred Stock". Our Board of Directors designated the Series A Convertible Preferred Stock solely to provide Boston Scientific a series of preferred stock into which Boston Scientific could convert its notes, if it voluntarily elected to do so. However, we have not filed a Certificate of Designations with the Secretary of State of the State of Delaware to create the Series A Convertible Preferred Stock, and we do not intend to file that Certificate of Designations unless and until Boston Scientific elects to convert its notes into shares of the Series A Convertible Preferred Stock. As of September 30, 2013, no shares of our preferred stock were issued or outstanding.

If Boston Scientific elected to convert its notes into shares of the Series A Convertible Preferred Stock, we would file with the Secretary of State of the State of Delaware a Certificate of Designations which provides the terms of the Series A Convertible Preferred Stock approved by our Board of Directors. Certain of the terms that would be set forth in the Certificate of Designations are summarized below:

Number of Shares

We would designate 600,000 shares of our preferred stock as Series A Convertible Preferred Stock.

Dividends

Holders of Series A Convertible Preferred Stock would receive dividends if, when and to the extent dividends are declared and paid with respect to our common stock.

Voting Rights

The affirmative vote of the holders of a majority of the Series A Convertible Preferred Stock would be necessary for us to amend our certificate of incorporation, if such amendment would adversely change the preferences or rights of the Series A Convertible Preferred Stock (which would include, without limitation, the liquidation preference or the conversion privilege described below). Likewise, the affirmative vote of the holders of a majority of the Series A Convertible Preferred Stock would be required to authorize any transaction involving a compulsory share exchange or other recapitalization if the Series A Convertible Preferred Stock would be converted into other securities, cash or property, except for any transaction involving a merger or reorganization or a sale of substantially all of our stock or assets if the holders of a majority of our outstanding equity securities before the transaction would not continue to hold a majority of the outstanding equity securities of the surviving entity. Otherwise, except as required by law, holders of the Series A Convertible Preferred Stock would vote together with the holders of our common stock, and the holders of the Series A Convertible Preferred Stock would receive a number of votes equal to the number of shares of common stock into which their shares of Series A Convertible Preferred Stock would then be convertible.

Liquidation

In the event of our liquidation, dissolution or winding up, each holder of Series A Convertible Preferred Stock would be paid, before any distribution or payment would be made upon any junior security of the company, including our common stock, an amount equal to $8.00 per share of Series A Convertible Preferred Stock. If the assets to be distributed among the holders of the Series A Convertible Preferred Stock would be insufficient to permit payment to such holders of the aggregate amount which they would be entitled to be paid, then the entire assets available for distribution would be distributed pro rata among such holders in proportion to the full preferential amounts to which they would otherwise be entitled on account of their Series A Convertible Preferred Stock.

Conversion

The Series A Convertible Preferred Stock would be convertible into common stock at any time at the election of the holder, initially on a one-for-one basis. The conversion price would be adjusted proportionately for events such as stock splits, stock dividends or other recapitalizations. In addition, following the issuance of any shares of Series A Convertible Preferred Stock, the conversion price would also be adjusted downward if we sold shares of our common stock at a price per share less than the then prevailing conversion price per share of the Series A Convertible Preferred Stock (which initially would be $8.00 per share). In those circumstances, the adjusted conversion price would be the share price at which we sold our common stock.

Delaware Anti-Takeover Law and Certain Provisions of our Certificate of Incorporation and Bylaws

Delaware Law

We are governed by Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years, did own, 15% or more of the corporation's outstanding voting stock. These provisions may have the effect of delaying, deferring or preventing a change in our control.

Certificate of Incorporation and Bylaw Provisions

Our certificate of incorporation:

- permits 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;
- provides that the authorized number of directors may be changed only by resolution of the Board of Directors;
- provides 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;
- requires 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;
- provides 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;

- does 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);

- provides 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

- provides 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.

These and other provisions contained in our certificate of incorporation and bylaws could delay or discourage some types of transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices, and may limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and, therefore, could adversely affect the price of our common stock.

Transfer Agent and Registrar

Our transfer agent is currently Continental Stock Transfer & Trust Company. The transfer agent's address is 17 Battery Place, 8th Floor, New York, NY 10004.

VALIDITY OF THE COMMON STOCK

The validity of the shares of common stock offered hereby and certain other legal matters will be passed upon for us by Baker, Donelson, Bearman, Caldwell & Berkowitz, PC, Memphis, Tennessee.

EXPERTS

The financial statements of MRI Interventions, Inc. as of December 31, 2012 and 2011 and for each of the three years in the period ended December 31, 2012 incorporated by reference into this prospectus and registration statement have been audited by Cherry Bekaert LLP, independent registered public accounting firm, as set forth in their report thereon incorporated by reference herein, and are incorporated by reference herein in reliance upon such report, given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1, as amended, under the Securities Act with respect to the shares of common stock being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to MRI Interventions, Inc. and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at http://www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street NE, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

We are subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at http://www.mriinterventions.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

Certain information about us is "incorporated by reference" to reports and exhibits we file with the SEC that are not included in this prospectus. We disclose important information to you by referring you to these documents. Any statement contained in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes such statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus. We incorporate by reference the documents listed below that we have filed with the SEC:

- Annual Report on Form 10-K for the year ended December 31, 2012 filed on March 11, 2013, and Annual Report on Form 10-K/A for the year ended December 31, 2012 filed on August 19, 2013;

- Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2013 filed on May 10, 2013, Quarterly Report on Form 10-Q/A for the quarterly period ended March 31, 2013 filed on August 19, 2013, and Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2013 filed on August 14, 2013;

- Current Reports on Form 8-K filed on January 22, 2013, January 25, 2013, February 6, 2013, March 7, 2013 (but only the Current Report on Form 8-K filed on that date containing information under Items 1.01, 2.03 and 9.01 of such form and including Exhibits 4.1 and 10.1 filed therewith), April 16, 2013, June 14, 2013, July 30, 2013 and August 13, 2013 (but only the Current Report on Form 8-K filed on that date containing information under Item 4.02 of such form); and

- The description of our common stock contained in our registration statement on Form 10 filed on December 28, 2011, as amended.

All documents that we file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act on or after the date of this prospectus and prior to the termination of the offering made pursuant to this prospectus are also incorporated herein by reference and will automatically update and supersede information contained or incorporated by reference in this prospectus. Nothing in this prospectus shall be deemed to incorporate information furnished to but not filed with the SEC pursuant to Item 2.02 or Item 7.01 of Form 8-K (or corresponding information furnished under Item 9.01 or included as an exhibit to Form 8-K).

You may request a copy of these filings, at no cost (other than exhibits and schedules to such filings, unless such exhibits or schedules are specifically incorporated by reference into this prospectus), by submitting a written request to our Investor Relations Department, MRI Interventions, Inc., One Commerce Square, Suite 2550, Memphis, Tennessee 38103.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. *Other Expenses of Issuance and Distribution*

We estimate that expenses in connection with the distribution described in this registration statement (other than brokerage commissions, discounts or other expenses relating to the sale of the shares by the selling securityholders) will be as set forth below. We will pay all of the expenses with respect to the distribution, and such amounts, with the exception of the Securities and Exchange Commission registration fee, are estimates.

	Amount to be paid
SEC registration fee	$ 2,928
Accounting fees and expenses	$ 10,000
Legal fees and expenses	$ 25,000
Printing and related expenses	$ 4,000
Total	$ 41,928

Item 15. *Indemnification of Directors and Officers*

As permitted by Delaware law, we have adopted provisions in our certificate of incorporation and bylaws that limit or eliminate the personal liability of directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, a director exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for any:

- breach of the director's duty of loyalty to us or our stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- act related to unlawful stock repurchases, redemptions or other distributions or payments of dividends; or
- transaction from which the director derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder's rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions will not alter a director's liability under federal securities laws. Our certificate of incorporation also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our bylaws also provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;
- we may advance expenses to our directors, officers, employees and other agents in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our bylaws are not exclusive.

We believe that indemnification under our bylaws covers at least negligence and gross negligence on the part of indemnified parties. Our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification provided for in our certificate of incorporation and bylaws, we have entered into separate indemnification agreements with each of our directors and executive officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and officers. There is no pending litigation or proceeding involving any of our directors or officers to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Item 16. ***Exhibits***

(a) Exhibits

Exhibit Number	**Description**
3.1	Amended and Restated Certificate of Incorporation (1)
3.2	Amended and Restated Bylaws (1)
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen of Common Stock Certificate (2)
4.3	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 (3)
4.4	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 (4)
4.5	Loan Agreement dated as of October 16, 2009 by and between SurgiVision, Inc. and Boston Scientific Corporation (5)
4.6	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)
4.7	Patent Security Agreement dated as of October 16, 2009 by and between SurgiVision, Inc. and Boston Scientific Corporation (7)
4.8	Amended and Restated Subordinated Secured Note Due 2016, issued to Brainlab AG (8)
4.9	Master Security Agreement dated April 5, 2011 by and between SurgiVision, Inc. and Brainlab AG (9)
4.10	Form of Subscription Agreement for 10% Secured Convertible Promissory Note Due 2014 (10)
4.11	Form of Securities Purchase Agreement by and among MRI Interventions, Inc. and the purchasers named therein (11)

Exhibit Number	Description
4.12	Form of Registration Rights Agreement by and among MRI Interventions, Inc. and the purchasers named therein (12)
4.13	Form of Warrant issued to purchasers in the July 2012 private placement to purchase shares of common stock of MRI Interventions, Inc. (13)
4.14	Form of Securities Purchase Agreement by and among MRI Interventions, Inc. and the investors party thereto (14)
4.15	Form of Registration Rights Agreement by and among MRI Interventions, Inc. and the investors party thereto (15)
4.16	Form of Warrant issued to purchasers in the January 2013 private placement to purchase shares of common stock of MRI Interventions, Inc. (16)
5.1	Opinion of Baker, Donelson, Bearman, Caldwell & Berkowitz (17)
23.1*	Consent of Cherry Bekaert LLP
23.2	Consent of Baker, Donelson, Bearman, Caldwell & Berkowitz, PC (included in Exhibit 5.1)
24.1	Power of attorney. Reference is made to the signature page. (17)

* Filed herewith.

(1) Filed as the like numbered Exhibit to the Company's Form 10-Q filed with the SEC on May 11, 2012, and incorporated by reference.

(2) Filed as the like numbered Exhibit to Amendment No. 1 to the Company's registration statement on Form 10 filed with the SEC on February 9, 2012, and incorporated by reference.

(3) Filed as Exhibit 4.4 to the Company's registration statement on Form 10 filed with the SEC on December 28, 2011, and incorporated by reference.

(4) Filed as Exhibit 10.6 to the Company's registration statement on Form 10 filed with the SEC on December 28, 2011, and incorporated by reference.

(5) Filed as Exhibit 10.24 to the Company's registration statement on Form 10 filed with the SEC on December 28, 2011, and incorporated by reference.

(6) Filed as Exhibit 10.37 to Amendment No. 3 to the Company's registration statement on Form 10 filed with the SEC on March 15, 2012, and incorporated by reference.

(7) Filed as Exhibit 10.25 to the Company's registration statement on Form 10 filed with the SEC on December 28, 2011, and incorporated by reference.

(8) Filed as Exhibit 4.1 to the Company's Form 8-K filed with the SEC on March 7, 2013, and incorporated by reference.

(9) Filed as Exhibit 10.18 to the Company's registration statement on Form 10 filed with the SEC on December 28, 2011, and incorporated by reference.

(10) Filed as Exhibit 3.7 to the Company's registration statement on Form 10 filed with the SEC on December 28, 2011, and incorporated by reference.

(11) Filed as Exhibit 10.1 to the Company's Form 8-K filed with the SEC on July 6, 2012, and incorporated by reference.

(12) Filed as Exhibit 10.2 to the Company's Form 8-K filed with the SEC on July 6, 2012, and incorporated by reference.

(13) Filed as Exhibit 4.1 to the Company's Form 8-K filed with the SEC on July 6, 2012, and incorporated by reference.

(14) Filed as Exhibit 10.1 to the Company's Form 8-K filed with the SEC on January 22, 2013, and incorporated by reference.

(15) Filed as Exhibit 10.2 to the Company's Form 8-K filed with the SEC on January 22, 2013, and incorporated by reference.

(16) Filed as Exhibit 4.1 to the Company's Form 8-K filed with the SEC on January 22, 2013, and incorporated by reference.

(17) Filed as the like numbered Exhibit to the Company's Form S-1 filed with the SEC on February 11, 2013, and incorporated by reference.

Item 17. ***Undertakings***

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Securities and Exchange Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by a registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which the prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however* , that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to the purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered therein and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to existing provisions or arrangements whereby the registrant may indemnify a director, officer or controlling person of the registrant against liabilities arising under the Securities Act, or otherwise, the registrant has been advised that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than for the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Memphis, State of Tennessee, on the 7th day of October, 2013.

MRI Interventions, Inc.

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

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Kimble L. Jenkins **Kimble L. Jenkins**	*Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)*	October 7, 2013
/s/ David W. Carlson **David W. Carlson**	*Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)*	October 7, 2013
* **Paul A. Bottomley**	*Director*	October 7, 2013
* **Charles E. Koob**	*Director*	October 7, 2013
* **James K. Malernee, Jr.**	*Director*	October 7, 2013
* **Michael A. Pietrangelo**	*Director*	October 7, 2013
* **Andrew K. Rooke**	*Director*	October 7, 2013
* **Michael J. Ryan**	*Director*	October 7, 2013
* **John N. Spencer, Jr.**	*Director*	October 7, 2013
* /s/ Kimble L. Jenkins By: **Kimble L. Jenkins**	*Attorney in Fact*	October 7, 2013

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference of our firm under the caption "Experts" in this amended registration statement and related prospectus of MRI Interventions, Inc. dated October 7, 2013 and to the incorporation by reference therein of our report, dated March 11, 2013 (except for Notes 2, 8 and 12 for which the date is August 19, 2013), with respect to the financial statements of MRI Interventions, Inc., included in its Annual Report on Form 10-K/A for the year ended December 31, 2012, filed with the Securities and Exchange Commission on August 19, 2013.

/s/ CHERRY BEKAERT LLP

Tampa, Florida
October 7, 2013