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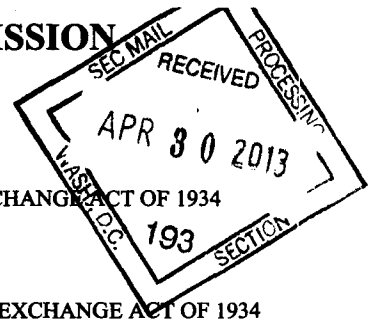
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549



FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2012.

or

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

For the transition period from _____ to _____

Commission File Number: **000-54575**

MRI INTERVENTIONS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**58-2394628**
(State or other jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
One Commerce Square, Ste. 2550 **Memphis, Tennessee** *(Address of principal executive offices)*	**38103** *(Zip Code)*

(901) 522-9300
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $0.01 par value per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. ☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☒ Yes ☐ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act

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

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

As of June 30, 2012, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $73,951,613, based on the closing sale price as reported on the OTC Bulletin Board.

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:

Class	**Outstanding at March 1, 2013**
Common Stock, $.01 par value per share	57,320,447 shares

DOCUMENTS INCORPORATED BY REFERENCE

None

MRI INTERVENTIONS, INC.

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements are contained principally in the sections entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations". 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;
- the anticipated progress of our research and product development activities;
- our ability to successfully complete the development of our current product candidates;
- our ability to obtain regulatory clearance or approval for our current product candidates;
- our ability to generate additional product candidates in the future;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- estimates regarding the sufficiency of our cash resources.

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

You should refer to the section of this Annual Report 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 Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We do not undertake to update any of the forward-looking statements after the date of this Annual Report, except to the extent required by applicable securities laws.

ITEM 1. BUSINESS

Overview

We are a medical device company that develops and commercializes innovative platforms for performing minimally invasive surgical procedures in the brain and heart under direct, intra-procedural magnetic resonance imaging, or MRI, guidance. Since our inception in 1998, we have focused on research and product development in the field of interventional MRI. From 1998 to 2002, we deployed significant resources to fund our efforts to develop the foundational capabilities for enabling MRI-guided interventions and to build an intellectual property position. In 2003, our focus shifted to identifying and building out commercial applications for the technologies we developed in prior years.

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.

- *Better Patient Outcomes.* We believe that if a physician can see the surgical field, the surgical instruments and the patient's anatomy all at the same time and in the same "imaging space," the physician can more efficiently perform a surgical intervention in the brain or heart. Our product platforms, subject to appropriate regulatory clearance or approval, are designed to enable physicians to see the target site, guide the surgical instrument to the site, deliver the therapy, monitor for adverse events and complications and confirm the desired results of the procedure, all under high resolution, intra-procedural magnetic resonance imaging. We believe that these capabilities will translate directly into better clinical outcomes for the patients undergoing the procedures due to improved efficiency, the potential for the reduction of adverse events and side effects, as well as the potential for faster recovery times.

- *Enhance Revenue Potential.* By providing direct, intra-procedural visualization, we believe our ClearPoint system can reduce the amount of time needed to perform the procedures for which it was designed. As a result, we believe that our ClearPoint system may improve the overall economics of the procedures for both the performing physician and the hospital. We believe that our ClearPoint system may also enable a physician to treat more patients in a given period of time, and treat patients who would otherwise not be able to be treated utilizing current surgical techniques.

- *Reduce Costs to the Healthcare System.* We believe that use of our products may result in more efficient utilization of healthcare resources and physician time. For example, our product platforms are designed to work in a hospital's existing MRI suite, which adds additional utility for an infrastructure investment that has already been made by the hospital. Further, if patient outcomes and procedure efficiencies are improved by use of our products, we believe that the result will be a reduction in overall healthcare costs.

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, 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 will serve as our distribution partner for the ClearPoint system. As of December 31, 2012, a total of 20 ClearPoint systems had been installed, 18 in the United States and two in Europe. 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 an exclusive co-development agreement with Siemens for the development and commercialization of the hardware and MRI software necessary for the ClearTrace system. We believe that our exclusive relationship with Siemens secures an important strategic market position 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.

In addition to our strategic relationships with Brainlab and Siemens, we also have entered into exclusive licensing and development agreements with Boston Scientific, pursuant to which Boston Scientific may incorporate certain of our technologies into its cardiac pacemaker and neuromodulation products. To augment our research and development activities, we also have meaningful collaborations with renowned academic institutions.

We have a significant intellectual property portfolio in the field of MRI-guided interventions. As of January 31, 2012, our portfolio included 81 patents and 98 patent applications, both United States and foreign, which we wholly-own, co-own or have licensed. Our technologies have been the subject of numerous peer-reviewed articles in medical and scientific journals. As a result of our product offerings, intellectual property position and collaborative relationships, we believe that we are well positioned to remain on the forefront of the emerging market for MRI-guided minimally invasive surgical procedures.

Industry Background

Magnetic Resonance Imaging

MRI is a widely practiced imaging technique that uses spatially varying magnetic fields to produce images of the human anatomy. Hydrogen nuclei, present in molecules throughout the body, are slightly magnetic. When placed in large external magnetic fields, they can be induced to emit or resonate radio frequency signals. These radio frequency signals are used to construct images of human anatomy, including high resolution images of soft tissue.

MRI has important and advantageous properties that differentiate it from other imaging methods. MRI scans can provide images of any part of the body, in any plane of view, and offer more detailed information than other modalities, including fluoroscopy and computed tomography. Some of the unique advantages of MRI include:

- soft tissue imaging that enables superior tissue visualization and enhanced differentiation between healthy and diseased tissues;
- unlimited orientation and positioning of the imaging plane;
- ability to directly acquire volumetric (three dimensional) data sets;
- ability to evaluate both the structure and certain functions of internal organs; and
- no harmful ionizing radiation exposure for either the patient or the physician.

There are approximately 4,500 1.5T MRI scanners and approximately 550 3T MRI scanners installed in hospitals throughout the United States. MRI scanners are available in a number of different configurations and field strengths, which refers to the strength of the magnet used to create the magnetic field. Magnetic field strength is measured in Tesla, or T. The most common field strength for MRI scanners is 1.5T. Higher field strength scanners such as 3T MRI scanners have been introduced in clinical practice and are gaining commercial market adoption, offering faster scanner speeds and even higher resolution images than 1.5T MRI scanners.

Minimally Invasive Surgical Procedures

Over the past few decades, one of the most significant medical trends has been the development of minimally invasive surgical methods and techniques. As its name implies, a minimally invasive procedure is a less invasive approach than open surgery. Minimally invasive procedures typically involve use of laparoscopic devices, catheter-based devices or remote-control manipulation of instruments once inside the body. Minimally invasive procedures in the brain have typically been performed using a complex technique known as stereotactic neurosurgery, under which a physician merges pre-operative images and data with specialized surgical instruments to help guide the surgical procedure in the brain.

Our Current Products and Product Candidates

ClearPoint Neuro Intervention System

General

Our ClearPoint system is designed to allow minimally invasive procedures in the brain to be performed in a hospital's existing MRI suite. The ClearPoint system provides guidance for the placement and operation of instruments or devices during the planning and operation of neurological procedures performed within the MRI suite using MR imaging. Our ClearPoint system is intended to be used as an integral part of procedures, such as biopsies and the insertion of catheters and electrodes, which have traditionally been performed using stereotactic methods. Our ClearPoint system is intended to be used with both 1.5T and 3T MRI scanners. Our research efforts for our ClearPoint system began in 2003. In June 2010, we received 510(k) clearance from the 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 our ClearPoint system. The CE mark is an international symbol of adherence to quality assurance standards and compliance with applicable European Union medical device directives, and it allows us to market the ClearPoint system in the European Union.

The first patient procedure using our ClearPoint system was performed by physicians at the University of California, San Francisco Medical Center in August 2010. As of December 31, 2012, a total of 20 ClearPoint systems had been installed, 18 in the United States and two in Europe. ClearPoint systems are in clinical use with MRI scanners from the three major manufacturers, Siemens, GE Healthcare and Philips Healthcare. Likewise, our ClearPoint system is also in use with the two major interventional MR/OR platforms, which are manufactured by IMRIS and Brainlab.

In April 2011, we entered into a co-development and distribution agreement with Brainlab, a leader in the development of software-driven medical technology that supports targeted, less-invasive patient treatment. 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.

The Need for Minimally Invasive Neurological Interventions

Millions of people suffer from neurological diseases including: movement disorders such as Parkinson's disease, essential tremor and dystonia; psychiatric disorders such as major depression, obsessive compulsive disorder and Alzheimer's disease; and brain tumors, such as glioblastoma multiforme. The first line of therapy for most of these conditions is systemic administration of drugs. For example, to treat the early stages of Parkinson's disease, a patient is often prescribed a drug called levodopa. Drugs such as levodopa can be effective in the earlier stages of the disease; however, as the disease progresses, systemic drugs may become less effective, and potentially ineffective, in treating the patient. Given the shortcomings of systemic drugs like levodopa, the medical community has focused significant resources to find new non-systemic or "local" therapies to treat these patients.

The development activity in, and the use of, local therapies is growing. For example, drug companies and researchers have identified and are investigating various compounds that are delivered directly into the diseased area of the brain, such as directly into the center of a tumor in the brain. Similarly, the medical community has developed a technique commonly referred to as focal lesioning, under which a special probe is inserted into a target area of the brain and a small area of diseased brain tissue is then destroyed by applying laser energy or radio frequency energy through the tip of the special probe. Physicians perform this procedure to treat disorders such as Parkinson's disease, essential tremor and epilepsy. The medical community has also developed another local therapy known as deep brain stimulation, or DBS. DBS uses mild electrical pulses from an implanted device to stimulate a small target region in the brain. A DBS system looks and operates much like a cardiac pacemaker, except that instead of sending pulses to the heart, it delivers electrical stimulation through the electrodes placed at a precisely targeted area in the brain. The FDA has approved the use of DBS for the treatment of Parkinson's disease and essential tremor. The FDA has also approved the use of DBS for the treatment of dystonia and obsessive compulsive disorder pursuant to humanitarian device exemptions. FDA approval is currently being sought for the use of DBS to treat epilepsy, and DBS is also being investigated as a therapy for treatment-resistant major depression.

These local therapies, among others, involve insertion of a catheter, probe or electrode into a target region of the brain, typically performed as a minimally invasive procedure. However, performing these minimally invasive interventions in the brain presents special challenges, including a need to reach a small therapeutic target often located deep within the brain, which target is often an area as small as a few millimeters in diameter. To reach these targets, the physician must act with precision to avoid damaging adjacent areas that are responsible for important neurological functions, such as memory or speech, or penetrating blood vessels which can lead to a life-threatening hemorrhage. The medical community developed stereotactic neurosurgery to address these obstacles. But, despite years of development and clinical experience, conventional stereotactic procedures remain complicated and time-consuming for many neurological interventions and can be extremely difficult on the patient.

Challenges with Conventional Stereotactic Neurosurgical Procedures

Conventional stereotactic neurosurgical procedures are performed in a standard operating room. With this method, a large, metal stereotactic frame is typically fixed to the patient's skull, using skull pins, to provide a fixed and common coordinate system. After the frame is attached to the patient's skull, the patient is then imaged pre-operatively, often using MRI, in order to obtain images showing both the stereotactic frame axes and the anatomical structures of the patient's brain. These pre-operative images are then loaded into a surgical planning workstation. Surgical planning software is used to identify the neurological target for the procedure, as well as to define a trajectory path from the skull, through the brain tissue, and to the target. The planned trajectory and target location are then calculated in relation to the frame axes and then used to guide the surgery.

Because conventional stereotaxy relies on pre-operative images, and not intra-procedural images, errors in the alignment of the pre-operative images with the patient's brain anatomy can, and often do, occur as a consequence of brain shift, variation in patient hydration, registration errors or misalignment of the frame. As a result, the physician often must undertake additional steps to further refine the process of locating the patient's neurological target. These steps include physiological "mapping" of the brain and require an additional procedural step called microelectrode recording, which is a tedious and time-consuming process in which small probes containing microelectrodes are inserted into the deep brain structures, usually multiple times. As these microelectrode recording probes are passed through brain tissue, they pick up electrical activity. The microelectrode recording system then converts the electrical activity into audible tones. In hearing these various audible tones, a trained neurologist or neurophysiologist can distinguish different regions of the brain. Based on these tones, locations are mapped against the pre-operative images and used to refine and adjust the neurological target as depicted on those pre-operative images. New coordinates are then calculated and a new trajectory is planned. To further confirm locations in the brain, various physiologic responses are induced or monitored with the microelectrodes. These physiological mapping steps require the patient to be awake during the surgery and off medications. Given the procedure's complexity, it is not uncommon for the procedure to last six or more hours.

Our ClearPoint System Solution

Instead of relying on the indirect guidance of pre-operative imaging, microelectrode recording and physiological responses from the patient, our ClearPoint system is based on a direct approach, in which a physician is guided by high resolution MRI during the procedure. By utilizing the direct approach of the ClearPoint system, the patient does not have to be awake and participating in his or her brain surgery. Instead, the patient can be under general anesthesia for the procedure and remain on his or her prescription drug regime. In addition, we believe the design of our ClearPoint system can significantly simplify how stereotactic neurological interventions are performed and can result in shorter procedure times.

A ClearPoint procedure is designed to be performed in a standard hospital-based MRI scanner. Our ClearPoint system is an integrated system comprised of hardware components, disposable components and intuitive, menu-driven software.

ClearPoint Hardware. Our hardware components consist primarily of an MR imaging head coil, head fixation frame, computer workstation and in-room monitor. The architecture of our imaging head coil allows for surgical access to the patient while maintaining high quality imaging capability. The head fixation frame is integrated with the head coil and is designed to optimize the placement of the head coil in proximity to the patient's head. For certain MRI scanner platforms, such as the MRI scanners manufactured by Philips Healthcare, our imaging head coil may not be needed. Our ClearPoint system software is installed on a computer workstation networked with an MRI scanner, for which we use a

commercially available laptop computer. The in-room monitor allows the physician to view the display of our ClearPoint system workstation from the scanner room while performing the procedure.

ClearPoint Disposables. The disposable components of our ClearPoint system consist primarily of our SmartFrame trajectory device, a hand controller and related accessories. Our SmartFrame device is an adjustable trajectory frame that attaches to the patient's skull and holds the targeting cannula. The hand controller attaches to our SmartFrame device, and it is used by the physician to adjust the roll, pitch and X and Y orientation of the targeting cannula while the patient is in the MRI scanner. The accessories include all other components necessary to facilitate the MRI-guided neurological procedure, such as our SmartGrid patch, which is an MRI-visible marking grid that enables rapid localization of the entry position into the brain, and our customized surgical draping, which creates a sterile field within the MRI scanner.

ClearPoint Software. Our ClearPoint system software guides the physician in surgical planning, device alignment, navigation to the target and procedure monitoring. The software receives standard images from the MRI scanner via a network connection. The software leads the physician through a series of predefined steps, including MR image acquisition, establishment of image orientation landmarks, target identification and selection, trajectory planning, entry point planning and marking, targeting cannula orientation and refinement, and confirmation that the desired anatomical target(s) have been reached. The software uses image segmentation algorithms to help locate and identify our SmartFrame device and its targeting cannula, as well as the anatomical structures of the brain. The software also performs geometric computations to provide the physician with information regarding the positioning of instruments inserted into the patient's brain relative to the target anatomical structures. At the completion of the procedure, the software generates an automated report that includes the key metrics from the procedure.

The ClearPoint Procedure. Our ClearPoint procedure is performed entirely within a standard hospital-based MRI suite. Once placed in the MRI scanner, the patient's head is immobilized in our imaging head coil and integrated head fixation frame with the patient's head accessible to the physician. The physician then places our MRI-visible SmartGrid patch onto the patient's head where the physician expects to enter the skull. The patient is then moved to the center of the scanner and images are taken of the patient's brain that include the target area and our SmartGrid patch. Once the imaging is complete, the images are transferred to our ClearPoint system workstation so that the physician can determine the specific target site within the brain and the optimal trajectory path for the placement of the interventional device. With the trajectory path established, our ClearPoint system software will identify the specific location on our SmartGrid patch that corresponds with where the planned trajectory intersects the skull. The physician will then mark the skull using our custom marking tool. At the site of the mark, the physician will create the burr hole, which is the small hole in the patient's skull through which the interventional device can be inserted into the brain.

Our SmartFrame device is then centered and attached over the burr hole. The target and planned trajectory is reconfirmed by the physician using our ClearPoint system workstation. Using the hand controller, the physician adjusts the trajectory of the MRI-visible SmartFrame device to align the instrument with the planned trajectory. During this process, the software estimates a number of turns and direction of turn on each of the hand controller's color coded thumbwheels to align the instrument to the planned trajectory.

Once our SmartFrame device has been aligned to the proper trajectory, the depth dimension is calculated by the software. Immediately before insertion and partway through insertion, images are taken to ensure that the probe is correctly tracking along the planned trajectory. The physician continues advancing the interventional device towards the target site until it "snaps" into place on the SmartFrame device indicating that the interventional device has reached the proper depth. At this time, images are taken at the target site to insure the interventional device is in the proper location relative to the desired target.

Regulatory Status

Our ClearPoint system has a general indication for use. Our 510(k) clearance from the FDA permits us to market and promote our ClearPoint system in the United States for use in general neurological procedures, which includes procedures such as biopsies, catheter insertions and electrode insertions. This is the same general indication for use that applies to other devices that have traditionally been used in the performance of stereotactic neurological procedures. Similar to other conventional stereotaxy-based systems, our ClearPoint system's general neurological indication for use does not reference specific neurological procedures.

In the European Union, our CE mark approval carries the same indication for use as our 510(k) clearance in the United States.

In January 2011, we received 510(k) clearance from the FDA for our SmartFlow neuro ventricular cannula. Our SmartFlow cannula, which is compatible with our ClearPoint system, is an MRI-compatible injection and aspiration cannula. It is indicated for use in the injection of Cytarabine, which is a chemotherapy drug, or the removal of cerebrospinal fluid from the ventricles of the brain during an intracranial procedure. The SmartFlow cannula is a disposable device intended for single patient use only and is not intended for implant.

The ClearTrace Cardiac Intervention System

At present, we are focusing most of our efforts and resources on the commercialization of our ClearPoint system, which we believe can transform the field of minimally invasive neurosurgery. Looking to the future, we hope to achieve a similar outcome for minimally invasive procedures in the heart. Our second product platform, the ClearTrace system, is a product candidate still in development. The ClearTrace system is designed to allow catheter-based minimally invasive procedures in the heart to be performed using continuous, intra-procedural MRI guidance.

General

Catheter-based cardiac interventions performed in a fluoroscopy suite, generally referred to as a Cath Lab or EP Lab, have been the standard of care for the treatment of many cardiac disorders, such as cardiovascular disease. Certain procedures, such as stent placement, are well suited for fluoroscopic imaging because they do not require continuous, detailed visualization of the cardiac tissue. However, other procedures are not well suited for fluoroscopy because of the clinical need for continuous, high resolution imaging of the cardiac anatomy along with the interventional instruments. One example of such a procedure is cardiac ablation to treat cardiac arrhythmias, such as atrial fibrillation. Another example is the precision delivery of stem cells directly into the wall of the heart, which represents a promising therapy being researched for the treatment of heart failure.

We anticipate that the ClearTrace system will be similar to the conventional Cath Lab or EP Lab, but with two critical distinctions. First, unlike the Cath Lab or EP Lab, we believe the ClearTrace system, once we have completed its development, will provide a continuous, high resolution, four dimensional imaging environment (the fourth dimension being time), which will include detailed visualization of cardiac tissue, along with the cardiac catheters used to deliver the therapy. We believe that this capability is required for the next generation of interventional cardiac therapies. Second, we anticipate that the ClearTrace system will eliminate all radiation exposure for both the patient and physician from the X-ray utilized in current procedures. Under current catheter-based treatments utilizing fluoroscopy, radiation exposure can exceed 45 minutes. We believe that the attributes of the ClearTrace system should position it to be the therapy of choice for cardiac ablation procedures to treat cardiac arrhythmias, including atrial fibrillation, and the ideal platform for delivering future biologic therapies to treat heart failure and other similar cardiac disorders. The ClearTrace system is designed for procedures that initially will be performed using a Siemens 3T MRI scanner.

We began preliminary research for an MRI-guided cardiac ablation procedure shortly following our inception in 1998. As a culmination of our research efforts, in May 2009, we entered into an exclusive co-development agreement with Siemens for the development and commercialization of the hardware and MRI software necessary for the ClearTrace system. Under the terms of this agreement, we are working with Siemens on the development of the ClearTrace software and the integration of system components. Once product development is completed, we will work with Siemens on the commercial launch and field support of the ClearTrace system. We believe that our exclusive relationship with Siemens secures an important strategic market position for the ClearTrace system.

Challenges with Current Treatments for Atrial Fibrillation

Cardiac arrhythmia is an abnormal beating of the heart that can result in insufficient blood flow, which may cause dizziness, inadequate function of important organs in the body, stroke and even death. Atrial fibrillation affects over three million people in the United States and approximately 6.7 million people worldwide, making it the most common form of cardiac arrhythmia. Atrial fibrillation is characterized by the irregular fluttering or very rapid beating of the atria resulting from malfunction of the electrical conduction system in the walls of the atria. Atrial fibrillation is a leading cause of stroke among persons 65 years or older and it is associated with increased risk of heart failure and other morbidity.

Most atrial fibrillation treatments are palliative and do not cure atrial fibrillation. The most common are anti-arrhythmic and anticoagulant drugs. However, anti-arrhythmic drug therapy often becomes less effective over time, with approximately half of the patients developing resistance to the drugs. In addition, anti-arrhythmic drugs have potentially severe side effects, including pulmonary fibrosis, impaired liver function, thyroid problems and the development of worse and even life-threatening ventricular arrhythmias.

One highly effective, curative therapy for atrial fibrillation used today is an open-heart operation, commonly known as the surgical "Cox-Maze" procedure, which has reported success rates as high as 96%. During this open heart procedure, the physician makes a series of cuts in a specific "maze-like" formation along the inside walls of the left atrium with a scalpel, and then sutures these cuts back together. The scars create an uninterrupted conduction block containing the chaotic electrical impulses that cause atrial fibrillation, thereby returning the heart to a normal rhythm. The open heart Cox-Maze procedure is usually done in tandem with another open heart procedure, such as a valve replacement or coronary artery bypass, because this operation is traumatic to the patient, very expensive, and typically associated with long hospital stays and a three to six month recovery time.

Because of the effectiveness of the Cox-Maze method, the medical community has worked for years to develop a less invasive approach that generates comparable clinical outcomes. The current minimally invasive approach is performed in the EP Lab with the physician relying upon fluoroscopic imaging to guide a catheter through a blood vessel into the right atrium, puncturing the septum and advancing the catheter into the left atrium of the heart. The physician then delivers energy through the catheter to create lesions and destroy the target tissue. During the procedure, the physician is assisted in guiding and positioning the catheter primarily by fluoroscopic imaging. However, fluoroscopic imaging has significant limitations, namely it does not permit the physician to see the cardiac anatomy and tissue, the location of the catheter in relation to the cardiac tissue, or the intra-procedural creation of the lesions necessary to create the conduction block. Furthermore, the use of fluoroscopy exposes both patient and physician to dangerous radiation for an extended period of time.

Thus far, the medical community has been unsuccessful in replicating the high success rates of the highly invasive Cox-Maze procedure using a minimally-invasive catheter-based procedural approach. Despite the sophistication of the procedures, the success rates of the catheter-based approaches have been disappointing, some as low as 50% to 75%. We believe that the low success rate of the current catheter-based approaches is a result of the physician's inability to see the cardiac tissue during the procedure. Unlike the imaging modalities used in the current catheter-based approach, an MRI-based procedure, such as one performed with the ClearTrace system, allows the physician to visualize a patient's cardiac tissue. With this capability, a physician can, for example, distinguish healthy cardiac tissue from fibrotic tissue and see gaps in the lesion lines. MRI can allow visualization of ablation lesions that are created during the procedure. Because of the unique cardiac tissue visualization and assessment capabilities of MRI, we believe the medical community is advancing towards an MRI-guided approach and we believe that an MRI-guided approach may finally deliver Cox-Maze-like success rates with a minimally invasive catheter-based procedure.

The ClearTrace System Solution

We believe the ClearTrace system will represent a new paradigm in performing cardiac interventions. Similar to our ClearPoint system, the ClearTrace system is designed as an integrated system of hardware components, disposable components and intuitive, menu-driven software.

ClearTrace Hardware. The hardware components will be centered around our ClearConnect system, which is an MRI-compatible hardware and cable management system to safely enable MRI-guided cardiac ablation procedures in an MRI scanner.

ClearTrace Disposables. The disposable components will include an ablation catheter, mapping catheter, coronary sinus catheter and septal puncture kit. Our ablation catheter will be used to perform MRI-guided delivery of ablative energy to create cardiac lesions. Our mapping catheter will be used for MRI-guided collection of intracardiac electrocardiogram signals and will include analog/digital filtering to enable electrocardiogram collection during scanning. Our coronary sinus catheter will be used to collect additional electrocardiogram signals and to provide cardiac pacing and defibrillation, as needed during the procedure. Our septal puncture kit will consist of a septal puncture needle, a dilator and sheath and will be used to perform an MRI-guided puncture of the septum of the heart to allow movement between the right atrium and left atrium. All catheters and components will be MRI-compatible and tightly integrated with the MRI scanner.

ClearTrace Software. The ClearTrace system will include software designed to assist the physician in: surgical planning; creating three dimensional volumes of cardiac chambers; navigating our ClearTrace catheters within the cardiac chambers; visualizing lesions as they are formed; tracking prior lesion locations; evaluating ablated cardiac tissue; and monitoring for possible adverse events. Under our co-development agreement, Siemens is responsible for developing the ClearTrace system software to our specifications. The ClearTrace system software will be integrated with our disposable components.

The ClearTrace Procedure. We believe the ClearTrace system will offer a novel, comprehensive solution for the planning, delivering and intra-procedural assessment of catheter-based cardiac interventions. The following discussion outlines what we believe will be the key steps in performing a ClearTrace system procedure to treat atrial fibrillation, as well as expected key ClearTrace system capabilities, subject to the completion of system development and receipt of appropriate regulatory clearance or approval.

A ClearTrace procedure will be performed in a standard, hospital-based 3T Siemens MRI scanner suite. At the start of a ClearTrace procedure, a MRI scan will be performed of the patient's heart and surrounding vasculature. Using the images from the scan, the ClearTrace system software will generate a three dimensional volumetric model of the patient's cardiac chambers that the physician will use as a guide while performing the procedure. Additional MRI images and patient data could be mapped onto the surface of the three dimensional model as needed by the physician. Referencing the three dimensional model and surface mapped image data and using real time MRI scans of the patient's heart, the physician will plan the cardiac ablation procedure.

The ClearTrace coronary sinus catheter then will be advanced through a blood vessel under MRI guidance and placed in the coronary sinus to collect electrocardiogram signals and to provide cardiac pacing and defibrillation, as may be needed during the procedure. The remaining ClearTrace catheters then will be advanced through a blood vessel under MRI guidance into the right atrium of the heart. Using the ClearTrace system plan, the physician will advance the catheters through the targeted site on the septum and into the left atrium. Referencing the ablation plan, and with continuous intra-procedural visualization of the catheters and patient anatomy, the physician will advance the catheters to the site of the first planned ablation. With the ClearTrace ablation catheter in the correct location, the physician will begin applying energy to the tip of the catheter to create a lesion.

During ablation, the ClearTrace system will present intra-procedural MR images that will allow the physician to see the changes in the tissue caused by the ablative energy, which we believe would give the physician visualization capabilities similar to what he or she has in the open heart Cox-Maze procedure. The physician will then repeat the process of creating and visualizing lesions within the left atrium until the ablation plan has been completed. The physician will complete the procedure by taking a final scan to confirm the proper placement of all lesions.

By allowing the physician to see the lesions during the procedure, we believe the physician will be able to make better decisions about where to ablate, what amount of energy to apply and how long to apply the energy. We believe this improved decision-making capability will result in improved outcomes and reduced adverse events. In addition to the ability to visualize the changes in the cardiac tissue, we believe the physician will also be able to use a loop catheter to measure electrical signals from the inside surface of the left atrium to further guide and confirm the effectiveness of the ablation process.

Other Potential Applications

We believe the ClearTrace system's unique ability to provide continuous, high resolution imaging of the cardiac anatomy, including the walls of the heart, during an interventional procedure will be valuable in treating other cardiac disorders. For example, we believe the ClearTrace system could serve as an ideal platform for delivering drugs and other therapeutic agents directly into the heart wall. The medical community is developing novel compounds that have the potential to address significant cardiac disorders, such as heart failure. However, some of these compounds must be injected directly into the heart wall with precision placement at the boundary of healthy and diseased tissue. Using the ClearTrace system, we believe a physician will be able to navigate within the heart to the boundary between healthy and diseased tissue, place the catheter tip on the boundary, inject the compound and watch the dispersion of the compound into the heart wall.

Regulatory Status

The ClearTrace system is still under development, and, as noted above, we are focusing most of our efforts and resources on the commercialization of our ClearPoint system. As development is ongoing, we cannot predict a timetable for completion of our development activities, and we are not able to estimate when we will make a filing seeking regulatory approval or clearance for the ClearTrace system.

In the United States, we believe that most components of the ClearTrace system will be Class II medical devices and will fall under the FDA's 510(k) regulatory process. However, the ablation catheter component will be a Class III medical device and will require FDA approval of a premarket approval application, or PMA. We anticipate that the initial market for the ClearTrace system will be the European Union, and therefore we plan to seek CE marking approval for the ClearTrace system at the appropriate time. To date, we have been conducting only animal studies and other preclinical work with respect to the ClearTrace system.

Licenses and Collaborative Relationships

In addition to our internally-developed technologies and devices, we have established and may continue to pursue licensing and other collaborative relationships with medical device companies and academic institutions to further the development and commercialization of our product platforms and our core technologies. Our current relationships are discussed below.

Brainlab

In April 2011, we entered into a co-development and distribution agreement with Brainlab. Our agreement with Brainlab has a term of five years. Pursuant to the agreement, we and Brainlab will work to potentially integrate our ClearPoint system technologies with Brainlab's own interventional MRI technologies for application in the MRI-guided neurological drug delivery field of use, subject to appropriate regulatory clearance or approval. Brainlab, at its expense, will explore the integration of our ClearPoint system technologies with Brainlab's interventional MRI technologies for other MRI-guided neurological procedures as well. Brainlab is responsible for obtaining any regulatory clearance or approval necessary to sell any product resulting from the integration of our respective technologies. During the term of the agreement, neither we nor Brainlab may enter into a collaborative arrangement with another party relating to the commercial development, sales or marketing of products in the MRI-guided neurological drug delivery field of use. In addition, Brainlab may not develop, market or sell in the MRI-guided neurological drug delivery field of use any product that performs substantially the same function as or otherwise competes with any of our ClearPoint products, other than products resulting from our co-development activities.

Under the agreement, we also granted Brainlab distribution rights with respect to our ClearPoint system. We appointed Brainlab as an exclusive distributor of ClearPoint products within the MRI-guided neurological drug delivery field of use and as a non-exclusive distributor of ClearPoint products for other MRI-guided neurological procedures. Brainlab's distribution territory includes the United States, the European Union and Canada, although we do not yet have regulatory approval to sell our ClearPoint system in Canada. As our distributor, we will supply products to Brainlab at agreed upon transfer prices. We believe the agreed-upon transfer prices will yield substantially the same financial return per unit as we receive on our own direct sales. As both we and Brainlab will be selling the ClearPoint products outside the MRI-guided neurological drug delivery field of use, our agreement specifies that, to the extent a ClearPoint system is installed at a hospital due to Brainlab's selling efforts, Brainlab will then be the party that sells all ClearPoint disposable products to that hospital.

Siemens

In May 2009, we entered into a cooperation and development agreement with Siemens to develop the hardware and MRI software systems for MRI-guided, catheter-based ablation to treat cardiac arrhythmias, such as atrial fibrillation. Under this agreement, Siemens is responsible for developing the software in accordance with our specifications, and we are responsible for developing the catheters and other hardware, other than the MRI scanner and workstation, necessary for the MRI-guided cardiac ablation procedures and for the integration work necessary to combine the software, catheters and other hardware to create the ClearTrace system. The agreement provides for exclusivity for a period of five years following the date of regulatory clearance and/or approval, determined on a country-by-country basis. During the exclusivity period, Siemens may not market or offer software that is intended to work with a third party's catheters to conduct an MRI-guided cardiac ablation procedure, and we may not sell or offer

any catheters that are intended to be used with an MRI scanner manufactured by a third party to conduct an MRI-guided cardiac ablation procedure. For two years after the exclusivity period ends, neither we nor Siemens may enter into an agreement or relationship with a third party that excludes or prevents the use of our devices with Siemens' MRI systems, and vice versa, in the field of MRI-guided cardiac ablation procedures. The agreement requires us to pay Siemens up to approximately $2,500,000 for Siemens' successful development of the software in accordance with our specifications. Under our co-development agreement, through December 31, 2012 we had paid Siemens approximately $1,374,000 in connection with Siemens' MRI software development work. 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. The term of the agreement will expire once (i) all software, catheter and other hardware development and integration work has been successfully completed, (ii) requisite regulatory clearances or approvals have been obtained in at least the United States, Canada and Europe, and (iii) the product has been clinically released in at least the United States, Canada and Europe. Prior to or upon expiration of the term of the cooperation and development agreement, we anticipate entering into a separate sales and marketing agreement with Siemens.

Boston Scientific

In connection with our research and development efforts for the ClearPoint and ClearTrace systems, we developed technologies that we believe can improve the MRI-safety profile of implantable medical leads. Implantable medical leads are thin, insulated wires that are connected to implantable generators, such as a pacemaker or neurostimulator, and deliver electrical pulses or stimulation to a specific area of the body, such as the heart or the brain. In 2005 and 2008, we entered into agreements with Boston Scientific that contemplate the potential use of our MRI-safety technologies in Boston Scientific's implantable leads, as further described below.

Background on our MRI-Safety Technologies for Implantable Leads

It is estimated that between 50% and 75% of patients with an implantable device are expected to need an MRI scan during the lifetime of their devices. However, implantable medical leads are susceptible to heating in the MRI environment. An MRI scanner transmits radio frequency energy during the scanning process. Because the implantable lead contains metallic wire, which acts like an antenna, some of the radio frequency energy transmitted by the MRI scanner is absorbed by the lead. This could cause the lead to heat. The extent to which an implantable lead may heat can depend on many factors, such as the lead itself, the position of the patient in the MRI scanner, the clinical scanning sequence used and the location and trajectory of the lead in the patient. Scientific studies have shown that implantable leads may heat during an MRI scan to temperatures that can burn or destroy tissue. If that happens in the heart or brain, the patient could suffer a stroke, paralysis or even death. As a result, people with active implantable devices generally are prohibited from undergoing an MRI scan.

We believe our technologies address this issue by maintaining lead temperatures well within safe levels during an MRI scan. Current safety standards for active implantable medical devices require that MRI-related heating may not exceed one degree Celsius in the brain and two degrees Celsius in the heart. Our testing has shown that our technologies limit lead heating to less than one degree Celsius. Therefore, we believe our MRI-safety technologies will permit a patient with an implantable medical device to undergo an MRI scan. Manufacturers' studies have shown that cardiologists identify "MRI compatibility" as one of the main features that would drive a change in brand preference.

Neuromodulation Agreements

In December 2005, we entered into a development agreement and license agreement with Boston Scientific in the neuromodulation field:

System and Lead Development and Transfer Agreement. The development agreement relates to the design and development of MRI-compatible and MRI-safe implantable leads for neuromodulation applications, such as implantable DBS leads. Under the development agreement, we could receive future milestone-based payments associated with successful development and regulatory approval of the leads.

Technology License Agreement. Under the license agreement, we granted Boston Scientific an exclusive, worldwide license with respect to certain of our owned or licensed intellectual property in the neuromodulation field to make, use, import, lease and sell neuro-related leads, neuro-related lead extensions, and neuro-related lead-type devices, such as implantable pulse generators. The license included a sublicense of applicable intellectual property that we licensed from The Johns Hopkins University, or Johns Hopkins, as further described below. Boston Scientific has agreed

to pay us royalties on net sales of products that are covered by a licensed patent; however, Boston Scientific has no obligation to include the licensed intellectual property in its products or product candidates. Pursuant to the development agreement described above, Boston Scientific is responsible for patent prosecution of the licensed intellectual property and the payment of costs associated with patent prosecution.

Implantable Cardiac Agreements

In March 2008, we entered into a development agreement and license agreement with Boston Scientific in the field of implantable medical leads for cardiac applications.

Development Agreement. Under the development agreement, we are working with Boston Scientific to assess the feasibility of and, upon successful completion of feasibility studies, to design and develop certain MRI-compatible, MRI-safe implantable cardiac rhythm management leads. Under the terms of the agreement, we could receive future milestone-based payments associated with successful development activities under the agreement as well as regulatory approval of different implantable lead types that incorporate our technology. However, we believe that Boston Scientific does not intend to incorporate our technology into each of the different types of implantable cardiac leads addressed by the agreement, which reduces the potential milestone-based payments we could receive. In addition, no earned milestone payments will be made unless and until the applicable lead is covered by an issued patent licensed to Boston Scientific pursuant to the technology license agreement described below. The development agreement is scheduled to expire upon FDA approval of a design for each different implantable lead type. The agreement provides Boston Scientific with a one-time option, which must be exercised within 60 days after successful completion of the first lead feasibility study, to cease further development and to terminate the development agreement. We are in discussions with Boston Scientific regarding whether the first lead feasibility study has been successfully completed. To date, we have not received any milestone payments from Boston Scientific under the development agreement.

Technology License Agreement. Under the license agreement, we granted Boston Scientific an exclusive, worldwide license with respect to certain of our owned or licensed intellectual property in the field of implantable medical leads for cardiac applications to make, have made, use, promote, market, import, distribute, lease, sell, offer for sale and commercialize products in that particular field of use. The license included a sublicense of applicable intellectual property that we licensed from Johns Hopkins. We received licensing fees of $13,000,000 in 2008. Boston Scientific has also agreed to pay us royalties on net sales of products that are covered by a licensed patent; however, Boston Scientific has no obligation to include our licensed intellectual property in its products or product candidates. Boston Scientific is responsible for patent prosecution of the licensed intellectual property and the payment of costs associated with patent prosecution. In the event it is determined that the first lead feasibility study under the development agreement described above has not been successfully completed, Boston Scientific will still have its one-time option to terminate the development agreement. Under those circumstances, if Boston Scientific subsequently elects to exercise its termination option, the license we granted Boston Scientific will automatically become non-exclusive with respect to some intellectual property, other intellectual property will be removed from the scope of the license and revert to us, and Boston Scientific will not be obligated to pay us future royalties or sublicense revenues based on sales of products covered by any issued patent that remains subject to the non-exclusive license.

Regulatory

Boston Scientific is responsible for making any regulatory filings with respect to its products that incorporate our MRI-safety technologies. To date, no such regulatory filing has been made with the FDA or any foreign authority. Boston Scientific will control the timing and manner of any regulatory filing, and it will be responsible for the costs associated with any regulatory filing. We do not anticipate that we will be able to influence the process or timing in any meaningful way. In the United States, we believe that any Boston Scientific product incorporating our MRI-safety technologies will be a Class III medical device and require a PMA submission.

The Johns Hopkins University

We have in place five exclusive license agreements with Johns Hopkins. For additional information regarding these licenses, see "Business–Intellectual Property."

Sales and Marketing

Commercializing our ClearPoint system involves marketing:

- to physicians, who care for patients suffering from neurological disorders, including neurosurgeons, who perform the neurological procedures, and neurologists, who interact with patients prior to and following the therapy and who refer patients to therapy;
- to hospitals involved in the treatment of neurological disorders and the opinion leaders at these hospitals; and
- to patients who suffer from neurological disorders.

There are approximately 3,500 neurosurgeons in the United States. Similar to many fields of medicine, some neurosurgeons elect to focus on a particular specialty within the neurological field. For example, some neurosurgeons focus their practice on spine surgeries, others more on open craniotomy surgeries and others more on minimally invasive approaches, such as functional neurosurgery. We believe our ClearPoint system may be most applicable to those functional neurosurgeons, of whom there are approximately 300 in the United States, but we also market our ClearPoint system to other neurosurgeons. We believe that our ClearPoint system represents an attractive platform for a neurosurgery team within a hospital to perform various general neurological procedures.

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 hospitals pursuant to our ClearPoint Placement Program, under which we install a system at the hospital but we retain title to the system. Under that program, we may make the reusable ClearPoint components available to a hospital for use during an agreed-upon period of time while the hospital evaluates and processes the purchase opportunity. In addition, under the ClearPoint Placement Program we may permit a hospital to pay for an installed system or its use over an agreed-upon period of time. 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. We believe that our intellectual property rights associated with our disposable products, coupled with the tight integration between the reusable components and the disposable products, are sufficient to protect our interests. As of December 31, 2012, 20 ClearPoint systems had been installed, which includes 12 systems under our ClearPoint Placement Program, six 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.

Presently, our commercialization efforts for our ClearPoint system are being coordinated primarily by our Vice President, Global Sales & Marketing. As of January 31, 2013, our sales and marketing team consisted of seven employees, and we expect to continue building a small, highly focused sales force to market our ClearPoint system products in the United States. In addition, our distribution relationship with Brainlab expands our sales and marketing capabilities for the ClearPoint system, both in the United States and in Europe.

Given the stage of development of the ClearTrace system, we have not developed a sales and marketing plan to commercialize ClearTrace either inside or outside the United States.

Research and Development

Continued innovation through research and development is critical to our future success. As of January 31, 2013, our research and development team consisted of five employees. We have assembled an experienced team with recognized expertise in both the development of medical devices and advanced MRI technologies, including interventional MRI microcoils and catheters. We believe that our current research and development team is sufficient for our current needs; however, we may increase the size of our team depending on the progress of our ongoing research and development efforts.

Our principal research and development goals are:

- to continue to enhance our ClearPoint system;
- to complete development of the hardware components of the ClearTrace system; and
- to provide technical support and expertise in the area of MRI safety to Boston Scientific under our development and license agreements.

We have historically spent a significant portion of our capital resources on research and development. Our research and development expenses were approximately $2,485,000, $4,251,000 and $5,681,000 for the years ended December 31, 2012, 2011 and 2010, respectively.

Manufacturing and Assembly

Our ClearPoint system includes off-the-shelf components, custom-made components produced to our proprietary specifications by various third parties and components that we assemble in our Irvine, California facility. We use third parties to manufacture these components to utilize their individual expertise, minimize our capital investment and help control costs. We purchase most custom-made components of our ClearPoint system from a single source due to quality considerations, lower costs and constraints resulting from regulatory requirements; however, we believe alternative sources are available, if needed. Generally, we purchase our components through purchase orders and do not have long-term contracts with most of our suppliers.

Our Irvine, California facility is structured to complete component processing, final assembly, packaging and distribution activities for our ClearPoint system. The assembly process is performed in a controlled environment as required by applicable regulation for medical device assembly. Our operations are subject to extensive regulation by the FDA under its Quality System Regulation, or QSR, which requires that manufacturers have a quality management system for the design and production of medical devices. In addition, to the extent we conduct business outside the United States, we are subject to international regulatory requirements.

Our Irvine, California facility is FDA-registered, and we believe it is compliant with the FDA's QSR. We are also certified to ISO standard 13485. We have instituted a quality management system, under which we have established policies and procedures that control and direct our operations with respect to design, procurement, manufacture, inspection, testing, installation, data analysis, training and marketing. We review and internally audit our compliance with these policies and procedures, which provides a means for continued evaluation and improvement. As required by our quality management system, we undertake an assessment and qualification process for each third-party manufacturer or supplier that we use. Typically, our third-party manufacturers and suppliers are certified to ISO standard 9001 and/or 13485. We also periodically perform audit procedures on our third-party manufacturers and suppliers to monitor their activities for compliance with our quality management system. Our facility and the facilities of the third-party manufacturers and suppliers we use are subject to periodic inspections by regulatory authorities, including the FDA and other governmental agencies.

Intellectual Property

We believe that in order to maintain a competitive advantage in the marketplace, we must develop and maintain the proprietary aspects of our technologies. We rely on a combination of patent, trademark, trade secret, copyright and other intellectual property rights and measures to protect our intellectual property.

Our patent portfolio includes rights to patents and patent applications that we own, whether wholly-owned or co-owned, or license from others. We seek patent protection in the United States and internationally for our products and technologies where and when we believe it is appropriate. United States patents are granted generally for a term of 20 years from the earliest effective priority date of the patent application. The actual protection afforded by a foreign patent, which can vary from country to country, depends on the type of patent, the scope of its claims and the availability of legal remedies in the country.

We also rely on other forms of intellectual property rights and measures, including trade secrets and nondisclosure agreements, to maintain and protect proprietary aspects of our products and technologies. We require our employees and consultants to execute confidentiality agreements in connection with their employment or consulting relationships with us. We also require our employees and consultants to disclose and assign to us all inventions conceived during the term of their employment or engagement while using our property or which relate to our business.

Patents and Patent Applications

We have a significant intellectual property portfolio in the field of MRI-guided interventions. As of January 31, 2013, our portfolio included 81 patents and 98 patent applications, both United States and foreign, which we wholly-own, co-own or have licensed.

Owned Patents and Patent Applications

As of January 31, 2013, we wholly owned:

- 15 issued United States patents (including one design patent);
- 29 pending United States patent applications (including five provisional applications);
- nine issued foreign patents; and
- 32 pending foreign patent applications (including three Patent Cooperation Treaty applications).

In addition, as of January 31, 2013, we co-owned with third-parties a total of eight issued United States patents, eight pending United States patent applications, 14 issued foreign patents and 15 pending foreign patent applications. Our owned, issued patents expire at various dates beginning in 2020.

Among our co-owned patents and patent applications, as of January 31, 2013, four issued United States patents and 10 issued foreign patents were co-owned by us and Johns Hopkins, three issued United States patents, eight pending United States patent applications, three issued foreign patent and 15 pending foreign patent applications were co-owned by us and Boston Scientific, and one issued United States patent and one issued foreign patent were co-owned by us and other third parties.

We have licensing and cross-licensing arrangements in place with Boston Scientific with respect to the patent and patent applications we co-own with them. As a result of those arrangements, we have exclusive rights to all fields outside neuromodulation and implantable medical leads for cardiac applications, and we have licensed the fields of neuromodulation and implantable medical leads for cardiac applications to Boston Scientific.

Pursuant to our licensing and development arrangements with Boston Scientific, we may be required to assign Boston Scientific title to the patents and patent applications that we own and that we license to Boston Scientific. This includes patents and patent applications that we wholly own, as well as patents and patent applications that we co-own with Boston Scientific and others. As of January 31, 2013, our licensing arrangements with Boston Scientific included seven wholly owned issued United States patents, two wholly owned pending United States patent applications, nine wholly owned issued foreign patents, five wholly owned pending foreign patent applications, eight co-owned issued United States patents, seven co-owned pending United States patent applications, 14 co-owned issued foreign patents and 15 co-owned pending foreign patent applications. During 2009, Boston Scientific loaned us $3,500,000 pursuant to the terms of three convertible promissory notes. While those loans remain outstanding, we must meet certain net working capital targets, be current on our payroll obligations, and not suffer an event of default under any indebtedness for borrowed money. If we fail to meet those requirements, we will be required to assign the patents and patent applications 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.

Patents and Patent Applications Licensed from Third-Parties

As of January 31, 2013, we had licensed rights to 17 United States and 18 foreign third-party issued patents, and we had licensed rights to five United States and nine foreign third-party pending patent applications. Our licensed, issued patents expire at various dates beginning in 2015.

License Arrangements

License Arrangements with The Johns Hopkins University

Our principal licensing arrangement is with Johns Hopkins. Shortly following our formation in 1998, we entered into a license agreement with Johns Hopkins pursuant to which we obtained an exclusive, worldwide license to a number of technologies owned by Johns Hopkins relating to devices, systems and methods for performing MRI-guided interventions, such as MRI-guided cardiac ablation procedures. The field of use for this exclusive license covers diagnostic or therapeutic methods, processes or devices using an intravascular, intralumen or intratissue miniature magnetic resonance coil detection probe. We are obligated to pay Johns Hopkins an annual maintenance fee, and we are also obligated to pay a royalty to Johns Hopkins based on the sale of products or provision of services covered by a licensed patent. To the extent we sublicense any licensed intellectual property to a third-party, we agreed to pay Johns Hopkins a percentage of revenue we receive as a result of the sublicense. Under our license agreements with Boston Scientific, we sublicensed intellectual property that is licensed from Johns Hopkins. Therefore, we are obligated to pay Johns Hopkins a percentage of any revenue we receive from sales by Boston Scientific of products covered by a sublicensed patent. This license agreement with Johns Hopkins will terminate upon the expiration of the last to expire of the licensed patents.

In December 2006, we entered into a second license agreement with Johns Hopkins under which we obtained an exclusive, worldwide license to certain MRI-safety technologies owned by Johns Hopkins. Under the agreement, we are obligated to pay a royalty to Johns Hopkins based on the sale of products or provision of services covered by a licensed patent, subject to a minimum annual payment. Likewise, to the extent we sublicense any intellectual property to a third party, we agreed to pay Johns Hopkins a percentage of revenue we receive as a result of the sublicense. Under our license agreements with Boston Scientific, we sublicensed intellectual property that is licensed from Johns Hopkins. Therefore, we are obligated to pay Johns Hopkins a percentage of any revenue we receive from sales by Boston Scientific of products covered by a sublicensed patent. This license agreement with Johns Hopkins will terminate upon the expiration of the last to expire of the licensed patents.

We entered into three additional exclusive license agreements with Johns Hopkins in June 2008 as described below. Our development efforts with respect to the technologies we licensed under those agreements are at an early stage.

- Under the first agreement, we obtained an exclusive, worldwide license to certain catheter technology owned by Johns Hopkins. Under this agreement, we are obligated to pay a royalty to Johns Hopkins based on the sale of products or provision of services incorporating the licensed technology and a license fee. Likewise, to the extent we sublicense any licensed technology to a third party, we agreed to pay Johns Hopkins a percentage of revenue we receive as a result of a sublicense of the licensed technology. This license agreement with Johns Hopkins will terminate upon the expiration of the last licensed patent.

- Under the second agreement, we obtained an exclusive, worldwide license to certain technology owned by Johns Hopkins relating to catheter-based MRI probes. Under this agreement, we are obligated to pay a royalty to Johns Hopkins based on the sale of products or provision of services incorporating the licensed technology and a contingent license fee in the event a United States patent issues for the licensed technology. Likewise, to the extent we sublicense any licensed technology to a third party, we agreed to pay Johns Hopkins a percentage of revenue we receive as a result of a sublicense of the licensed technology. This license agreement with Johns Hopkins will terminate upon the expiration of the last licensed patent or, if no patent issues, on June 30, 2028.

- Under the third agreement, we obtained an exclusive, worldwide license to certain technology owned by Johns Hopkins to measure the amount of radio frequency absorption in the human body during an MRI scan. Under this agreement, we are obligated to pay a royalty to Johns Hopkins based on the sale of products or provision of services incorporating the licensed technology. Likewise, to the extent we

sublicense any licensed technology to a third party, we agreed to pay Johns Hopkins a percentage of revenue we receive as a result of a sublicense of the licensed technology. This license agreement with Johns Hopkins will terminate upon the expiration of the last licensed patent or, if no patent issues, on June 30, 2028.

License Arrangements with Merge

In July 2007, we entered into a master service and license agreement with Merge Healthcare Canada Corp. (formerly known as Cedara Software Corp.), or Merge, for Merge to develop on our behalf, based on our detailed specifications, a customized software solution for our ClearPoint system. Merge is 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 utilized certain of its own pre-existing software code. Under our agreement with Merge, we received a non-exclusive, worldwide license to that code as an integrated component of our ClearPoint system software. In return, we agreed to pay Merge a license fee for each copy of our ClearPoint system software that we distribute. Except for Merge's pre-existing software code, the work performed by Merge was a "work-made-for-hire" and we exclusively own our ClearPoint system software. Our agreement with Merge provides for annual minimum licensing fees, but, with a purchase of licenses we made from Merge in June 2012, we have purchased the minimum number of licenses required under our agreement. Our license from Merge continues through July 2015, absent a mutual extension of the license term. If necessary, we could replace the licensed Merge code.

License Arrangements with the National Institutes of Health

In April 2009, we entered into a non-exclusive patent license agreement with the National Institutes of Health, or NIH, for certain intellectual property relating to techniques for three dimensional renderings of a patient's anatomy from MRI data in real time. The techniques underlying this intellectual property may be used in the development of the ClearTrace system. Under the terms of this agreement, the licensed field of use is devices and systems for MRI-guided medical procedures. Our licensed territory includes Australia, Canada, China, Europe, Israel, Japan and the United States, although there is no patent or patent application pending for the licensed intellectual property outside the United States. Pursuant to this agreement, we are obligated to make royalty payments to NIH based on the sale of products and the practice of processes covered by the licensed intellectual property, whether by us or any sublicensee. In addition, NIH is entitled to receive a single milestone payment in the event we receive a regulatory clearance or approval of a product or process covered by the licensed intellectual property.

Competition

The medical device industry is highly competitive, subject to rapid technological change and significantly affected by new product introductions and market activities of other participants. Therefore, our currently marketed products are, and future products we commercialize will be, subject to competition.

ClearPoint System

Currently, we are not aware of any other company that offers a direct MRI-guided stereotactic system for neurological interventions, although two companies, Monteris Medical Inc. and Visualase, Inc., do offer devices for laser ablation under direct MRI guidance. However, companies such as Brainlab, Elekta AB, FHC Inc., Medtronic, Inc. and Neurologica Corporation offer devices and systems for use in conventional stereotactic neurological procedures, such as surgical navigation workstations, frame-based and frameless stereotactic systems and portable computer tomography scanners, and these devices and systems are competitive with our ClearPoint system. Additionally, we could also face competition from other medical device and pharmaceutical companies that have the technology, experience and capital resources to develop alternative therapy methods, including MRI-guided technologies. Many of our competitors have substantially greater financial, manufacturing, marketing and technical resources than we have.

ClearTrace System

While we are not aware of any company that currently offers a direct MRI-guided cardiac ablation system, companies such as Imricor Medical Systems, Inc. and Philips Healthcare are in the process of developing such a system. We are not aware of any potential competitive advantages or disadvantages relative to any such system under development; however, if any such company develops, obtains regulatory clearance or approval and achieves

commercial success for a direct MRI-guided cardiac ablation system, the ClearTrace system could be rendered non-competitive or obsolete.

We also will face competition from companies who are engaged in the development and marketing of conventional catheter-based cardiac ablation systems and devices. These products include mapping systems using contact mapping, single-point spatial mapping and non-contact, multi-site electrical mapping technologies and ablation systems using radio frequency, ultrasound, laser and cryoablation technologies. These products evolve rapidly, and their manufacturers are constantly attempting to make them easier to use or more efficacious in performing procedures. Today, the vast majority of minimally invasive catheter-based cardiac ablation procedures are performed with these products. Because these products are currently in use while the ClearTrace system remains under development, physician preferences will have to shift for the ClearTrace system to gain market acceptance. We believe that the primary factors which will drive physician preference will be the relative success rates and ease of the procedure for physicians with respect to the ClearTrace system compared to the alternative technologies available.

We are aware of two companies, Hansen Medical, Inc. and Stereotaxis, Inc., which market systems to remotely control catheters during interventional cardiac ablation and other procedures using either robotic or magnetic steering. The nature of these systems potentially could provide better control over the catheter compared to manual manipulation by the physician; however, these systems do not provide the physician with detailed intra-procedural visualization of the cardiac tissue. Also, other manufacturers are attempting to market devices that access the exterior of the heart wall through an endoscopic surgical technique called thoracoscopy to treat atrial fibrillation. Because this procedure was developed recently, the clinical advantages and disadvantages of this approach compared to a catheter-based approach inside the heart have not been established. Therefore, we are not aware of any competitive advantages or disadvantages of this procedure relative to the anticipated ClearTrace system procedure.

Additionally, we will face competition from large companies who are engaged in the development and marketing of products for other treatments of cardiac arrhythmias, such as atrial fibrillation. Their products include drugs, implantable devices, such as implantable defibrillators and pacemakers, and the devices used in open-heart surgery. While both current drug therapy and implantable cardiac devices can be effective in treating the symptoms of atrial fibrillation, they do not provide a cure for the underlying disease. Open-heart surgery, such as the Cox-Maze procedure, can provide a cure for atrial fibrillation and reported success rates have been very high; however, it is an invasive surgical procedure that is traumatic to the patient, very expensive and typically associated with long hospital stays and recovery times.

Many of our potential competitors have an established presence in the field of cardiac electrophysiology, including cardiac ablation, such as Biosense Webster Inc., a division of Johnson & Johnson, Boston Scientific, Medtronic, Inc. and St. Jude Medical, Inc. These potential competitors have substantially greater financial and other resources than we do, including larger research and development staffs and more experience and greater capabilities in conducting research and development activities, testing products in clinical trials, obtaining regulatory clearances or approvals, and manufacturing, marketing and distributing products.

Regulatory Requirements of the United States Food and Drug Administration

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products sold in the United States are subject to regulation as medical devices under the federal Food Drug and Cosmetic Act, or FDCA, as implemented and enforced by the FDA. The FDA governs the following activities that we perform or that are performed on our behalf, to ensure that the medical products we manufacture, promote and distribute domestically or exported internationally are safe and effective for their intended uses:

- product design, preclinical and clinical development and manufacture;
- product premarket clearance and approval;
- product safety, testing, labeling and storage;
- record keeping procedures;
- product marketing, sales and distribution; and

- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions and repair or recall of products.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either premarket notification, or 510(k) clearance, or approval of a PMA from the FDA. The FDA classifies medical devices into one of three classes. Class I devices, considered to have the lowest risk, are those for which safety and effectiveness can be assured by adherence to the FDA's general regulatory controls for medical devices, which include compliance with the applicable portions of the FDA's QSR, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials (General Controls). Class II devices are subject to the FDA's General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device (Special Controls). Manufacturers of most Class II and some Class I devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA.

510(k) Clearance Pathway

When a 510(k) clearance is required, we will be required to submit a 510(k) application demonstrating that our proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMAs. By regulation, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance may take longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence.

Once filed, the FDA has 90 days in which to review the 510(k) application and respond. Typically, the FDA's response after reviewing a 510(k) application is a request for additional data or clarification. Depending on the complexity of the application and the amount of data required, the process may be lengthened by several months or more. If additional data, including clinical data, are needed to support our claims, the 510(k) application process may be significantly lengthened.

If the FDA issues an order declaring the device to be Not Substantially Equivalent, or NSE, the device is placed into a Class III or PMA category. At that time, a company can request a de novo classification of the product. De novo generally applies where there is no predicate device and the FDA believes the device is sufficiently safe so that no PMA should be required. The request must be in writing and sent within 30 days from the receipt of the NSE determination. The request should include a description of the device, labeling for the device, reasons for the recommended classification and information to support the recommendation. The de novo process has a 60-day review period. If the FDA classifies the device into Class II, a company will then receive an approval order to market the device. This device type can then be used as a predicate device for future 510(k) submissions. However, if the FDA subsequently determines that the device will remain in the Class III category, the device cannot be marketed until the company has obtained an approved PMA.

Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of the device, requires a new 510(k) clearance and may even, in some circumstances, require a PMA, if the change raises complex or novel scientific issues or the product has a new intended use. The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. If the FDA were to disagree with any of our determinations that changes did not require a new 510(k) submission, it could require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or PMA approval is obtained. If the FDA requires us to seek 510(k) clearance or PMA approval for any modifications, we may be required to cease marketing and/or recall the modified device, if already in distribution, until 510(k) clearance or PMA approval is obtained and we could be subject to significant regulatory fines or penalties.

The FDA continues its efforts to modernize its 510(k) process. In January 2011, the FDA announced an action plan that included 25 specific actions to improve the predictability, consistency and transparency of the 510(k) process. Although some of these specific actions have already been undertaken, the FDA continues to move forward on its action plan. As part of its efforts, in 2009, the FDA commissioned the Institute of Medicine to report on the 510(k) approval process. In July 2011, the Institute of Medicine released its report, in which it recommended, among other things, that the FDA forgo modifying the 510(k) process and, instead, eliminate the 510(k) process in favor of a new regulatory review framework. Although the FDA has indicated that the 510(k) process should not be eliminated, the FDA's continued modification of the 510(k) process, together with the Institute of Medicine's report, has created some regulatory uncertainty for the medical device industry, particularly as it relates to the time within which the FDA will conduct and complete its review of new applications.

PMA Approval Pathway

A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process, or is not otherwise exempt from the FDA's premarket clearance and approval requirements. A PMA must generally be supported by extensive data, including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. During the review period, the FDA will typically request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of our or our third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR. Once a PMA is approved, the FDA may require that certain conditions of approval, such as conducting a post market clinical trial, be met.

New PMAs or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. We have not submitted any of our product candidates for a PMA approval. However, we may in the future develop devices that will require the approval of a PMA, or seek to add new indications for use of existing products that require the approval of a PMA. There is no guarantee that the FDA will grant PMA approval of these specific indications for use or for our future products and failure to obtain necessary approvals for our future products would adversely affect our ability to grow our business.

Clinical Trials

Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) clearance. Such trials generally require an application for an investigational device exemption, or IDE, which is approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. A significant risk device is one that presents a potential for serious risk to the health, safety, or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board, or IRB, for the relevant clinical trial sites and must comply with FDA regulations, including, but not limited to, those relating to good clinical practices. To conduct a clinical trial, we also are required to obtain the patient's informed consent in a form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the United States. Similarly, in Europe, the clinical study must be approved by a local ethics committee and in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

Pervasive and Continuing Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. In addition to the requirements below, the Medical Device Reporting (MDR) regulations require that we 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 product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Additional regulatory requirements include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our approved devices;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply, when necessary, to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

As a manufacturer, we are subject to announced and unannounced inspections by the FDA to determine our compliance with FDA's QSR and other regulations. We have not yet been inspected by the FDA. We believe that we are in compliance with QSR and other regulations.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the United States Federal Trade Commission, or FTC, and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved or uncleared 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, a warning letter, injunction, seizure, civil fine or criminal penalty. 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 adoption of the products would be impaired.

Failure by us or by our third-party manufacturers and suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions including, but not limited to:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our marketed products;
- operating restrictions or partial suspension or total shutdown of production;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our marketed products;
- refusing or delaying requests for 510(k) clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our marketed products; or
- criminal prosecution.

International Marketing Approvals

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ.

The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Each European Union member state has implemented legislation applying these directives and standards at a national level. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. Devices that comply with the requirements of the laws of the relevant member state applying the applicable European Union directive are entitled to bear a CE mark and, accordingly, can be distributed throughout the member states of the European Union as well as in other countries, such as Switzerland and Israel, that have mutual recognition agreements with the European Union or have adopted the European Union's regulatory standards.

The method of assessing conformity with applicable regulatory requirements varies depending on the classification of the medical device, which may be Class I, Class IIa, Class IIb or Class III. Normally, the method involves a combination of self-assessment by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body, usually of the design of the device and of the manufacturer's quality system. A Notified Body is a private commercial entity that is designated by the national government of a member state as being competent to make independent judgments about whether a device complies with applicable regulatory requirements. An assessment by a Notified Body in one country with the European Union is required in order for a manufacturer to commercially distribute the device throughout the European Union. In addition, compliance with ISO 13485 issued by the International Organization for Standardization, among other standards, establishes the presumption of conformity with the essential requirements for CE marking. Certification to the ISO 13485 standard demonstrates the presence of a quality management system that can be used by a manufacturer for design and development, production, installation and servicing of medical devices and the design, development and provision of related services.

Healthcare Laws and Regulations

Third-Party Reimbursement

In the United States and elsewhere, healthcare providers that perform surgical procedures using medical devices such as ours generally rely on third-party payors, including governmental payors such as Medicare and Medicaid and private payors, to cover and reimburse all or part of the cost of the products. Consequently, sales of medical devices are dependent in part on the availability of reimbursement to the customer from third-party payors. The manner in which reimbursement is sought and obtained varies based upon the type of payor involved and the setting in which the product is furnished and utilized. In general, third-party payors will provide coverage and reimbursement for medically reasonable and necessary procedures and tests that utilize medical devices and may provide separate payments for the implanted or disposable devices themselves. Most payors, however, will not pay separately for capital equipment, such as our ClearPoint system. Instead, payment for the cost of using the capital equipment is considered to be covered as part of payments received for performing the procedure. In determining payment rates, third-party payors are increasingly scrutinizing the prices charged for medical products and services in comparison to other therapies. Our marketed products, and the procedures in which our marketed products will be used, may not be reimbursed by these third-party payors at rates sufficient to allow us to sell our marketed products on a competitive and profitable basis.

In addition, in many foreign markets, including the countries in the European Union, pricing of medical devices is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to limit payments by governmental payors for medical devices, and the procedures in which medical devices are used. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

Medicare and Medicaid

The Medicare program is a federal health benefit program administered by the Centers for Medicare and Medicaid Services, or CMS, that covers and pays for certain medical care items and services for eligible elderly and certain disabled individuals, and individuals with end stage renal disease. The Medicaid program is a federal-state partnership under which states receive matching federal payments to fund healthcare services for the poor. Because some private commercial health insurers and some state Medicaid programs may follow the coverage and payment policies for Medicare, Medicare's coverage and payment policies are significant to our business.

Medicare coverage for procedures in which our ClearPoint products are used currently exists in the hospital inpatient setting, which falls under Part A of the Medicare program. Under Medicare Part A, Medicare reimburses acute care hospitals a prospectively determined payment amount for beneficiaries receiving covered inpatient services in an acute care hospital. This method of payment is known as the prospective payment system, or PPS. Under PPS, the prospective payment for a patient's stay in an acute care hospital 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. Payments also are adjusted to reflect other factors, such as regional variations in labor costs and indirect medical education expenses. Medicare pays a fixed amount to the hospital based on the MS-DRG into which the patient's stay is classified, regardless of the actual cost to the hospital of furnishing the procedures, items and services that the patient's condition requires. Accordingly, acute care hospitals generally do not receive direct Medicare reimbursement under PPS for the specific costs incurred in purchasing medical devices. Rather, reimbursement for these costs is deemed to be included within the MS-DRG-based payments made to hospitals for the services furnished to Medicare-eligible inpatients in which the devices are utilized. For cases involving unusually high costs, a hospital may receive additional "outlier" payments above the pre-determined amount. In addition, there is a mechanism by which new technology services can apply to Medicare for additional payments above the pre-determined amount, although such requests have not been granted frequently.

Because PPS payments are based on predetermined rates and may be less than a hospital's actual costs in furnishing care, and due to recently enacted payment reforms, acute care hospitals have incentives to lower their inpatient operating costs by utilizing products, devices and supplies that will reduce the length of inpatient stays, decrease labor or otherwise lower their costs. For each MS-DRG, a relative weight is calculated representing the average resources required to care for cases grouped in that particular MS-DRG relative to the average resources used to treat cases in all MS-DRGs. MS-DRG relative weights are recalculated every year to reflect changes in technology and medical practice in a budget neutral manner. Under the MS-DRG payment system, there can be significant delays in

obtaining adequate reimbursement amounts for hospitals for new technologies such that reimbursement may be insufficient to permit broad acceptance by hospitals.

In addition to payments to hospitals for procedures using our technology, Medicare makes separate payments to physicians for their professional services. The American Medical Association, or AMA, has developed a coding system known as the Current Procedural Terminology, or CPT, codes, which have been adopted by the Medicare program to describe and develop payment amounts for certain physician services.

The Medicare physician fee schedule uses CPT codes (and other codes) as part of the determination of allowable payment amounts to physicians. In determining appropriate payment amounts for surgeons, CMS receives guidance from the AMA regarding the relative technical skill level, level of resources used, and complexity of a new surgical procedure. Generally, the designation of a new procedure code for a new procedure using a new product does not occur until after FDA clearance or approval of the product used in the procedure. Codes are assigned by either the AMA (for CPT codes) or CMS (for Medicare-specific codes), and new codes usually become effective on January 1st of each year.

One result of the current Medicare payment system, which is also utilized by most non-governmental third-party payors, is that a patient's treating physician orders a particular service and the hospital (or other facility in which the procedure is performed) bears the cost of delivery of the service. Hospitals have limited ability to align their financial interests with that 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 initiatives and 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 their overall number of vendors from which they purchase supplies, equipment and products. The Affordable Care Act could substantially change how health care is developed and delivered in the United States and may materially impact many aspects of our business and operations, including limiting the acceptance and availability of our products.

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. Such 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 yet to address 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 of physicians willing to participate in Medicare.

Commercial Insurers

In addition to the Medicare program, many private payors look to CMS policies as a guideline in setting their coverage policies and payment amounts. The current coverage policies of these private payors may differ from the Medicare program, and the payment rates they make may be higher, lower, or the same as the Medicare program. If CMS or other agencies decrease or limit reimbursement payments for doctors and hospitals, this may affect coverage and reimbursement determinations by many private payors. Additionally, some private payors do not follow the

Medicare guidelines, and those payors may reimburse only a portion of the costs associated with the use of our products, or none at all.

Fraud and Abuse Laws

Because of the significant federal funding involved in Medicare and Medicaid, Congress and the states have enacted, and actively enforce, a number of laws whose purpose is to eliminate fraud and abuse in federal healthcare programs. Our business is subject to compliance with these laws.

Anti-Kickback Laws

In the United States, there are federal and state anti-kickback laws that generally prohibit the payment or receipt of kickbacks, bribes or other remuneration in exchange for the referral of patients or other health-related business. The United States federal healthcare programs' Anti-Kickback Statute makes it unlawful for individuals or entities knowingly and willfully to solicit, offer, receive or pay 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 purchasing, leasing, or ordering, any good, facility, service, or item for which payment may be made in whole or in part under a federal healthcare program such as Medicare or Medicaid. The Anti-Kickback Statute covers "any remuneration," which has been broadly interpreted to include anything of value, including for example gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payments of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the arrangement can be found to violate the statute. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. In addition, several courts have permitted kickback cases brought under the federal False Claims Act to proceed, as discussed in more detail below.

Because the Anti-Kickback Statute is broadly written and encompasses many harmless or efficient arrangements, Congress authorized the Office of Inspector General of the United States Department of Health and Human Services, or OIG, to issue a series of regulations, known as "safe harbors." For example, there are regulatory safe harbors for payments to bona fide employees, properly reported discounts, and payments for certain investment interests. Although an arrangement that fits into one or more of these exceptions or safe harbors is immune from prosecution, arrangements that do not fit squarely within an exception or safe harbor do not necessarily violate the statute. The failure of a transaction or arrangement to fit precisely within one or more of the exceptions or safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that arguably implicate the Anti-Kickback Statute but do not fully satisfy all the elements of an exception or safe harbor may be subject to increased scrutiny by government enforcement authorities such as the OIG. The Affordable Care Act increases the investigatory authority of the OIG, clarifies that Anti-Kickback Statute claims can be brought under the federal civil False Claims Act, and provides for enhanced civil monetary penalties and expanded permissible exclusion authority.

Many states have laws that implicate anti-kickback restrictions similar to the Anti-Kickback Statute. Some of these state prohibitions apply regardless of whether federal healthcare program business is involved such as for self-pay or private pay patients.

Government officials have focused their enforcement efforts on marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and certain sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Federal Civil False Claims Act and State False Claims Laws

The federal civil False Claims Act imposes liability on any person or entity who, among other things, knowingly and willfully presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program, including Medicare and Medicaid. The "qui tam," or "whistleblower," provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government and to share in any monetary recovery. In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. Medical device companies, like us, can be held liable under false claims laws, even if they do not submit claims to the government where they are deemed to have caused submission of false claims by, among other things, providing incorrect coding or

billing advice about their products to customers that file claims, or by engaging in kickback arrangements with customers that file claims.

The False Claims Act also has been used to assert liability on the basis of misrepresentations with respect to the services rendered and in connection with alleged off-label promotion of products. Our future activities relating to the manner in which we sell our products and document our prices such as the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products, and the sale and marketing of our products, may be subject to scrutiny under these laws.

The Affordable Care Act is likely to increase the number of cases asserting civil False Claims Act violations since it removes a significant defense to such claims and clarifies that a violation of the Anti-Kickback Statute and the retention of a federal healthcare program overpayment are both actionable under the civil False Claims Act.

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between $5,500 to $11,000 for each separate false claim. There are many potential bases for liability under the False Claims Act. A number of states have enacted false claim laws analogous to the federal civil False Claims Act and many of these state laws apply where a claim is submitted to any state or private third-party payor. In this environment, our engagement of physician consultants in product development and product training and education could subject us to similar scrutiny. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

HIPAA Fraud and Other Regulations

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created a class of federal crimes known as the "federal health care offenses," including healthcare fraud and false statements relating to healthcare matters. The HIPAA healthcare fraud statute prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program, or to obtain by means of false of fraudulent pretenses, any money under the control of any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment and/or exclusion from government-sponsored programs. The Affordable Care Act also provides for civil monetary penalties for knowingly participating in certain federal healthcare offenses and enhances sentences under the Federal Sentencing Guidelines for such offenses. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment. Entities that are found to have aided or abetted in a violation of the HIPAA federal health care offenses are deemed by statute to have committed the offense and are punishable as a principal.

We are also subject to the United States Foreign Corrupt Practices Act and similar anti-bribery laws applicable in non-United States jurisdictions that generally prohibit companies and their intermediaries from making improper payments to non-United States government officials for the purpose of obtaining or retaining business. Because of the predominance of government sponsored healthcare systems around the world, most of our customer relationships outside of the United States will be with governmental entities and therefore subject to such anti-bribery laws.

HIPAA and Other Privacy & Security Laws

As a part of HIPAA, Congress enacted the Administrative Simplification provisions, which are designed to require the establishment of uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses, which are referred to as "covered entities." Several regulations have been promulgated under HIPAA's regulations including: the Standards for Privacy of Individually Identifiable Health Information, or the Privacy Rule, which restricts the use and disclosure of certain individually identifiable health information, the Standards for Electronic Transactions, which establishes standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures, and the Security Standards for the Protection of Electronic Protected Health Information, or the Security Rule, which requires covered entities to implement and maintain certain security measures to safeguard certain electronic health information. Although we do not believe we are a covered entity and therefore are not currently directly

subject to these standards, we expect that our customers generally will be covered entities and may ask us to contractually comply with certain aspects of these standards by entering into business associate agreements, when appropriate. While the government intended this legislation to reduce administrative expenses and burdens for the healthcare industry, our compliance with certain provisions of these standards entails significant costs for us.

The Health Information Technology for Economic and Clinical Health Act, or HITECH, which was enacted in February 2009, strengthens and expands the HIPAA Privacy and Security Rules and the restrictions on use and disclosure of patient identifiable health information. HITECH also fundamentally changed a business associate's obligations by imposing a number of Privacy Rule requirements and a majority of Security Rule provisions directly on business associates that were previously only directly applicable to covered entities. HITECH includes, but is not limited to, prohibitions on exchanging patient identifiable health information for remuneration (directly or indirectly), restrictions on marketing to individuals and obligations to agree to provide individuals an accounting of virtually all disclosures of their health information. Moreover, HITECH requires covered entities to report any unauthorized use or disclosure of patient identifiable health information that compromises the security or privacy of the information, known as a breach, to the affected individuals, the United States Department of Health and Human Services, or HHS, and depending on the size of any such breach, the media for the affected market. Business associates are similarly required to notify covered entities of a breach.

HITECH has increased civil penalty amounts for violations of HIPAA by either covered entities or business associates up to an annual maximum of $1.5 million for each uncorrected violation based on willful neglect. Imposition of these penalties is more likely now because HITECH significantly strengthens enforcement. It requires HHS to conduct periodic audits to confirm compliance and to investigate any violation that involves willful neglect. Additionally, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations of HIPAA Privacy and Security Rules that threaten the privacy of state residents.

In addition to federal regulations issued under HIPAA, some states have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. In those cases, it may be necessary to modify our planned operations and procedures to comply with the more stringent state laws. If we fail to comply with applicable state laws and regulations, we could be subject to additional sanctions. Further, the majority of states have enacted state data breach laws, which also require notification of certain alleged breaches of the privacy or security of personal information.

Federal and state consumer protection laws are being applied increasingly by the FTC and state attorneys general to regulate the collection, use, storage and disclosure of personal or patient information, through websites or otherwise, and to regulate the presentation of web site content. Courts may also adopt the standards for fair information practices promulgated by the FTC, which concern consumer notice, choice, security and access. Numerous other countries have or are developing laws governing the collection, use, disclosure and transmission of personal or patient information.

HIPAA as well as other federal and state laws apply to our receipt of patient identifiable health information in connection with research and clinical trials. We collaborate with other individuals and entities in conducting research and all involved parties must comply with applicable laws. Therefore, the compliance of the physicians, hospitals or other providers or entities with which we collaborate also impacts our business.

Employees

As of January 31, 2013, we had 25 full-time employees, of whom five were engaged in research and development, eight in manufacturing, seven in sales and marketing and five in general administrative and finance functions. None of our employees is covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

ITEM 1A. RISK FACTORS

Any investment in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below and all information contained in this Annual Report, before you decide whether to purchase our common stock. If any of the following risks or uncertainties actually occurs, our business, financial condition, results of operations and prospects would likely suffer, possibly materially. In addition, the trading price of our common stock could decline due to any of these risks or uncertainties, and you may lose part or all of your investment.

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 December 31, 2012, we had an accumulated deficit of approximately $65.5 million. The accumulated deficit has resulted principally from costs incurred in our research and development efforts and general operating expenses. We have incurred significant losses in each year since our inception in 1998. Net losses were approximately $5.7 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 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 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. 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 the MS-DRG classification system. 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 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, 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, have been, and may continue to be, negatively impacted by our focus on the commercialization of our ClearPoint system.

Under our co-development agreement, through December 31, 2012 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 FDCA or approval of a 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 will be required to pursue the PMA process in order to specifically indicate our ablation catheter for the treatment of atrial fibrillation.

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

We received 510(k) clearance to market our ClearPoint system for use in general neurological interventional procedures. In the future, we 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, 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 by issuing securities or through collaborative or licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

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

Risks Related to our Intellectual Property

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

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

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 received a non-exclusive, worldwide license from a third party to certain software code that is integrated into the software component of our ClearPoint system. In return, we agreed to pay the third party a license fee for each copy of the ClearPoint system software that we distribute, subject to certain minimum license purchase commitments which we have satisfied. Our agreement with the third party continues through July 2015. If we do not extend the agreement, we will not be able to purchase additional licenses after July 2015, which could impede our ability to commercialize our ClearPoint system until equivalent software could be identified, licensed or developed, and integrated into the software component of our ClearPoint system. These delays, if they occur, could harm our business, operating results and financial condition.

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

During 2009, Boston Scientific loaned us $3.5 million pursuant to the terms of three convertible promissory notes. Those loans mature in October, November and December 2014, respectively. While those loans remain outstanding, we must comply with the following requirements: (1) we must pay when due all of our payroll obligations; (2) we must not suffer an event of default under any indebtedness for borrowed money; (3) we must not have a net working capital deficiency of more than $(2.0) million as of the end of each month from January 2013 through March 2013; and (4) we must have a net working capital ratio, which is defined as our current assets divided by our current liabilities other than deferred revenue, of at least 0.80 as of the end of April 2013 and as of the end of each month thereafter.

If we fail to meet any of those requirements while our loans from Boston Scientific are outstanding, we will be required to assign Boston Scientific title to the patents and patent applications that we own and that we license to Boston Scientific. However, upon any such assignment to Boston Scientific, Boston Scientific will grant us an exclusive, royalty-free, perpetual worldwide license to the same patents and patent applications in all fields of use outside neuromodulation and implantable medical leads for cardiac applications. As of January 31, 2013, our licensing arrangements with Boston Scientific included seven wholly-owned issued United States patents, two wholly-owned pending United States patent applications, nine wholly-owned issued foreign patents, five wholly-owned pending foreign patent applications, eight co-owned issued United States patents, seven co-owned pending United States patent applications, 14 co-owned issued foreign patents and 15 co-owned pending foreign patent applications.

We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets or other proprietary information of their former employers.

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

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

Our success and ability to compete is dependent, in part, upon our ability to maintain the proprietary nature of our technologies. We rely on a combination of patent, copyright, trademark and trade secret law and nondisclosure agreements to protect our intellectual property. However, such methods may not be adequate to protect us or permit us to

gain or maintain a competitive advantage. Our patent applications may not issue as patents in a form that will be advantageous to us, or at all. Our issued patents, and those that may issue in the future, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing-related products.

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

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

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

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

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

We have entered into exclusive license agreements with 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 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 operations and financial results.

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

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

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

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

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

Under the FDCA 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.

- 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 will be subject to the data collecting, reporting and public disclosure obligation. Data collecting obligations must begin by August 1, 2013, with reporting obligations beginning on 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:

- keeping us informed of new developments in their respective fields of practice;

- advising us on our research and development projects related to their respective fields;

- advising us on improvements to methods, processes and devices related to their respective fields (such as advice on the development of prototype devices);

- assisting us with the technical evaluation of our methods, processes and devices related to their respective fields;

- advising us with respect to the commercialization of products in their respective fields; and

- providing training and other similar services on the proper use of our products.

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

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

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

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

- HIPAA and its implementing regulations, 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.

- 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, or FTC, and state attorneys general to regulate the collection, use, storage and disclosure of personal or patient information, through websites or otherwise, and to regulate the presentation of website content.

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

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

We are required to comply with federal and state laws governing the transmission, security and privacy of patient identifiable health information that we may obtain or have access to in connection with manufacture and sale of our products. We do not believe that we are a HIPAA covered entity because we do not submit electronic claims to third-party payors, but there may be limited circumstances in which we may operate as a business associate to covered entities if we receive patient identifiable data through activities on behalf of a healthcare provider. We may be required to make costly system modifications to comply with the HIPAA privacy and security requirements that will be imposed on us contractually through business associate agreements by covered entities and directly under HITECH 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, and Peter G. Piferi, our Chief Operating Officer. 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 and Mr. Piferi. Although we have obtained key employee insurance covering Mr. Jenkins and Mr. Piferi in the amount of $2,000,000, this would not fully compensate us for the loss of Mr. Jenkins' or Mr. Piferi's services.

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

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

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

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

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

- hiring, training, managing and supervising our personnel.

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

Risks Related to Our Shares of Common Stock

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

The shares of our common stock may trade infrequently and in low volumes 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, or the Exchange Act, and its rules. The Securities and Exchange Commission, or SEC, has adopted regulations that define "penny stock" to include common stock that has a market price of less than $5.00 per share, subject to certain exceptions. These rules include the following requirements:

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

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

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

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

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

In August 2012, we filed a registration statement with the SEC covering certain outstanding shares of our common stock and shares of our common stock underlying certain warrants held by some of our existing securityholders. That registration statement became effective in September 2012, and as such all of the shares of our common stock covered by the registration statement are now freely transferable, unless held by an affiliate of ours. Likewise, we filed a registration statement with the SEC in February 2012 to register approximately 9.0 million shares of our common stock and approximately 4.5 million shares of common stock issuable upon the exercise of warrants. Upon effectiveness of that registration statement, all of the shares of our common stock covered by the registration statement will be freely transferable, unless held by an affiliate of ours.

In addition to the shares of our common stock covered by those registration statements, as of January 31, 2013, approximately 34.3 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 10.3 million shares were held by our affiliates and approximately 24.0 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.

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

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

As of January 31, 2013, our directors and executive officers, together with their affiliates, beneficially owned, in the aggregate, 24.1% of our common stock. As a result, these stockholders, acting together, have substantial control over the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, have significant influence over the management and affairs of our company. Accordingly, this concentration of ownership may have the effect of:

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

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

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

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

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

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

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

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

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

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

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

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We are working with our independent legal and accounting advisors to identify those areas in which changes should be made to our financial and management control systems to manage our growth and our obligations as a public company. These areas include corporate controls and financial reporting and accounting systems, including requirements under the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act. Despite recent reforms as a result of the enactment of the JOBS Act, we will incur costs associated with our public company reporting requirements and corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and any securities exchange on which our stock trades, particularly after we are no longer an emerging growth company. We may need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees or as executive officers.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 2. PROPERTIES.

We lease approximately 7,400 square feet of space in Irvine, California under a lease that expires in September 2015, which we use as our principal research and development facility and for the assembly of certain of our products. We lease approximately 3,300 square feet of office space in Memphis, Tennessee, which we use as our executive offices. Our Memphis lease expires in November 2014. We believe that our Irvine, California and Memphis, Tennessee facilities are sufficient to meet our needs for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS.

In the ordinary course of our business, we may be subject to various claims, pending and potential legal actions for damages, investigations relating to governmental laws and regulations and other matters arising out of the normal conduct of our business. We are not aware of any material pending legal proceedings to which we are a party or of which any of our properties is the subject.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock has been traded on the over-the-counter market since May 21, 2012, under the symbol "MRIC." The following table provides the high and low bid information for our common stock during the periods indicated. This bid information reflects inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions. Prior to May 21, 2012, there was no established public trading market for our common stock.

Quarter Ended	High Bid	Low Bid
Fiscal 2013		
First Quarter 2013 (through March 1, 2013)	$ 1.95	$ 1.41
Fiscal 2012		
Fourth Quarter 2012 (through December 31, 2012)	$ 2.76	$ 1.52
Third Quarter 2012 (through September 30, 2012)	$ 4.05	$ 1.85
Second Quarter 2012 (beginning May 21, 2012 through June 30, 2012)	$ 2.20	$ 0.50

Holders

As of March 1, 2013, we had 57,320,447 shares of common stock outstanding and no shares of preferred stock outstanding. As of March 1, 2013, we had 661 stockholders of record. In addition, as of March 1, 2013, options and warrants to purchase 19,755,805 shares of common stock were outstanding.

Dividend Policy

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.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by stockholders (1)	3,854,475	$ 1.29	52,600
Equity compensation plans not approved by stockholders (1)(2)(3)	2,521,000	$ 1.79	--
Total	6,375,475	$ 1.49	52,600

(1) The information presented in this table is as of December 31, 2012.

(2) We adopted our 2010 Non-Qualified Stock Option Plan in December 2010. The plan provided for the issuance of non-qualified stock options to purchase up to 2,565,675 shares of our common stock. We awarded options to purchase 2,371,000 shares of our common stock under the plan, and we ceased making awards under the plan upon the adoption of our 2012 Incentive Compensation Plan.

(3) In November 2012, we entered into a written compensatory contract with Robert C. Korn, our Vice President, Global Sales & Marketing, pursuant to which we awarded Mr. Korn non-qualified stock options to purchase 150,000 shares of our common stock.

Certain Sales of Unregistered Securities

From October 2012 through December 2012, holders of warrants to purchase an aggregate of 226,411 shares of our common stock exercised their warrants. Of that aggregate number, warrants to purchase 125,000 shares of our common stock were exercised for cash, generating proceeds of $93,750. The remaining warrants were exercised on a cashless basis, which resulted in the net issuance of 73,142 shares of our common stock. Therefore, we issued a total of 198,142 shares of our common stock upon exercise of warrants.

In October 2012, we issued an aggregate of 51,928 shares of common stock to seven non-employee directors. These shares were issued in payment of compensation owed to the non-employee directors under our director compensation plan. The shares were issued at a price equal to the volume-weighted average price of our common stock for the 30-trading day period ending October 11, 2012.

ITEM 6. SELECTED FINANCIAL DATA.

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. This discussion and analysis contains forward-looking statements that are based upon current expectations and involve risks, assumptions and uncertainties. You should review the "Risk Factors" section of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements described in the following discussion and analysis.

Overview

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

In 2010, we received regulatory clearance from the FDA to market our ClearPoint system in the United States for general neurological procedures. In 2011, we also obtained CE marking approval for the ClearPoint system, which enables us to sell the ClearPoint system in the European Union. Substantially all of our product revenues for 2012 and 2011 relate to sales of our ClearPoint system products. We do not have regulatory clearance or approval to sell our ClearTrace system, and, therefore, we have not generated revenues from sales of that product candidate. In 2008, we received licensing fees totaling $13.0 million from Boston Scientific for our MRI-safety technologies, which we used to finance our operations and internal growth. We have also financed our operations and internal growth through private placements of securities, borrowings and interest earned on the net proceeds from our private placements and the Boston Scientific licensing fees. Prior to 2008, we were a development stage enterprise. We have incurred significant losses since our inception in 1998 as we devoted substantial efforts to research and development. As of December 31, 2012, we had an accumulated deficit of $65.5 million. We may continue to incur operating losses as we commercialize our ClearPoint system products, continue to develop our product candidates and to expand our business generally.

Factors Which May Influence Future Results of Operations

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

Revenues

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

The generation of recurring revenues through sales of our disposable components is an important part of our business model for our ClearPoint system. We first generated revenues through the sale of ClearPoint system disposable components in the third quarter of 2010. We anticipate that recurring revenues will constitute an increasing percentage of our total revenues as we leverage each new installation of our ClearPoint system to generate recurring sales of these disposable components.

Since inception, the most significant source of our revenues has been related to our collaborative agreements with Boston Scientific, principally from recognition of portions of the $13.0 million of licensing fees, which we received in 2008. Revenues associated with these licensing fees are recognized on a straight-line basis over a five year period, representing our estimated period of continuing involvement in the development activities, which period we estimate will end in the first quarter of 2013. Any additional payments related to substantive, performance-based milestones that

may be received under the agreement regarding implantable cardiac leads will be recognized upon receipt. These revenue recognition policies are more fully described in the "Critical Accounting Policies and Significant Judgments and Estimates" section below.

Cost of Product Revenues

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

Research and Development Costs

Our research and development costs consist primarily of costs associated with the conceptualization, design, testing and prototyping of our ClearPoint system products and our product candidates. This includes: the salaries, travel and benefits of research and development personnel; materials and laboratory supplies used by our research personnel; consultant costs; sponsored contract research and product development with third parties; and licensing costs. We anticipate that, over time, our research and development expenses may increase as we: (1) continue our product development efforts for the ClearTrace system; (2) continue to develop enhancements to our ClearPoint system; and (3) expand our research to apply our technologies to additional product applications. From our inception through December 31, 2012, we have incurred approximately $37 million in research and development expenses.

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

Selling, General and Administrative Expenses

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

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the financial statements as well as the reported expenses during the reporting periods. The accounting estimates that require our most significant, difficult and subjective judgments include revenue recognition, impairment of long-lived assets, computing the fair value of our derivative liability and the determination of share-based compensation and financial instruments. We evaluate our estimates and judgments on an ongoing basis. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

Revenue Recognition. Our revenues arise from: (1) the sale of ClearPoint system reusable components, including associated installation services; (2) the sale of ClearPoint disposable products; and (3) license and development arrangements. We evaluate the various elements of our arrangements based upon GAAP for multiple element arrangements to determine whether the various elements represent separate units of accounting. This evaluation requires subjective determinations about the fair value or estimated selling price of each element and whether delivered elements have stand-alone value and, therefore, are separable from the undelivered contract elements for revenue recognition purposes. We recognize revenue, in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 605-10-S99, "Revenue Recognition," when persuasive evidence of an arrangement exists, the fee is fixed or determinable, collection of the fee is probable and delivery has occurred. For all sales, we require either a purchase agreement or a purchase order as evidence of an arrangement.

(1) *Sale of ClearPoint system reusable components* — Revenues related to ClearPoint system sales are recognized upon installation of the system and the completion of training of at least one of the customer's physicians, which typically occurs concurrently with the ClearPoint system installation. ClearPoint system reusable components include software. This software is integral to the utility of the ClearPoint system as a whole, and as such, the provisions of FASB ASC 985-605, "Software Revenue Recognition," are not applicable. Sales of reusable components that have stand-alone value to the customer are recognized when risk of loss passes to the customer. Sales of reusable components to a distributor that has been trained to perform ClearPoint system installations are recognized at the time risk of loss passes to the distributor.

(2) *Sales of ClearPoint disposable products* — Revenues from the sale of ClearPoint disposable products utilized in procedures performed using the ClearPoint system, which occurs after the system installation is completed for a given customer, are recognized at the time risk of loss passes, which is generally at shipping point or the customer's location, based on the specific terms with that customer.

(3) *License and development arrangements* — Historically we have evaluated revenue recognition on an agreement-by-agreement basis, which has principally involved two license agreements with Boston Scientific. Both agreements provide for various potential revenue streams for us, including an up-front licensing fee for one of the licenses, various milestone payments, payments for research and development and consulting services, and royalties. In both license agreements, we concluded that all of the contract elements should be treated as a single unit of accounting. As such, all amounts received were initially recorded as deferred revenue and thereafter recognized as revenue over our estimated period of performance on a straight-line basis. In the case of the license with a possible repayment obligation provision, revenue was not recognized until the repayment obligation period expired; the revenue that had been deferred was recognized in the year ended December 31, 2012. Note 2 to our financial statements, "Significant Accounting Policies—Revenue Recognition," more fully describes the deliverables under these license agreements including our rights, obligations and cash flows.

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

Share-based compensation. We account for compensation for all arrangements under which employees and others receive shares of stock or other equity instruments (including options and warrants) in accordance with FASB ASC 718,"Compensation – Stock Compensation." Under ASC 718, the fair value of each award is estimated and amortized as compensation expense over the requisite vesting period. The fair value of our share-based awards is estimated on the grant date using the Black-Scholes valuation model. This valuation model requires the input of highly subjective assumptions, including the expected stock volatility, estimated award terms and risk-free interest rates during the expected terms. To estimate the expected terms, we utilize the "simplified" method for "plain vanilla" options discussed in the SEC's Staff Accounting Bulletin 107, or SAB 107. We believe that all factors listed within SAB 107 as pre-requisites for utilizing the simplified method apply to us and for our share-based compensation arrangements. We intend to utilize the simplified method for the foreseeable future until more detailed information about exercise behavior becomes available. We based our estimate of expected volatility on the average of historical volatilities of publicly traded companies we deemed similar to us because we lack adequate relevant historical volatility data. We will consistently apply this methodology until a sufficient amount of historical information regarding the volatility of our share prices becomes available. We utilize risk-free interest rates based on zero-coupon United States treasury instruments, the terms of which are consistent with the expected terms of the share-based awards. We have not paid and do not anticipate paying cash dividends on shares of our common stock; therefore, the expected dividend yield is

assumed to be zero. The fair value of share-based payments are generally amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods. We believe there is a high degree of subjectivity involved when using option pricing models to estimate share-based compensation under ASC 718. Currently, there is not a market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of share-based awards is determined in accordance with ASC 718 using an option pricing model, that value may not be indicative of the fair value observed in a market transaction between a willing buyer and a willing seller. If factors change and we employ different assumptions in the application of ASC 718 in future periods than those currently applied under ASC 718, the compensation expense we record in future periods under ASC 718 may differ significantly from what we have historically reported.

Total share-based compensation expense for the years ended December 31, 2012, 2011 and 2010 was $2.0 million, $990,000 and $245,000, respectively. As of December 31, 2012 there was $1.9 million of unrecognized compensation cost related to nonvested share-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of approximately 1.8 years.

Research and development costs. Expenses related to research, design and development of products are charged to research and development costs as incurred. These expenditures include direct salary and employee benefit related costs for research and development personnel, costs for materials used in research and development activities and costs for outside services. Since most of the expenses associated with our development service revenues relate to existing internal resources, these amounts are included in research and development costs.

Results of Operations

Comparison of the Year Ended December 31, 2012 to the Year Ended December 31, 2011

($s in thousands)	Year Ended December 31, 2012	2011	Percentage Change
Revenues	$ 5,058	$ 3,818	32%
Cost of product revenues	556	656	(15)%
Research and development:			
Research and development costs	2,485	4,251	(42)%
Reversal of R&D obligations	(883)	-	NM
Selling, general and administrative expenses	6,030	4,832	25%
Other expense, net	2,577	2,390	8%
Net loss	(5,707)	(8,311)	(31)%

NM= not meaningful

Revenues. Revenues were $5.1 million for the year ended December 31, 2012, compared to $3.8 million for the year ended December 31, 2011, an increase of $1.3 million, or 32%. License fee revenues related to our license agreements with Boston Scientific were $3.3 million for the year ended December 31, 2012 compared with $2.6 million for the year ended December 31, 2011. During the year ended December 31, 2012, we recorded development service revenues of $541,000 related to development services we provided to a third party, compared to $63,000 for the year ended December 31, 2011. Product revenues for both of the years ended December 31, 2012 and 2011 were $1.2 million. Approximately $150,000 of the product revenues for the year ended December 31, 2012 relate to the sale of ClearPoint system reusable components, compared to $730,000 in the year ended December 31, 2011. Substantially all of the remaining product revenues for the year ended December 31, 2012 and 2011 relate to sales of ClearPoint disposable products. The increase in disposable product sales reflects an increasing number of ClearPoint procedures being performed as adoption of the ClearPoint system increases.

Cost of Product Revenues. Cost of product revenues was $556,000 for the year ended December 31, 2012, compared to $656,000 for the year ended December 31, 2011, a decrease of $100,000, or 15%. The decrease in cost of product revenues resulted from the change in sales mix as ClearPoint disposable sales represented 87% of product sales for the year ended December 31, 2012, compared with only 39% for the prior year. Margins on the sale of our ClearPoint system disposable components are typically significantly higher than on the sale of our ClearPoint system's reusable components. The decrease due to the change in sales mix was partially offset an increase of $110,000 in depreciation expense for loaned systems installed under our ClearPoint Placement Program, which was driven by the

additional number of loaned systems installed at customer facilities during the year ended December 31, 2012, compared with the year ended December 31, 2011.

Research and Development Costs. Research and development costs were $2.5 million for the year ended December 31, 2012, compared to $4.3 million for the year ended December 31, 2011, a decrease of $1.8 million, or 42%. The primary driver of the decrease was a reduction in spending related to our ClearTrace development program, as we incurred $750,000 in expense for ClearTrace related sponsored research during the year ended December 31, 2011, compared to none for the year ended December 31, 2012. A reduction of $584,000 in consulting and personnel costs, again mostly related to ClearTrace system development, also contributed to the decrease. We scaled back our ClearTrace development program spending while we were seeking additional funding and as we focused more time and resources on ClearPoint commercialization efforts. We experienced a decrease in research and development costs of $362,000 related to our Key Personnel Incentive Program (see the explanation of reversal of R&D obligation below) when comparing the year ended December 31, 2012 with the year ended December 31, 2011. In addition, we recorded a credit of $97,000 during the year ended December 31, 2012 related to sponsored research as we negotiated with a research partner to reduce amounts we were invoiced prior to December 31, 2011, but which we had not yet paid, in order to reflect an adjustment for work that was specified in our agreement with the research partner but was not completed.

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

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $6.0 million for the year ended December 31, 2012, compared with $4.8 million for the year ended December 31, 2011, an increase of $1.2 million, or 25%. The increase relates mostly to share-based compensation expense of $862,000 associated with warrants we issued in May 2012 to two non-employee directors to purchase 1.25 million shares of our common stock and additional warrants we issued during the year to a service provider, two research contributors and a long-time financial adviser to purchase 411,666 shares of our common stock. All of these warrants had an exercise price of $1.00 per share and were immediately vested upon issuance, and the fair value of these warrants was computed using the Black-Scholes pricing model. We also experienced increased spending of approximately $215,000 related to fees paid for investor relations services and filing agent costs associated with our being a public company. In addition, our hiring costs increased by $161,000, and our share-based compensation expense related to employee stock options increased by $108,000. These increases were partially offset by a reduction in expenses for professional services, which were down $96,000 when comparing the year ended December 31, 2012 with the year ended December 31, 2011.

Other Expense, Net. Net interest expense for the year ended December 31, 2012 was $2.6 million, compared with $2.5 million for the year ended December 31, 2011, an increase of $86,000. Interest expense which was accrued during the year ended December 31, 2012 was $534,000, compared to $1.2 million for the year ended December 31, 2011. The reduction in interest that was accrued related to the conversion of convertible notes payable into shares of our common stock in February 2012, which notes payable were outstanding for all or part of the year ended December 31, 2011. The remainder of the interest expense recorded during year ended December 31, 2012 was mostly related to the $1.9 million write-off of deferred debt issuance costs and unamortized debt discounts associated with the conversion of convertible notes payable into shares of our common stock in February 2012. The remainder of interest expense recorded during the year ended December 31, 2011 related to amortization of debt discounts and deferred debt issuance costs. Interest income was approximately $14,000 for the year ended December 31, 2012, compared with $3,000 for the year ended December 31, 2011.

Comparison of the Year Ended December 31, 2011 to the Year Ended December 31, 2010

($s in thousands)	Year Ended December 31, 2011	2010	Percentage Change
Revenues	$ 3,818	$ 2,669	43%
Cost of product revenues	656	16	NM
Research and development costs	4,251	5,681	(25)%
Selling, general and administrative expenses	4,832	4,699	3%
Costs of withdrawn IPO	-	1,789	NM
Other income (expense), net	(2,390)	62	NM
Net loss	(8,311)	(9,454)	12%

NM = not meaningful

Revenues. Revenues were $3.8 million for the year ended December 31, 2011, compared to $2.7 million for the year ended December 31, 2010. License fee revenue related to our license agreement with Boston Scientific for implantable cardiac medical leads was $2.6 million during both years. Product revenues for the years ended December 31, 2011 and 2010 were $1.2 million and $69,000, respectively. The increase relates to sales of our ClearPoint system reusable and disposable components. We initiated the commercial launch of our ClearPoint system in 2010 after receiving FDA regulatory clearance in June 2010. Higher ClearPoint product sales during the year ended December 31, 2011 reflect increased adoption of our ClearPoint system.

Cost of Product Revenues. Cost of product revenues was $656,000 for the year ended December 31, 2011, compared to $16,000 for the year ended December 31, 2010. The increase in cost of product revenues was due to the increase in product revenues and the change in our sales mix. All product revenues for the year ended December 31, 2010 were related to sales of our ClearPoint system disposable products. On the other hand, approximately 38% of our product revenues for the year ended December 31, 2011 were from sales of our disposable products with the remainder representing sales of our reusable components. Gross margin is significantly higher on sales of our ClearPoint system disposable products than sales of our ClearPoint system reusable products.

Research and Development Costs. Research and development costs were $4.3 million for the year ended December 31, 2011, compared to $5.7 million for the year ended December 31, 2010, a decrease of $1.4 million, or 25%. This decrease was due primarily to: (i) a decrease of $976,000 in ClearTrace system software development expenses related to the timing of achievement of development milestones by our third party software development partner; (ii) a decrease of $349,000 in software development expenses related to our ClearPoint system as very little development work was left to be completed in 2011; and (iii) a decrease of $344,000 due to a reduction in the use of outside consultants. These decreases were partially offset by an increase in compensation related to our Key Personnel Incentive Program of $206,000 and an increase in share-based compensation expense related to R&D personnel of $215,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $4.8 million for the year ended December 31, 2011 compared to $4.7 million for the year ended December 31, 2010, an increase of $133,000, or 3%. The change relates to an increase of $530,000 in share-based compensation expense related to stock options granted in December 2010, which was mostly offset by a decrease related to the costs associated with the settlement of a trademark dispute recorded in 2010 of $425,000. All monies owed under the terms of the settlement agreement were paid in 2011, except for approximately $71,000 which was paid in early 2012.

Costs of Withdrawn IPO. In 2009, we filed a registration statement with the SEC relating to the initial public offering, or IPO, of shares of our common stock. In 2010, we made the decision to withdraw our registration statement and to cancel the planned IPO. Costs which had been deferred, totaling $1.8 million, were recorded as costs of withdrawn IPO in the statement of operations in 2010.

Other Income (Expense), Net. Net other expense was $2.4 million for the year ended December 31, 2011 compared with net other income of $61,000 for the year ended December 31, 2010. Net interest expense was $2.5 million for the year ended December 31, 2011, compared to $1.6 million for the year ended December 31, 2010. The increase in interest expense relates to interest on increased borrowings and related amortization of debt discounts and deferred financing costs. We issued notes payable in the principal amount of $7.1 million during 2010 that were outstanding for the full year in 2011. In addition, we issued notes payable during 2011 in the principal amount of $4.9

million. Net interest expense for the year ended December 31, 2010 was more than offset by a gain of $1.2 million recorded on the revaluation of our derivative liability and other income of $416,000 related to grants received under the Qualifying Therapeutic Discovery Project provided by the United States Treasury Department.

Liquidity and Capital Resources

For the years ended December 31, 2012, 2011 and 2010, we incurred net losses of $5.7 million, $8.3 million, and $9.5 million, respectively, and the cumulative net loss since our inception through December 31, 2012 was $65.5 million. We expect such losses to continue through at least the year ended December 31, 2013 as we continue to commercialize our ClearPoint system and pursue research and development activities. Net cash used in operations was $7.4 million, $6.2 million, and $7.7 million for the years ended December 31, 2012, 2011, and 2010, respectively. Since inception, we have financed our activities principally from the sale of equity securities, the issuance of convertible notes and license arrangements.

Our primary financing activities during the years ended December 31, 2012, 2011, and 2010 were:

- our July 2012 PIPE financing, which resulted in net proceeds of $5.5 million;
- the unit offering we completed in February 2012, which resulted in net proceeds of $4.9 million, $3.4 million of which we received in 2012 and $1.5 million of which we received in 2011;
- the unit offering we completed in September 2011, which resulted in net proceeds of $1.3 million;
- our issuance of a convertible note payable in April 2011, which resulted in net proceeds of $2.0 million;
- our November 2010 unit offering, which resulted in net proceeds of $3.0 million; and
- our March 2010 convertible notes payable offering, which resulted in net proceeds of $3.8 million.

In January 2013, we completed a private offering in which we sold securities for net proceeds of approximately $9.9 million. While we expect to continue to use cash in operations, we believe our existing cash and cash equivalents at December 31, 2012 of $1.6 million, combined with the net proceeds from our January 2013 private offering, will be sufficient to meets our anticipated cash requirements through at least March 2014. During 2013, we plan to increase our spending on sales and marketing activities as we complete the commercial rollout of our ClearPoint system, from which we expect to increase ClearPoint product revenues. Certain planned expenditures are discretionary and could be deferred if required to do so to fund critical operations. To the extent our available cash and cash equivalents are insufficient to satisfy our long-term operating requirements, we will need to seek additional sources of funds, from the sale of additional equity, debt or other securities or through a credit facility, or modify our current business plan. There can be no assurance that we will be able to obtain additional financing on commercially reasonable terms. The sale of additional equity or convertible debt securities will likely result in dilution to our current stockholders.

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

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

* See Note 8 to our December 31, 2012 audited financial statements.

Cash Flows

	Years Ended December 31,		
($s in thousands)	2012	2011	2010
Cash used in operating activities	$ (7,434)	$ (6,240)	$ (7,707)
Cash used in investing activities	(127)	(26)	(62)
Cash provided by financing activities	9,036	4,834	6,777
Net increase (decrease) in cash and cash equivalents	$ 1,475	$ (1,432)	$ (992)

Net Cash Flows from Operating Activities. Net cash used in operating activities for the years ended December 31, 2012, 2011, and 2010 primarily reflects the net loss for each year, which was reduced in part by amortization, depreciation and share-based compensation expense, but which increased by the change in deferred revenue. Net cash used in operating activities for the year ended December 31, 2012 also reflects a use of cash related to the $3.0 million reduction in accounts payable and certain accrued expenses as we paid down certain outstanding balances. Net cash used in operating activities for the years ended December 31, 2011 and 2010 reflect increases in accounts payable and accrued expenses of $2.2 million and $3.5 million, respectively, as sources of cash as we extended payment terms while we sought additional funding. The losses for each year resulted mostly from selling, general and administrative expenses and from funding research and development activities.

Net Cash Flows from Investing Activities. Net cash flows from investing activities for the years ended December 31, 2012, 2011 and 2010 were $(127,000), $(26,000) and $(62,000), respectively. Net cash used in investing activities for each of the periods was primarily related to the purchase of property and equipment to support operations at our Irvine, California facility and the acquisition of intellectual property licenses.

Net Cash Flows from Financing Activities. Net cash provided by financing activities for the year ended December 31, 2012 relates to the $5.5 million of net proceeds generated from our July 2012 PIPE financing transaction and the $3.4 million of net proceeds generated in 2012 from the unit offering we concluded in February 2012. Net cash provided by financing activities for the year ended December 31, 2011 relates mostly to the proceeds from our issuance of a $2.0 million convertible note payable in April 2011 and $2.8 million we received in two unit offerings in which we issued both convertible notes payable and warrants to purchase shares of our common stock. Net cash provided by

financing activities for the year ended December 31, 2010 relates to the net proceeds of $3.8 million from our issuance of convertible notes payable and $3.0 million we received in a unit offering in which we issued shares of our common stock and secured notes payable.

Operating Capital and Capital Expenditure Requirements

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

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

- the cost and timing of expanding our sales, marketing and distribution capabilities and other corporate infrastructure;
- the cost of establishing inventories;
- the effect of competing technological and market developments;
- the scope, rate of progress and cost of our research and development activities;
- the achievement of milestone events under, and other matters related to, our agreements with Boston Scientific and Siemens;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- the cost and timing of any clinical trials;
- the cost and timing of regulatory filings, clearances and approvals; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Report of Independent Registered Public Accounting Firm and Financial Statements are set forth on pages F-1 to F-30 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Management's Evaluation of Disclosure Controls and Procedures

We have established disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Exchange Act. Our disclosure controls and procedures are designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others within our organization. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2012 to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2012 (the end of the period covered by this Annual Report on Form 10-K).

Management's Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report on management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

As of the year ended December 31, 2012, there were no significant changes in our internal control over financial reporting that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Directors and Executive Officers

The following table sets forth information about our directors, executive officers and other key employees as of January 31, 2013.

Name	Age	Position(s)
Directors and Executive Officers		
Kimble L. Jenkins	50	President, Chief Executive Officer and Chairman of Board of Directors
Paul A. Bottomley	59	Director
Bruce C. Conway[(2)]	61	Director
Charles E. Koob[(2)(3)]	68	Director
James K. Malernee, Jr.[(1)(3)]	65	Director
Michael A. Pietrangelo[(1)(2)]	70	Director
Andrew K. Rooke[(3)]	56	Director
Michael J. Ryan	34	Director
John N. Spencer, Jr.[(1)]	72	Director
David W. Carlson	48	Chief Financial Officer
Peter G. Piferi	53	Chief Operating Officer
Carol J. Barbre	52	Vice President, Product Management
Robert C. Korn	47	Vice President, Global Sales & Marketing
Oscar L. Thomas	42	Vice President, Business Affairs and Secretary

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Corporate Governance and Nominating Committee

Kimble L. Jenkins joined our Board of Directors in September 2002 and presently serves as our Chairman. Mr. Jenkins has served as our President since January 2003, and he has also served as our Chief Executive Officer since September 2004. Mr. Jenkins served in those offices on a part-time basis until May 2008, at which time Mr. Jenkins began serving as our President and Chief Executive Officer on a full-time basis. Prior to May 2008, Mr. Jenkins was also a Managing Director with the investment bank Morgan Keegan & Company, Inc., where he founded that firm's Private Equity Group in 1998. Mr. Jenkins has over 20 years of experience building and working with growth stage companies. Mr. Jenkins holds a Bachelor of Arts from Brown University and a Juris Doctorate from Georgetown University Law Center. As our Chief Executive Officer, Mr. Jenkins offers unique insight and vision into our operations, our competition and the medical device industry.

Paul A. Bottomley is a founder of the company and has been a member of our Board of Directors since December 1998. Dr. Bottomley joined Johns Hopkins in 1994. Since 1997, Dr. Bottomley has served as the Director of the Division of MR Research in the Department of Radiology at Johns Hopkins. Previously, Dr. Bottomley worked at General Electric Company's Research and Development Center from 1980 to 1994 where he played a key role in the development of their MRI clinical product and was awarded the Center's highest honor, its Coolidge Medal and Fellowship, for these developments in 1990. He was awarded the Society of Magnetic Resonance in Medicine's Gold Medal for his contributions to MRI in 1989. He holds over 30 U.S. patents and has written more than 150 scientific journal publications. Dr. Bottomley also serves as a consultant to us. As a pioneer in MR research, Dr. Bottomley offers expertise in the practical application of our technologies and the commercial opportunities for our products and product candidates.

Bruce C. Conway joined our Board of Directors in May 2011. From 1992 to 2010, Mr. Conway served as a consultant for numerous early stage companies in creating and implementing individualized business strategies designed to result in a liquidity event. He has significant experience working with companies in the biomedical, alternative energy, oil and gas exploration, agriculture, water and real estate industries. Mr. Conway previously served on the board of directors for Whitehall Corporation, a publicly traded defense and electronics company prior to its acquisition by Aviation Sales Company in 1998. As a consultant to, and investor with, numerous early stage companies, Mr. Conway offers substantial expertise in the area of formation and implementation of corporate and operational strategy.

Charles E. Koob joined our Board of Directors in August 2008. From 1970 to 2008, Mr. Koob practiced competition, trade regulation and antitrust law at the law firm of Simpson Thacher & Bartlett and served as the co-head of the firm's litigation department for a portion of his tenure. For much of his career, Mr. Koob served as a strategic advisor for the boards of directors of many public companies. Mr. Koob presently serves on the board of directors of MiMedx Group, Inc., a publicly traded biomedical products company, DemeRx, Inc., a privately held biotechnology company, and Stanford Hospital & Clinics. As a byproduct of Mr. Koob's sophisticated former legal practice, Mr. Koob offers expertise in the areas of corporate governance, contract negotiation and organizational and strategic leadership.

James K. Malernee, Jr. joined our Board of Directors in March 2010. Dr. Malernee is a cofounder of Cornerstone Research, Inc., a consulting firm specializing in analytical support to attorneys in all phases of commercial litigation and regulatory proceedings, and he currently serves as Chairman of that firm. Over the last twenty years with Cornerstone Research, he has directed research on complex business issues related to a wide variety of cases. In recent years, Dr. Malernee has specialized in securities matters, supervising hundreds of cases dealing with material disclosure, loss causation, insider trading, mergers and acquisitions, targeted repurchases, minority buyouts, stock trading behavior, valuation and class certification. Dr. Malernee has served as a board member and consultant to major corporations, and he has taught finance at the University of Texas at Austin and business strategy at the Stanford Graduate School of Business. Dr. Malernee is also a consultant to RealPage, Inc., a publicly traded provider of property management solutions. Through his academic and professional pursuits, Dr. Malernee offers expertise in finance and business strategy as well as an understanding of corporate disclosure and governance practices.

Michael A. Pietrangelo joined our Board of Directors in March 2010. From 1972 through 1989, Mr. Pietrangelo was employed by Schering-Plough Corporation in various capacities including President of the Personal Care Products Group. From 1989 to 1990, he served as President and Chief Operating Officer of Western Publishing Company. From 1990 to 1994, Mr. Pietrangelo was the President and Chief Executive Officer of CLEO, Inc., a subsidiary of Gibson Greetings, Inc. From 1994 until 1998, he served as President of Johnson Products Company, a subsidiary of IVAX Corporation. Since 1998, Mr. Pietrangelo has practiced law at Pietrangelo Cook PLC. Mr. Pietrangelo previously served as a director of Medicis Pharmaceutical Corporation, a publicly traded pharmaceutical company, prior to its acquisition by Valeant Pharmaceuticals International, Inc. in December 2012. Mr. Pietrangelo currently serves on the board of directors of the American Parkinson Disease Association, a not-for-profit organization focused on serving the Parkinson's community, and Universal Insurance Holdings, Inc., a publicly traded insurance holding company. Mr. Pietrangelo also serves as the managing partner of Theraplex Company LLC, a privately held company. As a result of his diverse professional background, Mr. Pietrangelo offers a unique combination of legal expertise and operational acumen.

Andrew K. Rooke joined our Board of Directors in July 2011. Mr. Rooke owns and manages Rooke Fiduciary Management, a private trust company, which specializes in the investment management of publicly held securities and the oversight of a multitude of trust investments. Mr. Rooke is also President and a director of Withington Foundation, a private foundation. Over the years, he has acquired, managed and sold a number of private companies as well as commercial real estate properties. Mr. Rooke was also previously employed by the former securities firm Kidder, Peabody & Co. With significant experience in financing, analyzing, investing in and managing investments in public and private companies, Mr. Rooke offers expertise in strategic and financial matters.

Michael J. Ryan joined our Board of Directors in May 2011. Mr. Ryan is Director of Corporate Business Development at Boston Scientific, where he leads business development activities in the field of neuromodulation. Prior to joining Boston Scientific in 2005, Mr. Ryan was a Senior Consultant at Decision Resources, providing management consulting services to the pharmaceutical and biotech industries. With his background, Mr. Ryan offers insight into the medical device industry, particularly as it relates to neurological applications.

John N. Spencer, Jr. joined our Board of Directors in March 2010. Mr. Spencer is a certified public accountant and was a partner of Ernst & Young LLP where he spent more than 38 years until his retirement in 2000. Mr. Spencer serves on the board of directors of GeoVax Labs, Inc., a publicly traded biotechnology company, and until April 2009, served on the board of directors of Firstwave Technologies, Inc., formerly a publicly traded customer relationship management software company. In addition, he serves as a consultant to various companies, primarily relating to financial accounting and reporting matters. By virtue of his experience at Ernst & Young, where he was the partner in charge of its life sciences practice for the southeastern United States, together with his continuing expertise as a director of, and a consultant to, other publicly traded and privately held companies, Mr. Spencer offers expertise in accounting, finance and the medical device industry.

David W. Carlson joined us in February 2010 as Vice President, Finance and was promoted to Chief Financial Officer in April 2010. Mr. Carlson has 18 years of experience in financial leadership roles in the medical device industry. From 1999 to 2009, he served in various financial management positions as a Vice President of Finance and Senior Finance Director at Medtronic, Inc., a global leader in medical technologies. He was serving as the Corporate Controller of Sofamor Danek, Inc., a then publicly traded medical device company, when it was acquired by Medtronic, Inc. in 1999. Mr. Carlson is a certified public accountant, and was formerly an auditor for PricewaterhouseCoopers LLP.

Peter G. Piferi joined us in December 2006 as our Chief Operating Officer. Mr. Piferi has over 20 years of experience in the areas of product development, operations, engineering and production in the medical device industry. From March 2003 to December 2006, Mr. Piferi served as Vice President, Endovascular Technologies for Edwards Lifesciences Corporation. In addition, Mr. Piferi has served as Vice President at Kriton Medical Inc. and Orbus Medical Technologies, Inc. and as Director of Advanced Engineering at Cordis Corporation.

Carol J. Barbre joined us in May 2008 as Vice President, Product Management. Ms. Barbre has 20 years of experience in the medical device industry in the areas of marketing and business development, with a focus on new medical therapies. From May 2007 to May 2008, Ms. Barbre served as Senior Director of Marketing for Edwards Lifesciences Corporation, a publicly traded medical device company. From 2002 to May 2007, Ms. Barbre served as Global Marketing Director for Bolton Medical, Inc., a privately held medical device company.

Robert C. Korn joined us in November 2012 as Vice President, Global Sales & Marketing. Mr. Korn has over 20 years of experience in the health care industry focused in the medical device sales and marketing business. During his career, Mr. Korn gained experience in developing and implementing sales and marketing strategies for both Fortune 500 and startup companies. He has also worked extensively on business development and acquisition opportunities in the medical device sector. From May 2005 to November 2012, Mr. Korn served as a Regional Sales Director with Medtronic Surgical Technologies, the neurosurgery, ear, nose and throat (ENT) and advanced energy business of Medtronic, Inc., a publicly traded medical device company. From April 2004 to April 2005, he served as Senior Vice President for Vassol, Inc., a private company, where he was responsible for the company's sales and marketing functions. Prior to Vassol, Mr. Korn held various sales leadership positions with Codman, a Johnson & Johnson company, and he also held multiple sales and marketing positions with the Bayer Corporation's Diagnostics Division.

Oscar L. Thomas joined us in April 2008 as Vice President, Business Affairs. In addition, Mr. Thomas serves as our Secretary. From January 2003 to April 2008, Mr. Thomas was a partner in the Corporate and Securities Practice Group of the law firm Bass, Berry & Sims PLC. Mr. Thomas spent 12 years in private practice representing clients in a broad range of transactions, including licensing transactions, development collaborations, joint ventures, merger and acquisition transactions, and debt and equity financings.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers and the beneficial owners of greater than 10% of our common stock to file initial reports of ownership and reports of changes in ownership with the SEC. Directors and executive officers are required by SEC regulations to furnish us with copies of these reports. Except as described in the following sentence, we are not aware of any required Section 16(a) reports that were not filed on a timely basis. We are, however, aware that the Form 4 report filed by Mr. Bruce Conway, one of our directors, on August 21, 2012 incorrectly reflected the nature of Mr. Conway's beneficial ownership of 4,500 shares of our common stock that were purchased on August 20, 2012 and August 21, 2012. Mr. Conway filed an amended Form 4 report on August 24, 2012 to correct the inadvertent error.

Copies of the insider trading reports can be found at our corporate website at www.mriinterventions.com, on the "Investors" page, under the category "SEC Filings". The inclusion of our website address in this Annual Report does not include or incorporate by reference the information on our website into this Annual Report.

Code of Business Conduct and Ethics

Our Board of Directors has adopted a Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics applies to all of our employees, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions) and directors. The Code of Business Conduct and Ethics is posted on our website at www.mriinterventions.com. We will provide a copy of this document to any person, without charge, upon request, by writing to our Investor Relations Department, One Commerce Square, Suite 2550, Memphis, TN 38103. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics, or waivers of such provisions, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors on our website identified above. The inclusion of our website address in this Annual Report does not include or incorporate by reference the information on our website into this Annual Report.

Audit Committee Matters

The information required by this Item with respect to the audit committee of our Board of Directors is set forth in Item 13 of this Annual Report in the section entitled "Board Committees".

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table shows the compensation awarded or paid to, or earned by, our Chief Executive Officer and our three other most highly compensated executive officers for the years ended December 31, 2012, 2011 and 2010. We refer to these executive officers as our "named executive officers".

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)[1]	All Other Compensation ($)[2]	Total ($)
Kimble L. Jenkins	2012	$ 325,000	$ --	$ 265,320[3]	33,188[4]	$623,508[5]
Chief Executive Officer	2011	260,000	--	--	7,194	267,194
and President	2010	308,750	--	556,100[6]	6,527	871,377[7]
Peter G. Piferi	2012	250,000	--	223,960[8]	21,948[9]	495,908[10]
Chief Operating Officer	2011	200,000	--	--	3,558	203,558
	2010	241,667	--	468,950[11]	3,355	713,972[12]
Oscar L. Thomas	2012	225,000	--	186,120[13]	27,501[14]	438,621[15]
Vice President, Business Affairs	2011	190,000	--	--	6,938	196,938
	2010	212,500	--	390,100[16]	5,757	608,357[17]
David W. Carlson	2012	225,000	--	136,400[18]	32,898[19]	394,298[20]
Chief Financial Officer	2011	175,000	--	--	8,170	183,170
	2010	179,327	--	282,200[21]	5,084	466,611[22]

(1) These amounts do not represent cash compensation paid to the named individual. These non-cash amounts represent only the aggregate grant date fair value of the option awards as computed in accordance with ASC Topic 718. For a discussion of the assumptions made in the valuation of the awards, see the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations–Critical Accounting Policies and Significant Judgments and Estimates–Share-based Compensation" and note 2 to the financial statements included elsewhere in this Annual Report.

(2) Until otherwise noted, these amounts consist of the group medical, life and disability premiums that we paid.

(3) Does not represent cash compensation. Represents only the aggregate grant date fair value in accordance with ASC Topic 718 for options to purchase an aggregate of 603,000 shares of our common stock issued to Mr. Jenkins.

(4) Of this amount, $24,375 represents payment of a portion of the amount owed from the temporary salary reduction previously taken by Mr. Jenkins to conserve cash for our operations.
(5) Of this amount, the cash compensation paid to Mr. Jenkins totaled only $349,375.
(6) Does not represent cash compensation. Represents only the aggregate grant date fair value in accordance with ASC Topic 718 for options to purchase an aggregate of 670,000 shares of our common stock issued to Mr. Jenkins.
(7) Of this amount, the cash compensation paid to Mr. Jenkins totaled only $308,750.
(8) Does not represent cash compensation. Represents only the aggregate grant date fair value in accordance with ASC Topic 718 for options to purchase an aggregate of 509,000 shares of our common stock issued to Mr. Piferi.
(9) Of this amount, $17,708 represents payment of a portion of the amount owed from the temporary salary reduction previously taken by Mr. Piferi to conserve cash for our operations.
(10) Of this amount, the cash compensation paid to Mr. Piferi totaled only $267,708.
(11) Does not represent cash compensation. Represents only the aggregate grant date fair value in accordance with ASC Topic 718 for options to purchase an aggregate of 565,000 shares of our common stock issued to Mr. Piferi.
(12) Of this amount, the cash compensation paid to Mr. Piferi totaled only $241,667.
(13) Does not represent cash compensation. Represents only the aggregate grant date fair value in accordance with ASC Topic 718 for options to purchase an aggregate of 423,000 shares of our common stock issued to Mr. Thomas.
(14) Of this amount, $18,750 represents payment of a portion of the amount owed from the temporary salary reduction previously taken by Mr. Thomas to conserve cash for our operations.
(15) Of this amount, the cash compensation paid to Mr. Thomas totaled only $243,750.
(16) Does not represent cash compensation. Represents only the aggregate grant date fair value in accordance with ASC Topic 718 for options to purchase an aggregate of 470,000 shares of our common stock issued to Mr. Thomas.
(17) Of this amount, the cash compensation paid to Mr. Thomas totaled only $212,500.
(18) Does not represent cash compensation. Represents only the aggregate grant date fair value in accordance with ASC Topic 718 for options to purchase an aggregate of 310,000 shares of our common stock issued to Mr. Carlson.
(19) Of this amount, $23,750 represents payment of a portion of the amount owed from the temporary salary reduction previously taken by Mr. Carlson to conserve cash for our operations.
(20) Of this amount, the cash compensation paid to Mr. Carlson totaled only $248,750.
(21) Does not represent cash compensation. Represents only the aggregate grant date fair value in accordance with ASC Topic 718 for options to purchase an aggregate of 340,000 shares of our common stock issued to Mr. Carlson.
(22) Of this amount, the cash compensation paid to Mr. Carlson totaled only $179,327.

Outstanding Equity Awards at December 31, 2012

The table below sets forth information regarding the outstanding equity awards held by our named executive officers at December 31, 2012.

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Kimble L. Jenkins	5,000[1]	—[1]	3.20	March 28, 2017
	2,500[2]	—[2]	9.64	September 16, 2018
	2,500[3]	—[3]	9.64	November 8, 2018
	2,500[4]	—[4]	9.64	December 10, 2019
	66,652[5]	—[5]	9.64	September 1, 2013
	339,467[6]	169,733[6]	1.80	December 13, 2020
	107,200[7]	53,600[7]	1.80	December 13, 2020
David W. Carlson	172,267[6]	86,133[6]	1.80	December 13, 2020
	54,400[7]	27,200[7]	1.80	December 13, 2020
Peter G. Piferi	286,267[6]	143,133[6]	1.80	December 13, 2020
	90,400[7]	45,200[7]	1.80	December 13, 2020
Oscar L. Thomas	238,134[6]	119,066[6]	1.80	December 13, 2020
	75,200[7]	37,600[7]	1.80	December 13, 2020

(1) The vesting of shares subject to this option occurred on the date of grant, March 28, 2007.
(2) The vesting of shares subject to this option occurred on the date of grant, September 16, 2008.
(3) The vesting of shares subject to this option occurred on the first anniversary of the date of grant, November 8, 2009.
(4) The vesting of shares subject to this option occurred on April 22, 2010, which was the day immediately preceding the 2010 annual meeting of our stockholders.
(5) One-third of the shares subject to this option vested on the first anniversary of the grant date, December 22, 2010. An additional one-third of the shares subject to this option vested on the second anniversary of the grant date, December 22, 2011. The remaining shares subject to this option vested on the third anniversary of the grant date, December 22, 2012.
(6) One-third of the shares subject to this option vested on the first anniversary of the grant date, December 13, 2011. An additional one-third of the shares vested on the second anniversary of the grant date, December 13, 2012. The remaining shares subject to this option vest on the third anniversary of the grant date, December 13, 2013.
(7) One-third of the shares subject to this option vested on July 3, 2012, which is the date we achieved a "target equity financing," defined as one or more equity financing transactions that result in cumulative gross proceeds of at least $10 million. An additional one-third of the shares vested on the second anniversary of the option grant date, December 13, 2012. The remaining shares subject to this option vest on the third anniversary of the grant date, December 13, 2013.

Option Exercises

None of our named executive officers exercised stock options in 2012.

Employment Agreements

In June 2012, we entered into employment agreements with each of our named executive officers, Messrs. Jenkins, Carlson, Piferi and Thomas, the material terms of which are summarized below.

Term

Under each of the employment agreements, the employment of the executive may be terminated by either party upon written notice to the other party.

Compensation

The base salaries of the executives are as follows:

Executive	Base Salary[1]	Bonus
Kimble L. Jenkins	$ 325,000	[2]
Peter G. Piferi	$ 250,000	[2]
David W. Carlson	$ 225,000	[2]
Oscar L. Thomas	$ 225,000	[2]

(1) Each executive's salary is subject to adjustment at the discretion of the compensation committee, subject to certain limitations.

(2) Each executive is eligible for a cash bonus in an amount and upon terms and conditions determined by the compensation committee.

In addition, under each employment agreement, each executive is eligible for equity compensation in an amount and based upon goals and criteria determined by the compensation committee and entitled to participate in any benefit plan from time to time in effect for our executives and/or employees generally, subject to the eligibility provisions of that plan.

If we terminate the employment of the executive without cause or if the executive terminates his employment for good reason, as those terms are defined in each employment agreement, then the executive will receive: (i) any base salary and bonus compensation earned but unpaid as of the termination date; (ii) an amount equal to his base salary in effect on the termination date; (iii) an amount equal to his average bonus for the previous two years, if any; (iv) $18,000; and (v) reimbursement of business expenses he incurred as of the termination date. In addition, under each employment agreement, if we terminate the employment of the executive without cause or the executive terminates his employment for good reason, any unvested stock options and restricted stock previously granted to the executive will become fully vested on the termination date and, in the case of stock options, will be exercisable until the earlier of three years after the termination date or the final expiration date provided for in the applicable award agreement.

If we terminate the employment of the executive with cause or if the executive terminates his employment voluntarily, as those terms are defined in each employment agreement, then the executive will receive: (i) any base salary and bonus compensation earned but unpaid as of the termination date; and (ii) reimbursement of business expenses he incurred as of the termination date.

Change in Control Payments

Upon a change of control involving a sale transaction, as those terms are defined in each employment agreement, any unvested stock options and restricted stock previously granted to the executive will become fully vested, and the executive will receive a bonus in the following amount:

Executive	Change of Control Sale Transaction Bonus
Kimble L. Jenkins	$ 455,000
Peter G. Piferi	$ 350,000
David W. Carlsonf	$ 315,000
Oscar L. Thomas	$ 315,000

In addition, if we terminate the employment of the executive without cause, or if the executive terminates his employment for good reason, in either case within two months prior to or within 12 months following the sale transaction, then he will be entitled to receive a lump sum payment equal to: (i) any base salary and bonus compensation earned but unpaid as of the termination date; (ii) the "COC Multiplier," which is defined below, times his base salary in effect on the termination date; (iii) the COC Multiplier times the greater of the average of his highest two bonuses paid in the previous three years or his current year target bonus, if any; (iv) $18,000; and (v) reimbursement of business expenses he incurred as of the termination date.

The COC Multiplier is based on the value of the sale transaction and is determined as follows:

Value of Sale Transaction	COC Multiplier
Less than $30,000,000	0
$ 30,000,000 - 49,999,999.99	0.5
$ 50,000,000 - 69,999,999.99	0.75
$ 70,000,000 - 89,999,999.99	1.0
$ 90,000,000 - 109,999,999.99	1.25
$110,000,000 or more	1.5

Upon a change of control not involving a sale transaction, any unvested stock options and restricted stock previously granted to the executive will become fully vested. In addition, if we terminate the employment of the executive without cause, or if the executive terminates his employment for good reason, in either case within two months prior to or within 12 months following the change of control, then he will be entitled to receive a lump sum payment equal to: (i) any base salary and bonus compensation earned but unpaid as of the termination date; (ii) two times his base salary in effect on the termination date; (iii) two times the greater of the average of his two highest bonuses paid in the previous three years or his current year target bonus, if any; (iv) $18,000; and (v) reimbursement of business expenses he incurred as of the termination date.

For purposes of these benefits, a change of control is deemed to occur, in general, if there is: (1) a change in our ownership; (2) a change in our effective control; or (3) a change in the ownership of a substantial portion of our assets. For purposes of this definition, a change in our ownership will occur on the date on which any one person, or more than one person acting as a group, acquires ownership of our stock that, together with stock already held by such person or group, constitutes more than 50% of the total fair market value or total voting power of our stock. A change in our effective control will occur on the date on which either (i) a person, or more than one person acting as a group, acquires ownership of our stock possessing 30% or more of the total voting power of our stock, taking into account all such stock acquired during the 12-month period ending on the date of the most recent acquisition, or (ii) a majority of the members of our Board of Directors is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of our Board of Directors prior to the date of the appointment or election. A change in the ownership of a substantial portion of our assets will occur on the date on which any one person, or more than one person acting as a group, other than a person or group of persons that is related to us, acquires assets from us that have a total gross fair market value equal to or more than 40% of the total gross fair market value of all of our assets immediately prior to such acquisition or acquisitions, taking into account all such assets acquired during the 12-month period ending on the date of the most recent acquisition.

Non-Competition; Non-Solicitation; Confidentiality; Assignment of Inventions

In connection with the employment agreements, each of the executives also entered into a confidentiality agreement and non-compete agreement, which agreements impose on the executive customary restrictive covenants prohibiting the disclosure of our confidential information, requiring the executive to assign us any invention discovered in the scope of his employment, prohibiting him from competing with us during the term of his employment and for one year following the termination of his employment, and prohibiting him from soliciting our employees, consultants and contractors during the term of his employment and for two years following the termination of his employment.

2012 Director Compensation

The following table sets forth information with respect to the compensation of our non-employee directors in 2012.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1]	All Other Compensation ($)	Total ($)
Paul A. Bottomley	$ 8,500	$ 19,800	$ 60,000[2]	$ 88,050
Bruce C. Conway	10,625	19,800	102,850[3]	133,275
Charles E. Koob	12,750	19,800	—	32,550
James K. Malernee, Jr.	11,750	19,800	—	31,550
Michael A. Pietrangelo	13,750	19,800	—	33,550
Andrew K. Rooke	9,875	19,800	411,400[3]	441,075
Michael J. Ryan	8,500	19,800	—	28,300
John N. Spencer, Jr.	11,375	19,800	—	31,175

(1) These amounts do not represent cash compensation paid to the named individuals. These non-cash amounts represent the aggregate grant date fair value of option awards as computed in accordance with ASC Topic 718. For a discussion of the assumptions made in the valuation of the awards, see the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations–Critical Accounting Policies and Significant Judgments and Estimates–Share-based Compensation" and note 2 to the financial statements included elsewhere in this Annual Report.

(2) This amount represents compensation under Dr. Bottomley's consulting agreement.

(3) This amount does not represent cash compensation paid to the named individual. This non-cash amount represents the aggregate grant date fair value of a warrant issued to the named individual, as computed in accordance with ASC Topic 718. The warrant was not issued in connection with the named individual's service as a director. For a discussion of the assumptions made in the valuation of the grant, see the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations–Critical Accounting Policies and Significant Judgments and Estimates–Share-based Compensation" and note 2 to the financial statements included elsewhere in this Annual Report.

Compensation Risks

We have assessed our compensation programs and have concluded that our compensation policies and practices do not create risks that are reasonably likely to have a material adverse effect on us. Our compensation program is relatively simple and has only three material elements: base salary; annual bonus; and long-term equity compensation. Base salary represents a fixed amount of payment and therefore does not encourage any excessive risk taking. The compensation committee has determined annual bonus amounts by subjectively analyzing company and individual performance for the prior year and only rewarding individual and company performance that, in the opinion of the compensation committee, had a positive effect on stockholder value. The subjective nature of the compensation committee's determinations regarding both the award and the amount of annual bonuses and equity grants provides a significant control over the incentive of an employee to take undue risk in order to receive a larger annual bonus or equity grant. Finally, our long-term equity compensation program generally involves only the issuance of options to our employees. We believe that the equity component of our compensation program serves to align the interest of management with the interests of stockholders and does not encourage excessive risk taking. Based on the foregoing, we

believe that our compensation policies and practices do not create inappropriate or unintended significant risk to the company as a whole. We also believe that our compensation arrangements provide incentives that do not encourage risk-taking beyond the organization's ability to effectively identify and manage significant risks; are compatible with effective internal controls and the risk management practices of the company; and are supported by the oversight and administration of the compensation committee with regard to executive compensation programs.

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee has ever been an executive officer or employee of ours. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our Board of Directors or compensation committee.

Benefit Plans

1998 Stock Option Plan

We adopted the 1998 Stock Option Plan on June 24, 1998 to enable us to attract, retain and motivate our officers, directors, employees and consultants. Of the 375,000 shares of common stock that were eligible for issuance pursuant to awards made under this plan, 287,500 shares of common stock were subject to outstanding options as of January 31, 2013. As of such date, the outstanding options had a weighted average exercise price of $0.89 per share and had expiration dates ranging from April 12, 2014 to October 21, 2014. We terminated this plan, effective June 24, 2008, with respect to future grants such that no new options may be awarded under this plan.

2007 Stock Incentive Plan

We adopted the 2007 Stock Incentive Plan on March 28, 2007 to enable us to attract, retain and motivate our officers, directors, employees and consultants. Of the 625,000 shares of common stock that were eligible for issuance pursuant to awards made under this plan, 114,875 shares of common stock were subject to options outstanding as of January 31, 2013. As of such date, the outstanding options had a weighted average exercise price of $6.43 per share and had expiration dates ranging from March 28, 2017 to December 10, 2019. Although this plan remains in effect and options under the plan remain outstanding, we ceased making awards under the plan upon the adoption of our 2010 Incentive Compensation Plan.

2010 Equity Plans

We adopted our 2010 Incentive Compensation Plan on April 23, 2010, and we adopted our 2010 Non-Qualified Stock Option Plan on December 13, 2010. The principal purpose of both plans was to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards. Of the 1,250,000 shares of common stock that were eligible for issuance pursuant to awards made under the 2010 Incentive Compensation Plan, 494,700 shares of common stock were subject to options outstanding as of January 31, 2013. As of such date, the outstanding options had exercise prices of $1.80 per share and had expiration dates of December 13, 2020. Of the 2,565,675 shares of common stock that were eligible for issuance pursuant to awards made under the 2010 Non-Qualified Stock Option Plan, 2,371,000 shares of common stock were subject to options outstanding January 31, 2013. As of such date, the outstanding options had exercise prices of $1.80 per share and had expiration dates of December 13, 2020. Although these plans remain in effect and options under the plans remain outstanding, we ceased making awards under these plans upon the adoption of our 2012 Incentive Compensation Plan.

2012 Incentive Compensation Plan

We adopted our 2012 Incentive Compensation Plan, or the 2012 Plan, on February 10, 2012. The principal purpose of the 2012 Plan is to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards. The 2012 Plan is also designed to permit us to make cash-based awards and equity-based awards intended to qualify as "performance-based compensation" under Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code.

Eligibility. Awards may be granted under the 2012 Plan to officers, directors (including non-employee directors) and other employees of our company or any of our subsidiaries or other affiliates, to any individual who is an advisor, consultant or other provider of services to us or any of our subsidiaries or other affiliates and to any other individuals who are approved by our Board of Directors as eligible to participate in the plan. Only our employees or those of any of our subsidiaries are eligible to receive incentive stock options.

Administration, Amendment and Termination. Our compensation committee will have the power and authority to administer the 2012 Plan. The compensation committee will have the authority to interpret the terms and intent of the 2012 Plan, determine eligibility for and terms of awards for participants and make all other determinations necessary or advisable for the administration of the 2012 Plan. To the extent permitted by law, our compensation committee may delegate authority under the 2012 Plan to our Chief Executive Officer or to our other executive officers under conditions and limitations the compensation committee may establish.

The compensation committee may amend, suspend or terminate the 2012 Plan at any time with respect to any shares of common stock as to which awards have not been made. No such action may amend the 2012 Plan without the approval of stockholders if the amendment is required to be submitted for stockholder approval by applicable law, rule or regulation.

Awards. Awards under the 2012 Plan may be made in the form of: options, SARs, stock awards, restricted share units, cash bonuses or other incentive award granted under the 2012 Plan, whether singly, in combination, or in tandem. Any of the foregoing awards may be made subject to attainment of performance goals over any applicable performance period.

Shares Subject to the Plan. The aggregate number of shares of our common stock that may be issued initially pursuant to awards under the 2012 Plan is 3,000,000 shares. The maximum number of shares that may be issued pursuant to the exercise of incentive stock options under the 2012 Plan is 3,000,000. Shares issued under the 2012 Plan may be authorized but unissued shares or treasury shares. Any shares covered by an award, or portion of an award, granted under the 2012 Plan that is forfeited or canceled, expires or is settled in cash will be deemed not to have been issued for purposes of determining the maximum number of shares available for issuance under the plan. Of the 3,000,000 shares of common stock that are eligible for issuance pursuant to awards made under the 2012 Plan, 2,947,400 shares of common stock were subject to options outstanding as of January 31, 2013. As of such date, the outstanding options had a weighted average exercise price of $1.05 per share and had expiration dates ranging from of April 13, 2022 to November 10, 2022.

Adjustment of Shares Subject to 2012 Plan. In the event of certain changes in our capitalization, the compensation committee will adjust, among other award terms, the number and kind of shares or property that may be delivered in connection with awards and the exercise price, grant price or purchase price relating to any award in such manner as the compensation committee determines to be necessary to prevent dilution or enlargement of the rights of participants.

Effect of Change of Control. Upon the occurrence of a change of control, the compensation committee may:

- accelerate, vest or cause the restrictions to lapse with respect to all or any portion of an award under the 2012 Plan;
- cancel such awards for fair value (as determined by the compensation committee);
- provide for the issuance of substitute awards that will substantially preserve the otherwise applicable terms of any affected awards previously granted under the 2012 Plan, as determined by the compensation committee; or
- provide that for a period of at least 10 days prior to the change of control, option awards will be exercisable as to all shares of common stock subject thereto and that upon the occurrence of the change of control, such awards will terminate and be of no further force or effect.

Corporate Performance Objectives. Section 162(m) of the Code limits public companies to an annual deduction for federal income tax purposes of $1,000,000 for compensation paid to their Chief Executive Officer and, based on recent IRS interpretation, the three most highly compensated executive officers determined at the end of each year.

Performance-based compensation is excluded from this limitation. The 2012 Plan is designed to permit the compensation committee to grant awards that qualify as performance-based for purposes of satisfying the conditions of Section 162(m) at such time as the 2012 Plan becomes subject to Section 162(m).

Key Personnel Incentive Program

We have adopted the Key Personnel Incentive Program, or the program, to provide a key employee and consultant with the opportunity to receive incentive bonus payments upon a consummation of a sale transaction, as defined in the program. The compensation committee of our Board of Directors is responsible for administering the program, and the only participants in the program are Paul A. Bottomley and Parag Karmarkar. The program will terminate on the earlier of December 31, 2025 or the occurrence of a sale transaction.

In the event of a sale transaction, each of the participants will be entitled to receive a bonus payment under the program as of the date of the transaction. Mr. Karmarkar would receive a bonus equal to $1,000,000. Dr. Bottomley would receive a bonus equal to (i) $1,000,000, plus (ii) 1.4% of the amount by which the "net proceeds" from the sale transaction exceed $50,000,000, but not to exceed $700,000. For purposes of the program, the "net proceeds" from a sale transaction will be the portion of the aggregate cash and non-cash consideration paid or payable in connection with the consummation of the sale transaction that is distributed, or otherwise available for distribution, to holders of our common stock.

Cardiac EP Business Participation Plan

We have adopted the Cardiac EP Business Participation Plan, or the plan, to enable us to provide a key product development advisor and consultant with financial rewards in the event that we sell our business operations relating to catheter-based MRI-guided cardiac ablation to treat cardiac arrhythmias, which we refer to as our cardiac EP business operations. The cardiac EP business operations include our operations relating to the ClearTrace system for MRI-guided cardiac ablation to treat cardiac arrhythmias, but it does not include our operations relating to our ClearPoint system or any other product or product candidate. The sole participant in the plan is Dr. Nassir F. Marrouche.

In the event that we sell our cardiac EP business operations, whether on a stand-alone basis or as part of the sale of our entire company, the participant will receive a payment under the plan equal to (i) the transaction value paid for or allocated to the cardiac EP business operations in the sale, multiplied by (ii) the participant's "participation interest" at the time of the sale. The participant was initially awarded a participation interest of 6.6%. Pursuant to the terms of the plan, that percentage interest is equitably reduced from time to time to take into account equity financing transactions in which we issue shares of our common stock or securities convertible into shares of our common stock in exchange for cash proceeds. As of January 31, 2012, the participant's participation interest was 3.2%. The plan will terminate on June 2, 2025.

401(k) Plan

We offer a 401(k) plan pursuant to Section 401(k) of the Code. All full time United States employees are eligible to participate in the plan. The plan permits pretax contributions by participants not to exceed annual amounts allowable under the Code. Participants are fully vested in their contributions.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information as of January 31, 2013 regarding the beneficial ownership of our common stock by:

- each person, or group of affiliated persons, who is known by us to own beneficially five percent or more of our common stock;
- each of our directors;
- each of our named executive officers; and
- all our directors and executive officers as a group.

Percentage ownership calculations for beneficial ownership are based on 57,316,725 shares outstanding as of January 31, 2013.

Except as otherwise indicated below, the address of each officer, director and five percent stockholder listed below is c/o MRI Interventions, Inc., One Commerce Square, Suite 2550, Memphis, TN 38103.

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options and warrants that are either immediately exercisable or exercisable within 60 days of January 31, 2013. Likewise, the rules also include shares of common stock issuable pursuant to the conversion of convertible promissory notes that are either immediately convertible or convertible within 60 days of January 31, 2013. These shares are deemed to be outstanding and beneficially owned by the person holding those options, warrants or convertible notes for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them.

Beneficial Owner	Number of Shares Owned	% of Shares Outstanding
5% Stockholders		
Brainlab AG Kapellenstr. 12 85622 Feldkirchen, Germany	3,939,815[(1)]	6.4[(1)]
Sabby Management, LLC 10 Mountainview Road, Suite 205 Upper Saddle River, NJ 07458	2,916,668[(2)]	5.1
Directors and Named Executive Officers		
Kimble L. Jenkins	1,527,788[(3)]	2.6
David W. Carlson	315,952[(4)]	*
Paul A. Bottomley	243,417[(5)]	*
Bruce C. Conway	3,956,794[(6)]	6.9
Charles E. Koob	550,969[(7)]	1.0
James K. Malernee, Jr.	471,720[(8)]	*
Michael A. Pietrangelo	463,003[(9)]	*
Andrew K. Rooke	6,321,141[(10)]	10.7
Michael J. Ryan	4,167	*
John N. Spencer, Jr.	103,508[(11)]	*
Peter G. Piferi	465,952[(12)]	*
Oscar L. Thomas	402,619[(13)]	*
All directors and executive officers as a group (14 persons)	14,880,198[(14)]	24.1

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

(1) As of January 31, 2013, Brainlab AG was the beneficial owner of 3,939,815 shares, or 6.4% of shares outstanding, all of which shares were issuable upon conversion of a convertible note in the principal amount of $2,000,000. However, on March 6, 2013, the terms of the convertible note were amended, among other things, to remove the equity conversion feature. As such, Brainlab AG no longer beneficially owns the shares.

(2) Represents shares held by Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. (collectively, the "Sabby Funds"). Each of the Sabby Funds has indicated that Sabby Management, LLC and Hal Mintz have shared voting and investment power over the shares held by such fund. 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.

(3) Includes 525,819 shares that Mr. Jenkins has the right to acquire through the exercise of options.

(4) Includes 226,667 shares that Mr. Carlson has the right to acquire through the exercise of options.
(5) Includes 108,334 shares that Dr. Bottomley has the right to acquire through the exercise of options.
(6) Includes 32,891 shares jointly held with his spouse, 239,000 shares held solely by his spouse, 350,000 shares that Mr. Conway has the right to acquire through the exercise of warrants, and 1,292,911 shares in the aggregate owned by the Alden M. Conway Trust, the Chase T. Conway Trust, the Merritt Elizabeth Conway Trust, the Edna N. Conway Irrevocable Trust FBO Alden M. Conway, the Edna N. Conway Irrevocable Trust FBO Chase T. Conway, the Edna N. Conway Irrevocable Trust FBO Merritt Elizabeth Conway and the Conway Family GST Trust. Mr. Conway is the trustee of each of the aforementioned trusts and has voting and investment power of each trust's shares, which are held in trust for the benefit of members of his family. Also includes 51,000 shares in the aggregate owned by the Gordon McShane Trust for Alden M. Conway, the Gordon McShane Trust for Chase T. Conway and the Gordon McShane Trust for Merritt E. Conway. Mr. Conway's spouse serves as trustee for each such trust and has voting and investment power of each trust's shares, which are held in trust for the benefit of Mr. Conway's children.
(7) Includes 20,000 shares held jointly with his spouse and 42,084 shares that Mr. Koob has the right to acquire through the exercise of options.
(8) Includes 147,727 shares that Dr. Malernee has the right to acquire through the exercise of warrants and 33,334 shares that Dr. Malernee has the right to acquire through the exercise of options.
(9) Includes 132,500 shares that Mr. Pietrangelo has the right to acquire through the exercise of warrants and 33,334 shares that Mr. Pietrangelo has the right to acquire through the exercise of options.
(10) Includes 500,000 shares owned by Payne Partners, LLC, 260,102 shares owned by Withington Foundation, 2,058,207 shares owned by Rooke Fiduciary Management, 1,000,000 shares that Mr. Rooke has the right to acquire through the exercise of warrants, and 925,000 shares that Rooke Fiduciary Management has the right to acquire through the exercise of warrants. Mr. Rooke has voting and investment power over the shares owned by Payne Partners, LLC, Withington Foundation and Rooke Fiduciary Management, as well as any shares acquired by Rooke Fiduciary Management through the exercise of warrants. Also includes 1,577,832 shares owned by 12 trusts established for the benefit of Mr. Rooke and his family members. Mr. Rooke is the trustee of each of those trusts and he has voting and investment power of each trust's shares.
(11) Includes 56,433 shares jointly held with his spouse, 9,991 shares that Mr. Spencer and his spouse have the right to acquire through the exercise of warrants, and 33,334 shares that Mr. Spencer has the right to acquire through the exercise of options.
(12) Includes 376,667 shares that Mr. Piferi has the right to acquire through the exercise of options.
(13) Includes 313,334 shares that Mr. Thomas has the right to acquire through the exercise of options.
(14) Includes 2,818,309 shares owned by entities controlled by a director, 2,921,743 shares owned by trusts for which a director or his spouse serves as trustee, 3,386,293 shares issuable upon the exercise of options and warrants, and 925,000 shares issuable upon the exercise of warrants held by an entity controlled by a director.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item with respect to securities authorized for issuance under our equity compensation plans is set forth in Item 5 of this Annual Report in the section entitled "Equity Compensation Plan Information".

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

Policies and Procedures for Related Person Transactions

We adopted a related person transactions policy, pursuant to which our executive officers, directors and principal stockholders, including their immediate family members, are not permitted to enter into a related person transaction with us without the consent of our audit committee. Any request for us to enter into a transaction with an executive officer, director, principal stockholder or any of such persons' immediate family members, other than transaction available to all employees generally or involving less than $5,000 when aggregated with similar transactions, must be presented to our audit committee for review, consideration and approval, unless the transaction involves an employment or other compensatory arrangement approved by the compensation committee. All of our directors, executive officers and employees are required to report to our audit committee any such related person transaction. In approving or rejecting the proposed agreement, our audit committee will take into account, among other factors it deems appropriate, whether the proposed related person transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances, the extent of the person's interest in the

transaction and, if applicable, the impact on a director's independence. After consideration of these and other factors, the audit committee may approve or reject the transaction. Consistent with the policy, if we should discover related person transactions that have not been approved, the audit committee will be notified and will determine the appropriate action, including ratification, rescission or amendment of the transaction.

Related Person Transactions

The following is a description of transactions since January 1, 2010 to which we have been a party, in which the amount involved in the transaction exceeds $43,000, which is 1% of the average of our total assets at year-end for our last two completed fiscal years, and in which any of our executive officers, directors and principal stockholders, including their immediate family members, had or will have a direct or indirect material interest.

In November 2010, we issued an aggregate of 10,714,286 units in a private offering in which we received gross proceeds of approximately $3,000,000. We issued the units to existing stockholders and other existing investors. Each unit consisted of a junior secured note and one share of our common stock. We issued 10,714,286 shares of common stock and junior secured notes in the aggregate principal amount of approximately $3,000,000. The notes mature 10 years from the date of issuance and accrue interest at the rate of 3.5% per year. The notes are secured by a security interest in all of our assets. All outstanding principal and interest on the notes is due in a single payment upon maturity. Four of our executive officers, Kimble L. Jenkins, David W. Carlson, Peter G. Piferi and Oscar L. Thomas, purchased an aggregate of 882,726 units in the offering for $247,164. In addition, three of our non-employee directors, Paul A. Bottomley, Charles E. Koob and John C. Thomas, Jr., also purchased an aggregate of 567,203 units for $158,816 in the offering. Five other non-employee directors had advanced a total of $190,000 to the company in anticipation of the offering. However, due to the investment allocations for the offering, those five non-employee directors were not able to purchase units. We returned all funds advanced by the five non-employee directors without interest.

In June through September 2011, we issued unsecured convertible notes in the aggregate principal amount of $1,310,000 to five of our directors, Bruce C. Conway, Charles E. Koob, James K. Malernee, Jr., Michael A. Pietrangelo, John N. Spencer, Jr., and an entity controlled by another director, Andrew K. Rooke. The note holders also received warrants to purchase shares of our common stock. The notes mature two years from the date of issuance, unless earlier converted, and accrue interest at the rate of 15% per year. The warrants were immediately exercisable, have a term of five years, and have an exercise price of $0.01 per share. All principal and accrued interest on the notes automatically converted into shares of our common stock at a conversion price of $0.60 per share upon the effectiveness of our registration statement on Form 10 in February 2012.

On May 9, 2012, we issued an aggregate of $1,250,000 warrants to two non-employee directors, Bruce C. Conway and Andrew K. Rooke, in recognition of their long-standing support of the company. The warrants were fully vested and exercisable upon issuance, have an exercise price of $1.00 per share and have a term of five years.

In July 2012, we entered into securities purchase agreements with certain investors for the sale of shares of our common stock and warrants to purchase shares of our common stock in a private placement offering. In the offering, we sold to the investors 5,454,523 shares of common stock, together with warrants to purchase 2,727,274 shares of common stock, for aggregate gross proceeds of $6.0 million. The warrants were fully vested and exercisable upon issuance, have a term of five years from the date of issuance and had an original exercise price of $1.45 per share. As a result of our January 2013 financing, described below, the exercise price of the warrants has been adjusted to $1.41 per share. Four of our non-employee directors, Bruce C. Conway, James K. Malernee, Jr., Michael A. Pietrangelo and John N. Spencer, Jr., invested $269,980 in the offering and acquired, in the aggregate, 245,435 shares of our common stock and warrants to purchase 122,718 shares of our common stock.

In January 2013, we entered into a securities purchase agreement with certain investors for the sale of shares of our common stock and warrants to purchase shares of our common stock in a private placement offering. In the offering, we sold to the investors 9,201,684 shares of common stock, together with warrants to purchase 4,600,842 shares of common stock, for aggregate gross proceeds of $11.0 million. The warrants were fully vested and exercisable upon issuance, have a term of five years from the date of issuance and have an exercise price of $1.75 per share. Four of our non-employee directors, Bruce C. Conway, James K. Malernee, Jr., Michael A. Pietrangelo and John N. Spencer, Jr., invested $402,000 in the offering and acquired, in the aggregate, 335,000 shares of our common stock and warrants to purchase 167,500 shares of our common stock.

Dr. Paul Bottomley, one of our directors, serves as a consultant to the company. Under his agreement, Dr. Bottomley's consulting fee is $60,000 per year.

In addition to the foregoing disclosure, the terms of the Key Personnel Incentive Plan, which is more fully described in Item 11 of this Annual Report in the section entitled "Benefit Plans—Key Personnel Incentive Plan," is incorporated and restated herein.

Indemnification Agreements

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.

Board Independence

We have not applied to list our securities on a national securities exchange or an inter-dealer quotation system which has requirements that a majority of our Board of Directors be independent. However, for purposes of determining independence, we have adopted the provisions of Nasdaq Marketplace Rule 5605. Our Board of Directors undertook a review of the composition of our Board of Directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board of Directors has determined that none of Drs. Bottomley or Malernee or Messrs. Conway, Koob, Pietrangelo, Rooke or Spencer, representing seven of our nine directors, has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under Rule 5605(a)(2) of the Nasdaq Marketplace Rules. In making such determination, our Board of Directors considered the relationships that each such director has with us and all other facts and circumstances the Board of Directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each director.

Board Committees

Our Board of Directors has an audit committee, a compensation committee, and a corporate governance and nominating committee.

Audit Committee

Our audit committee consists of Messrs. Pietrangelo and Spencer and Dr. Malernee. Mr. Spencer serves as the Chairman of the audit committee. The functions of the audit committee include:

- overseeing the audit and other services of our independent registered public accounting firm and being directly responsible for the appointment, compensation, retention and oversight of the independent registered public accounting firm, who will report directly to the audit committee;
- reviewing and pre-approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services;
- overseeing compliance with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as required;
- reviewing our annual and quarterly financial statements and reports and discussing the financial statements and reports with our independent registered public accounting firm and management;
- reviewing and approving all related person transactions;

- reviewing with our independent registered public accounting firm and management significant issues that may arise regarding accounting principles and financial statement presentation, as well as matters concerning the scope, adequacy and effectiveness of our internal controls over financial reporting;

- establishing procedures for the receipt, retention and treatment of complaints received by us regarding internal controls over financial reporting, accounting or auditing matters; and

- preparing the audit committee report for inclusion in our proxy statement for our annual meeting.

Our Board of Directors has determined that at this time, Mr. Spencer is an audit committee financial expert within the meaning of SEC regulations. Our Board of Directors has determined that all the members of the audit committee satisfy the independence requirements for service on the audit committee. Both our independent registered public accounting firm and management will periodically meet privately with our audit committee.

A copy of the charter for our audit committee is posted on our website at www.mriinterventions.com. The inclusion of our website address in this Annual Report does not include or incorporate by reference the information on our website into this Annual Report.

Compensation Committee

Our compensation committee consists of Messrs. Conway, Koob and Pietrangelo. Mr. Pietrangelo serves as the Chairman of the compensation committee. The functions of the compensation committee include:

- determining the compensation and other terms of employment of our Chief Executive Officer and other executive officers and reviewing and approving our performance goals and objectives relevant to such compensation;

- administering and implementing our incentive compensations plans and equity-based plans, including approving option grants, restricted stock and other awards;

- evaluating and recommending to our Board of Directors the equity incentive-compensation plans, equity-based plans and similar programs advisable for us, as well as modifications or terminations of our existing plans and programs;

- reviewing and approving the terms of any employment-related agreements, severance arrangements, change-in-control and similar agreements/provisions and any amendments, supplements or waivers to the foregoing agreements with our Chief Executive Officer and other executive officers;

- to the extent required, reviewing and discussing the Compensation Discussion & Analysis for our annual report and proxy statement with management and determining whether to recommend to our Board of Directors the inclusion of the Compensation Discussion & Analysis in the annual report and proxy statement; and

- preparing a report on executive compensation for inclusion in our proxy statement for our annual meeting.

Each member of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Code. Furthermore, our Board of Directors has determined that Messrs. Conway, Koob and Pietrangelo each satisfy the independence standards for compensation committees established by the Nasdaq Marketplace Rules.

A copy of the charter for our compensation committee is posted on our website at www.mriinterventions.com. The inclusion of our website address in this Annual Report does not include or incorporate by reference the information on our website into this Annual Report.

Corporate Governance and Nominating Committee

Our corporate governance and nominating committee consists of Messrs. Koob and Rooke and Dr. Malernee. The functions of the corporate governance and nominating committee include:

- evaluating director performance on the Board of Directors and applicable committees of the Board of Directors;
- interviewing, evaluating, nominating and recommending individuals for membership on our Board of Directors;
- evaluating nominations by stockholders of candidates for election to our Board of Directors;
- reviewing and recommending to our Board of Directors any amendments to our corporate governance documents; and
- making recommendations to the Board of Directors regarding management succession planning.

Our Board of Directors has determined that Messrs. Koob and Rooke and Dr. Malernee each satisfy the independence standards for the corporate governance and nominating committees established by the Nasdaq Marketplace Rules.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Independent Registered Public Accounting Firm's Fees

The following table shows the fees billed for audit and other services provided by Cherry Bekaert LLP (formerly Cherry, Bekaert & Holland, L.L.P.), our independent registered public accounting firm, for the years ended December 31, 2011 and 2012.

Year	Audit Fees[1]	Audit-Related Fees[2]	Tax Fees[3]	All Other Fees	Total Fees
2011	$ 70,926	-	-	-	$ 70,926
2012	$ 176,096	-	-	-	$ 176,096

(1) "Audit Fees" consist of fees for professional services provided in connection with the audit of our financial statements and review of our quarterly financial statements. "Audit Fees" also includes fees for services provided in connection with other statutory or regulatory filings or engagements, such as consents and review of documents filed with the SEC.

(2) "Audit-Related Fees" consist of fees for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not reported as "Audit Fees."

(3) "Tax Fees" consist of fees for professional services provided in connection with tax compliance, tax advice and tax planning, including tax return preparation.

Audit Committee Pre-Approval Policies and Procedures

Applicable SEC rules require the audit committee of our Board of Directors to pre-approve audit and non-audit services provided by our independent registered public accounting firm. In 2010, our audit committee began pre-approving all services by our independent registered public accounting firm and has pre-approved all new services since that time.

The audit committee pre-approves all audit and non-audit services to be performed for MRI Interventions by its independent registered public accounting firm. The audit committee does not delegate its responsibilities under the Exchange Act to our management. The audit committee has delegated to the chairman of the audit committee the authority to grant pre-approvals of audit services of up to $25,000; provided that any such pre-approvals are required to be presented to the full audit committee at its next scheduled meeting.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)(1) The following documents are filed under "Item 8. Index to Financial Statements and Supplementary," pages F-1 through F-30, and are included as part of this Annual Report on Form 10-K:

(a)(2) Financial statement schedules are omitted as they are not applicable.

(a)(3) See Item 15(b) below.

(b) Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (1)
3.2	Amended and Restated Bylaws (1)
3.3	Third Amended and Restated Investor Rights' Agreement dated September 20, 2006 (2)
3.4	Form of Subscription Agreement for 10% Secured Convertible Promissory Note Due 2014 (2)
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4.
4.2	Specimen of Common Stock Certificate (3)
4.3	Form of 10% Senior Unsecured Convertible Note Due 2012 (2)
4.4	Form of Junior Secured Promissory Note Due 2020, as amended by that certain Omnibus Amendment dated as of April 5, 2011, as further amended by that certain Second Omnibus Amendment dated as of October 14, 2011 (4)
4.5	10% Subordinated Secured Convertible Note Due 2016 issued to Brainlab AG, as amended (4)
4.6	Form of Unsecured Convertible Promissory Note Due 2013, as amended (2)
4.7	Form of 10% Secured Convertible Promissory Note Due 2014 (2)
4.8	Form of Amendment to 10% Senior Unsecured Convertible Note Due 2012 (2)

Exhibit Number	Description
4.9	Form of Warrant issued to purchasers in the July 2012 private placement to purchase shares of common stock of MRI Interventions, Inc. (5)
4.10	Form of Warrant issued to purchasers in the January 2013 private placement to purchase shares of common stock of MRI Interventions, Inc. (10)
4.11	Amended and Restated Subordinated Secured Note Due 2016, issued to Brainlab AG (11)
10.1+	1998 Stock Option Plan (2)
10.2+	2007 Stock Incentive Plan (2)
10.3+	Amended and Restated Key Personnel Incentive Program (2)
10.4+	2010 Incentive Compensation Plan (2)
10.5+	2010 Non-Qualified Stock Option Plan (2)
10.6	Junior Security Agreement by and between MRI Interventions, Inc. and Landmark Community Bank, in its capacity as collateral agent, dated as of November 5, 2010, as amended by that certain First Amendment dated April 5, 2011, and as further amended by that certain Second Amendment dated October 14, 2011 (2)
10.7	Security Agreement by and between MRI Interventions, Inc. and Landmark Community Bank, in its capacity as collateral agent, dated as of October 14,2011 (2)
10.8+	Form of Indemnification Agreement (2)
10.9†	License Agreement by and between SurgiVision, Inc. and The Johns Hopkins University entered into on or around June 20, 1998, as amended by that certain Amendment to License Agreement dated as of January 15, 2000, and as further amended by that certain Addendum to License Agreement entered into on or around December 7, 2004 (2)
10.10†	License Agreement by and between SurgiVision, Inc. and The Johns Hopkins University entered into on or around December 7, 2006 (2)
10.11†	Technology License Agreement dated as of December 30, 2005 by and between SurgiVision, Inc. and Boston Scientific Neuromodulation Corporation (formerly known as Advanced Bionics Corporation), as amended by that certain Omnibus Amendment dated June 30, 2007, as further amended by that certain Omnibus Amendment #2 dated March 19, 2008 (6)
10.12†	System and Lead Development and Transfer Agreement dated as of December 30, 2005 by and between SurgiVision, Inc. and Boston Scientific Neuromodulation Corporation (formerly known as Advanced Bionics Corporation), as amended by that certain Amendment No. 1 dated May 31, 2006, as further amended by that certain Omnibus Amendment dated June 30, 2007, as further amended by that certain Omnibus Amendment #2 dated March 19, 2008 (6)
10.13†	Technology License Agreement dated as of March 19, 2008 by and between SurgiVision, Inc. and Cardiac Pacemakers, Inc. (2)
10.14†	Development Agreement dated as of March 19, 2008 by and between SurgiVision, Inc. and Cardiac Pacemakers, Inc. (2)

Exhibit Number	Description
10.15†	Cooperation and Development Agreement, dated as of May 4, 2009, by and between SurgiVision, Inc. and Siemens Aktiengesellschaft, Healthcare Sector (6)
10.16	Consulting Agreement with Dr. Paul Bottomley (4)
10.17†	Co-Development and Distribution Agreement dated as of April 5, 2011 by and between SurgiVision, Inc. and Brainlab AG, as amended by that certain First Amendment dated as of July 18, 2011 (6)
10.18†	Master Security Agreement dated April 5, 2011 by and between SurgiVision, Inc. and Brainlab AG (2)
10.19†	Patent License Agreement – Nonexclusive entered into on or around April 27, 2009 by and between SurgiVision, Inc. and National Institutes of Health (2)
10.20†	Master Services and Licensing Agreement dated as of July 20, 2007 by and between SurgiVision, Inc. and Cedara Software Corp., as amended by that certain First Amendment dated January 18, 2011 (6)
10.21†	Exclusive License Agreement entered into on or around June 30, 2008 by and between SurgiVision, Inc. and The Johns Hopkins University (2)
10.22†	Exclusive License Agreement entered into on or around June 30, 2008 by and between SurgiVision, Inc. and The Johns Hopkins University (2)
10.23†	Exclusive License Agreement entered into on or around June 30, 2008 by and between SurgiVision, Inc. and The Johns Hopkins University (2)
10.24	Loan Agreement dated as of October 16, 2009 by and between SurgiVision, Inc. and Boston Scientific Corporation (2)
10.25†	Patent Security Agreement dated as of October 16, 2009 by and between SurgiVision, Inc. and Boston Scientific Corporation (2)
10.26†	Research Agreement by and between SurgiVision, Inc. and The University of Utah entered into on or around July 2, 2007, as amended by that certain First Amendment to the Research Agreement entered into on or around January 8, 2008, as further amended by that certain Second Amendment to the Research Agreement dated April 24, 2009, as further amended by that certain Third Amendment to the Research Agreement dated May 1, 2009, as further amended by that certain Fourth Amendment to the Research Agreement entered into on or around February 25, 2010, as further amended by that certain Fifth Amendment to the Research Agreement dated December 31, 2010, and as further amended by that certain Sixth Amendment to the Research Agreement dated November 28, 2011 (6)
10.27	Lease Agreement, dated as of April 21, 2008, by and between Shaw Investment Company, LLC and Surgi-Vision, Inc., as amended by that certain Amendment to Lease dated January 20, 2011, as further amended by that certain Amendment to Lease dated March 26, 2012 (1)
10.29+	SurgiVision, Inc. Cardiac EP Business Participation Plan (2)
10.30+	Cardiac EP Business Participation Plan Award Agreement, dated June 3, 2010, by and between SurgiVision, Inc. and Nassir F. Marrouche (2)

Exhibit Number	Description
10.31+	Amended and Restated Key Personnel Incentive Award Agreement, dated June 2, 2010, by and between SurgiVision, Inc. and Paul A. Bottomley (2)
10.32+	Key Personnel Incentive Award Agreement, dated June 2, 2010, by and between SurgiVision, Inc. and Paul A. Bottomley (2)
10.33+	Amended and Restated Key Personnel Incentive Award Agreement, dated June 2, 2010, by and between SurgiVision, Inc. and Parag V. Karmarkar (2)
10.34+	MRI Interventions, Inc. 2012 Incentive Compensation Plan (3)
10.35+	MRI Interventions, Inc. 2012 Incentive Compensation Plan Form of Incentive Stock Option Agreement (3)
10.36+	MRI Interventions, Inc. 2012 Incentive Compensation Plan Form of Non-Qualified Stock Option Agreement (3)
10.37†	Amendment No. 1 to Loan Agreement Secured Convertible Promissory Notes and Patent Security Agreement effective February 2, 2012, between MRI Interventions, Inc. and Boston Scientific Corporation (6)
10.38†	Omnibus Amendment No. 3 to Technology License Agreement and System and Lead Development and Transfer Agreement effective February 2, 2012, between MRI Interventions, Inc. and Boston Scientific Neuromodulation Corporation (6)
10.39	Separation Agreement, dated as of May 8, 2012, by and between John Keane and MRI Interventions, Inc. (7)
10.40	Employment Agreement, dated as of June 19, 2012, by and between Kimble L. Jenkins and MRI Interventions, Inc. (8)
10.41+	Employment Agreement, dated as of June 19, 2012, by and between Peter G. Piferi and MRI Interventions, Inc. (8)
10.42+	Employment Agreement, dated as of June 19, 2012, by and between David W. Carlson and MRI Interventions, Inc. (8)
10.43+	Employment Agreement, dated as of June 19, 2012, by and between Oscar L. Thomas and MRI Interventions, Inc. (8)
10.44†	Second Amendment to the Master Services and Licensing Agreement, dated as of June 22, 2012, by and between Merge Healthcare Canada Corp. and MRI Interventions, Inc. (9)
10.45	Form of Securities Purchase Agreement by and among MRI Interventions, Inc. and the purchasers named therein (5)
10.46	Form of Registration Rights Agreement by and among MRI Interventions, Inc. and the purchasers named therein (5)
10.47+	Employment Agreement, dated as of November 10, 2012, by and between Robert C. Korn and MRI Interventions, Inc. (12)

Exhibit Number	Description
10.48+	MRI Interventions, Inc. Non-Employee Director Compensation Plan (12)
10.49	Form of Securities Purchase Agreement by and among MRI Interventions, Inc. and the investors party thereto (10)
10.50	Form of Registration Rights Agreement by and among MRI Interventions, Inc. and the investors party thereto (10)
10.51	Second Amendment to Co-Development and Distribution Agreement, dated March 6, 2013, between MRI Interventions, Inc. and Brainlab AG (11)
23.1*	Consent of Cherry Bekaert LLP, formerly known as Cherry, Bekaert & Holland, L.L.P.
24.1*	Power of Attorney (included on the signature pages hereto)
31.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934
31.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934
32++	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Rule 13a-14(b) Under the Securities Exchange Act of 1934 and Section 1350 of Chapter 63 of Title 18 of the United States Code.
101.INS**	XRBL Instance
101.SCH**	XBRL Taxonomy Extension Schema
101.CAL**	XBRL Taxonomy Extension Calculation
101.DEF**	XBRL Taxonomy Extension Definition
101.LAB**	XBRL Taxonomy Extension Labels
101.PRE**	XBRL Taxonomy Extension Presentation

* Filed herewith.

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

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

\+ Indicates management contract or compensatory plan.

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

(1) Incorporated by reference to the Company's Form 10-Q filed with the Commission on May 11, 2012.

(2) Incorporated by reference to the Company's registration statement on Form 10 filed with the Commission on December 28, 2011.

(3) Incorporated by reference to Amendment No. 1 to the Company's registration statement on Form 10 filed with the Commission on February 9, 2012.

(4) Incorporated by reference to Amendment No. 2 to the Company's registration statement on Form 10 filed with the Commission on February 28, 2012.

(5) Incorporated by reference to the Company's Form 8-K filed with the Commission on July 6, 2012.

(6) Incorporated by reference to Amendment No. 3 to the Company's registration statement on Form 10 filed with the Commission on March 15, 2012.

(7) Incorporated by reference to the Company's Form 8-K filed with the Commission on May 14, 2012.

(8) Incorporated by reference to the Company's Form 8-K filed with the Commission on June 21, 2012.

(9) Incorporated by reference to the Company's Form 8-K filed with the Commission on June 26, 2012.

(10) Incorporated by reference to the Company's Form 8-K filed with the Commission on January 22, 2013.

(11) Incorporated by reference to the Company's Form 8-K filed with the Commission on March 7, 2013.

(12) Incorporated by reference to the Company's registration statement on Form S-1 filed with the Commission on February 11, 2013.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MRI INTERVENTIONS, INC.

Date: March 11, 2012

/s/ Kimble L. Jenkins

Kimble L. Jenkins
Chief Executive Officer and
Chairman of the Board of Directors
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Kimble L. Jenkins and David W. Carlson, and each of them, acting individually, as his attorney-in-fact, each with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and 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)*	March 11, 2013
/s/ David W. Carlson David W. Carlson	*Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)*	March 11, 2013
/s/ Paul A. Bottomley Paul A. Bottomley	*Director*	March 11, 2013
/s/ Bruce C. Conway Bruce C. Conway	*Director*	March 11, 2013
/s/ Charles E. Koob Charles E. Koob	*Director*	March 11, 2013
/s/ James K. Malernee, Jr. James K. Malernee, Jr.	*Director*	March 11, 2013
/s/ Michael A. Pietrangelo Michael A. Pietrangelo	*Director*	March 11, 2013
/s/ Andrew K. Rooke Andrew K. Rooke	*Director*	March 11, 2013
/s/ Michael J. Ryan Michael J. Ryan	*Director*	March 11, 2013
/s/ John N. Spencer, Jr. John N. Spencer, Jr.	*Director*	March 11, 2013

MRI INTERVENTIONS, INC.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
MRI Interventions, Inc.

We have audited the accompanying balance sheets of MRI Interventions, Inc. (the "Company") as of December 31, 2012 and 2011, and the related statements of operations, stockholders' deficit and cash flows for the years ended December 31, 2012, 2011 and 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purposes of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the accompanying financial statements referred to above present fairly, in all material respects, the financial position of MRI Interventions, Inc. as of December 31, 2012 and 2011 and the results of its operations and its cash flows for the years ended December 31, 2012, 2011 and 2010 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the financial statements, during 2012, the Company recognized a net loss of approximately $5.7 million. Further, the Company had a net loss of approximately $8.3 million in 2011 and $9.5 million in 2010. At December 31, 2012 the Company had incurred cumulative losses of approximately $65.5 million. Management's plans in regard to this matter are described in Note 1.

/s/ Cherry Bekaert LLP
Tampa, Florida
March 11, 2013

MRI INTERVENTIONS, INC.

Balance Sheets

	December 31, 2012	December 31, 2011
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,620,005	$ 145,478
Accounts receivable	445,432	401,580
Inventory	899,702	968,818
Cost of deferred product revenue	47,639	-
Prepaid expenses and other current assets	63,234	19,773
Total current assets	3,076,012	1,535,649
Property and equipment, net	1,287,115	1,218,830
Software license inventory	1,137,500	-
Deferred financing costs	24,219	214,469
Other assets	26,900	61,481
Total assets	$ 5,551,746	$ 3,030,429
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,961,195	$ 4,037,168
Accrued compensation	278,124	1,011,413
Accrued interest	-	971,733
Other accrued liabilities	1,177,142	2,015,046
Derivative liability	789	-
Related party deferred license revenue	650,000	2,600,000
Deferred product revenue	112,725	-
Convertible notes payable, net of unamortized discount of $117,405	-	3,953,595
Total current liabilities	4,179,975	14,588,955
Related party deferred revenue	-	1,396,374
Related party accrued interest	-	799,102
Other accrued liabilities	574,722	209,143
Related party convertible notes payable, net of unamortized discount of $0 and $432,706 at December 31, 2012 and 2011, respectively	4,338,601	4,377,294
Convertible notes payable, net of unamortized discount discount of $0 and $316,610 at December 31, 2012 and 2011, respectively	2,000,000	3,308,390
Junior secured notes payable, net of unamortized discount of $2,804,451 and $2,805,686 at December 31, 2012 and December 31, 2011, respectively	195,549	194,314
Total liabilities	11,288,847	24,873,572
Commitments and contingencies (Notes 5, 8, 10 and 11)	-	-
Stockholders' deficit:		
Series A convertible preferred stock; $.01 par value; 8,000,000 shares authorized, 7,965,000 shares issued and outstanding at December 31, 2011	-	7,965,000
Common stock, $.01 par value; at December 31, 2012, 100,000,000, 48,418,830 and 48,093,000 shares authorized, issued, and outstanding, respectively; at December 31, 2011, 70,000,000 16,410,820, and 16,084,990 shares authorized, issued, and outstanding, respectively	484,187	164,108
Additional paid-in capital	60,953,692	31,495,593
Treasury stock, at cost, 325,830 common shares	(1,679,234)	(1,679,234)
Accumulated deficit	(65,495,746)	(59,788,610)
Total stockholders' deficit	(5,737,101)	(21,843,143)
Total liabilities and stockholders' deficit	$ 5,551,746	$ 3,030,429

See notes to financial statements.

MRI INTERVENTIONS, INC.

Statements of Operations

	Years Ended December 31,		
	2012	**2011**	**2010**
Revenues:			
Related party license revenues	$ 3,346,374	$ 2,600,000	$ 2,600,000
Service revenues	541,182	63,328	-
Product revenues	1,170,679	1,154,838	69,450
Total revenues	5,058,235	3,818,166	2,669,450
Costs and operating expenses:			
Cost of product revenues	555,703	656,414	16,314
Research and development:			
Research and development costs	2,484,503	4,251,476	5,681,031
Reversal of R&D obligation (see Note 10)	(882,537)	-	-
Selling, general, and administrative	6,029,844	4,831,814	4,698,786
Costs of withdrawn IPO	-	-	1,788,609
Total costs and operating expenses	8,187,513	9,739,704	12,184,740
Operating loss	(3,129,278)	(5,921,538)	(9,515,290)
Other income (expense):			
Gain (loss) on change in fair value of derivative liability	(789)	-	1,227,500
Other income, net	3,586	104,850	413,623
Interest income	14,152	3,481	10,403
Interest expense	(2,594,807)	(2,498,204)	(1,590,471)
Net loss	$ (5,707,136)	$ (8,311,411)	$ (9,454,235)
Net loss per share attributable to common stockholders:			
Basic and diluted	$ (0.14)	$ (0.52)	$ (1.40)
Weighted average shares outstanding:			
Basic and diluted	40,374,048	15,961,371	6,773,714

See notes to financial statements.

MRI INTERVENTIONS, INC.

Statements of Stockholders' Deficit
Years Ended December 31, 2010, 2011, and 2012

	Convertible Preferred Stock Series A		Common Stock		Additional Paid-in	Treasury	Accumuluated	
	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	Total
Balances, January 1, 2010	7,965,000	$ 7,965,000	5,129,280	$ 54,551	$ 25,794,862	$ (1,679,234)	$ (42,022,964)	$ (9,887,785)
Employee share-based compensation	-	-	-	-	245,462	-	-	245,462
Fair value of conversion feature of senior unsecured convertible notes payable	-	-	-	-	834,555	-	-	834,555
Warrants issued in connection with senior unsecured convertible notes payable	-	-	-	-	120,218	-	-	120,218
Elimination of fractional shares resulting from the reverse stock split	-	-	(103)	(1)	(514)	-	-	(515)
Issuance of common stock in payment of director fees	-	-	16,527	165	29,584	-	-	29,749
Issuance of common stock in connection with the sale of unit securities	-	-	10,714,286	107,143	2,668,157	-	-	2,775,300
Net loss for the year	-	-	-	-	-	-	(9,454,235)	(9,454,235)
Balances, December 31, 2010	7,965,000	7,965,000	15,859,990	161,858	29,692,324	(1,679,234)	(51,477,199)	(15,337,251)
Employee share-based compensation	-	-	-	-	989,902	-	-	989,902
Warrants issued in connection with senior unsecured convertible notes payable	-	-	-	-	649,734	-	-	649,734
Fair value of conversion feature of 2011 junior secured convertible notes payable	-	-	-	-	163,633	-	-	163,633
Proceeds from exercise of warrants	-	-	225,000	2,250	-	-	-	2,250
Net loss for the year	-	-	-	-	-	-	(8,311,411)	(8,311,411)
Balances, December 31, 2011	7,965,000	7,965,000	16,084,990	164,108	31,495,593	(1,679,234)	(59,788,610)	(21,843,143)
Employee share-based compensation	-	-	-	-	1,168,034	-	-	1,168,034
Beneficial conversion feature of convertible notes payable	-	-	-	-	383,204	-	-	383,204
Warrants issued with convertible notes payable	-	-	-	-	383,204	-	-	383,204
Warrants issued to placement agents and subagents	-	-	-	-	237,299	-	-	237,299
Conversion of convertible notes and accrued interest into common stock	-	-	16,397,727	163,977	11,216,232	-	-	11,380,209
Conversion of Series A preferred stock into common stock	(7,965,000)	(7,965,000)	7,965,000	79,650	7,885,350	-	-	-
Non-employee share based compensation	-	-	-	-	863,257	-	-	863,257
Common stock issued in exchange for settlement of software license obligations	-	-	1,500,000	15,000	1,647,500	-	-	1,662,500
Issuance of common stock in payment of director fees	-	-	51,928	519	124,106	-	-	124,625
July 2012 unit offering	-	-	5,454,523	54,545	5,461,950	-	-	5,516,495
Exercise of options and warrants	-	-	638,832	6,388	87,963	-	-	94,351
Net loss for the year	-	-	-	-	-	-	(5,707,136)	(5,707,136)
Balances, December 31, 2012	-	$ -	48,093,000	$ 484,187	$ 60,953,692	$ (1,679,234)	$ (65,495,746)	$ (5,737,101)

See notes to financial statements.

MRI INTERVENTIONS, INC.

Statements of Cash Flows

	Years Ended December 31,		
	2012	**2011**	**2010**
Cash flows from operating activities:			
Net loss	$ (5,707,136)	$ (8,311,411)	$ (9,454,235)
Adjustments to reconcile net loss to net cash flows from operating activities:			
Depreciation and license amortization	416,970	354,885	266,223
Expenses paid through the issuance of common stock	124,625	-	29,749
Share-based compensation	2,031,291	989,902	245,462
Loss (gain) on change in fair value of derivative liability	789	-	(1,227,500)
Amortization and write-off of debt issuance costs and original issue discounts	2,061,078	1,359,687	889,624
Write-off of costs of withdrawn IPO	-	-	1,788,609
Increase (decrease) in cash resulting from changes in:			
Accounts receivable	(43,852)	(370,040)	(31,540)
Inventory	(270,686)	91,519	(1,214,962)
Cost of deferred product revenue	(47,639)	-	-
Prepaid expenses and other current assets	(43,461)	(3,233)	38,487
Other assets	16,581	4,520	19,520
Accounts payable and accrued expenses	(2,738,727)	2,244,576	3,543,310
Deferred revenue	(3,233,649)	(2,600,000)	(2,600,000)
Net cash flows from operating activities	(7,433,816)	(6,239,595)	(7,707,253)
Cash flows from investing activities:			
Purchases of property and equipment	(127,453)	(26,101)	(61,704)
Net cash flows from investing activities	(127,453)	(26,101)	(61,704)
Cash flows from financing activities:			
Net proceeds from pre-public unit offerings	3,424,950	2,831,610	3,000,000
Net proceeds from issuance of convertible notes	-	2,000,000	3,777,142
Net proceeds from PIPE financing	5,516,495	-	-
Proceeds from warrant exercises	94,351	2,250	-
Net cash flows from financing activities	9,035,796	4,833,860	6,777,142
Net change in cash and cash equivalents	1,474,527	(1,431,836)	(991,815)
Cash and cash equivalents, beginning of year	145,478	1,577,314	2,569,129
Cash and cash equivalents, end of year	$ 1,620,005	$ 145,478	$ 1,577,314
SUPPLEMENTAL CASH FLOW INFORMATION			
Cash paid for:			
Income taxes	$ -	$ -	$ 49,250
Interest	$ 33,200	$ -	$ -

See notes to financial statements.

MRI INTERVENTIONS, INC.

Statements of Cash Flows

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

- In February 2012, the terms of related party notes payable were modified (see Note 6) and accrued interest of $838,601 was added to the principal balances of the original notes.

- Upon the effectiveness of the Company's Form 10 registration statement in February 2012, the principal balance of convertible notes payable totaling $10,811,500 and the related accrued interest of $974,311 were converted into shares of the Company's common stock (see Notes 7 and 8). In addition, unamortized debt discounts totaling $405,602 at the conversion date related to the relative fair value of warrants issued in connection with the issuance of the convertible notes (originally accounted for as equity) were offset against additional paid-in capital.

- In February 2012, warrants with a fair value of $237,299 (recorded as deferred financing costs and additional paid-in capital) were issued to the placement agent and its sub-placement agents in connection with the Company's sale of units consisting of secured convertible notes and common stock warrants (see Note 7).

- In January and February 2012, both the $383,204 relative fair value of warrants and the $383,204 intrinsic value of the beneficial conversion feature associated with notes issued by the Company in an offering of units (see Note 7) were recorded as additional paid-in capital and a discount to the convertible notes payable.

- In June 2012, the Company issued 1,500,000 shares of its common stock in exchange for settlement of accounts payable of $612,500 and the purchase of software licenses in the amount of $1,050,000 (see Note 10).

- In 2010, warrants (recorded as deferred financing costs and additional paid-in capital) were issued with a fair value of $120,218 to the placement agent in connection with the sale of the senior unsecured convertible notes.

- The $163,633 fair value of the warrants and the $163,633 intrinsic value of the beneficial conversion feature associated with the notes, issued in the 2011 Unit Offering (see Note 7) were recorded as additional paid-in capital and a discount to the convertible notes payable.

- At December 31, 2012, and 2011, deferred financing costs in the amount of $24,219 and $66,500, respectively, were included in accrued expenses.

- ClearPoint reusable components were transferred from inventory to loaned systems, which is a component of property and equipment, during the years ended December 31, 2012, 2011 and 2010 with costs of $339,802, $550,105 and $173,870, respectively.

See notes to financial statements.

1. Description of the Business and Liquidity

MRI Interventions, Inc. (the "Company") is a medical device company focused on the development and commercialization of technology that enables physicians to see inside the brain and heart using direct, intra-procedural magnetic resonance imaging, or MRI, guidance while performing minimally invasive surgical procedures. The Company was incorporated in the State of Delaware on March 12, 1998.

The Company's ClearPoint system, an integrated system comprised of reusable components and disposable products, is designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. In 2010, the Company received 510(k) clearance from the Food and Drug Administration ("FDA") to market the ClearPoint system in the United States for general neurological interventional procedures. The Company's ClearTrace system is a product candidate under development that is designed to allow catheter-based minimally invasive procedures in the heart to be performed in an MRI suite. The Company has also entered into exclusive licensing and development agreements (see Note 5) with affiliates of Boston Scientific Corporation ("BSC"), pursuant to which BSC may incorporate certain of the Company's MRI-safety technologies into BSC's implantable leads for cardiac and neurological applications.

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

Liquidity and Management's Plans

For the years ended December 31, 2012, 2011 and 2010, the Company incurred net losses of $5,707,136, $8,311,411, and $9,454,235, respectively, and the cumulative net loss since the Company's inception through December 31, 2012 was $65,495,746. The Company expects such losses to continue through at least the year ended December 31, 2013 as it continues to commercialize its ClearPoint system and pursue research and development activities. Net cash used in operations was $7,433,816, $6,239,595, and $7,707,253 for the years ended December 31, 2012, 2011, and 2010, respectively. Since inception, the Company has financed its activities principally from the sale of equity securities, the issuance of convertible notes and license arrangements.

The Company's primary financing activities during the years ended December 31, 2012, 2011, and 2010 were:

- the July 2012 PIPE financing, which resulted in net proceeds of $5,516,495;
- the unit offering the Company completed in February 2012, which resulted in net proceeds of $4,946,560, $3,424,950 of which were received in 2012 and $1,521,610 of which were received in 2011;
- the unit offering the Company completed in September 2011, which resulted in net proceeds of $1,310,000;
- the issuance of a convertible note payable in April 2011, which resulted in net proceeds of $2,000,000;
- the November 2010 unit offering, which resulted in net proceeds of $3,000,000; and
- the March 2010 convertible notes payable offering, which resulted in net proceeds of $3,777,142.

In January 2013, the Company completed a private offering (see Note 11) in which it sold securities for net proceeds of approximately $9,900,000. While the Company expects to continue to use cash in operations, the Company believes its existing cash and cash equivalents at December 31, 2012 of $1,620,005, combined with the net proceeds from the January 2013 private offering, will be sufficient to meets its anticipated cash requirements through at least March 2014. During 2013, the Company plans to increase its spending on sales and marketing activities as it completes the commercial rollout of its ClearPoint system, from which the Company expects to increase ClearPoint system product revenues. Certain planned expenditures are discretionary and could be deferred if the Company is required to do so to fund critical operations. To the extent the Company's available cash and cash equivalents are insufficient to satisfy its long-term operating requirements, the Company will need to seek additional sources of funds, from the sale of additional equity, debt or other securities or through a credit facility, or modify its current business plan. There can be no assurances that the Company will be able to obtain additional financing on commercially reasonable terms. The sale of additional equity or convertible debt securities will likely result in dilution to the Company's current stockholders.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Concentrations of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company holds its cash and cash equivalents on deposit with financial institutions in the United States insured by the Federal Deposit Insurance Corporation ("FDIC"). At December 31, 2012 no amounts on deposit were in excess of FDIC limits.

The Company is subject to risks common to emerging companies in the medical device industry including, but not limited to: new technological innovations, dependence on key personnel, dependence on key suppliers, changes in general economic conditions and interest rates, protection of proprietary technology, compliance with changing government regulations and taxes, uncertainty of widespread market acceptance of products, access to credit for capital purchases by customers, and product liability claims. Certain components used in manufacturing have relatively few alternative sources of supply and establishing additional or replacement suppliers for such components cannot be accomplished quickly. The inability of any of these suppliers to fulfill the Company's supply requirements may negatively impact future operating results.

Receivables at December 31, 2012 and all product revenues for the year ended December 31, 2012 relate to sales to a limited number of customers located in the United States ("U.S.") and to one distributor outside of the U.S. Sales to two of these hospital customers and the distributor each represented between 14% and 16% of total product sales, respectively. The Company may perform credit evaluations of its customers' financial condition and, generally, requires no collateral from its customers. The Company will provide an allowance for doubtful accounts when collections become doubtful, but the Company has not experienced any credit losses or recorded any allowances to date.

Cash and Cash Equivalents

Cash and cash equivalents include all highly liquid investments with an original maturity of three months or less.

Fair Value Measurements

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

The table below reflects the carrying values and the estimated fair values of the Company's outstanding notes payable at December 31, 2012:

	Carrying Values	Estimated Fair Value
Related party BSC convertible notes payable	$ 4,338,601	$ 3,636,380
Convertible note payable	2,000,000	2,000,000
Junior secured notes payable	195,549	1,920,844

The difference between the carrying value of the related party BSC convertible notes payable, which is equal to the face value due to troubled debt restructuring accounting (see Note 6), and the estimated fair value is attributable to the fact that no interest is charged per the terms of the convertible notes payable, which is below market. The difference between the carrying value and the fair value of the junior secured notes payable relates to an unamortized debt discount. This discount resulted from the relative fair value assigned to the junior secured notes payable at the time of issuance, as the notes were issued in connection with a unit offering, with the units consisting of a note payable and shares of the Company's common stock.

The Company measures certain financial assets and liabilities at fair value on a recurring basis. GAAP provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to quoted prices in active markets for identical assets and liabilities ("Level 1"), the next priority is given to quoted prices for similar assets or liabilities in active markets or quoted prices for identical or similar assets or liabilities in markets that are not active, that is, markets in which there are few transactions for the asset or liability ("Level 2") and the lowest priority to unobservable inputs ("Level 3"). See Note 6 for fair value information related to the Company's derivative liability, which is the only asset or liability carried at fair value by the Company on a recurring basis at December 31, 2012.

Inventory

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

Property and Equipment

Property and equipment, including loaned ClearPoint systems, are recorded at cost and are depreciated on a straight-line basis over their estimated useful lives, principally five to seven years. Leasehold improvements are depreciated on a straight-line basis over the lesser of their estimated useful lives or the life of the related lease.

Impairment of Long-Lived Assets

The Company evaluates the recoverability of its long-lived assets (finite-lived intangible assets and property and equipment). Whenever events or changes in circumstances indicate that the carrying amount of such assets may not be fully recoverable, the expected undiscounted future cash flows are compared to the net book value of the related assets. If the net book value of the related assets exceeds the undiscounted expected future cash flows of the assets, the carrying amount would be reduced to the present value of the expected future cash flows and an impairment loss would be recognized. The Company has not recorded any impairment losses for the years ended December 31, 2012, 2011, or 2010.

Revenue Recognition

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

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

(2) *Sales of ClearPoint disposable products* - Revenues from the sale of ClearPoint disposable products utilized in procedures performed using the ClearPoint system are recognized at the time risk of loss passes, which is generally at shipping point or upon delivery to the customer's location, depending upon the specific terms agreed upon with each customer.

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

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

  This agreement required achievement of specified milestones in the development of an MRI-safe implantable lead by December 31, 2012. The agreement provided that, if the milestones were not achieved by that date and such failure was not the result of BSC Neuro's failure to reasonably cooperate with the Company in pursuing the milestones, the Company would be required to repay BSC Neuro certain amounts, including any development expenses and milestone payments previously made to the Company under the agreement and any patent prosecution costs incurred by BSC Neuro with respect to the intellectual property licensed under the agreement. In drafting that provision of the agreement, the parties contemplated that the Company would be the party primarily performing the lead development activities, with assistance to be provided by BSC Neuro. However, subsequent to the execution of the agreement, BSC Neuro assumed responsibility for the lead development efforts under the agreement, and, consequently, BSC Neuro wholly controlled the pace and progress of the development efforts. The existence of the repayment provision indicated that the sales price was not fixed or determinable and all monies received should be deferred until such time that BSC Neuro acknowledged that the repayment provision would not be triggered. BSC Neuro acknowledged that the repayment will not be triggered and, as such, the related party revenue under this agreement that had previously been deferred has been recognized by the Company during the year ended December 31, 2012.

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

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

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

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

- *Service Revenues* - In 2011, the Company entered into an agreement to provide development services to a third party. Under this agreement, the Company earns revenue equal to costs incurred for outside expenses related to the development services provided, plus actual direct internal labor costs (including the cost of employee benefits), plus an overhead markup of the direct internal labor costs incurred. Revenue is recognized in the period in which the Company incurs the related costs. During the years ended December 31, 2012 and 2011, the Company recorded service revenues of approximately $531,000 and $63,000, respectively, related to this agreement. From time to time, the Company may also perform development services for other third parties evidenced by either a development agreement or a purchase order. During 2012, the Company recorded revenues totaling $10,000 for such services. The Company did not recognize any service revenues for the year ended December 31, 2010.

Research and Development Costs

Costs related to research, design and development of products are charged to research and development expense as incurred. These costs include direct salary and employee benefit related costs for research and development personnel, costs for materials used in research and development activities and costs for outside services. Since most of the expenses associated with the Company's development service revenues relate to existing internal resources, these amounts are included in research and development costs.

Costs of Withdrawn IPO

In 2009, the Company filed a registration statement with the SEC relating to the initial public offering ("IPO") of shares of the Company's common stock. In 2010, the Company made the decision to withdraw its registration statement and to cancel the planned IPO. Costs which had been deferred totaling $1,788,609 were recorded as costs of withdrawn IPO in the statement of operations in 2010.

Other Income (Expense)

During 2010 the Company recorded other income related to grants received under the Qualifying Therapeutic Discovery Project program administered under section 48D of the Internal Revenue Code. Included in net other income in 2010 is other income related to the grants of $415,615, which is net of expenses paid to a service firm that assisted the Company in completing the grant applications.

Income Taxes

The Company accounts for income taxes under FASB ASC 740, "Income Taxes." Deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax basis. Such assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in tax rates is recognized in the period that includes the enactment date.

Due to uncertainties surrounding the realization of the deferred income tax assets in future periods, the Company has recorded a 100% valuation allowance against its net deferred income tax assets. If it is determined in the future that it is more likely than not that any deferred income tax assets are realizable, the valuation allowance will be reduced by the estimated net realizable amounts.

Net Loss Per Share

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

	As of December 31,		
	2012	**2011**	**2010**
Stock options	6,432,127	3,679,977	3,762,477
Warrants	8,763,836	1,922,944	435,986
Shares under convertible note agreements	4,454,362	1,046,263	997,678
	19,650,325	6,649,184	5,196,141

Share-Based Compensation

The Company accounts for compensation for all arrangements under which employees and others receive shares of stock or other equity instruments (including options and warrants) in accordance with FASB ASC 718, "Compensation – Stock Compensation." Under ASC 718, the fair value of each award is estimated as of the grant date and amortized as compensation expense over the requisite vesting period. The fair values of the Company's share-based awards are estimated on the grant dates using the Black-Scholes valuation model. This valuation model requires the input of highly subjective assumptions, including the expected stock volatility, estimated award terms and risk-free interest rates during the expected terms. To estimate the expected terms, the Company utilizes the "simplified" method for "plain vanilla" options discussed in the SEC's Staff Accounting Bulletin 107 ("SAB 107"). The Company believes that all factors listed within SAB 107 as pre-requisites for utilizing the simplified method apply to the Company and the Company's share-based compensation arrangements. The Company intends to utilize the simplified method for the foreseeable future until more detailed information about exercise behavior becomes available. The Company based its estimate of expected volatility on the average of historical volatilities of publicly traded companies it deemed similar to the Company because the Company lacks its own relevant historical volatility data. The Company will consistently apply this methodology until a sufficient amount of historical information regarding the volatility of the Company's own share prices becomes available. The Company utilizes risk-free interest rates based on a zero-coupon U.S. treasury instruments, the terms of which are consistent with the expected terms of the stock awards. The Company has not paid and does not anticipate paying cash dividends on its shares of common stock; therefore, the expected dividend yield is assumed to be zero.

Fair Value Determination of Privately-Held Equity Securities

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

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

Derivative Financial Instruments

The Company accounts for derivative financial instruments in accordance with FASB ASC Topic 815, "Derivatives and Hedging," which establishes accounting and reporting standards for derivative instruments and hedging activities, including certain derivative instruments embedded in other financial instruments or contracts and requires recording of all derivatives on the balance sheet at their fair values (Note 6). Changes in the fair values of derivatives are recorded each period as gains or losses in the statements of operations unless the derivatives qualify for hedge accounting. At December 31, 2012 and 2011, the Company did not have any derivative instruments that were designated as hedges.

New Accounting Pronouncements

In June 2011, the FASB issued new accounting guidance related to the presentation of comprehensive income that increases comparability between GAAP and International Financial Reporting Standards ("IFRS"). This guidance requires companies to present the components of net income and other comprehensive income either as one continuous statement or as two consecutive statements, eliminating the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. Public entities are required to apply this guidance for fiscal years and interim periods within those years, beginning after December 15, 2011. The Company adopted this guidance during the year ended December 31, 2012, and the adoption of this guidance had no impact on the Company's results of operations or financial position and is not expected to have a significant impact on the Company's future results of operations or financial position.

In May 2011, the FASB issued guidance to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between GAAP and IFRS. This update changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. This guidance was effective for annual periods beginning after December 15, 2011 (the 2012 fiscal year) and applied prospectively. As this guidance is only disclosure related, it did not have any effect on the carrying value of the assets or liabilities on the Company's balance sheet as of December 31, 2012.

For the year ended December 31, 2012, the Company adopted the accounting standard update regarding fair value measurement. This update was issued to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and International Financial Reporting Standards. This standard update also changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. The adoption of this standard update did not have a significant impact on the Company's financial statements.

In July 2012, the accounting standard update regarding testing of intangible assets for impairment was issued. This standard update allows companies the option to perform a qualitative assessment to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired. An entity is not required to calculate the fair value of an indefinite-lived intangible asset and perform the quantitative impairment test unless the entity determines that it is more likely than not the asset is impaired. The Company will adopt this standard update during the first quarter of 2013. The adoption of this standard update is not expected to have a significant impact on the Company's financial statements.

3. Inventory

Inventory consists of the following as of December 31:

	2012	2011
Work in process	$ 494,290	$ 454,366
Software license inventory	344,500	467,000
Finished goods	60,912	47,452
Inventory included in current assets	899,702	968,818
Software license inventory (see Note 10)	1,137,500	-
	$ 2,037,202	$ 968,818

4. Property and Equipment

Property and equipment consist of the following as of December 31:

	2012	2011
Equipment	$ 1,044,969	$ 934,253
Furniture and fixtures	105,376	106,054
Leasehold improvements	157,236	157,236
Computer equipment and software	114,786	101,482
Loaned systems	1,063,777	723,975
	2,486,144	2,023,000
Less accumulated depreciation and amortization	(1,199,029)	(804,170)
Total property and equipment, net	$ 1,287,115	$ 1,218,830

Depreciation and amortization expense for the years ended December 31, 2012, 2011, and 2010 was $398,970, $336,885, and $246,331, respectively.

The Company may loan the reusable components of a ClearPoint system to a customer. Any such customer can then use the loaned ClearPoint system to perform procedures using ClearPoint disposable products which are purchased from the Company. Accordingly, the $1,063,777 and $723,975 of loaned systems at December 31, 2012 and 2011, respectively, represent the historical cost of ClearPoint reusable components transferred from inventory to property and equipment. Depreciation on loaned ClearPoint systems is computed using the straight-line method based on an estimated useful life of five years. At December 31, 2012 and 2011, accumulated depreciation on loaned systems was $242,132 and $73,846, respectively.

5. Related Party License Agreements

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

BSC Neuro Agreement

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

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

The Company did not receive any up-front license payments pursuant to the BSC Neuro Agreement. In addition to other potential payments under the agreement as described above, the Company could receive over $500,000 in incentive payments for incremental development work, but only if and to the extent BSC Neuro requests the Company to perform such work. The Company does not expect such a request to be made.

The BSC Neuro Agreement required specified milestones in the development of an MRI-safe implantable lead to be achieved by December 31, 2012. The BSC Neuro Agreement provided that, if the milestones were not achieved by that date and such failure was not the result of BSC Neuro's failure to reasonably cooperate with the Company in pursuing the milestones, the Company would be required to repay BSC Neuro certain amounts, including any development expenses and milestone payments previously made to the Company under the agreement and any patent prosecution costs incurred by BSC Neuro with respect to the intellectual property licensed under the agreement. However, BSC Neuro assumed responsibility from the Company for the lead development efforts under the agreement, and, consequently, BSC Neuro wholly controlled the pace and progress of the development efforts. BSC Neuro has acknowledged that the repayment provision will not be triggered, consequently, the Company recognized revenue of approximately $746,000 during the year ended December 31, 2012 which had been previously recorded as deferred revenue.

BSC Cardiac Agreement

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

Pursuant to the BSC Cardiac Agreement, in addition to prospective royalty payments on net sales of licensed products, the Company received a non-refundable licensing fee of $13,000,000 in 2008, and the Company could receive future milestone-based payments associated with the successful development and regulatory approval of the various implantable cardiac leads that incorporate the Company's technology, subject to certain patents being issued on patent applications licensed to BSC Cardiac. However, there can be no assurance of the amount of milestone-based payments the Company ultimately will receive under the BSC Cardiac Agreement, if any. The Company believes that BSC Cardiac does not intend to incorporate the Company's technology into each of the different types of implantable cardiac leads addressed by the agreement, which reduces the potential milestone-based payments the Company could receive. The Company recorded the $13,000,000 payment received in 2008 as deferred revenue and is recognizing revenue over the five year estimated period of continuing involvement (see Note 2, Revenue Recognition). The Company determined the five year estimated period of continuing involvement based upon the Company's internal development plan and projected timeline for the different implantable cardiac leads. The Company reevaluates its estimated remaining period of continuing involvement at each reporting period, and any changes will be incorporated into the determination of revenue recognition on a prospective basis.

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

The remaining related party deferred license revenue under the BSC Cardiac Agreement of $650,000 at December 31, 2012 is expected to be recognized as revenue during 2013.

6. Related Party Notes Payable

Related Party BSC Convertible Notes Payable

In 2009, the Company entered into a convertible note payable arrangement with BSC. During 2009, the Company borrowed an aggregate of $3,500,000 from BSC under this arrangement pursuant to three convertible notes payable (the "BSC Notes"). These borrowings accrued interest at 10% per year and were scheduled to mature on the second anniversary of the date on which the funds were advanced. Effective February 2, 2012, the Company entered into a loan modification with BSC (also see Note 5) pursuant to which (i) interest accrued under each of the BSC Notes as of February 2, 2012 was added to the principal balance of the note, (ii) beginning February 2, 2012, the interest rate of each of the BSC Notes was reduced from 10% per year to 0%, and (iii) the maturity date of each of the BSC Notes was extended by three years (until October through December 2014). The Company recorded interest expense under the BSC Notes of $39,499, $388,678, and $356,452 during the years ended December 31, 2012, 2011, and 2010, respectively. As of February 2, 2012, the outstanding aggregate loan balance, including principal and interest, owed to BSC was $4,338,601. Pursuant to ASC 470-60, "Troubled Debt Restructurings by Debtors," the loan modification was considered a "Troubled Debt Restructuring." However, because the total future cash payments required under the new terms of the BSC Notes were not reduced from what was owed at the time of the loan modification, no gain was recorded under Troubled Debt Restructuring accounting.

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

The Company analyzed the terms of the conversion feature of the BSC Notes under ASC Topic 815, "Derivatives and Hedging," and determined, based upon the conversion price reset provision that the conversion feature should be accounted for as a derivative liability (see Note 2, Summary of Significant Accounting Policies – Fair Value Measurements). Under this guidance the conversion feature was initially measured at fair value upon the issuance of the BSC Notes and has been adjusted to the current fair value at the end of each reporting period.

Changes in fair value are recorded in other income (expense) in the related statements of operations. The Company calculates the fair value of this derivative liability utilizing the Black-Scholes pricing model. The fair value of the derivative liability was computed using Level 2 inputs at December 31, 2012 and Level 3 inputs for all reporting periods prior to 2012. The assumptions used in calculating the fair value of the derivative liability are as follows:

	December 31,	
	2012	**2011**
Dividend yield	0%	0%
Expected volatility	41.98%	46.58%
Risk free interest rate	0.31%	0.25%
Expected remaining term (years)	1.8	0.15
Common stock price	$1.60	$0.60

The changes in the fair value of the derivative liability are as follows:

Derivative liability at January 1, 2010	$ 1,227,500
Gain on change in fair value of derivative liability	(1,227,500)
Derivative liability at December 31, 2010 and 2011	-
Loss on change in fair value of derivative liability	789
Derivative liability at December 31, 2012	$ 789

Related Party 2011 Unsecured Convertible Notes Payable

In June through September 2011, the Company issued unsecured convertible notes (the "Summer 2011 Notes") in the aggregate amount of $1,310,000 to six non-employee directors of the Company. The note holders also received warrants to purchase 1,310,000 shares of the Company's common stock in the aggregate. The Summer 2011 Notes had two-year maturities and accrued interest at 15% per year. The warrants were fully vested upon issuance, have a term of two years, and have an exercise price of $0.01 per share. The original terms of the Summer 2011 Notes provided for automatic conversion of the notes into shares of the Company's common stock upon consummation of an initial public offering of shares of the Company's common stock, based on a conversion price equal to 60% of the public offering price. In addition, the original terms of the Summer 2011 Notes provided for optional conversion of the notes, at the election of the note holder, upon consummation of a reverse merger of the Company into a public shell company, based on a conversion price equal to 60% of the fair market value of the Company's common stock at the time of the merger. The Summer 2011 Notes were amended in December 2011 to provide for automatic conversion of the principal and all accrued interest into shares of the Company's common stock upon the effectiveness of a Form 10 registration statement filed by the Company with the SEC under the Exchange Act, based on a conversion price of $0.60 per share. Upon the effectiveness of the Company's Form 10 on February 27, 2012, all of the Summer 2011 Notes, representing an aggregate of $1,425,865 in principal and accrued interest, were converted into 2,376,447 shares of the Company's common stock.

The Company analyzed the terms of the warrants based on the provisions of FASB, ASC 480, "Distinguishing Liabilities from Equity," and determined that they qualified for equity accounting. Under guidance in ASC 470, the Company allocated the $1,310,000 in proceeds proportionately between the Summer 2011 Notes and the common stock warrants issued to the note holders based on their relative fair values. The relative fair value of the common stock warrants, $486,102, was recorded as additional paid in capital. The Summer 2011 Notes were recorded at the principal amount of $1,310,000 less a discount of $486,102. This discount was being amortized to interest expense over the term of the Summer 2011 Notes using the effective interest method. The fair value of the Summer 2011 Notes was estimated based on an assumed market interest rate for notes of similar terms and risk. The fair value of the $0.01 common stock warrants was determined using the Black-Scholes pricing model. The Company determined the fair value of its common stock to be $0.60 per share at each of the dates the warrants were issued. In conjunction with the conversion of the Summer 2011 Notes, the Company applied the guidance in FASB ASC 470-20, "Debt with Conversion and Other Options," and wrote-off the unamortized discount of $405,602 associated with the relative fair value of the warrants, which were issued with the Summer 2011 Notes, against additional paid-in capital.

The table below summarizes related party notes payable at December 31:

	2012	2011
BSC Notes - principal	$ 4,338,601	$ 3,500,000
Summer 2011 Notes - principal	-	1,310,000
Total related party notes payable - principal	4,338,601	4,810,000
Summer 2011 Notes - unamortized discount	-	(432,706)
Total related party notes payable - unamortized discount	-	(432,706)
BSC Notes - net	4,338,601	3,500,000
Summer 2011 Notes - net	-	877,294
Total related party notes payable - net	$ 4,338,601	$ 4,377,294

7. Other Notes Payable

2010 Unsecured Convertible Notes Payable

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

2011 Unit Offering Notes

In October 2011, the Company initiated a private placement of securities in which the Company offered units, each unit consisting of a 10% junior secured convertible note ("2011 Unit Offering Note") in the principal amount of $100,000 and a warrant to purchase 50,000 shares of the Company's common stock. The 2011 Unit Offering Notes were scheduled to mature three years from the date of issuance and accrued interest at 10% per year. Per the terms of the 2011 Unit Offering Notes, all principal and accrued interest automatically converted into shares of the Company's common stock based on a conversion price of $0.60 per share on the effective date of the Company's Form 10 on February 27, 2012. The warrants were fully vested upon issuance, have a term of five years, and have an exercise price of $0.75 per share. Upon completion of the unit offering in February 2012, the Company had sold 54.305 units resulting in the issuance of convertible notes in the aggregate principal amount of $5,430,500 and warrants to purchase 2,715,250 shares of common stock. Of the 54.305 units sold, 38.055 units were sold after December 31, 2011. The Company's placement agent for the unit offering, and its sub-placement agents, received an aggregate cash fee equal to 10% of the gross proceeds from the offering, as well as warrants to purchase an aggregate of 941,288 shares of the Company's common stock at $0.60 per share. The fair value of these warrants of $237,299 was calculated using the Black-Scholes pricing model. The $237,299 was recorded as a deferred offering cost to be amortized to interest expense using the effective interest method over the term of the 2011 Unit Offering Notes.

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

2011 Junior Secured Convertible Note Payable and Strategic Agreement

In April 2011, the Company issued a $2,000,000 subordinated secured convertible note ("April 2011 Note") to a medical device co-development partner ("Strategic Partner"). The April 2011 Note matures in April 2016, unless earlier converted, and it accrues interest at the rate of 10% per year. Interest is payable at maturity if the note is not converted. The April 2011 Note is secured by a security interest in the assets of the Company, which security interest is junior and subordinate to the security interest that secures the BSC Notes (see Note 6). In the event the Company closes a qualified financing, which is defined as an equity financing in which the Company issues shares of its preferred stock and receives at least $10,000,000 in net proceeds, the principal and accrued interest of the April 2011 Note will automatically convert into shares of the preferred stock that are issued in the qualified financing if the number of shares to be issued upon conversion represents at least 10% of the Company's outstanding shares of stock on a fully diluted basis. If the number of shares that would be issued upon conversion represents less than 10% of the Company's outstanding shares of stock on a fully diluted basis, the conversion will be at the Strategic Partner's election. Under the original terms, the Strategic Partner had the right to accelerate the maturity date of the April 2011 Note if the Company did not consummate a qualified financing within 180 days following the issue date of the note. The terms of the April 2011 Note were amended in September 2011 to extend the period within which to complete a qualified financing from 180 days to 360 days (April 2012) and to establish a maximum conversion price of $0.60 per share (again, only in connection with the closing of a qualified financing). The April 2011 Note was further amended in February 2012 to remove the acceleration provision mentioned above related to the consummation of a qualified financing and to provide the Strategic Partner the option to convert the April 2011 Note into shares of the Company's common stock at a conversion price of $0.60 per share at any time on or before February 23, 2013 (see Note 11), regardless of whether there is a qualified financing within that period of time.

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

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

Summary of Convertible Notes Payable

The table below summarizes convertible notes payable by liability classification at December 31:

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

2010 Junior Secured Notes

In November 2010, the Company issued an aggregate of 10,714,286 units and received proceeds of $3,000,000. The units were sold to existing stockholders of the Company and existing holders of other Company securities. Each unit consisted of a junior secured note, and one share of the Company's common stock. The Company issued 10,714,286 shares of common stock and junior secured notes in the aggregate principal amount of $3,000,000. The notes mature in November 2020 and accrue interest at the rate of 3.5% per annum. The notes are secured by a security interest in the assets of the Company, which security interest is junior and subordinate to the security interests that secure the BSC Notes and the April 2011 Note. All outstanding principal and interest on the notes will be due and payable in a single payment upon maturity.

Under guidance in FASB ASC 470, the Company allocated the $3,000,000 in proceeds from the sale of the units between the junior secured notes and the shares of common stock issued based on their relative fair values with $2,775,300 being recorded as equity. The junior secured notes were recorded at the principal amount of $3,000,000 less a discount of $2,775,300. This discount is being amortized to interest expense over the 10 year term of the notes using the effective interest method. The fair value of the notes was estimated based on an assumed market interest rate for notes of similar terms and risk. The fair value of the Company's common stock was estimated by management using a market approach, with input from a third-party valuation specialist.

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

8. Stockholders' Equity

July 2012 Private Placement

In July 2012, the Company entered into securities purchase agreements for the private placement of shares of the Company's common stock and warrants to purchase shares of the Company's common stock, at a purchase price of $1.10 per unit (the "July PIPE Financing"). Each unit consisted of one share of common stock and a warrant to purchase one-half share of common stock. The pricing for the July PIPE Financing was set by the Company on June 25, 2012.

In the July PIPE Financing, the Company sold to the investors 5,454,523 shares of common stock, together with warrants to purchase 2,727,274 shares of common stock, for aggregate gross proceeds of $6,000,000. Each warrant is exercisable for five years from the date of issuance and has an exercise price of $1.45 per share, subject to adjustment from time to time for stock splits or combinations, stock dividends, stock distributions, recapitalizations and other similar transactions. In addition, the exercise price of the warrants will be subject to weighted average anti-dilution protection, such that the exercise price will be adjusted downward on a weighted average basis to the extent the Company issues common stock or common stock equivalents in a financing transaction at a price below the then prevailing warrant exercise price (see Note 11). Non-employee directors of the Company invested a total of $269,980 in the July PIPE Financing. The Company's placement agent for the July PIPE Financing, and its sub-placement agents, earned cash commissions of $480,000 as well as warrants to purchase 409,093 shares of the Company's common stock. The placement agent warrants have the same terms and conditions as the investor warrants, except that the placement agent warrants have an exercise price of $1.10 per share.

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

Preferred Stock

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

On February 10, 2012, the stockholders of the Company also approved an Amended and Restated Certificate of Incorporation to be filed in connection with the effectiveness of the Company's Form 10 registration statement. The Company filed the Amended and Restated Certificate of Incorporation with the state of Delaware on February 27, 2012, and it became effective upon filing. Under such Amended and Restated Certificate of Incorporation, the Company has the authority to issue up to 25,000,000 shares of preferred stock, and the Board of Directors has the authority, without further action by the stockholders, to issue up to that number of shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. In June 2012, the Board of Directors established the terms of a series of preferred stock known as "Series A Convertible Preferred Stock". The Board of Directors designated the Series A Convertible Preferred Stock solely to provide BSC a series of the Company's preferred stock into which BSC could elect to convert the BSC Notes other than in connection with a qualified financing (see Note 6). The Company has not issued any shares of the Series A Convertible Preferred Stock. Likewise, the Company has not filed a Certificate of Designations with the Secretary of State of the State of Delaware to create the Series A Convertible Preferred Stock. The Company does not intend to file such Certificate of Designations unless and until BSC elects to convert its BSC Notes into shares of the Series A Convertible Preferred Stock.

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

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

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

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

Stock Incentive Plans

At December 31, 2011, the Company had four share-based compensation plans (a "1998 Plan", a "2007 Plan", and two "2010 Plans", and referred to collectively herein as the "Plans"). The Plans provide for the granting of share-based awards, such as incentive and non-qualified stock options, to employees, directors, consultants and advisors. One of the 2010 Plans also provides for cash-based awards. Awards may be subject to a vesting schedule as set forth in each individual award agreement. The Company terminated the 1998 Plan, effective June 24, 2008, with respect to future grants such that no new options may be awarded under the 1998 Plan on or after June 24, 2008. Upon adoption of the 2010 Plans, the Company also ceased making awards under its 2007 Plan. A total of 3,815,675 shares of the Company's common stock were reserved for issuance under the 2010 Plans, and awards with respect to a total of 3,246,450 shares have been made under the 2010 Plans. In February 2012, the stockholders of the Company approved the creation of a new share-based incentive plan (the "2012 Plan"). With the adoption of the 2012 Plan, no additional grants under the 2010 Plans will be made. A total of 3,000,000 shares of the Company's common stock were reserved for issuance under the 2012 Plan, of which awards as to 2,947,400 shares had been made as of December 31, 2012, thus, 52,600 shares remained available for award grants as of December 31, 2012 under the 2012 Plan.

Activity with respect to stock options issued by the Company is summarized as follows:

	Options Outstanding	Options Exercisable	Range of Exercise Prices	Weighted-average Exercise price per share	Intrinsic Value (1)
Balance at January 1, 2010	669,777		$ 0.88 - 24.00	$ 4.28	$ 3,694,400
Exercisable at January 1, 2010		483,364	0.88 - 24.00	2.78	3,424,333
Granted (2)	3,246,450		1.80	1.80	
Cancelled or forfeited	(153,750)		3.20 - 24.00	5.06	
Outstanding at December 31, 2010	3,762,477		0.88 - 24.00	2.11	262,500
Exercisable at December 31, 2010		433,746	0.88 - 24.00	3.03	262,500
Cancelled or forfeited	(82,500)		1.80 - 24.00	4.93	
Outstanding at December 31, 2011	3,679,977		0.88 - 9.64	2.05	-
Exercisable at December 31, 2011		1,501,659	0.88 - 9.64	2.15	-
Granted (2)	3,097,400		1.00 2.13	1.08	
Exercised	(14,000)		1.80 - 9.64	1.80	
Cancelled or forfeited	(331,250)		1.80 - 9.64	2.14	
Outstanding at December 31, 2012	6,432,127		0.88 - 9.64	1.58	1,846,040
Exercisable at December 31, 2012		2,386,909	0.88 - 9.64	2.13	205,000

(1) Intrinsic value is calculated as the estimated fair value of the Company's stock at the end of the related period less the option exercise price of in-the-money options.
(2) All options granted during the years ended December 31, 2010 and 2012 were granted with exercise prices which were deemed to be the fair market value of the Company's stock on the date of grant.

The following table summarizes information about stock options at December 31, 2012:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted - Average Remaining Contractual Life	Weighted - Average Exercise Price	Number Exercisable	Weighted - Average Exercise Price
$0.88-1.17	3,033,900	8.53	$ 0.99	287,500	$ 0.89
1.63-2.13	3,216,700	8.16	1.79	1,917,882	1.80
3.20-9.64	181,527	3.55	7.61	181,527	7.61
	6,432,127	8.20	1.58	2,386,909	2.13

The weighted average grant date fair value of options granted during the years ended December 31, 2010 and 2012 was $0.83 and $0.48, respectively, and no options were granted in 2011. A summary of the status of the Company's nonvested stock options during the years ended December 31, 2010, 2011 and 2012 is presented below:

Nonvested Stock Options	Shares	Weighted - Average Grant Date Fair Value
Nonvested January 1, 2010	186,413	$ 2.41
Granted	3,246,450	0.83
Forfeited	(41,667)	1.92
Vested	(62,465)	2.31
Nonvested December 31, 2010	3,328,731	0.88
Forfeited	(51,833)	0.88
Vested	(1,098,580)	0.89
Nonvested December 31, 2011	2,178,318	0.87
Granted	3,097,400	0.48
Forfeited	(258,517)	0.85
Vested	(971,984)	1.04
Nonvested December 31, 2012	4,045,218	0.56

As of December 31, 2012 there was a total of approximately $1,948,000 of unrecognized compensation cost related to share-based compensation arrangements granted under the Plans. That cost is expected to be recognized over a weighted-average period of approximately 1.8 years.

The assumptions used in calculating the fair value using the Black-Scholes option-pricing model are set forth in the following table for options issued by the Company in 2012 and 2010 (no options were issued in 2011):

	Years Ended December 31,	
	2012	2010
Dividend yield	0%	0%
Expected Volatility	45.17% to 45.32%	44.81%
Risk free Interest rates	0.83% to 1.13%	2.36%
Expected lives (years)	6.0	6.0

Warrants

In May 2012, the Company issued an aggregate of 1,250,000 common stock warrants to two non-employee directors in recognition of their long-standing support of the Company. The warrants were immediately vested and exercisable upon issuance, have an exercise price of $1.00 per share, and have a term of five years. The fair value of the 1,250,000 warrants issued was $514,250, which was calculated using the Black-Scholes valuation model. In addition, during year ended December 31, 2012, the Company issued 421,666 warrants to third parties with an exercise price of $1.00 and having a fair value of $349,003. The aggregate fair value of the aforementioned warrants of $863,253 was recorded as a selling, general and administrative expense during year ended December 31, 2012.

Warrants have been issued for terms of up to five years. Common stock warrants issued, expired, and outstanding during the years ended December 31, 2010, 2011 and 2012 are as follows:

	Shares	Weighted - Average Exercise Price
Outstanding at January 1, 2010	410,542	$ 0.42
Issued	25,444	8.00
Outstanding at December 31, 2010	435,986	3.74
Expired	(410,542)	3.48
Issued	2,122,500	0.29
Exercised	(225,000)	0.01
Outstanding at December 31, 2011	1,922,944	0.43
Issued	7,652,071	1.05
Shares withheld on net settled exercises	(186,347)	0.70
Exercised	(624,832)	0.67
Outstanding at December 31, 2012	8,763,836	0.95

The assumptions used in calculating the fair value of warrants utilizing the Black-Scholes pricing model are as follows:

	Year Ended December 31,		
	2012	2011	2010
Dividend yield	0%	0%	0%
Expected Volatility	40.96% to 46.88%	48.67% to 49.36%	44.81%
Risk free Interest rates	0.19% to 0.77%	0.81% to 1.13%	2.36%
Expected lives (years)	1.6 to 5.0	5.0	5.0

9. Income Taxes

The Company had no income tax expense for the years ended December 31, 2012, 2011 and 2010. As the Company has incurred net operating losses, it has recognized valuation allowances for all net deferred income tax assets. The tax effect of temporary differences and net operating losses that give rise to components of deferred income tax assets and liabilities consist of the following:

	As of December 31,	
	2012	2011
Deferred income tax assets (liabilities):		
Property and equipment	$ (54,443)	$ (144,185)
Deferred revenue	246,740	1,517,024
Accrued expenses	288,338	1,138,800
Share based compensation related	1,094,927	451,557
Other	546,636	275,650
Net operating loss carryforwards	19,816,443	18,509,210
	21,938,641	21,748,056
Less valuation allowance	(21,938,641)	(21,748,056)
	$ -	$ -

The Company has a cumulative federal net operating loss of approximately $52,000,000 as of December 31, 2012 which begins to expire in 2015. Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation", as defined, there are annual limitations on the amount of the net operating loss and other deductions which are available to the Company. The Company has not determined whether such ownership change has occurred. However, given the equity transactions in which the Company has engaged, the Company believes that the use of the net operating losses shown as deferred tax assets will be significantly limited.

Management has evaluated the effect of guidance provided by GAAP regarding accounting for uncertainty in income taxes and determined the Company has no uncertain tax positions that could have a significant impact on its financial statements. The Company's income tax returns after 2008 remain open for examination.

10. Commitments

Leases

The Company leases office space in Tennessee and California under non-cancellable operating leases. The leases expire in 2014 and 2015, respectively.

Future minimum lease payments under non-cancellable operating leases are as follows:

Years ending December 31,	
2013	$ 142,680
2014	140,583
2015	62,638
Total minium payments	$ 345,901

Rent expense under all operating leases was approximately $145,000, $174,000 and $181,000 for the years ended December 31, 2012, 2011, and 2010, respectively.

Licenses

Certain license arrangements require minimum royalty payments. As of December 31, 2012, future minimum royalty payments are as follows:

Years ending December 31,	
2013	$ 95,000
2014	95,000
2015	95,000
2016	95,000
2017	95,000
Thereafter	915,000
Total minium payments	$ 1,390,000

Royalty payment amounts may be greater than the minimum required payment amounts based on the negotiated royalty rates. If the Company sublicenses the intellectual property that is licensed from the licensor and the Company receives any royalty payment under or with respect to such sublicense, the Company is obligated to pay the licensor an agreed upon percentage of any such payment(s). Under the terms of these license agreements, the Company is required to reimburse the licensor for all costs associated with patent filing, prosecution and maintenance as well as expenses related to enforcing the related patent rights. The Company may terminate these license agreements for any reason, upon giving the licensor either 60 or 90 days written notice, depending on the agreement. The Company has not sold any products to date that are subject to royalties under the arrangements mentioned above that provide for minimum royalty payments.

Co-Development Agreement

The Company has entered into a co-development agreement whereby it would pay up to approximately $2,476,000 in milestone-based payments for software development to be used in conjunction with products being developed by the Company. The software, upon completion, will be owned by the co-developer and sold through licenses. The co-developer will pay the Company a fixed amount per license sold by the co-developer until the Company recoups its investment in the software. At December 31, 2012, the Company has made a total of $1,373,889 in milestone payments.

Shared Research Agreements

The Company entered into research agreements with certain universities whereby the Company committed to pay certain research-related expenses. At December 31, 2012, the Company's accounts payable balance includes approximately $599,000 related to one of these agreements. In addition, as of December 31, 2012, the Company is obligated to make payments totaling approximately $238,000, all payable in 2013 for research to be performed in 2013, under another such agreement.

Master Services and Software License Agreement

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

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

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

In addition, in September 2012, the Company and the software development partner entered into a new statement of work under the Master Software Agreement, pursuant to which the software development partner agreed to make certain enhancements to the ClearPoint system software in exchange for payments to be made over a twelve month period of $300,000 in the aggregate. A total of $100,000 was paid under this statement of work in 2012; the balance of $200,000 is scheduled to be paid in 2013.

Cardiac EP Business Participation Plan

In June 2010, the Company adopted a plan to provide a key product development advisor and consultant with financial rewards in the event that the Company sells its business operations relating to catheter-based MRI-guided cardiac ablation to treat cardiac arrhythmias, which the Company refers to as its cardiac EP operations. In the event that the Company sells its cardiac EP operations, whether on a stand-alone basis or as part of the sale of the Company, the participant will receive a payment under the plan equal to (i) the transaction value paid for or allocated to the cardiac EP operations in the sale, multiplied by (ii) the participant's "participation interest" at the time of the sale. The participant was initially awarded a participation interest of 6.6%. However, pursuant to the terms of the plan, the participation interest is equitably reduced from time to time to take into account equity financing transactions in which the Company issues shares of its common stock, or securities convertible into shares of its common stock, in exchange for cash proceeds. At December 31, 2012, the participation interest was 3.7%. The plan will terminate in June 2025.

Employment Agreements

During 2012, the Company entered into employment agreements (each, an "Employment Agreement," and collectively, the "Employment Agreements") with five executive officers (each, an "Executive," and collectively, the "Executives"). Among other provisions customary for agreements of this nature, the Employment Agreements provide for severance in the event of a termination without cause or if the Executive terminates his employment for good reason, as those terms are defined in each Employment Agreement. Likewise, the Employment Agreements provide for certain payments in connection with a change of control transaction.

Key Personnel Incentive Program

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

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

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

11. Subsequent Events

January 2013 Private Placement

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

In the January Financing Transaction, the Company sold to the investors 9,201,684 shares of common stock, together with warrants to purchase 4,600,842 shares of common stock, for aggregate gross proceeds of approximately $11,000,000, before commissions and offering expenses. Each warrant is exercisable for five years from the date of issuance and has an exercise price of $1.75 per share, subject to adjustment from time to time for stock splits or combinations, stock dividends, stock distributions, recapitalizations and other similar transactions. In the event the Company issues shares of its common stock or common stock equivalents in a financing transaction after the January Financing Transaction at a price below the then prevailing warrant exercise price, the exercise price of the warrants will be adjusted downward to the price at which the Company issues the common stock or common stock equivalents. Additionally, the warrants contain a net-cash settlement feature which gives the warrant holder the right to net-cash settlement using the Black-Scholes valuation model in the event certain transactions occur. The Company will apply guidance in ASC 815-40 to account for the net-cash settlement provision of the warrants which will result in a portion of the net proceeds of the January Financing Transaction being recorded as a derivative liability. Thereafter, the fair value of this derivative liability will be calculated each reporting period and the liability adjusted through charges or credits to the statements of operations. Non-employee directors of the Company invested a total of $402,000 in the January Financing Transaction. The Company's placement agents for the January Financing Transaction earned commissions of approximately $1,100,000.

In connection with the January Financing Transaction, the Company entered into a registration rights agreement with the investors pursuant to which the Company agreed to prepare and file a registration statement with the SEC covering the resale of the shares of common stock and the shares of common stock underlying the warrants issued in the financing. The Company must bear the costs, including legal and accounting fees, associated with the registration of those shares. The Company filed that registration statement on February 11, 2013. The Company will be required to use its best efforts to have the registration statement declared effective as soon as practicable. In the event the registration statement is not declared effective by the SEC on or prior to the effectiveness deadline set forth in the registration rights agreement, or if the Company fails to continuously maintain the effectiveness of the registration statement (with certain permitted exceptions), the Company will incur certain damages to the investors, up to a maximum amount of 12% of the investors' investments in the January Financing Transaction, or approximately $1,300,000.

As a consequence of the January Financing Transaction described above, the exercise price of the warrants issued by the Company in the July PIPE Financing (see Note 8) has been adjusted from $1.45 per share to $1.41 per share.

Modification of Terms of April 2011 Note (see Note 7)

On February 21, 2013, the Strategic Partner delivered notice to the Company of the Strategic Partner's election to convert the April 2011 Note into shares of the Company's common stock at the conversion price of $0.60 per share. However, prior to the issuance of those conversion shares, on March 6, 2013 the Company and the Strategic Partner entered into a loan modification, and, as a result, the Strategic Partner revoked its election to convert the April 2011 Note into shares of common stock. Under the loan modification, the April 2011 Note was amended (i) to remove the equity conversion feature, such that the April 2011 Note is no longer convertible into any shares of the Company's capital stock, (ii) to reduce the interest rate, beginning March 6, 2013, from 10% per year to 5.5% per year, (iii) to ease certain loan covenants, and (iv) to reflect a new note principal balance of $4,289,444, which represents the sum of (A) the original principal balance of the April 2011 Note in the amount of $2,000,000, plus (B) interest accrued under the April 2011 Note through March 6, 2013 in the amount of $389,444, plus (C) $1,900,000. Both principal and interest will be due on the original maturity date in April of 2016. The Company will apply guidance in FASB ASC 470-50, "Debt Modifications and Extinguishments," which requires calculating the fair value of the April 2011 Note, as of the loan modification date, based on the amended terms. The difference between the fair value and the carrying value will be recorded as a charge to the statement of operations during the three months ended March 31, 2013.

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