

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

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**Amendment No. 2  
to  
FORM 10**

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**GENERAL FORM FOR REGISTRATION OF SECURITIES  
Pursuant to Section 12(b) or (g) of  
The Securities Exchange Act of 1934**

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**MRI Interventions, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**58-2394628**  
(I.R.S. Employer  
Identification No.)

**MRI Interventions, Inc.**  
**One Commerce Square, Suite 2550**  
**Memphis, TN 38103**  
(Address of principal executive offices)

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

**Securities to be registered pursuant to Section 12(b) of the Act:**

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Title of each class  
to be so registered

N/A

Name of each exchange on which  
each class is to be registered

N/A

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

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### **EXPLANATORY NOTE**

MRI Interventions, Inc. is filing this General Form for Registration of Securities on Form 10, or this registration statement, to register its common stock, par value \$0.01 per share, pursuant to Section 12(g) of the Securities Exchange Act of 1934. Unless otherwise mentioned or unless the context requires otherwise, when used in this registration statement, the terms “company,” “we,” “us,” and “our” refer to MRI Interventions, Inc.

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

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

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

### **FORWARD LOOKING STATEMENTS**

This registration statement contains forward-looking statements. 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
- the estimates regarding the sufficiency of our cash resources.

In some cases, you can identify forward-looking statements by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” and similar expressions intended to identify forward-looking statements, although not all forward-looking statements contain these words. Although we believe that we have a reasonable basis for each forward-looking statement contained in this registration statement, 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.

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You should refer to the section of this registration statement 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 registration statement 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 registration statement, 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 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.

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Our ClearPoint system is in commercial use. In June 2010, we received 510(k) clearance from the Food and Drug Administration, or FDA, to market our ClearPoint system in the United States for general neurological interventional procedures. In February 2011, we also obtained CE marking approval for the ClearPoint system, which enables us to sell the ClearPoint system in the European Union. In April 2011, we entered into a co-development and distribution agreement with Brainlab, a leader in the image-guided surgery field, under which Brainlab will serve as our distribution partner for the ClearPoint system. As of January 31, 2012, a total of 14 ClearPoint systems have been installed, 13 in the United States and one in Europe. ClearPoint systems are in clinical use in connection with MRI scanners from the three major MRI scanner 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 63 patents and 113 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.

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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 January 31, 2012, a total of 14 ClearPoint systems have been installed, 13 in the United States and one in Europe. ClearPoint systems are in clinical use in connection with MRI scanners from the three major MRI scanner 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 multiform. The first line of therapy for

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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 during 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.

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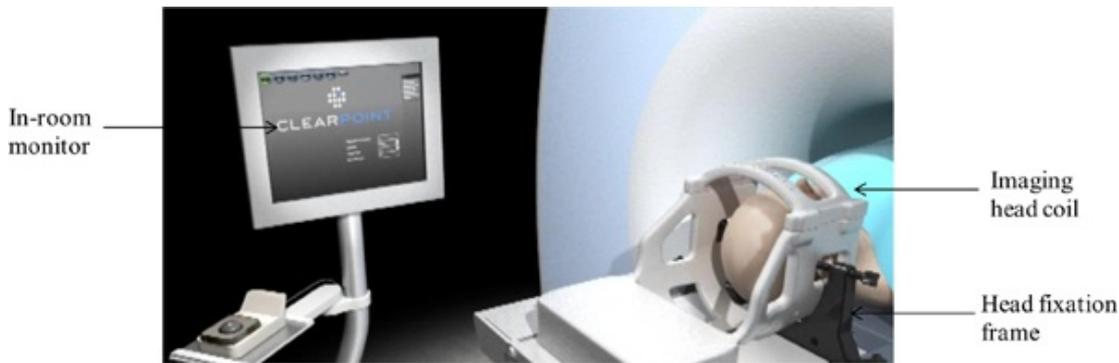
### *Our ClearPoint System Solution*

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 magnetic resonance imaging 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.

The ClearPoint hardware is shown in the following image.

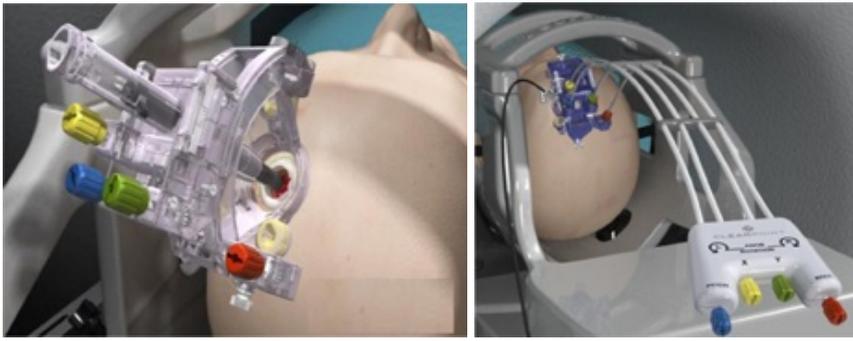


*ClearPoint Disposables.* The disposable components of our ClearPoint system consist primarily of our SmartFrame trajectory device, a hand controller and related accessories. Our SmartFrame device is an adjustable trajectory frame that attaches to the patient's skull and holds the targeting cannula. 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.

The following images show our SmartFrame device attached to the patient's head, as well as the hand controller attached to the SmartFrame device.

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*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 following is a sample screenshot of our ClearPoint system software being used to select a trajectory path to a target location in the brain.



*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.

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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. As with other conventional stereotaxy-based systems, unless and until we receive FDA clearance or approval for use of our ClearPoint system for specific indications, uses in procedures other than general neurological procedures could be considered off-label uses of our ClearPoint system. We are not permitted to promote our system, or train physicians, for off-label uses. However, in their practice of medicine, physicians may lawfully choose to use medical devices for off-label uses. Therefore, similar to other conventional stereotaxy-based systems, a physician may use our ClearPoint system for specific indications that are not included in the FDA-cleared labeling. As they currently do with other conventional stereotaxy-based systems, we expect physicians will use our ClearPoint system in a variety of specific neurological procedures, including DBS electrode placement, direct drug delivery and focal lesioning.

In the European Union, our CE marking approval includes all components of our ClearPoint system, other than our imaging head coil. The CE mark for the ClearPoint system carries the same indication for use as our 510(k) clearance. We have applied for CE marking approval for our imaging head coil, and we expect to obtain that approval in the first quarter of 2012.

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***

#### *General*

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.

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.

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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 together with Siemens on the development of the ClearTrace software and the integration of system components. Once product development is completed, we will work together 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.

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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

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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 we have not made any filings seeking regulatory approval or clearance for the ClearTrace system in the United States or in any foreign jurisdiction. 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 we plan to seek CE marking approval for the ClearTrace system. To date, we have been conducting animal studies and other preclinical work with respect to the ClearTrace system. At this time, we are not able to estimate when we will make a filing seeking regulatory approval or clearance for the ClearTrace system.

### **Our Strategy**

Our key objective is to develop and commercialize medical systems to enable minimally invasive surgical procedures to be performed under direct, intra-procedural MRI guidance. Key elements of our strategy to achieve this objective are:

- ***Maximize installation and adoption of our ClearPoint system.*** We are focusing our marketing efforts on key physicians and hospitals to adopt use of our ClearPoint system for general neurological interventional procedures. Working with Brainlab as our distribution partner, our strategy is to convince those physicians that our ClearPoint system offers a better procedural solution for their patients. With the physicians serving as our internal champions, we will continue to work with the physicians to encourage hospitals to install our ClearPoint system in their existing MRI suites. In hospitals where our ClearPoint system has been installed, we will focus on selling our disposable components to generate recurring revenue.

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- ***Continue development of the ClearTrace system.*** We will continue to co-develop the ClearTrace system with Siemens. Together, we will work to generate awareness among leading physicians of the benefits of an MRI-guided approach to cardiac ablation for the treatment of cardiac arrhythmias, such as atrial fibrillation. Upon regulatory approval, we will work with Siemens to promote installation of the MRI software and our hardware components for the ClearTrace system within Siemens' MRI customer base. In hospitals where the ClearTrace system has been installed, we will focus on selling our disposable components to generate recurring revenue.
- ***Build upon our core technologies to continue to develop MRI-based products.*** Our research and development efforts to date have focused on developing novel MRI-related technologies. We have significant intellectual property protection in this particular area. As the field of MRI-guided interventions grows, we intend to develop future enhancements to the ClearPoint and ClearTrace systems, as well as researching opportunities for new products.

### **Licenses and Collaborative Relationships**

In addition to our internally-developed technologies and devices, we have established and intend to continue to pursue licenses and collaborative relationships with medical device companies and academic institutions to further the development and commercialization of our product platforms and our core technologies. Our current licenses and collaborative 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 together 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

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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. As of December 31, 2011, we have paid Siemens \$850,000 and, in addition, we have accrued payables of approximately \$524,000. Once the software for the ClearTrace system is commercially available, Siemens will pay to 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 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 up to \$800,000 in future milestone-based payments associated with successful development and regulatory approval of the leads. The development agreement provides that if the milestones are not completed by December 31, 2012, and the failure to achieve the milestones was not the result of Boston Scientific's failure to cooperate with us in the pursuit of the milestones, we are required to repay Boston Scientific certain amounts, including any milestone payments previously paid to us by Boston Scientific under this agreement and any patent prosecution costs incurred by Boston Scientific with respect to the intellectual property licensed to Boston Scientific pursuant to the technology license agreement described below. As of December 31, 2011, the potential obligation to Boston Scientific was approximately \$750,000, plus costs incurred by Boston Scientific in prosecuting the licensed intellectual property. However, Boston Scientific has assumed responsibility for the neuromodulation lead development efforts under this agreement. Given that Boston Scientific is wholly responsible for the pace and progress of the development efforts, we do not believe we will have any repayment obligation to Boston Scientific in the event the development milestones are not completed by December 31, 2012.

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*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, 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 different types of MRI-compatible, MRI-safe implantable cardiac rhythm management leads. Under the terms of the agreement, we could receive up to \$20,000,000 in future milestone-based payments associated with successful development activities under the agreement as well as regulatory approval of the different implantable lead types. 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.

*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 The Johns Hopkins University. 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 University of Utah*

In July 2007, we entered into a research agreement with The University of Utah, or Utah. Under the agreement, Utah personnel are conducting research activities and experiments to develop knowledge, techniques, methods and technologies related to MRI-guided cardiac ablation, including a specific focus on MRI-guided cardiac ablation to treat atrial fibrillation. Those research activities are being performed through Utah's Comprehensive Arrhythmia Research and Management (CARMA) Center, the mission of which is to redefine the diagnosis and management of atrial fibrillation through an interdisciplinary program of basic and clinical research focused on the understanding, diagnosis, and clinical treatment of atrial fibrillation. The CARMA Center has brought together multiple disciplines in cardiology, advanced MR imaging, image processing and biomedical research, and we believe the CARMA Center is on the forefront of using MRI in the management and treatment of patients suffering from atrial fibrillation. Pursuant our agreement, Utah granted us a non-exclusive, worldwide license to any intellectual property created or conceived by Utah personnel in the performance of the research. In addition, we also received the first option to license exclusively any such intellectual property. Our agreement with Utah will terminate March 31, 2012, unless we and Utah agree to extend the term.



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### *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 a hospital by loaning the equipment. Our disposable and reusable ClearPoint products are tightly integrated, which allows us to leverage each new installation of a system to generate recurring sales of our disposable products. 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 January 31, 2012, 14 ClearPoint systems have been installed, which includes seven systems we provided to hospitals under our loan program, five systems we sold, and two systems we installed at hospitals pursuant to the terms of research or clinical trial agreements. As of January 31, 2012, we also had agreements to provide loaned systems to four additional hospitals, but those systems have not yet been installed.

Presently, our sales and marketing efforts for our ClearPoint system are being coordinated primarily by our Vice President, Sales, our Vice President, Product Management and our two Clinical Engineering Managers, one of whom is located on the east coast of the United States and the other of whom is located on the west coast of the United States. 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 significantly 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, 2012, our research and development team, which is based primarily in our Irvine, California facility, consisted of eight 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.

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Our principal research and development goals are:

- to complete development of the ClearTrace system in cooperation with Siemens;
- to continue to enhance our ClearPoint 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 \$6,068,000, \$5,681,000 and \$4,251,000 for the years ended December 31, 2009, 2010 and 2011, 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.

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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, 2012, our portfolio included 63 patents and 113 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, 2012, we wholly owned nine issued United States patents (including one design patent), 27 pending United States patent applications (including three provisional applications), seven issued foreign patent and 42 pending foreign patent applications (including one Patent Cooperation Treaty application). In addition, as of January 31, 2012, we co-owned with third-parties a total of seven issued United States patents, eight pending United States patent applications, 11 issued foreign patents and 19 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, 2012, four issued United States patents, 10 issued foreign patents and one pending foreign patent application were co-owned by us and The Johns Hopkins University, two issued United States patents, eight pending United States patent applications, one issued foreign patent and 17 pending foreign patent applications were co-owned by us and Boston Scientific, and one issued United States patent and one pending foreign patent application 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, 2012, our licensing arrangements with Boston Scientific included six wholly owned issued United States patents, three wholly owned pending United States patent applications, seven wholly owned issued foreign patents, seven wholly owned pending foreign patent applications, seven co-owned issued United States patents, eight co-owned pending United States patent applications, 11 co-owned issued foreign patents and 19 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, 2012, we had licensed rights to 14 United States and 15 foreign third-party issued patents, and we had licensed rights to six United States and 11 foreign third-party pending patent applications. Our licensed, issued patents expire at various dates beginning in 2015.

### ***License Arrangements***

Our license arrangements are discussed below. The underlying agreements are filed as exhibits to this registration statement.

#### *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



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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. In addition, Johns Hopkins has the option to terminate the license in the event a commercial sale of a licensed product or a licensed service does not occur by June 30, 2012. We do not expect to have a commercial sale of a licensed product or a licensed service by that date. We will discuss with Johns Hopkins the removal of that termination clause, or an extension of the stated time period, if necessary.
- 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 Cedara Software Corp.*

In July 2007, we entered into a master service and license agreement with Cedara Software Corp. (d/b/a Merge OEM), or Cedara, for Cedara to develop on our behalf, based on our detailed specifications, a customized software solution for our ClearPoint system. Cedara 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, Cedara

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utilized certain of its own pre-existing software code. Under our agreement with Cedara, 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 Cedara a license fee for each copy of our ClearPoint system software that we distribute. Except for Cedara's pre-existing software code, the work performed by Cedara was a "work-made-for-hire" and we exclusively own our ClearPoint system software. The agreement provides for annual minimum licensing fees. Our license from Cedara continues through July 2015, absent a mutual extension of the license term. If necessary, we could replace the licensed Cedara code.

### *License Arrangements with the National Institutes of Health*

In April 2009, we entered into a patent license agreement with the National Institutes of Health, or NIH, that covers techniques for three dimensional renderings of the patient's anatomy from MRI data in real time. The techniques underlying this patent may be used in the development of the ClearTrace system. Under the terms of this agreement, we have a non-exclusive license to a pending United States patent application within the field of 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**

### *General*

The length of time required for products to be developed and to receive regulatory and, in some cases, reimbursement clearance or approval is an important competitive factor. However, even if we are successful in obtaining regulatory clearances or approvals, the medical device industry is characterized by rapid and significant technological change. Thus, the development by others of new treatment methods, including novel drugs, medical devices or surgical techniques could render our product candidates non-competitive or obsolete. As a result, product development involves a high degree of risk and there can be no assurance that our current or new product development efforts will result in any commercially successful products.

### *ClearPoint System*

Our success depends on convincing hospitals, neurosurgeons, neurologists and patients to utilize our 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. and Medtronic, Inc. offer instruments and systems for use in conventional stereotactic neurological procedures, such as surgical navigation workstations and frame-based and frameless stereotactic systems, and these instruments 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*

Our success depends on convincing hospitals, physicians and patients to utilize the ClearTrace system for performing cardiac ablation procedures. While we are not aware of any companies that currently offer 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 of these companies 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.

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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, 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;

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- 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 premarket approval application, or 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. If we are required to follow a de novo process, an additional 60 to 90 days or more will be added on to the original 90 days required for the initial 510(k) review.

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

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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 (IOM) to report on the 510(k) approval process. In July 2011, the Institute of Medicine, which had previously been commissioned by the FDA to review the 510(k) process, released its report, in which the Institute of Medicine 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

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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 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

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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.

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### **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 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. On July 30, 2008, CMS released a list of potential topics for national coverage determinations. This list included ablation for atrial fibrillation and specifically asked whether the evidence was adequate to demonstrate health benefits in patients who receive the procedure. On October 21, 2009, the Medicare Evidence Development and Coverage Advisory Committee, or MedCAC, held a meeting on the adequacy of the available evidence for catheter ablation for the treatment of atrial fibrillation. Although CMS has not formally opened a national coverage analysis on this topic, the agency clearly is interested in the clinical evidence of atrial fibrillation treatments and any national coverage decisions it makes could have a material effect on our potential business in this area.

Medicare coverage for the procedures in which our products would be 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 DRGs. Payments also are adjusted to reflect regional variations in labor costs, indirect medical education expenses, payments for hospitals that treat a disproportionate share of poor patients, and other factors. As of October 1, 2007, CMS implemented a revised version of the DRG system that uses 745 Medicare Severity DRGs, or MS-DRGs, instead of the approximately 540 DRGs Medicare previously used. The MS-DRGs are intended to account more accurately for the patient's severity of illness when assigning each patient's stay to a payment classification. 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

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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, 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 enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 enacted on March 30, 2010, or, together, the Health Care Reform Law, 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 Health Care Reform Law provides for the establishment of a Medicare shared savings program, which goes 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 Health Care Reform Law 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 Health Care Reform Law 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.

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Among other things, the Health Care Reform Law will ultimately increase the overall pool of persons with access to health insurance in the United States. Although such an increase in covered lives should ultimately benefit hospitals, the Health Care Reform Law, also includes a number of cuts in Medicare reimbursement to hospitals that may take effect prior to hospitals' realizing 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 Health Care Reform Law 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.

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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 Health Care Reform Law 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 or retention of a federal healthcare program overpayment are 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 or 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 Health Care Reform Law 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

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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 the HITECH Act, 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. Most of the HITECH provisions became effective in February 2010 and was expected that the HHS would final regulations to implement many of the new provisions in 2011. Those regulations have not yet been released. HHS has already issued regulations governing breach notification which were effective in September 2009.

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 uncorrected violations 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. HHS held training sessions on the HIPAA rules and enforcement for state attorneys general in the spring of 2011.

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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, 2012, we had 22 full time employees, of whom eight were engaged in research and development, five in manufacturing, four 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**

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

As of December 31, 2011, we had an accumulated deficit of approximately \$59,789,000. The accumulated deficit has resulted principally from costs incurred in our research and development efforts and general operating expenses. We have incurred significant losses in each year since our inception in 1998. Net losses were approximately \$8,311,000 for the year ended December 31, 2011, approximately \$9,454,000 for the year ended December 31, 2010, and approximately \$7,159,000 for the year ended December 31, 2009. We may continue to incur significant operating losses as we continue to invest capital in the sales and marketing of our products, development of our product candidates and our business generally. We also expect that our general and administrative expenses will increase due to additional operational and regulatory burdens associated with operating as a public company.

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

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

We expect 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 market acceptance unless we 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, including:

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- the shift in location of the procedure from the operating room to the MRI suite;
- the hospital's ability and willingness to satisfy the increased demand for the MRI suite;
- the cost to the hospital to purchase or otherwise use our products;
- the amount of reimbursement available from third-party payors;
- insufficient supporting clinical data; and
- the familiarity of the physician, and the physician having achieved successful results, with other devices and approaches.

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

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

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

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

We do not know if hospitals will consider third-party reimbursement levels adequate to cover the cost of our ClearPoint system. Furthermore, we do not know if physicians will consider third-party reimbursement levels adequate to compensate them for performing the procedures in which our products are used. Failure by hospitals and physicians to receive an amount that they consider to be adequate reimbursement for procedures in which our products are used will deter them from purchasing or using our products and limit our sales growth.

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

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The Health Care Reform Law 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 Health Care Reform Law provides for the establishment of a Medicare shared savings program, which goes 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 Health Care Reform Law 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 Health Care Reform Law may limit the acceptance and availability of our products, which could have an adverse effect on our financial results and business.

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

In the United States, we believe that existing billing codes apply to procedures using our ClearPoint system. Reimbursement levels for procedures using our ClearPoint system or any product that we may market in the future could be decreased or eliminated as a result of future legislation, regulation or reimbursement policies of third-party payors. Any such decrease or elimination would adversely affect the demand for our ClearPoint system or any product that we may market in the future and our ability to sell our products on a profitable basis. For example, on July 30, 2008, Centers for Medicare and Medicaid Services, or CMS, the federal agency that administers the Medicare Program, released a list of potential topics for national coverage determinations. This list included ablation for atrial fibrillation and specifically asked whether the evidence was adequate to demonstrate health benefits in patients who receive the procedure. On October 21, 2009, the Medicare Evidence Development and Coverage Advisory Committee held a meeting on the adequacy of the available evidence for catheter ablation for the treatment of atrial fibrillation. Although CMS has not formally opened a national coverage analysis on this topic, the agency has shown that it is interested in the clinical evidence of atrial fibrillation treatments and any national coverage decisions it makes could have a material effect on the ClearTrace system and our potential business in this area. Furthermore, if procedures using our ClearPoint system gain market acceptance and the number of these procedures increases, CMS, 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 Health Care Reform Law will ultimately increase the overall pool of persons with access to health insurance in the United States. Although such an increase in covered lives should ultimately benefit hospitals, the Health Care Reform Law also includes a number of cuts in Medicare reimbursement to hospitals that may take effect prior to the time hospitals realize the financial benefit of a larger pool of insured persons. Those cuts in Medicare reimbursement could adversely impact the operations and finances of hospitals, reducing their ability to purchase medical devices, such as our products. Further, Congress has not yet addressed in a comprehensive and permanent manner the pending reduction in Medicare payments to physicians under the sustainable growth rate formula, which if not resolved will likely result in an overall reduction in physicians willing to participate in Medicare.

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

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

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***We have limited internal manufacturing resources, and if we 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. Manufacturers often encounter difficulties in scaling up production, such as problems involving yields, quality control and assurance, and shortages of qualified personnel. If the scaled-up production process is not efficient or produces a product that does not meet quality and other standards, we may be unable to meet market demand and our revenues, business and financial prospects would be adversely affected.

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

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

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

We have limited experience in the sales and marketing of medical devices. Currently, our sales and marketing efforts for our ClearPoint system are being coordinated primarily by our Vice President, Sales, our Vice President, Product Management and our two Clinical Engineering Managers. We expect to continue building a small, highly focused sales force to market 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 distribution relationship with Brainlab significantly expands our sales and marketing capabilities for the ClearPoint system. However, for ClearPoint products that Brainlab sells, our revenues will be lower than if we sell the ClearPoint products ourselves. Likewise, 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 we fail to obtain regulatory approval for our ClearPoint system in additional foreign jurisdictions, we will not be able to expand the commercialization of our products abroad.***

We obtained CE marking approval for our ClearPoint system in February 2011, which enables us to market the ClearPoint system in the European Union. To sell our ClearPoint system in other foreign jurisdictions, we will have to obtain separate regulatory approvals from those foreign jurisdictions as well. 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

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jurisdictions. The foreign regulatory approval process may include all of the risks associated with obtaining FDA clearance or approval in addition to other risks. In addition, the time required to obtain foreign clearance or approval may differ from that required to obtain FDA clearance or approval and we may not obtain foreign regulatory clearances or approvals on a timely basis, if at all. We may not be able to file for regulatory clearance or approval and may not receive necessary clearance or approval to commercialize our ClearPoint system in any additional foreign market, either of which would preclude sale of our ClearPoint system outside the United States other than in the European Union.

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

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

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

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

***The Health Care Reform Law and other payment and policy changes may have a material adverse effect on us.***

In addition to the reimbursement changes discussed above, the Health Care Reform Law will also impose a 2.3% excise tax on the sale of any taxable human medical device after December 31, 2012, subject to certain exclusions, by the manufacturer, producer or importer of such devices. The total cost to the industry is expected to be approximately \$20 billion over ten years. This new and significant tax burden could have a material negative impact on the results of our operations and the operations of our strategic partners. Further, the Health Care Reform Law 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 Health Care Reform Law may ultimately expand the pool of potential end-users of 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.

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

***Our future success depends 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.***

We do not have the necessary regulatory clearances or approvals to market the ClearTrace system in the United States or in any foreign market. In the United States, without FDA clearances or approvals, we cannot market a new medical device, or a new use of, or claim for, or significant modification to, an existing product, unless an exemption applies. To obtain FDA clearance or approval, we must first receive either premarket clearance under Section 510(k) of the federal Food, Drug, and Cosmetic Act or approval of a PMA from the FDA.

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

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

Outside the United States, the regulatory approval process varies among jurisdictions and can involve substantial additional testing. Clearance or approval by the FDA does not ensure clearance or approval by regulatory authorities in other jurisdictions, and clearance or approval by one foreign regulatory authority does not ensure clearance or approval by regulatory authorities in other foreign jurisdictions. The foreign regulatory approval process may include all of the risks associated with obtaining FDA clearance or approval in addition to other risks. In addition, the time required to obtain foreign clearance or approval may differ from that required to obtain FDA clearance or approval and we may not obtain foreign regulatory clearances or approvals on a timely basis, if at all. We may not be able to file for regulatory clearance or approval and may not receive necessary clearance or approval to commercialize a product candidate in any foreign market, either of which would preclude sale of that product candidate in foreign jurisdictions.

The ClearTrace system is still under development. We have not made any regulatory filings with the FDA or any foreign regulatory authority with respect to that system. We anticipate that the initial market for the ClearTrace system will be the European Union and we plan to seek CE marking approval for the ClearTrace system, although there can be no assurance that we will receive CE marking approval. To date, we have been conducting animal studies and other preclinical work with respect to 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.

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.

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

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

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

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

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

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

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***If the third parties on which we may need to rely to conduct any clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval for the ClearTrace system or any additional claims that we may seek for our ClearPoint system.***

We do not have the independent ability to conduct pre-clinical and clinical trials. To the extent that we will need to conduct such trials, we will need to rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance or approval for a product candidate or additional claims we may seek for our products on a timely basis, if at all. As such, our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

***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 Biosense Webster Inc., a division of Johnson & Johnson, Medtronic, Inc. and St. Jude Medical Inc.

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;

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- established manufacturing operations and contract manufacturing relationships; and
- significantly greater name recognition and more recognizable trademarks.

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

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

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

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

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

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

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

We have entered into a co-development agreement with Siemens to develop the hardware and MRI software necessary for the ClearTrace system. There can be no assurance that our co-development efforts will be successful or that we will complete development of the ClearTrace system hardware and MRI software. Under our agreement,

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Siemens is responsible for developing the software for the ClearTrace system, and we are responsible for developing the catheters and other hardware, other than the MRI scanner and workstation. The co-development agreement requires us to pay Siemens up to approximately \$2,500,000 for Siemens' successful development of the software in accordance with our specifications. As of December 31, 2011, we have paid Siemens \$850,000 and, in addition, we have accrued payables of approximately \$524,000. 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 Siemens does not successfully commercialize the software, or if our agreement with Siemens is terminated, we may not recover our investment in the software.

***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. We are working with Boston Scientific to incorporate our MRI-safety technologies into Boston Scientific's implantable medical leads for cardiac and neuromodulation applications. There is no assurance that our joint 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 product candidates. Even if Boston Scientific incorporates our licensed intellectual property into its product candidates, Boston Scientific may be unable to obtain regulatory clearance or approval or successfully commercialize the related products, in which case we would not receive royalties in the amounts that we currently anticipate.

### **Risks Related to our Need for Financing**

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

At December 31, 2011, we had cash and cash equivalents of approximately \$145,000, and stockholders' deficit of approximately \$21,843,000. In addition, we had a net loss for the year ended December 31, 2011 of approximately \$8,311,000.

As discussed in the notes to our financial statements included elsewhere in this registration statement, our cumulative net loss since inception and the net losses we incurred in 2011, 2010 and 2009 raise substantial doubt that we will be able to continue operations as a going concern. Our independent auditors included an explanatory paragraph regarding the uncertainty of whether we will be able to continue operations as a going concern in their report on our financial statements for the year ended December 31, 2011. Our ability to continue as a going concern is dependent upon us generating cash flow sufficient to fund operations and reducing operating expenses. Our business plans may not be successful in addressing these issues. If we cannot continue as a going concern, our stockholders may lose their entire investment in us.

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

We anticipate that we will require between \$5 million and \$10 million of additional capital in order to continue to establish effective marketing and sales capabilities for our ClearPoint system and to conduct the research and development and regulatory clearance and approval activities necessary to bring the ClearTrace system to market. We believe that our existing cash resources, together with cash generated from sales of our products and cash generated from our financing activities, will be sufficient to meet our anticipated needs into June 2012. However, our operating plans may change, and we may need additional funds sooner than anticipated to meet our operational needs and capital requirements for product commercialization, product development, clinical trials, and regulatory clearances and approvals.

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

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

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

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As of January 31, 2012, our portfolio included nine wholly-owned issued United States patents (including one design patent), 27 wholly-owned pending United States patent applications (including three provisional applications), seven co-owned issued United States patents, eight co-owned pending United States patent applications, seven wholly-owned issued foreign patent, 42 wholly-owned pending foreign patent applications (including one Patent Cooperation Treaty application), 11 co-owned issued foreign patents and 19 co-owned pending foreign patent applications. In addition, as of January 31, 2012, we had licensed rights to 14 United States and 15 foreign third-party issued patents, and we had licensed rights to six United States and 11 foreign third-party pending patent applications. United States patents and patent applications may be subject to interference proceedings and United States patents may be subject to reissue and reexamination proceedings in the United States Patent and Trademark Office. Foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices. Any of these proceedings could result in either loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of the patent or patent application. Changes in either patent laws or in interpretations of patent laws may also diminish the value of our intellectual property or narrow the scope of our protection. Interference, reexamination and opposition proceedings may be costly and time consuming, and we, or the third parties from whom we license intellectual property, may be unsuccessful in such proceedings. Thus, any patents that we own or license may provide limited or no protection against competitors. In addition, our pending patent applications and those we may file in the future may not result in patents being issued or may have claims that do not cover our products or product candidates. Even if any of our pending or future patent applications are issued, they may not provide us with adequate protection or any competitive advantages. Our ability to develop additional patentable technology is also uncertain.

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

***Others may assert that our ClearPoint system or the ClearTrace system 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 asserted, would be held valid, enforceable and infringed. We cannot assure that a court or administrative body would agree with any arguments or defenses we may have concerning invalidity, unenforceability or non-infringement of any third-party patent.

The medical device industry has been characterized by extensive litigation and administrative proceedings regarding patents and other intellectual property rights, and companies have employed such actions to gain a competitive advantage. If third parties assert infringement or other intellectual property claims against us, our technical and management personnel will experience a significant diversion of time and effort and we will incur large expenses defending our company. If third parties in any patent action are successful, our patent portfolio may be damaged, we may have to pay substantial damages and we may be required to stop selling our marketed 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 marketed products or product candidates from infringement or our patents from claims of invalidity or unenforceability, or to defend our marketed products or product candidates 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.

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***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 would be delayed, potentially hurting our competitive position.***

We license software from a third party that is integrated into the software component of our ClearPoint system. Our license continues through July 2015. If we are unable to continue to license this third-party software, we would not be able to continue 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, beginning on the effective date of this registration statement: (1) we must pay when due all of our payroll obligations; (2) we must not suffer an event of default under any indebtedness for borrowed money; (3) we must maintain net working capital, which is defined as our current assets minus our current liabilities other than deferred revenue, of at least \$(7.6) million as of the end of each month through May 2012; (4) we must maintain net working capital of at least \$(6.0) million as of the end of each month from June 2012 through December 2012; (5) we must maintain net working capital of at least \$(2.0) million as of the end of each month from January 2013 through March 2013; and (6) 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, 2012, our licensing arrangements with Boston Scientific included six wholly owned issued United States patents, three wholly owned pending United States patent applications, seven wholly owned issued foreign patents, seven wholly owned pending foreign patent applications, seven co-owned issued United States patents, eight co-owned pending United States patent applications, 11 co-owned issued foreign patents and 19 co-owned pending foreign patent applications.

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

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

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

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

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

Despite our efforts to safeguard our unpatented and unregistered intellectual property rights, we may not be successful in

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

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

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

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

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

### **Risks Related to Regulatory Compliance**

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

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

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

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

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

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

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

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

***Our products may in the future be subject to product recalls that could harm our reputation, business operations and financial results.***

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design, manufacture or labeling. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is

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

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

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

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

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

Under the federal Food, Drug, and Cosmetic Act and other similar laws, we are prohibited from labeling or promoting our ClearPoint system, or training physicians, for 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 uses of our products that are not cleared or approved, whether on our website, in product brochures or in customer communications. This prohibition means that the FDA could deem it unlawful for us to make claims about the use of our ClearPoint system for specific neurological procedures, such as DBS electrode placement procedures, or proactively discuss or provide information or training on the use of our ClearPoint system for those specific neurological procedures. However, although manufacturers are not permitted to promote for off-label uses, in their practice of medicine, physicians may lawfully choose to use medical devices for off-label uses. Therefore, a physician could use our ClearPoint system for uses not covered by the cleared labeling. This would constitute an off-label use. We expect that physicians will use our ClearPoint system for a variety of specific neurological procedures.

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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. Due to these legal constraints, our sales and marketing efforts will focus on the general technical attributes and benefits of our ClearPoint system and the FDA cleared indications for use. 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 marketed products or the procedures in which our marketed 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 Health Care Reform Law will likely increase the number of whistleblower cases brought against providers and suppliers of health care items and services.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, in addition to the privacy and security rules normally associated with it, which are discussed below, established new federal crimes for knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services.
- State and foreign law equivalents and analogues of each of the above federal laws, such as anti-kickback and false claims laws and the Foreign Corrupt Practices Act, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, or when physicians are employees of a foreign government entity.
- The Health Care Reform Law imposes certain reporting obligations on manufacturers of drugs, devices and biologics. Specifically, on March 31, 2013, and on the 90th day of each calendar year thereafter, these manufacturers must report all payments or other transfers of value to or on behalf of a physician or teaching hospital by such manufacturers as well as any ownership or investment interest held by physicians in such manufacturers. On December 19, 2011, CMS issued proposed regulations to implement this so-called "Sunshine" provision of the Health Care Reform Law. The proposed regulations suggest that we will be subject to such data collecting, reporting and public disclosure obligation. Data collecting obligations will commence on the effective date of final regulations, which is expected in 2012 with reporting obligations beginning on March 31, 2013. Violations of the reporting requirements are subject to civil monetary penalties, capped at \$150,000 annually for failing to report, and \$1,000,000 for knowingly failing to report. Reported data will be made publicly available by September 30, 2013.

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- The Health Care Reform Law 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 have agreements with physicians that may be scrutinized or may be subject to reporting requirements in the future, including consulting contracts for product development in which we compensate physicians for various services, including:

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

We may enter into similar agreements with physicians in the future. Likewise, we may enter into agreements with physicians to provide training and other similar services on the proper use of our products.

The Health Care Reform Law 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 Health Care Reform Law, 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 surgeons 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.

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

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

- HIPAA and its implementing regulations, the HIPAA Privacy and Security Rules, apply to covered entities, which include most healthcare facilities that purchase and use our products. The HIPAA Privacy and Security Rules set forth minimum standards for safeguarding individually identifiable health information, impose certain requirements relating to the privacy, security and transmission of individually identifiable health information and provide certain rights to individuals with respect to that information. HIPAA also requires covered entities to contractually bind third parties, known as business associates, in the event that they perform an activity or service for or on behalf of the covered entity that involves access to patient identifiable health information.
- The federal Health Information Technology for Economic and Clinical Health Act, or HITECH, which was enacted in February 2009, strengthens and expands the HIPAA Privacy and Security Rules and its restrictions on use and disclosure of patient identifiable health information, including imposing liability on business associates of “covered entities”.
- Both HITECH and most states have data breach laws that necessitate the notification in certain situations of a breach that compromises the privacy or security of personal information.
- Other federal and state laws restricting the use and protecting the privacy and security of patient information may apply, many of which are not preempted by HIPAA.
- Federal and state consumer protection laws are being applied increasingly by the United States Federal Trade Commission, or FTC, and state attorneys’ general to regulate the collection, use, storage and disclosure of personal or patient information, through websites or otherwise, and to regulate the presentation of website content.
- Other countries also have, or are developing, laws governing the collection, use and transmission of personal or patient information.
- Federal and state laws regulating the conduct of research with human subjects.

We are required to comply with federal and state laws governing the transmission, security and privacy of patient identifiable health information that we may obtain or have access to in connection with manufacture and sale of our marketed 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 such as training providers on the use of our products or investigating product performance or if our products store patient identifiable health information on behalf of a healthcare provider. We may be required to make costly system modifications to comply with the HIPAA privacy and security requirements that will be imposed on us contractually through business associate agreements by covered entities and directly under HITECH provisions that became effective in February 2010. Because the final regulatory changes to the HIPAA regulations required as part of HITECH have not yet been released, we are unable to predict what the impact on our business may be. Our failure to comply may result in criminal and civil liability because the potential for enforcement action against business associates is now greater. Enforcement actions can be costly and interrupt regular operations which may adversely affect our business.

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In addition, numerous other federal and state laws protect the confidentiality of patient information as well as employee personal information, including state medical privacy laws, state social security number protection laws, state data breach laws and federal and state consumer protection laws. These various laws in many cases are not preempted by the HIPAA rules and may be subject to varying interpretations by the courts and government agencies, creating complex compliance issues for us and our customers and potentially exposing us to additional expense, adverse publicity and liability.

In connection with any clinical trials we conduct, we will be subject to state and federal privacy and human subject protection regulations. The HIPAA requirements and other human subjects research laws could create liability for us or increase our cost of doing business because we must depend on our research collaborators to comply with the applicable laws. We may adopt policies and procedures that facilitate our collaborators' compliance, and contractually require compliance, but we cannot ensure that non-employee collaborators or investigators will comply with applicable laws. As a result, unauthorized uses and disclosures of research subject information in violation of the law may occur. These violations may lead to sanctions that will adversely affect our business.

### **Risks Related to Facilities, Employees and Growth**

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

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

We adopted our Key Personnel Incentive Plan, which is described in more detail in "Executive Compensation—Benefit Plans," to provide Dr. Paul Bottomley, who is a key research advisor, and Mr. Parag Karmarkar, who is a key member of our engineering team, the opportunity to receive incentive bonus payments based on future performance of services to us or upon a sale of our company. However, if Dr. Bottomley or Mr. Karmarkar dies, becomes disabled or is involuntarily terminated by us without cause, we nevertheless would be obligated to make the incentive bonus payments otherwise provided under the plan. The obligation to make these payments could have a material adverse effect on our financial position. We may obtain life insurance on Dr. Bottomley and Mr. Karmarkar to reduce our financial exposure in the event of a participant's death. We also adopted the Cardiac EP Business Participation Plan, which is described in more detail in "Executive Compensation—Benefit Plans," to provide Dr. Nassir Marrouche, who is a key product development advisor, 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. If we sell our cardiac EP business operations or our entire company, we will be required to make a payment to Dr. Marrouche which is calculated as a percentage of the purchase price paid for, or allocated to, our cardiac EP business operations.

*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. We plan to continue to grow our business and will need to hire additional personnel to support this growth. We believe that there are only a limited number of individuals with the requisite skills to serve in many of our key positions, and we compete for key personnel with other medical device companies, as well as universities and research institutions. 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. Employees that hold shares of our common stock or options to purchase our common stock may be more likely to leave us following the establishment of a public market for our common stock. If we are unable to attract and retain the personnel we need to succeed, our business and growth could be harmed.

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

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:

- implementing appropriate operational and financial systems and controls;
- expanding our assembly capacity and increasing production;
- expanding our sales and marketing infrastructure and capabilities;
- 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 common stock has no active trading market. Unless an active trading market develops for our common stock, you may be unable to sell your shares.***

Currently, there is no active trading market for our common stock, and an active trading market for our common stock may not develop or be sustained. There are a number of factors that will make it difficult for an active trading market in our common stock to develop. These factors include:

- stock analysts, stock brokers, institutional investors and other members of the investment community may be reluctant to follow us or create a market in our stock;
- our stock may be deemed to be “penny stock,” which means stock traded at a price less than \$5.00 per share, which will make it unsuitable for some investors to purchase; and
- there are a limited number of stock brokers that will be willing to act as market makers for our common stock, which is essential for establishing an active trading market.

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We intend to have our common stock quoted on the OTC Bulletin Board. This market lacks the credibility of established stock markets and is characterized by a lack of liquidity, sporadic trading and larger gaps between bid and ask prices. Compared to a seasoned issuer with stock traded on an established market, which typically results in a large and steady volume of trading activity, there may be periods when trading activity in our shares is minimal or nonexistent. Trading in our common stock will likely be characterized by large swings in market prices. Unless an active trading market for our common stock is developed and maintained, you may be unable to sell your stock at or above the price you paid, or at all.

***If a trading market in our common stock does develop, our stock price is likely to be volatile.***

If a trading market in our common stock develops, the market will likely be subject to wide fluctuations in price. Additionally, stocks quoted on the OTC Bulletin Board have traditionally experienced significant price and volume fluctuations that often are unrelated or disproportionate to the operating performance of a company traded in such markets. 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.

***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, 2012, our directors and executive officers, together with their affiliates, beneficially owned, in the aggregate, 30.5% 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:

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

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

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We are working with our independent legal and accounting advisors to identify those areas in which changes should be made to our financial and management control systems to manage our growth and our obligations as a public company. These areas include corporate control, disclosure controls and procedures and financial reporting and accounting systems, including requirements under the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act. 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 the securities exchange on which our stock trades. We will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees or as executive officers.

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

### **Item 2. Financial Information**

We have derived the following statement of operations data for the years ended December 31, 2011, 2010 and 2009 and balance sheet data as of December 31, 2011 and 2010 from our audited financial statements included elsewhere in this registration statement. We have derived the following statement of operations data for the years ended December 31, 2008 and 2007 and balance sheet data as of December 31, 2009, 2008 and 2007 from our audited financial statements not included in this registration statement. You should read the financial data set forth below in conjunction with our financial statements and related notes and the information under "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of our results to be expected in any future period.

(in thousands except for share and per share amounts)	Years Ended December 31,				
	2011	2010	2009	2008	2007
<b>Statement of Operations Data:</b>					
Related party license revenue	\$ 2,663	\$ 2,600	\$ 2,600	\$ 1,950	\$ —
Product revenues	1,155	69	—	—	—
Total revenues	<u>3,818</u>	<u>2,669</u>	<u>2,600</u>	<u>1,950</u>	<u>—</u>
Costs and operating expenses:					
Cost of product revenues	656	16	—	—	—
Research and development	4,251	5,681	6,068	4,258	2,099
Selling, general and administrative	4,832	4,699	3,596	2,920	1,413
Costs of withdrawn IPO	—	1,789	—	—	—
Gain on settlement of accounts payable	—	—	—	—	—
Operating loss	<u>(5,922)</u>	<u>(9,515)</u>	<u>(7,064)</u>	<u>(5,229)</u>	<u>(3,512)</u>
Other income (expense):					
Other income (expense)	105	414	—	—	—
Gain on change in fair value of derivative liability	—	1,228	—	—	—
Interest income (expense), net	<u>(2,495)</u>	<u>(1,580)</u>	<u>(46)</u>	<u>(201)</u>	<u>(185)</u>
Loss before income taxes	<u>(8,311)</u>	<u>(9,454)</u>	<u>(7,110)</u>	<u>(5,430)</u>	<u>(3,697)</u>
Income tax expense	<u>—</u>	<u>—</u>	<u>49</u>	<u>—</u>	<u>—</u>
Net loss	<u>\$ (8,311)</u>	<u>\$ (9,454)</u>	<u>\$ (7,159)</u>	<u>\$ (5,430)</u>	<u>\$ (3,697)</u>
Net loss per share (basic and diluted)	<u>\$ (0.52)</u>	<u>\$ (1.40)</u>	<u>\$ (1.34)</u>	<u>\$ (1.04)</u>	<u>\$ (0.74)</u>
Weighted average shares outstanding (basic and diluted)	<u>15,961,371</u>	<u>6,773,714</u>	<u>5,336,633</u>	<u>5,245,081</u>	<u>5,024,515</u>

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(amounts in thousands)	As of December 31,					
	2011	2010	2009	2008	2007	2006
<b>Balance Sheet Data:</b>						
Cash and cash equivalents	\$ 145	\$ 1,577	\$ 2,569	\$ 9,921	\$ 3,612	\$ 6,068
Total assets	3,030	4,563	4,674	10,955	3,730	6,110
Notes payable—current (principal)	4,071	—	—	—	—	—
Notes payable—current (discount)	(117)	—	—	—	—	—
Notes payable—current (net)	3,954	—	—	—	—	—
Notes payable—long-term (principal)	11,435	10,571	3,500	—	1,500	1,000
Notes payable—long-term (discount)	(3,555)	(4,000)	(1,129)	—	—	—
Notes payable—long-term (net)	7,880	6,571	2,371	—	1,500	1,000
Total liabilities	24,874	19,900	14,561	12,720	1,661	1,289
Accumulated deficit	(59,789)	(51,477)	(42,023)	(34,864)	(29,434)	(25,737)
Total stockholders' equity (deficit)	(21,843)	(15,337)	(9,888)	(1,764)	2,069	4,820

**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 included elsewhere in this registration statement. 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 registration statement 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 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 magnetic resonance imaging to guide the procedures. Both systems are designed to work in a hospital's existing MRI suite. We believe that our two product platforms, subject to appropriate regulatory clearance and approval, will deliver better patient outcomes, enhance revenue potential for both physicians and hospitals, and reduce costs to the healthcare system.

In 2010, we received regulatory clearance from the FDA to market our ClearPoint system in the United States for general neurological procedures. In February 2011, we also obtained CE marking approval for the ClearPoint system, which enables us to sell the ClearPoint system in the European Union. Substantially all \$1.2 million in 2011 product revenues relate to sales of our ClearPoint system products in the United States. We do not have regulatory clearance or approval to sell our ClearTrace system and, therefore, we have not generated revenues from sales of that product candidate. In 2008, we received licensing fees totaling \$13.0 million from Boston Scientific for our MRI-safety technologies, which we used to finance our operations and internal growth. We have also financed our operations and internal growth through private placements of securities, borrowings and interest earned on the net proceeds from our private placements and the Boston Scientific licensing fees. Prior to 2008, we were a development stage enterprise. We have incurred significant losses since our inception in 1998 as we have devoted substantially all of our efforts to research and development. As of December 31, 2011, we had an accumulated deficit of \$59.8 million. We may continue to incur significant operating losses as we commercialize our ClearPoint system products, continue to develop our product candidates and expand our business generally. We also expect that our general and administrative expenses will increase due to additional operational and regulatory costs and burdens associated with operating as a public company.

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

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

#### ***Revenues***

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

The generation of recurring revenues through sales of our disposable components is an important part of our business model for our ClearPoint system. We first generated revenues through the sale of ClearPoint system disposable components in the third quarter of 2010. We anticipate that recurring revenues will constitute an increasing percentage of our total revenues as we leverage each new installation of our ClearPoint system to generate recurring sales of these disposable components. With respect to a single hospital, we do not anticipate that sales of the reusable components of our ClearPoint system will generate recurring revenues.

Since inception, our revenues relate primarily to our collaborative agreements with Boston Scientific, principally from recognition of portions of the \$13.0 million of licensing fees, which we received in 2008. Revenues associated with these licensing fees are recognized on a straight-line basis over a five year period, which is our estimated period of continuing involvement in the development activities. Additional payments related to substantive, performance-based milestones that may be received under the agreement regarding implantable cardiac leads will be deferred upon receipt and achievement of the specified milestones and recognized over our estimated period of continuing involvement. These revenue recognition policies are more fully described in the "Critical Accounting Policies and Significant Judgments and Estimates" section below. We did not report any revenues in 2007.

#### ***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. From our inception through December 31, 2011, we have incurred approximately \$35 million in research and development expenses. We anticipate that research and development expenses will increase as we: (1) continue to develop enhancements to our ClearPoint system; (2) continue our product development efforts for the ClearTrace system; and (3) expand our research to apply our technologies to additional product applications.

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

#### ***Selling, General and Administrative Expenses***

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

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### **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 registration statement, 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. In addition, we evaluated repayment provisions associated with one of the license agreements which, under certain conditions, would require us to return payments received under the agreement. We recognize revenue, in accordance with Accounting Standards Codification, or 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 incidental to the utility of the ClearPoint system as a whole, and as such, the provisions of ASC 985-605, Software Revenue Recognition, are not applicable.

(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 various 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 possible repayment obligation provisions, revenue recognition will not occur until the repayment obligation period expires. 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.

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*Inventory.* Inventory is carried at the lower of cost (first-in, first-out method) or net realizable value. All items included in inventory relate to our ClearPoint system. We periodically review our inventory for obsolete items and provide a reserve upon identification of potential obsolete items.

*Valuation Allowance for Deferred Tax Assets and Liabilities.* Deferred 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 bases. Deferred tax 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 on deferred tax assets and liabilities of a change in tax rates is recognized in the period that included the enactment date.

Valuation allowances are recorded for deferred tax assets when the recoverability of such assets is not deemed more likely than not.

We have evaluated the effect of guidance provided by GAAP regarding accounting for uncertainty in income taxes. In that regard, we have evaluated all tax positions that could have a significant effect on the financial statements and determined that we have no uncertain tax positions at December 31, 2011 that could have a significant effect on our financial statements. Our returns after 2006 remain open for examination.

*Impairment of long-lived assets.* We evaluate the recoverability of our 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. When this occurs, 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 expected undiscounted future cash flows of the assets, the carrying amount will be reduced to the present value of the expected future cash flows and an impairment loss would be recognized. As of December 31, 2011, we have not recorded any impairment losses.

*Share-based compensation.* We account for compensation for all arrangements under which employees and others receive shares of stock or equity instruments (including options and warrants) in accordance with FASB ASC Topic 718 “*Compensation – Stock Compensation*”, or ASC Topic 718. Under ASC Topic 718, the fair value of each award is estimated and amortized as compensation expense over the requisite service 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 price volatility and estimated option term. As we have been operating as a private company, we are unable to use actual price volatility and option life data as input assumptions within our Black-Scholes valuation model. Prior to October 2009, we used expected volatilities based on the historical volatility of the industry sector in which we operate, in accordance with the guidance set forth in ASC Topic 718.

Beginning in October 2009, we based our estimate of expected volatility on the average historical volatilities of publicly traded companies we deemed similar due to our lack of historical volatility data of our own. We will consistently apply this methodology until a sufficient amount of historical information regarding the volatility of our share price becomes available.

To estimate the expected term, we chose to utilize the “simplified” method for “plain vanilla” options as discussed in the Securities and Exchange Commission’s Staff Accounting Bulletin 107, or SAB 107. We believe that all factors listed in SAB 107 as pre-requisites for utilizing the simplified method are true for us and for our share-based payment arrangements. We intend to utilize the simplified method for the foreseeable future until more detailed information about exercise behavior becomes available.

Our risk-free interest rates are based on a zero-coupon U.S. treasury instrument, the term of which is consistent with the expected term of the stock options. We have not paid and do not anticipate paying cash dividends on our shares of 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.

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We believe there is a high degree of subjectivity involved when using option pricing models to estimate share-based compensation under ASC Topic 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 stock option awards is determined in accordance with ASC Topic 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 Topic 718 in future periods than those currently applied under ASC Topic 718, the compensation expense we record in future periods under ASC Topic 718 may differ significantly from what we have historically reported.

Total share-based compensation expense for the years ended December 31, 2011, 2010 and 2009 was \$1.0 million, \$0.2 million and \$0.1 million, respectively. As of December 31, 2011 there was \$1.8 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 1.9 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 costs for research and development personnel, costs for materials used in research and development activities and costs for outside services.

*Derivative Financial Instruments.* We account for derivative instruments in accordance with FASB ASC Topic 815, 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 recognition of all derivatives on the balance sheet at fair value. We calculate the fair value of these instruments using the Black-Scholes valuation model. Changes in the fair value of derivatives are recorded each period as a gain or loss in the statement of operations unless the derivative qualifies for hedge accounting. At December 31, 2011, at December 31, 2010 and at December 31, 2009, we did not have any derivative instruments that were designated as hedges.

## Results of Operations

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

(\$s in thousands)	Year Ended December 31,		Percentage Change
	2011	2010	
<b>Revenues</b>	\$ 3,818	\$ 2,669	43%
<b>Cost of product revenues</b>	656	16	NM
<b>Research and development costs</b>	4,251	5,681	(25)%
<b>Selling, general and administrative expenses</b>	4,832	4,699	3%
<b>Costs of withdrawn IPO</b>	—	1,789	NM
<b>Other income (expense), net</b>	(2,390)	61	NM
<b>Net loss</b>	(8,311)	(9,454)	12%

NM = not meaningful

*Revenues.* Revenue was \$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 periods. Product revenues for the years ended December 31, 2011 and 2010 were \$1.2 million and for \$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 \$0.7 million 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.

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*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 \$1.0 million 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 \$0.3 million 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 \$0.3 million 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 \$0.2 million and an increase in share-based compensation expense related to R&D personnel of \$0.2 million.

*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 \$0.1 million, or 3%. The change relates to an increase of \$0.5 million 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 \$0.4 million. 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.

*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 \$0.4 million related to grants received under the Qualifying Therapeutic Discovery Project provided by the United States Treasury Department.

### *Comparison of the Year Ended December 31, 2010 to the Year Ended December 31, 2009*

<i>(\$s in thousands)</i>	<b>Year Ended December 31,</b>		<b>Percentage Change</b>
	<b>2010</b>	<b>2009</b>	
<b>Revenues</b>	\$ 2,669	\$ 2,600	3%
<b>Cost of product revenues</b>	16	—	NM
<b>Research and development costs</b>	5,681	6,068	(6)%
<b>Selling, general and administrative expenses</b>	4,699	3,596	31%
<b>Costs of withdrawn IPO</b>	1,789	—	NM
<b>Other income (expense), net</b>	61	(46)	NM
<b>Net loss</b>	(9,454)	(7,159)	(32)%

**NM = not meaningful**

*Revenues.* Revenues were \$2.7 million for the year ended December 31, 2010 compared to \$2.6 million for the year ended December 31, 2009, an increase of 3%. Licensing fee revenues related to our license agreement with Boston Scientific for implantable cardiac medical leads was \$2.6 million during both periods. Sales of ClearPoint system disposable products of \$0.1 million for the year ended December 31, 2010 comprised the increase.

*Research and Development Costs.* Research and development costs were \$5.7 million for the year ended December 31, 2010, compared to \$6.1 million for the year ended December 31, 2009, a decrease of \$0.4 million, or

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6%. This decrease was due primarily to: (i) a decrease in personnel related costs of \$0.6 million related mostly to reallocation of resources from development related activities in 2009 to selling and operational activities in 2010; (ii) a reduction in prototyping, testing and third party engineering services related to our ClearPoint system of approximately \$0.5, as more ClearPoint system development work was being performed in 2009; and (iii) a decrease of \$0.2 million in software development expenses related to our ClearPoint system, as more software development work was performed in 2009. These decreases were partially offset by an increase in ClearTrace system software development expenses related to the timing of achievement of development milestones and an increase of \$0.3 million in compensation expense related to incentive compensation earned under our Key Personnel Incentive Program.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses were \$4.7 million for the year ended December 31, 2010 compared to \$3.6 million for the year ended December 31, 2009, an increase \$1.1 million, or 31%. The increase was due primarily to: (i) an increase of \$0.9 million in selling, marketing, and other operations costs associated with our commercial launch of our ClearPoint system; (ii) an increase of \$0.4 million related to settlement of a trademark dispute; (iii) an increase of \$0.1 in professional services related to patent filings; and (iv) a \$0.1 million increase in share-based compensation expense. These increases were partially offset by a decrease in bonus and related expenses of \$0.4 million.

*Other Income (Expense), Net.* Net other income was \$61,000 for the year ended December 31, 2010, compared to net other expense of \$46,000 for the year ended December 31, 2009. Net interest expense was \$1.6 million for the year ended December 31, 2010, compared to \$0.2 million for the year ended December 31, 2009. The increase in interest expense relates to interest on increased borrowings and related amortization of debt discount and deferred financing costs. We issued notes payable in the aggregate principal amount of \$3.5 million in the fourth quarter of 2009 that were outstanding for all of 2010. In addition, we issued notes payable during 2010 in the aggregate principal amount of \$7.1 million. Net interest expense for the year ended December 31, 2010 was more than offset by the combination of a gain of \$1.2 million recorded on the revaluation of our derivative liability and other income of \$0.4 million related to grants received under the Qualifying Therapeutic Discovery Project provided by the United States Treasury Department.

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### **Liquidity and Capital Resources**

We received \$13.0 million in licensing fees in 2008 under one of our agreements with Boston Scientific. We recognize revenue from these licensing fees over the estimated time period to complete our development work under the agreement. In addition, under the terms of the agreements, we could receive up to \$20.8 million in future milestone-based payments, subject to our achievement of the milestones stipulated in the agreements and the issuance of certain patents licensed to Boston Scientific, of which there can be no assurance. In addition to payments received from Boston Scientific, we have financed our operations and internal growth almost exclusively through private placements of preferred stock and borrowings. We have incurred significant losses since our inception in 1998. As of December 31, 2011, we had an accumulated deficit of \$59.8 million. Our accumulated deficit resulted primarily from research and development activities and the costs to support such efforts as recorded in general and administrative costs.

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

In March 2010, we issued 10% senior unsecured convertible notes in the aggregate principal amount of \$4.1 million in a private placement. The notes mature two years from the date of issuance and accrue interest at the rate of 10% per year. When issued, the notes did not provide for conversion into shares of our common stock upon the effectiveness of this registration statement. However, all of the note holders amended their notes to provide for the automatic conversion of their notes, including the principal and all accrued interest, into shares of our common stock upon the effectiveness of this registration statement, based on a conversion price of \$1.00 per share. We expect those notes will convert into 4,868,041 shares of our common stock upon the effectiveness of this registration statement.

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In November 2010, we closed a private placement in which we sold units to existing stockholders and other existing investors in the company. Each unit consisted of a junior secured note and one share of our common stock. In the aggregate, we issued 10,714,286 units and received proceeds of \$3.0 million, meaning we issued 10,714,286 shares of common stock and promissory notes in the aggregate principal amount of \$3.0 million. The notes mature 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 our assets. The notes are not convertible into shares of our common stock or any other securities. All outstanding principal and interest on the notes will be due and payable in a single payment upon maturity.

In April 2011, we issued a 10% subordinated secured convertible note in the principal amount of \$2.0 million to Brainlab. The note matures in April 2016, unless earlier converted, and it accrues interest at the rate of 10% per year. All outstanding principal and interest on the note will be due and payable in a single payment upon maturity. The note is secured by a security interest in all our assets. In the event we close a financing transaction in which we issue shares of our preferred stock and receive at least \$10.0 million in net proceeds, the principal and accrued interest of Brainlab's note will automatically convert into shares of the preferred stock issued in the financing, based on the lower of the price paid by investors in the financing or \$0.60 per share, if the number of shares to be issued upon conversion represents at least 10% of our outstanding shares of stock on a fully diluted basis. If the number of shares that would be issued upon conversion represents less than 10% of our outstanding shares of stock on a fully diluted basis, the note will convert into the shares of preferred stock that are issued in the financing, based on the lower of the price paid by investors in the financing or \$0.60 per share, only upon Brainlab's election to convert. Brainlab's note was amended as of February 23, 2012 to give Brainlab the option, at any time on or prior to February 23, 2013, to convert the principal and accrued interest under its note into shares of our common stock, based on a conversion price of \$0.60 per share. At that conversion price, Brainlab would have received 3,628,513 shares of our common stock upon conversion of its note as of February 23, 2012.

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

In October 2011, we began a private placement of our securities in which we offered units, with each unit consisting of a 10% secured convertible note in the principal amount of \$100,000 and a warrant to purchase 50,000 shares of our common stock. The notes mature three years from the date of issuance, unless earlier converted, and accrue interest at 10% per year. The notes are secured by a security interest in all our assets. The notes, including the principal and all accrued interest, convert automatically into shares of our common stock upon the effectiveness of this registration statement, based on a conversion price of \$0.60 per share. Likewise, a note holder may elect at any time to convert the note into shares of our common stock, based on a conversion price of \$0.60 per share. The warrants vest immediately, have a term of five years, and have an exercise price of \$0.75 per share. We received gross proceeds of \$5.4 million in connection with the unit offering. The placement agent for the financing received a cash fee equal to 10% of the gross proceeds, as well as a warrant to purchase that number of shares of our common stock equal to 8% of the number of shares of our common stock issuable upon conversion of the notes and exercise of the warrants sold in this financing. We intend to use the proceeds from the financing for working capital and general corporate purposes. We expect the notes issued in the unit offering will convert into 9,153,248 shares of our common stock upon the effectiveness of this registration statement. The warrants issued in the unit offering are exercisable for 2,717,500 shares of our common stock.

The actual column of the table below presents a summary of our balance sheet at December 31, 2011 which was derived from our audited financial statements included elsewhere in this registration statement. The pro forma adjustments reflect the impact of the conversions of convertible securities into shares of our common stock upon the effectiveness of this registration statement. The table below reflects the following adjustments as if they occurred on December 31, 2011:

- senior unsecured convertible notes issued in March 2010 in the aggregate principal amount of \$4.1 million plus \$0.8 million in accrued interest converting into shares of our common stock at a conversion price of \$1.00 per share;
- unsecured convertible notes issued in June through September 2011 in the aggregate principal amount of \$1.3 million plus \$0.1 million in accrued interest converting into shares of our common stock at a conversion price of \$0.60 per share;
- junior secured convertible notes issued in October through December 2011 in the aggregate principal amount of \$1.6 million plus \$15,000 in accrued interest converting into shares of our common stock at a conversion price of \$0.60 per share;
- debt discounts of \$0.9 million and deferred financing costs of \$0.2 million associated with these convertible notes charged to expense;
- 7,965,000 shares of our preferred stock converting into shares of our common stock on a 1-for-1 basis; and

- junior secured convertible notes issued in January through February 2012 in the aggregate principal amount of \$3.8 million converting into shares of our common stock at a conversion price of \$0.60 per share.

	As of December 31, 2011		
	Actual	Pro Forma Adjustments	Pro Forma As Adjusted
Cash	\$ 145,478	\$ 3,424,950	\$ 3,570,428
All other assets	2,884,951	(214,469)	2,670,482
<b>Total assets</b>	<b>\$ 3,030,429</b>	<b>\$ 3,210,481</b>	<b>\$ 6,240,910</b>
<b>Current liabilities:</b>			
Notes Payable, net of unamortized discount	\$ 3,953,595	\$ (3,953,595)	\$ —
Accrued interest	971,733	(824,511)	147,222
Deferred revenue	2,600,000	—	2,600,000
All other current liabilities	7,063,627	—	7,063,627
Total current liabilities	14,588,955	(4,778,106)	9,810,849
<b>Long-term liabilities:</b>			
Notes Payable, net of unamortized discounts	7,879,998	(2,185,684)	5,694,314
Accrued interest	921,603	—	921,603
Deferred revenue	1,396,374	—	1,396,374
All other long-term liabilities	86,642	—	86,642
Total long-term current liabilities	10,284,617	(2,185,684)	8,098,933
<b>Total liabilities</b>	<b>24,873,572</b>	<b>(6,963,790)</b>	<b>17,909,782</b>
<b>Stockholders' deficit</b>			
Series A convertible preferred stock	7,965,000	(7,965,000)	—
Additional paid-in capital, common and treasury stock	29,980,467	19,394,356	49,374,823
Accumulated deficit	(59,788,610)	(1,255,085)	(61,043,695)
<b>Total stockholders' deficit</b>	<b>(21,843,143)</b>	<b>10,174,271</b>	<b>(11,668,872)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 3,030,429</b>	<b>\$ 3,210,481</b>	<b>\$ 6,240,910</b>

*Net Cash Flows from Operating Activities.* Net cash flows from operating activities for the years ended December 31, 2011, 2010 and 2009 was \$(6.2) million, \$(7.7) million and \$(9.5) million, respectively. The use of cash in the years ended December 31, 2011, 2010 and 2009 resulted primarily from funding research and development activities and from incurring supporting selling, general and administrative expenses.

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*Net Cash Flows from Investing Activities.* Net cash flows from investing activities for the years ended December 31, 2011, 2010 and 2009 was \$(26,000), \$(0.1) million and \$(0.3) million, respectively. Net cash used in investing activities for each of the periods was primarily related to the purchase of property and equipment to establish and support operations at our Irvine, California facility and the acquisition of intellectual property licenses.

*Net Cash Flows from Financing Activities.* Net cash flows from financing activities for the years ended December 31, 2011, 2010 and 2009 was \$4.8 million, \$6.8 million and \$2.4 million, respectively. Net cash flows from financing activities for each period noted above related primarily to the proceeds from our issuance the notes and other securities described above.

*Operating Capital and Capital Expenditure Requirements.* To date, we have not achieved profitability. We could continue to incur substantial net losses for the next several years 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.

As of December 31, 2011, we had \$145,000 in cash and cash equivalents. 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. As described above, we are in the process of conducting a private placement of securities to raise capital for our business. We believe that our existing cash resources, together with cash generated from sales of our products and cash generated from our recently completed financing transaction, will be sufficient to meet our anticipated cash requirements into June 2012. If our available cash and cash equivalents, cash generate from product sales and the net proceeds from our recently completed financing transaction are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or enter into a credit facility. The sale of additional equity and debt securities may result in dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned commercialization, research and development activities, which could materially harm our business.

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

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

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

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The following table summarizes our outstanding future contractual obligations as of December 31, 2011 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	3-5 years	After 5 years
<i>(\$s in thousands)</i>					
Operating Leases	\$ 259	\$ 138	\$ 121	\$ —	\$ —
Notes Payable	19,927	4,885	7,992	3,000	4,050
Co-Development	1,102	1,102	—	—	—
Software Licenses	1,050	350	700	—	—
Incentive Compensation Plan	2,700	675	1,350	675	—
Minimum Royalty Payments	1,460	70	190	190	1,010
Total	\$ 26,498	\$ 7,220	\$ 10,353	\$ 3,865	\$ 5,060

Our commitments under operating leases shown above consist of payments relating to our facilities under leases that as of December 31, 2011 expire in 2012 and 2014. Our note payable obligations consist of the principal amounts and interest that will be payable under the convertible notes we issued to Boston Scientific, the senior unsecured convertible notes we issued in March 2010, the junior secured notes we issued in November 2010, the secured convertible note we issued to Brainlab, the unsecured convertible notes we issued from June through September 2011 and the secured convertible notes issued from October through December 2011. Co-development obligations consist of the payment obligations to Siemens in connection with the ClearTrace system software development. Although reflected in the table, Siemens has agreed in principle to modify the terms of our agreement such that Siemens will fund future development work performed by it under our agreement. Software license obligations represent minimum purchase commitments under a master service and license agreement for the license of software code that is used in our ClearPoint system. Incentive compensation plan obligations represent amounts payable to participants under a key personnel incentive program. Minimum royalty payment obligations consist of the minimum royalty payments due to a licensor.

### Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk for changes in interest rates relates to our cash equivalents on deposit in demand deposit accounts and certificates of deposit. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. We do not currently use derivative financial instruments. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations. As of December 31, 2011, substantially all of our transactions have been denominated in United States dollars, accordingly, we do not have any material exposure to foreign currency rate fluctuations.

### Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

### Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board, or FASB, issued additional guidance on fair value measurements. The updated guidance provides a consistent definition of fair value and aligns the fair value measurement and disclosure requirements between U.S. GAAP and International Financial Reporting Standards, or IFRS, amends certain guidance primarily related to fair value measurements for financial instruments, and enhances disclosure requirements particularly for Level 3 fair value measurements. The guidance is effective prospectively for fiscal years beginning after December 15, 2011 and interim periods within those years. Early adoption is permitted. We do not expect the adoption of this guidance will have a material impact on our financial statements.

In June 2011, the FASB issued new accounting guidance related to the presentation of comprehensive income that increases comparability between U.S. GAAP and IFRS. This guidance will require 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

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interim periods within those years, beginning after December 15, 2011. Nonpublic entities should begin applying these requirements for fiscal years ending after December 15, 2012, and interim and annual periods thereafter. We do not believe the adoption of this guidance will materially impact our results of operations or financial position.

### **Item 3. *Properties***

We lease approximately 7,400 square feet of space in Irvine, California under a lease that expires in September 2012, which we use as our principal research and development facility and for the assembly of certain of our products. We have the right to extend our Irvine lease for three additional years upon prior written notice and the fulfillment of certain conditions.

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 also have a license to use approximately 1,400 square feet of space in Baltimore, Maryland, which we have used for advanced research and development activities. The term of our license agreement for our Baltimore facility expires at the end of February 2012.

We believe that our Irvine, California and Memphis, Tennessee facilities are sufficient to meet our needs for the foreseeable future.

### **Item 4. *Security Ownership of Certain Beneficial Owners and Management***

The following table sets forth information as of January 31, 2012 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 35,000,740 shares outstanding as of January 31, 2012, which includes and assumes:

- 16,084,990 shares of common stock outstanding as of January 31, 2012;
- conversion of all outstanding shares of our preferred stock into 7,965,000 shares of common stock, upon the effectiveness of this registration statement; and
- conversion of \$8,186,437 in principal amount of, and interest on, convertible promissory notes into 10,950,750 shares of common stock, upon the effectiveness of this registration statement.

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, 2012. 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, 2012. 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.

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<u>Beneficial Owner</u>	<u>Number of Shares Owned</u>	<u>% of Shares Outstanding</u>
<b>5% Stockholders</b>		
None		
<b>Directors and Named Executive Officers</b>		
Kimble L. Jenkins <sup>(1)</sup>	1,276,070	3.6
David W. Carlson <sup>(2)</sup>	175,418	*
Paul A. Bottomley <sup>(3)</sup>	214,833	*
Bruce C. Conway <sup>(4)</sup>	3,244,583	9.3
Charles E. Koob <sup>(5)</sup>	570,737	1.6
James K. Malernee, Jr. <sup>(6)</sup>	223,083	*
Michael A. Pietrangelo <sup>(7)</sup>	85,444	*
Andrew K. Rooke <sup>(8)</sup>	4,926,874	13.7
Michael J. Ryan	—	—
John N. Spencer, Jr. <sup>(9)</sup>	44,028	*
Peter G. Piferi <sup>(10)</sup>	232,418	*
Oscar L. Thomas <sup>(11)</sup>	208,352	*
John T. Keane <sup>(12)</sup>	30,000	*
All directors and executive officers as a group (14 persons) <sup>(13)</sup>	11,437,173	30.5

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

- (1) Includes 226,601 shares that Mr. Jenkins has the right to acquire through the exercise of options.
- (2) Includes 86,133 shares that Mr. Carlson has the right to acquire through the exercise of options.
- (3) Includes 87,667 shares that Dr. Bottomley has the right to acquire through the exercise of options.
- (4) Includes 32,891 shares jointly held with his spouse, 131,562 shares held solely by his spouse, 59,444 shares issuable upon the conversion of a convertible note in the principal amount of \$50,000, 404,913 shares issuable upon the conversion of convertible notes in the aggregate principal amount of \$225,000, and 20,661 shares in the aggregate owned by 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 and the Edna N. Conway Irrevocable Trust FBO Merritt Elizabeth Conway. 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 his children.
- (5) Includes 50,000 shares that Mr. Koob has the right to acquire through the exercise of warrants and 21,417 shares that Mr. Koob has the right to acquire through the exercise of options, and 88,055 shares issuable upon the conversion of a convertible note in the principal amount of \$50,000.
- (6) Includes 75,000 shares that Dr. Malernee has the right to acquire through the exercise of warrants, 12,667 shares that Dr. Malernee has the right to acquire through the exercise of options, and 132,083 shares issuable upon the conversion of a convertible note in the principal amount of \$75,000.
- (7) Includes 25,000 shares that Mr. Pietrangelo has the right to acquire through the exercise of warrants, 12,667 shares that Mr. Pietrangelo has the right to acquire through the exercise of options, and 44,027 shares issuable upon the conversion of a convertible note in the principal amount of \$25,000.
- (8) Includes 500,000 shares owned by Payne Partners, LLC, 260,102 shares owned by Withington Foundation, 925,000 shares that Rooke Fiduciary Management has the right to acquire through the exercise of warrants, and 1,663,940 shares issuable upon the conversion of convertible notes in the aggregate principal amount of \$925,000 held by Rooke Fiduciary Management. Mr. Rooke has voting and investment power over the shares owned by Payne Partners, LLC and Withington Foundation, as well as any shares acquired by Rooke Fiduciary Management through the exercise of warrants or the conversion of convertible notes. 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.
- (9) Includes 10,000 shares that Mr. Spencer has the right to acquire through the exercise of warrants, 12,667 shares that Mr. Spencer has the right to acquire through the exercise of options, and 17,611 shares issuable upon the conversion of a convertible note in the principal amount of \$10,000 held jointly by Mr. Spencer and his spouse.
- (10) Includes 143,133 shares that Mr. Piferi has the right to acquire through the exercise of options.
- (11) Includes 119,067 shares that Mr. Thomas has the right to acquire through the exercise of options.
- (12) Includes 30,000 shares that Mr. Keane has the right to acquire through the exercise of options.
- (13) Includes 760,102 shares owned by entities controlled by a director, 1,598,493 shares owned by trusts for which a director serves as trustee, 2,410,073 shares issuable upon conversion of convertible notes in the aggregate principal amount of \$1,360,000, 942,351 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.

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### Item 5. *Directors and Executive Officers*

The following table sets forth information about our directors, executive officers and other key employees as of January 31, 2012.

Name	Age	Position(s)
<b><i>Directors and Executive Officers</i></b>		
Kimble L. Jenkins	49	President, Chief Executive Officer and Chairman of Board of Directors
Paul A. Bottomley	58	Director
Bruce C. Conway	60	Director
Charles E. Koob	67	Director
James K. Malemee, Jr.	64	Director
Michael A. Pietrangelo	69	Director
Andrew K. Rooke	55	Director
Michael J. Ryan	33	Director
John N. Spencer, Jr.	71	Director
Peter G. Piferi	52	Chief Operating Officer
David W. Carlson	47	Chief Financial Officer
Carol J. Barbre	51	Vice President, Product Management
John T. Keane	45	Vice President, Sales
Oscar L. Thomas	41	Vice President, Business Affairs and Secretary

**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.

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**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 also serves on the board of directors of MiMedx Group, Inc., a publicly traded biomedical products company, and DemeRx, Inc., a privately held biotechnology company. 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 and Managing Director 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. 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 is also a director of Medicis Pharmaceutical Corporation, a publicly traded pharmaceutical company, serving on the executive committee (Chair), compliance committee (Chair), and nominating and governance committee. Mr. Pietrangelo also 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 currently 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 a private trust company, which specializes in the investment management of publicly held securities and the oversight of a multitude of trust investments. 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.

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**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.

**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.

**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.

**John T. Keane** joined us in April 2010 as Vice President, Sales. Mr. Keane has over 20 years of sales experience in the medical device industry. From October 2006 until April 2010, Mr. Keane served as the Worldwide Director of Sales for Stereotactic Surgery, Radiosurgery, Image Guided Surgery, Brain Mapping and Service Agreements for Integra Radionics, Inc., a subsidiary of Integra Lifesciences Corporation, a publicly traded medical device manufacturer. From 2004 to 2006, Mr. Keane served as an Academic Center Representative for I-Flow Corporation, formerly a publicly traded medical device company that merged with a subsidiary of Kimberly-Clark Corporation, a publicly traded corporation, in 2009. From 1996 to 2004, Mr. Keane was the National Leader of Academic Sales Representatives at Baxter International Inc., a publicly traded global, diversified health care company.

**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.

### **Board Composition**

Our Board of Directors consists of nine members. Each director's term of office runs from the time of his election until the next following annual meeting of our stockholders and until a successor has been elected or until the director's earlier death, resignation or removal. Our certificate of incorporation that will become effective upon the effectiveness of this registration statement provides that the authorized number of directors may be changed only by resolution of the Board of Directors and that a director may be removed only for cause by the affirmative vote of the holders of a majority of our voting stock.

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### **Item 6. *Executive Compensation***

#### **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 Discussion and Analysis**

##### ***Introduction***

Our compensation discussion and analysis discusses the total compensation for our named executive officers, and it describes our overall compensation philosophy, objectives and practices. Our compensation philosophy and objectives generally apply to all of our employees and all of our employees are eligible to participate in the main components of our compensation program: salary; annual bonus; and equity compensation. The relative value of each of these components for individual employees varies based on job role and responsibility, as well as our financial performance.

##### ***Compensation Philosophy and Objectives***

Our compensation approach is necessarily tied to our stage of development. Our compensation philosophy is to offer our executive officers, including our named executive officers, compensation and benefits that meet our goals of attracting, retaining and motivating highly skilled management, which is necessary to achieve our financial and strategic objectives and create long-term value for our stockholders. Accordingly, our executive officer compensation program is designed to link compensation to corporate and individual performance and to align executive officers' interests with stockholder value creation by subjectively analyzing both corporate and individual performance in determining appropriate base salary, bonus and equity compensation awards.

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We believe compensation should be determined within a framework that is intended to reward individual contribution and the achievement of company objectives. Within this overall philosophy, our objectives are to:

- attract, retain and motivate our executives by providing a total compensation program that takes into consideration our strategic business needs;
- align the financial interests of the executive officers with those of our stockholders, both in the short and long term;
- provide incentives for achieving and exceeding performance expectations; and
- appropriately reward executive officers for creating long-term stockholder value.

Each of our named executive officers is an “at-will” employee. However, some of our named executive officers have employment letters that set forth the basic terms of their employment. The compensation committee is considering the advisability of entering into formal employment agreements with some of our named executive officers following the effectiveness of this registration statement.

On an annual basis, our compensation committee has utilized its business judgment to establish:

- base salaries for our named executive officers based on the recommendations of our Chief Executive Officer and the compensation committee’s exercise of its subjective judgment;
- annual cash bonuses based on the recommendations of our Chief Executive Officer and a subjective analysis by the compensation committee of both the company’s performance and each named executive officer’s performance for the most recently completed fiscal year; and
- any long term equity compensation awards to the named executive officers based on the recommendations of the Chief Executive Officer and the compensation committee’s exercise of its subjective judgment.

### ***Role of Directors and Executive Officers in Setting Compensation***

Prior to September 2008, we did not have a compensation committee and compensation decisions for our named executive officers were approved by our Board of Directors upon the recommendation of our Chief Executive Officer. The compensation recommendations of our Chief Executive Officer have been largely discretionary, based on our Chief Executive Officer’s subjective assessment of the particular executive officer, publicly available data relating to compensation of executive officers at other medical device companies and input from our other executive officers. There is no particular mathematical formula for deriving executive compensation from these sources. As we gain experience as a public company, we expect that the specific direction, emphasis and components of our executive compensation program will continue to evolve. For example, over time, we expect to reduce our reliance upon subjective determinations made by our Chief Executive Officer in favor of a more empirically-based approach that could involve benchmarking the compensation paid to our named executive officers against peer companies that we identify and the use of clearly defined, objective targets to determine incentive compensation awards.

The compensation committee typically considers, but is not required to accept, the recommendations of our Chief Executive Officer regarding the performance and proposed base salary and bonus and equity awards for the other named executive officers, as well as himself. The compensation committee may also request the assistance of our Chief Financial Officer in evaluating the financial, accounting and tax implications of various compensation awards paid to the named executive officers. However, our Chief Financial Officer does not recommend or determine the amounts or types of compensation paid to the named executive officers. Our Chief Executive Officer and certain of our other named executive officers may attend compensation committee meetings, as requested by the compensation committee. None of our named executive officers, including our Chief Executive Officer, attend any portion of the compensation committee meetings during which his or her compensation is established and approved.

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We believe that the levels of compensation we provide should be appropriate for our business needs and circumstances. To date, the compensation committee has not engaged a compensation consultant. Rather, the compensation committee and our Chief Executive Officer applied subjective discretion to make compensation decisions and they have not used a specific formula or matrix to set compensation in relation to compensation paid by other medical device companies. Our compensation committee designed our executive compensation program based on the compensation committee's general knowledge of compensation practices and the application of such knowledge to successfully attract and retain the named executive officers. Our compensation committee has not established any percentile targets for the levels of compensation provided to our named executive officers. To date, the compensation committee has not performed reviews of our compensation programs with those of similarly-situated companies, nor has it engaged in benchmarking of compensation paid to our named executive officers. Our historical approach has been to consider compensation practices and relevant factors rather than establishing compensation at specific benchmark percentiles. This enabled us to respond to dynamics in the labor market and provided us with flexibility in maintaining and enhancing our named executive officers' engagement, focus, motivation and enthusiasm for our future. However, as mentioned above, we expect to build some of these objective practices into our compensation approach over time.

The amount of past compensation, including annual discretionary bonus awards, and amounts realizable from prior stock option awards, is generally not a significant factor in the compensation committee's considerations, because these awards would have been earned based on prior years' performances or granted in connection with a named executive officer's initial hire.

Our named executive officers are not subject to mandated stock ownership or stock retention guidelines. It is the belief of the compensation committee that the equity component of our executive compensation program ensures that our named executive officers are also owners and those components work to align the named executive officers' goals with the best interests of stockholders.

### ***Elements of Our Executive Compensation Program***

The principal elements of our executive compensation program have been base salary, a discretionary cash bonus and long-term equity compensation in the form of stock options. Each of these compensation elements satisfies one or more of our compensation objectives.

We have not adopted any policies with respect to long-term versus currently-paid compensation, but feel that both elements are necessary for achieving our compensation objectives. Currently-paid compensation provides financial stability for each of our named executive officers and an immediate reward for short-term company and individual performance, while long-term compensation rewards achievement of strategic long-term objectives and contributes toward overall stockholder value. Similarly, while we have not adopted any policies with respect to cash versus equity compensation, we feel that it is important to encourage or provide for a meaningful amount of equity ownership by our named executive officers as to help align their interests with those of stockholders, one of our compensation objectives. We combine the compensation elements for each named executive officer in a manner that the compensation committee believes, in its discretion and judgment, is consistent with the executive's contributions to our company and our overall goals with respect to executive compensation.

### ***Base Salary***

We believe that base salary is an important component of compensation as it provides a degree of financial stability for our named executive officers and is critical to recruiting and retaining our named executive officers. Base salary is also designed to recognize the scope of responsibilities placed on each named executive officer and reward each executive for his or her unique leadership skills, management experience and contributions. We make a subjective determination of base salary after considering such factors collectively.

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### *Annual Cash Bonuses*

Our cash bonus compensation is designed to motivate executives to achieve superior performance in their areas of responsibility. To date, we have awarded only discretionary annual cash bonuses based upon a subjective evaluation of corporate and individual performance by the compensation committee or, prior to its creation, our Board of Directors.

### *Long-Term Equity Compensation*

We grant stock options to our named executive officers, as we believe that such grants further our compensation objectives of aligning the interests of our named executive officers with those of our stockholders, encouraging long-term performance, and providing a simple and easy-to-understand form of equity compensation that promotes executive retention. We view such grants both as incentives for future performance and as compensation for past accomplishments.

We generally have used stock options, rather than other forms of long-term incentives, because they create value for the executive only if stockholder value is increased through an increased share price. Our Board of Directors determined the exercise price based on internal or third-party valuation reports. In the future, the exercise price of stock options will be the fair market value of our common stock on the grant date. We have made discretionary grants of equity compensation, from time to time, as determined by the Board of Directors or after its creation, the compensation committee, taking into consideration such factors as individual performance and market conditions. The timing of any such equity grants was determined based on achievement by the named executive officer, and not any effort to time the grants in coordination with changes in our stock price.

### *Stock Ownership Guidelines*

We currently do not have stock ownership guidelines.

### *Perquisites and Other Benefits*

As a general matter, we do not intend to offer perquisites or other benefits to any executive officer, including the named executive officers, with an aggregate value in excess of \$10,000, because we believe we can provide better incentives for desired performance with compensation in the forms described above. We recognize that, from time to time, it may be appropriate to provide some perquisites or other benefits in order to attract, motivate and retain our executives, with any such decision to be reviewed and approved by the compensation committee as needed.

Our named executive officers are eligible to participate in standard employee benefit plans, including medical, dental, vision, life and any other employee benefit or insurance plan made available to employees. We maintain a 401(k) plan, which is intended to be a tax-qualified defined contribution plan under Section 401(k) of the Internal Revenue Code, or the Code. In general, all of our U.S. employees are eligible to participate in this plan. The 401(k) plan includes a salary deferral arrangement pursuant to which participants may elect to reduce their current compensation by up to 90% or the statutory limit, \$16,500 in 2010, whichever is less, and have the amount of the reduction contributed to the 401(k) plan. We made no matching contributions during 2010; however, we may add this benefit in the future for all employees.

### *Analysis of 2011 Compensation for Named Executive Officers*

#### *Base Salary*

The 2011 salaries for our named executive officers were established as follows:

- The base salary of Mr. Kimble L. Jenkins, our President and Chief Executive Officer, remained unchanged at \$325,000 per year.

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- The base salary of David W. Carlson, our Chief Financial Officer, remained unchanged at \$225,000 per year.
- The base salary of Mr. Peter G. Piferi, our Chief Operating Officer, remained unchanged at \$250,000 per year.
- The salary of Mr. Oscar L. Thomas, our Vice President, Business Affairs, remained unchanged at \$175,000 per year. Mr. Thomas is also entitled to receive guaranteed bonus payments equal to \$12,500 per calendar quarter in accordance with the initial terms of his hiring. Since those bonus payments are guaranteed, they are considered to be part of Mr. Thomas' base salary, which totals \$225,000 per year.
- The base salary of Mr. John T. Keane, our Vice President, Sales, remained unchanged at \$220,000 per year.

However, effective October 1, 2010 and continuing through December 31, 2011, Messrs. Jenkins, Carlson, Piferi and Thomas voluntarily agreed to reduce their salaries temporarily to conserve cash for our operations. Taking into account the salary reductions, the actual base salaries paid to each of our named executive officers in 2011 and the amount of salary reductions were as follows:

<u>Named Executive Officer</u>	<b>2011</b>	<b>2011</b>
	<b>Actual Base Salary Paid</b>	<b>Salary Reductions</b>
Kimble L. Jenkins	\$260,000	65,000
David W. Carlson	175,000	50,000
Peter G. Piferi	200,000	50,000
Oscar L. Thomas	190,000	35,000
John T. Keane	220,000	—

### *Annual Cash Bonuses*

No annual cash bonuses were paid to our named executive officers for 2011.

### *Long-Term Equity Compensation*

No stock options or other long-term equity compensation was awarded to our named executive officers for 2011. Historically, the compensation committee has considered the grant of stock options to our named executive officers based on the recommendations made to the compensation committee by Mr. Jenkins, as our Chief Executive Officer. Mr. Jenkins did not request the compensation committee to consider the grant of stock options to any of our named executive officers for 2011, based primarily on the limited number of shares available for issuance under our equity compensation plans. The absence of stock option grants to our named executive officers for 2011 was not based on any evaluation or analysis by the compensation committee of the company's performance or the performance of any of our named executive officers.

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### ***Effect of Accounting and Tax Treatment on Compensation Decisions***

In the review and establishment of our compensation programs, we consider the anticipated accounting and tax implications to us and our executives. While we consider the applicable accounting and tax treatment, these factors alone are not dispositive, and we also consider the cash and non-cash impact of the programs and whether a program is consistent with our overall compensation philosophy and objectives.

Section 162(m) of the Code imposes a limit on the amount of compensation that we may deduct in any one year with respect to covered employees, unless specific and detailed criteria are satisfied. Performance-based compensation, as defined in the Code, is fully deductible if the programs are approved by stockholders and meet other requirements. In general, we have determined that we will not seek to limit executive compensation so that all of such compensation is deductible under Section 162(m). However, from time to time, we monitor whether it might be in our interests to structure our compensation programs to satisfy the requirements of Section 162(m). We seek to maintain flexibility in compensating our executives in a manner designed to promote our corporate goals and, as a result, our compensation committee has not adopted a policy requiring all compensation to be deductible. Our compensation committee will continue to assess the impact of Section 162(m) on our compensation practices and determine what further action, if any, is appropriate.

### ***Conclusion***

The compensation committee believes that our executive leadership is a key element to our success and that the compensation package offered to our named executive officers is a key element in attracting and retaining the appropriate personnel.

The Board of Directors and, since its creation, the compensation committee each believes it has maintained compensation for our named executive officers at levels that are reflective of the talent and success of the individuals being compensated, and with the inclusion of additional compensation directly tied to performance, the compensation committee believes executive compensation will be sufficiently comparable to our industry peers to allow us to retain our key personnel at costs which are appropriate for us.

The compensation committee will continue to develop, analyze and review its methods for aligning executive officers' long-term compensation with the benefits generated for stockholders. The compensation committee believes the idea of creating ownership helps align management's interests with the interests of stockholders. The compensation committee has no pre-determined timeline for implementing new or ongoing long-term incentive plans. New plans are reviewed, discussed and implemented as the compensation committee feels it is necessary or appropriate as a measure to incent, retain and reward our named executive officers.

### **Summary Compensation Table**

The following table shows the compensation awarded or paid to, or earned by, our Chief Executive Officer, our Chief Financial Officer, and our three other most highly compensated executive officers for the years ended December 31, 2011, 2010 and 2009. We refer to these executive officers in this registration statement as our "named executive officers".

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Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards (\$) <sup>(1)</sup>	All Other Compensation (\$) <sup>(2)</sup>	Total (\$)
Kimble L. Jenkins	2011	\$260,000	\$ —	\$ —	\$ 7,194	\$267,194
Chief Executive Officer and President	2010	308,750	—	556,100 <sup>(3)</sup>	6,527	871,377 <sup>(4)</sup>
	2009	325,000	110,000	192,060 <sup>(5)</sup>	5,355	632,415 <sup>(5)</sup>
David W. Carlson	2011	175,000	—	—	8,170	183,170
Chief Financial Officer	2010	179,327	—	282,200 <sup>(6)</sup>	5,084	466,611 <sup>(7)</sup>
	2009	—	—	—	—	—
Peter G. Piferi	2011	200,000	—	—	3,558	203,558
Chief Operating Officer	2010	241,667	—	468,950 <sup>(8)</sup>	3,355	713,972 <sup>(9)</sup>
	2009	250,000	100,000	—	2,860	352,860
Oscar L. Thomas	2011	190,000	—	—	6,938	196,938
Vice President, Business Affairs	2010	212,500	—	390,100 <sup>(10)</sup>	5,757	608,357 <sup>(11)</sup>
	2009	225,000	80,000	—	5,355	310,355
John T. Keane	2011	220,000	57,000 <sup>(12)</sup>	—	7,158	284,150
Vice President, Sales	2010	165,000	54,000 <sup>(12)</sup>	74,700 <sup>(13)</sup>	4,750	298,450 <sup>(14)</sup>
	2009	—	—	—	—	—

- (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 registration statement.
- (2) 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 670,000 shares of our common stock issued to Mr. Jenkins.
- (4) Of this amount, the cash compensation paid to Mr. Jenkins totaled only \$308,750.
- (5) In September 2004, Mr. Jenkins purchased 500,000 shares of our common stock, which he paid for by delivering to us a non-recourse promissory note. In December 2009, we filed a registration statement for a planned initial public offering of our common stock. Section 402(a) of the Sarbanes-Oxley Act required that the note be repaid prior to the filing of that registration statement. Our Board of Directors formed a special committee of independent directors to review and evaluate any potential transaction with Mr. Jenkins with respect to his loan. The special committee approved, and our Board of Directors ratified, a transaction pursuant to which, on December 22, 2009, Mr. Jenkins sold us 66,652 shares of common stock valued at \$9.64 per share and we issued to Mr. Jenkins an option to purchase 66,652 shares of common stock with an exercise price of \$9.64 per share. Our Board of Directors determined that the fair market value of our common stock as of December 22, 2009 was \$9.64 per share. We paid most of the stock purchase price for Mr. Jenkins’ shares by cancelling Mr. Jenkins’ promissory note and we paid the remaining portion of approximately \$47,833 in cash. See “Certain Relationships and Related Party Transactions—Related Person Transactions.” The purpose of the transaction was to satisfy Mr. Jenkins’ promissory note to enable us to file our registration statement for the planned initial public offering while maintaining as closely as possible the original economics of Mr. Jenkins’ loan transaction. The December 22, 2009 stock option we issued to Mr. Jenkins, when computed in accordance with ASC Topic 718, resulted in \$183,960 of non-cash compensation to Mr. Jenkins.
- (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 340,000 shares of our common stock issued to Mr. Carlson.
- (7) Of this amount, the cash compensation paid to Mr. Carlson totaled only \$179,327.
- (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 565,000 shares of our common stock issued to Mr. Piferi.
- (9) Of this amount, the cash compensation paid to Mr. Piferi totaled only \$241,667.
- (10) 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.
- (11) Of this amount, the cash compensation paid to Mr. Thomas totaled only \$212,500.
- (12) Represents commissions paid to Mr. Keane in connection with his ClearPoint sales activities.
- (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 90,000 shares of our common stock issued to Mr. Keane.
- (14) Of this amount, the cash compensation paid to Mr. Keane totaled only \$219,000.

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**Grants of Plan-Based Awards**

There were no grants of plan-based awards to our named executive officers in 2011.

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### Outstanding Equity Awards at December 31, 2011

The table below sets forth information regarding the outstanding equity awards held by our named executive officers at December 31, 2011.

Name	Option Awards			
	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 <sup>(1)</sup>	— <sup>(1)</sup>	3.20	March 28, 2017
	2,500 <sup>(2)</sup>	— <sup>(2)</sup>	9.64	September 16, 2018
	2,500 <sup>(3)</sup>	— <sup>(3)</sup>	9.64	November 8, 2018
	2,500 <sup>(4)</sup>	— <sup>(4)</sup>	9.64	December 10, 2019
	44,435 <sup>(5)</sup>	22,217 <sup>(5)</sup>	9.64	September 1, 2013
David W. Carlson	169,734 <sup>(6)</sup>	339,466 <sup>(6)</sup>	1.80	December 13, 2020
	— <sup>(7)</sup>	160,800 <sup>(7)</sup>	1.80	December 13, 2020
	86,134 <sup>(6)</sup>	172,266 <sup>(6)</sup>	1.80	December 13, 2020
Peter G. Piferi	— <sup>(7)</sup>	81,600 <sup>(7)</sup>	1.80	December 13, 2020
	143,134 <sup>(6)</sup>	286,266 <sup>(6)</sup>	1.80	December 13, 2020
Oscar L. Thomas	— <sup>(7)</sup>	135,600 <sup>(7)</sup>	1.80	December 13, 2020
	119,067 <sup>(6)</sup>	238,133 <sup>(6)</sup>	1.80	December 13, 2020
John T. Keane	— <sup>(7)</sup>	112,800 <sup>(7)</sup>	1.80	December 13, 2020
	15,000 <sup>(6)</sup>	30,000 <sup>(6)</sup>	1.80	December 13, 2020
	15,000 <sup>(6)</sup>	30,000 <sup>(6)</sup>	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 vest 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. The remaining shares subject to this option vest ratably on the second and third anniversaries of the grant date, December 13, 2012 and December 13, 2013.
- (7) The shares subject to this option vest ratably on the first, second and third anniversaries of the grant date, December 13, 2011, December 13, 2012 and December 13, 2013, provided that no shares vest until such time as we have closed a target equity financing, which is defined as one or more equity financing transactions that results in cumulative gross proceeds of at least \$10 million.

### Option Exercises

None of our named executive officers exercised stock options in 2011.

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### Employment Agreements

Each of our named executive officers is an “at-will” employee. However, some of our named executive officers have employment letters that set forth the basic terms of their employment. The compensation committee is considering the advisability of entering into formal employment agreements with some of our named executive officers following the effectiveness of this registration statement.

### Potential Payments Upon Change of Control

<u>Name</u>	<u>Benefit</u>	<u>Change of Control</u>
Kimble L. Jenkins	Stock option acceleration <sup>(1)</sup>	—
David W. Carlson	Stock option acceleration <sup>(1)</sup>	—
Peter G. Piferi	Stock option acceleration <sup>(1)</sup>	—
Oscar L. Thomas	Stock option acceleration <sup>(1)</sup>	—
John T. Keane	Stock option acceleration <sup>(1)</sup>	—

- (1) Assumes change of control effective as of December 31, 2011 and excludes vested options and stock held as of such date. Stock option acceleration is calculated as the intrinsic value of the unvested options on December 31, 2011. The intrinsic value is calculated as the difference between the market value of our common stock as of December 31, 2011, and the exercise price of the stock option. We do not believe that the fair market value as of December 31, 2011, exceeds the exercise price of the options. There was no public market for our common stock in 2011.

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.

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### 2011 Director Compensation

The following table sets forth information with respect to the compensation of our non-employee directors in 2011.

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$) <sup>(1)</sup>	All Other Compensation (\$)	Total (\$)
Lenox D. Baker <sup>(2)</sup>	\$ 2,625	\$ —	\$ —	\$ 2,625
Paul A. Bottomley	8,500	—	60,000 <sup>(3)</sup>	68,500
Bruce C. Conway	5,750	—	—	5,750
Charles E. Koob	11,750	—	—	11,750
James K. Malernee, Jr.	11,500	—	—	11,500
Michael A. Pietrangelo	11,750	—	—	11,750
Andrew K. Rooke	4,250	—	—	4,250
Michael J. Ryan	4,000	—	—	4,000
John N. Spencer, Jr.	12,500	—	—	12,500
John C. Thomas, Jr. <sup>(4)</sup>	4,250	—	—	4,250

- (1) These amounts do not represent cash compensation paid to the named individual. These non-cash amounts represent the aggregate grant date fair value of such options 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 registration statement.
- (2) In connection with his retirement as a director, Dr. Baker did not stand for re-election to the Board of Directors at our 2011 annual meeting of stockholders which was held on May 13, 2011.
- (3) This amount was compensation paid under Dr. Bottomley’s consulting agreement.
- (4) Mr. Thomas ceased serving as our Chief Financial Officer in April 2010. In June 2011, Mr. Thomas, who had been a director since April 2004, made the decision to step down from our Board of Directors. Accordingly, Mr. Thomas submitted his resignation from our Board of Directors effective June 27, 2011.

### 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 December 31, 2011. 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, 129,875 shares of common stock were subject to options outstanding as of December 31, 2011. As of such date, the outstanding options had a weighted average exercise price of \$6.77 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.

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Of the 1,250,000 shares of common stock that were eligible for issuance pursuant to awards made under the 2010 Incentive Compensation Plan, 824,950 shares of common stock were subject to options outstanding as of December 31, 2011. 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 as of December 31, 2011. 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.

The following summary is qualified in its entirety by reference to the text of the 2012 Plan, which is filed as an exhibit to this registration statement.

*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.

*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.

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*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 based on future performance of services to the company or 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, 2015 or the occurrence of a sale transaction.

### ***Service Bonuses***

Until the occurrence of a sale transaction, each participant will be entitled to receive semi-annual service bonuses beginning on June 30, 2012 and continuing through December 31, 2015 if the participant continues to provide services to us as our consultant or employee as of the respective payment dates. Pursuant to their awards, Dr. Bottomley and Mr. Karmarkar would receive service bonuses totaling up to \$1,700,000 and \$1,000,000, respectively, payable in eight equal semi-annual installments. If the participant's consultancy or employment is (i) terminated due to the participant's death or disability, or (ii) involuntarily terminated by us other than for cause, as defined in the program, then the participant will be deemed vested, as of the termination date, in all future service bonus payments, and we will pay that aggregate amount no later than March 15 of the year following the year in which the termination occurred.

### ***Bonus Upon 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 if the participant continues to provide services to us as our consultant or employee as of the date of the transaction. Mr. Karmarkar would receive a bonus equal to \$1,000,000, less any service bonus payments made to Mr. Karmarkar as described above. 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, less (iii) any service bonus payments made to Dr. Bottomley as described above. Following a sale transaction, neither participant will be entitled to receive any further service bonuses.

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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 December 31, 2011, the participant’s participation interest was 6.6%. However, the participant’s participation interest will be appropriately reduced to take into account the shares of common stock issuable in connection with conversions upon the effectiveness of this registration statement. 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.

### **Limitations on Directors’ Liability and Indemnification Agreements**

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

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

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

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

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

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

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

### **Item 7. *Certain Relationships and Related Transactions, and Director Independence***

#### **Policies and Procedures for Related Person Transactions**

We adopted a related person transactions policy, to be effective upon effectiveness of this registration statement, 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, in which the amount involved exceeds the lesser of \$120,000 or 1% of the average of our total assets at year end for the last two completed fiscal years, must be presented to our audit committee for review, consideration and approval. 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. Under 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, 2009 to which we have been a party, in which the amount involved in the transaction exceeds \$38,000, 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 September 2004, Mr. Jenkins, our Chief Executive Officer, purchased 500,000 shares of our common stock for an aggregate purchase price of \$480,000. Mr. Jenkins paid the purchase price by delivering to us a non-recourse promissory note in the principal amount of \$480,000, and Mr. Jenkins pledged the purchased shares as security for the note. The note was amended and restated on September 30, 2008 to extend the maturity date. As of December

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22, 2009, the outstanding balance on the note was \$594,687 (including \$114,687 of accrued interest). In December 2009, we filed a registration statement for a planned initial public offering of our common stock. Section 402(a) of the Sarbanes-Oxley Act required that Mr. Jenkin's note be repaid prior to the filing of that registration statement. Our Board of Directors formed a special committee of independent directors to review and evaluate any potential transaction with Mr. Jenkins with respect to his loan. The special committee approved, and our Board of Directors ratified, a transaction pursuant to which, on December 22, 2009, Mr. Jenkins sold us 66,652 shares of common stock valued at \$9.64 per share and we issued to Mr. Jenkins an option to purchase 66,652 shares of common stock with an exercise price of \$9.64 per share. Our Board of Directors determined that the fair market value of our common stock as of December 22, 2009 was \$9.64 per share. We paid a portion of the stock purchase price, approximately \$594,687, by cancelling Mr. Jenkins' promissory note and the remainder, approximately \$47,833, was paid in cash. The purpose of the transaction was to satisfy Mr. Jenkins' promissory note to enable us to file of our registration statement for the planned initial public offering while maintaining as closely as possible the original economics of Mr. Jenkins' loan transaction.

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. Upon the effectiveness of this registration statement, all principal and accrued interest on the notes automatically convert into shares of our common stock at a conversion price of \$0.60 per share.

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 disclosure above, the terms of the Key Personnel Incentive Plan, which is more fully described in the section entitled "Benefit Plans—Key Personnel Incentive Plan", is incorporated and restated herein.

### **Third Amended and Restated Investors Rights' Agreement**

Pursuant to our Third Amended and Restated Investors Rights' Agreement, or Rights Agreement, certain of our stockholders and their affiliates and transferees have registration rights. For more information concerning the Rights Agreement and other registration rights we have granted, please see "Description of Capital Stock—Registration Rights."

### **Indemnification Agreements**

We have entered into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our certificate of incorporation and bylaws. See "Management—Limitations on Directors' Liability and Indemnification Agreements".

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### **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.

### **Item 8. *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 9. *Market Price of and Dividends on the Registrant’s Common Equity and Related Stockholder Matters***

#### **Market Information**

There is no established public trading market for our common stock.

#### **Holders**

As of January 31, 2012, we had 16,084,981 shares of common stock outstanding and 7,965,000 shares of preferred stock outstanding that are convertible into 7,965,000 shares of common stock upon the effectiveness of this registration statement. As of January 31, 2012, we also had convertible notes in the aggregate principal amount of approximately \$7.4 million outstanding that are convertible into 10,950,750 shares of common stock upon the effectiveness of this registration statement. As of January 31, 2012, we had approximately 600 stockholders, assuming the conversion of all outstanding shares of our preferred stock, as well as convertible notes in the aggregate principal amount of approximately \$7.4 million, into shares of our common stock upon the effectiveness of this registration statement. In addition, as of January 31, 2012, options and warrants to purchase 6,021,421 shares of common stock were issued and outstanding, as were convertible notes in the aggregate principal amount of approximately \$6.2 million that, as of January 31, 2012, did not automatically convert into shares of common stock upon the effectiveness of this registration statement.

#### **Dividends**

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.

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### 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 security holders	1,242,325	\$ 2.11	425,050
Equity compensation plans not approved by security holders(1)	2,371,000	\$ 1.80	194,675
Total	3,613,325	\$ 1.91	619,725

- (1) Our Board of Directors adopted our 2010 Non-Qualified Stock Option Plan on December 13, 2010. That plan has not been approved by our stockholders. The plan provided for the issuance of non-qualified stock options to purchase up to 2,565,675 shares of our common stock. We ceased making awards under this plan upon the adoption of our 2012 Incentive Compensation Plan.

#### Item 10. Recent Sales of Unregistered Securities

The following sets forth information regarding all unregistered securities sold since December 31, 2008:

1. We granted stock options to employees, consultants and directors to purchase an aggregate of 29,250 shares of common stock under our 2007 Stock Incentive Plan, 851,450 shares of common stock under our 2010 Incentive Compensation Plan, and 2,395,000 shares of common stock under our 2010 Non-Qualified Stock Option Plan. The issuance of these options was exempt from registration under Section 4(2) of the Securities Act, as a sale not involving a public offering, or pursuant to Rule 701 under the Securities Act.

2. On December 22, 2009, we issued to Mr. Jenkins an option to purchase 66,652 shares of our common stock at an exercise price of \$9.64 per share. The issuance of this option was exempt from registration under 4(2) of the Securities Act, as a sale not involving a public offering.

3. During 2009, Boston Scientific loaned us \$3.5 million pursuant to the terms of three convertible promissory notes. Each loan accrued interest at the rate of 10% per year, compounded annually, and each loan was scheduled to mature on the second anniversary of the date on which the funds were advanced. Effective February 2, 2012, we entered into a loan amendment with Boston Scientific which extended the maturity dates of each loan by three years and also reduced the interest rate of each loan from 10% to 0%, beginning February 2, 2012. The Boston Scientific loans are secured by a first priority security interest in all of our assets. Under the terms of the loans, we will be required to prepay all or a portion of the loans upon the consummation of any qualified financing, which is any equity financing in which shares of our preferred stock are issued in exchange for cash proceeds. Upon consummation of a qualified financing from Medtronic, Inc., St. Jude Medical, Inc., or Johnson & Johnson, or any of their respective subsidiaries or affiliates, up to 100% of the cash proceeds from such qualified financing must be used to prepay the outstanding amount of the loans. Upon consummation of a qualified financing from any other investor, up to 25% of the cash proceeds from such qualified financing must be applied by us to prepay the outstanding amount of the loans. We can prepay each loan at any time prior to its respective maturity date. At the option of Boston Scientific, the loans are convertible at any time into one share of a new series of our preferred stock for every \$8.00 outstanding under the loans at the time of conversion. The shares of the new series of preferred stock issuable upon such an optional conversion by Boston Scientific must be agreed upon between us and Boston Scientific. In addition, in the event we conduct a qualified financing, Boston Scientific may elect to convert the loans into shares of the series of preferred stock that we issue in the qualified financing, based on a conversion price equal to the lowest price paid by investors in the qualified financing for a share of preferred stock. In the event Boston Scientific has not converted the loans into shares of preferred stock prior to the time we consummate an initial public offering of shares of our common stock in which we receive gross cash proceeds of at least \$20 million, Boston Scientific will lose its right to convert the loans into equity.

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4. In March 2010, we issued 10% senior unsecured convertible notes in the aggregate principal amount of approximately \$4.1 million to 50 accredited investors in a private placement. The notes automatically convert into shares of our common stock upon the closing of an initial public offering of shares of our common stock at the lesser of \$8.00 per share or 80% of the public offering price. In addition, subject to prior maturity, prepayment and/or certain adjustments, holders of the notes may convert the outstanding principal amount of their notes into shares of our common stock at any time, based on a conversion price of \$8.00 per share. The notes mature two years from the date of issuance, unless earlier converted, and accrue interest at the rate of 10% per year. When issued, the notes did not provide for conversion into shares of our common stock upon the effectiveness of this registration statement. However, all of the note holders amended their notes to provide for the automatic conversion of their notes, including the principal and all accrued interest, into shares of our common stock upon the effectiveness of this registration statement, based on a conversion price of \$1.00 per share. In connection with the financing transaction in which the notes were originally issued, we engaged Gilford Securities Incorporated to serve as our placement agent. As placement agent, Gilford Securities Incorporated received a cash fee of approximately \$285,000 and a warrant exercisable for 25,444 shares of our common stock at a price equal to the lesser of \$8.00 per share or 80% of the public offering price in an initial public offering.

5. In November 2010, we issued an aggregate of 10,714,286 units in a private placement and 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 \$3,000,000. The notes mature 10 years from the date of issuance and accrue interest at the rate of 3.5% per annum. The notes are secured by a security interest in all of our assets. The notes are not convertible into shares of our common stock or any other securities. All outstanding principal and interest on the notes will be due in a single payment upon maturity.

6. In April 2011, we issued a 10% subordinated secured convertible promissory note in the principal amount of \$2,000,000 to Brainlab. The note matures in April 2016, unless earlier converted, and it accrues interest at the rate of 10% per year. All outstanding principal and interest on the note will be due in a single payment upon maturity. In the event we close an equity financing in which we issue shares of our preferred stock and receive at least \$10,000,000 in net proceeds, the note will automatically convert into the shares of preferred stock that are issued in the financing, based on the lower of the price paid by investors in the financing or \$0.60 per share, if the number of shares to be issued upon conversion represents at least 10% of our outstanding shares of stock on a fully diluted basis. If the number of shares that would be issued upon conversion represents less than 10% of our outstanding shares of stock on a fully diluted basis, the note will convert into the shares of preferred stock that are issued in the financing, based on the lower of the price paid by investors in the financing or \$0.60 per share, only upon Brainlab's election to convert. Brainlab's note was amended as of February 23, 2012 to give Brainlab the option, at any time on or prior to February 23, 2013, to convert the principal and all accrued interest under its note into shares of our common stock, based on a conversion price of \$0.60 per share.

7. In June through September 2011, we issued unsecured convertible notes in the aggregate principal amount of \$1,310,000 to six non-employee directors. The note holders also received warrants to purchase shares of 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. When issued, the notes provided for conversion into shares of our common stock (i) upon consummation of an initial public offering, of shares of our common stock, based on a conversion price equal to 60% of the public offering price, or (ii) upon consummation of a reverse merger of our company into a publicly held shell company, based on a conversion price equal to 60% of the fair market value of our common stock at the time of the merger. The notes were subsequently amended to provide that the principal and all accrued interest under the notes will automatically convert into shares of our common stock upon the effectiveness of this registration statement, based on a conversion price of \$0.60 per share.

8. In October 2011, we began a private placement of our securities to accredited investors in which we offered units, with each unit consisting of a 10% secured convertible note in the principal amount of \$100,000 and a warrant to purchase 50,000 shares of our common stock. The notes mature three years from the date of issuance, unless earlier converted, and accrue interest at 10% per year. The notes are secured by a security interest in all our assets. The

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notes, including the principal and all accrued interest, convert automatically into shares of our common stock upon the effectiveness of this registration statement, based on a conversion price of \$0.60 per share. Likewise, a note holder may elect at any time to convert the note into shares of our common stock, based on a conversion price of \$0.60 per share. The warrants are immediately exercisable, have a term of five years, and have an exercise price of \$0.75 per share. We received gross proceeds of \$5,430,500 in connection with this financing, or the unit offering, from 63 accredited investors. The placement agent for the unit offering received a cash fee equal to 10% of the gross proceeds, as well as a warrant to purchase that number of shares of our common stock equal to 8% of the number of shares of our common stock issuable upon conversion of the notes and exercise of the warrants sold in the offering, at an exercise price of \$0.60 per share.

We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraphs (3) through (8) by virtue of Section 4(2) of the Securities Act and/or Rule 506 of Regulation D. Such sales and issuances did not involve any public offering, were made without general solicitation or advertising and each purchaser was a sophisticated investor with access to all relevant information necessary to evaluate the investment and represented to us that the shares were being acquired for investment.

### **Item 11. *Description of Registrant's Securities to be Registered***

#### **Common Stock**

As of December 31, 2011, we had 70,000,000 authorized shares of common stock, \$0.01 par value per share. Under our certificate of incorporation that will become effective upon the effectiveness of this registration statement, we will have 125,000,000 authorized shares of common stock, \$0.01 par value per share.

#### ***Voting Rights***

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

#### ***Dividends***

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

#### ***Liquidation***

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

#### ***Rights and Preferences***

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

#### ***Fully Paid and Nonassessable***

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

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### **Preferred Stock**

Under our certificate of incorporation that will become effective upon the effectiveness of this registration statement, we will have 25,000,000 authorized shares of preferred stock, \$0.01 par value per share. The Board of Directors will have the authority, without further action by the stockholders, to issue up to that number of shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. The Board of Directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of MRI Interventions and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. Upon the effectiveness of this registration statement, no shares of preferred stock will be issued or outstanding.

### **Registration Rights**

#### *Rights Agreement*

In 1998 shortly following our formation, some of our initial investors entered into an investor rights agreement with us, which, among other things, provided demand and piggyback registration rights. We amended the investor rights agreement from time to time thereafter to extend the registration rights under the investor rights agreement to new investors. The investor rights agreement was most recently amended in 2006 in connection with a preferred stock offering, and it remains in place as the Rights Agreement.

#### *Demand and Form S-3 Registration Rights*

Pursuant to the Rights Agreement, at any time beginning six months after the consummation of the initial public offering of shares of our common stock, the holders of approximately 11,800,000 shares of our common stock, or registrable shares, will have the right to require us to register the registrable shares under the Securities Act under specified circumstances. We will not be required to effect a demand registration for 120 days following the effectiveness of a registration statement relating to an underwritten public offering of our securities. Under specified circumstances, we also have the right to defer filing of a requested registration statement for a period of not more than 120 days, which right may not be exercised more than twice during any period of 12 consecutive months. These registration rights are subject to additional conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances.

If we are eligible to file a registration statement on Form S-3, each holder of registrable shares of our common stock has the right to demand that we file additional registration statements, including a shelf registration statement, for such holders on Form S-3. We will not be required to effect more than four demand registrations in total, of which no more than two may be required to be effected by us at any time after the second anniversary of this offering and then only on Form S-3.

#### *Piggyback Registration Rights*

Pursuant to the Rights Agreement, at any time beginning six months after the consummation of the initial public offering of shares of our common stock, whenever we propose to file a registration statement under the Securities Act, other than with respect to a registration related to employee benefit plans, debt securities, or corporate reorganizations, the holders of registrable shares are entitled to notice of the registration and have the right to include their registrable shares in such a registration. As of December 31, 2011, the holders of approximately 11,800,000 shares of our common stock and common stock issuable upon conversion of our preferred stock would have been entitled to notice of the registration and would have been entitled to include their shares of common stock in the registration statement. The underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in the registration statement.

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### *Rule 144 Transfers*

Despite the demand and piggyback registration rights described above, we will not be obligated to register any holder's registrable shares pursuant to the Rights Agreement to the extent such holder can sell all of such holder's registrable shares pursuant to Rule 144 promulgated under the Securities Act in a single transaction without registration or any other restrictions.

### *Additional Piggyback Registration Rights*

Whenever we propose to file a registration statement under the Securities Act in connection with the secondary offering of shares of our common stock by any of our stockholders, the holders of the notes and warrants issued in the unit offering, or any shares of common stock issued upon conversion of the notes or exercise of the warrants, will be entitled to notice of the registration and will have the right to include their shares of common stock issued or issuable upon conversion of the notes or exercise of the warrants in the registration. The underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in the registration statement.

### *Expenses of Registration*

We are required to pay all expenses relating to any demand or piggyback registration, other than underwriting discounts and commissions.

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

#### *Delaware Law*

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

#### *Certificate of Incorporation and Bylaw Provisions*

Our certificate of incorporation that will become effective upon the effectiveness of this registration statement:

- permits our Board of Directors to issue shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control;
- provides that the authorized number of directors may be changed only by resolution of the Board of Directors;
- provides that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- requires that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

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- provides that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder's notice;
- does not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provides that special meetings of our stockholders may be called only by the chairman of the Board of Directors, our Chief Executive Officer or by the Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provides that stockholders will be permitted to amend our amended and restated bylaws only upon receiving at least 66 2/3% of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

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

### **Item 12. *Indemnification of Directors and Officers***

Our certificate of incorporation, which will become effective upon the effectiveness of this registration statement, contains provisions permitted under Delaware law relating to the liability of directors. These provisions eliminate a director's personal liability for monetary damages resulting from a breach of fiduciary duty, except in circumstances involving wrongful acts, such as any:

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

These provisions do not limit or eliminate our rights or any stockholder's rights to seek non-monetary relief, such as an injunction or rescission, in the event of a breach of director's fiduciary duty. These provisions will not alter a director's liability under federal securities laws.

As permitted by Section 145 of the Delaware General Corporation Law, our bylaws, which will become effective upon the effectiveness of this registration statement, require us to indemnify our directors and executive officers to the fullest extent not prohibited by the Delaware law. We may limit the extent of such indemnification by individual contracts with our directors and executive officers. Further, we may decline to indemnify any director or executive officer in connection with any proceeding initiated by such person or any proceeding by such person against us or our directors, officers, employees or other agents, unless such indemnification is expressly required to be made by law or the proceeding was authorized by our Board of Directors.

We have entered into indemnity agreements with each of our current directors and certain of our executive officers to give such directors and officers additional contractual assurances regarding the scope of the indemnification set forth in our certificate of incorporation and bylaws and to provide additional procedural protections. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought, nor are we aware of any threatened litigation that may result in claims for indemnification.

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We have the power to indemnify our other officers, employees and other agents, as permitted by Delaware law, but we are not required to do so.

We maintain a directors' and officers' insurance and company reimbursement policy. The policy insures directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses us for those losses against which we have lawfully indemnified the directors and officers. The policy contains various exclusions and limitations.

Reference is made to the following documents filed as exhibits to this registration statement regarding relevant indemnification provisions described above and elsewhere herein:

<u>Exhibit Document</u>	<u>Number</u>
Form of Amended and Restated Certificate of Incorporation	3.3
Form of Amended and Restated Bylaws	3.4
Third Amended and Restated Investor Rights' Agreement dated September 20, 2006	3.5
Form of Indemnification Agreement	10.8

### **Item 13. *Financial Statements and Supplementary Data***

Our financial statements appear on pages F-1 through F-61 of this registration statement.

### **Item 14. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

We have not had a change in our independent registered public accounting firm during its last two fiscal years or through the date of this filing. We have not had any disagreements with our current public accounting firm during the last two fiscal years or through the date of this filing on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreement, if not resolved to the satisfaction of the public accounting firm, would have caused it to make reference to the subject matter of the disagreement in connection with its report on the registrant's financial statements.

### **Item 15. *Financial Statements and Exhibits***

#### (a) Financial Statements

Our financial statements appear on pages F-1 through F-61 of this registration statement.

#### (b) Exhibits

<u>Number</u>	<u>Description</u>
3.1**	Amended and Restated Certificate of Incorporation, as amended
3.2**	By-laws, as amended
3.3	Form of Amended and Restated Certificate of Incorporation of MRI Interventions, Inc. to be effective upon the effectiveness of this registration statement
3.4**	Form of Amended and Restated Bylaws of MRI Interventions, Inc. to become effective upon the effectiveness of this registration statement
3.5**	Third Amended and Restated Investor Rights' Agreement dated September 20, 2006
3.6**	Certificate of Designation, Preferences and Rights of Series A Convertible Preferred Stock, as amended
3.7**	Form of Subscription Agreement for 10% Secured Convertible Promissory Note Due 2014

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4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6 and 3.7
4.2**	Specimen of Common Stock Certificate
4.3**	Form of 10% Senior Unsecured Convertible Note Due 2012
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
4.5	10% Subordinated Secured Convertible Note Due 2016 issued to Brainlab AG, as amended
4.6**	Form of Unsecured Convertible Promissory Note Due 2013, as amended
4.7**	Form of 10% Secured Convertible Promissory Note Due 2014
4.8**	Form of Amendment to 10% Senior Unsecured Convertible Note Due 2012
10.1**	1998 Stock Option Plan
10.2**	2007 Stock Incentive Plan
10.3**	Amended and Restated Key Personnel Incentive Program
10.4**	2010 Incentive Compensation Plan
10.5**	2010 Non-Qualified Stock Option Plan
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
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
10.8**	Form of Indemnification Agreement
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
10.10†**	License Agreement by and between SurgiVision, Inc. and The Johns Hopkins University entered into on or around December 7, 2006
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
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

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- 10.13†\*\* Technology License Agreement dated as of March 19, 2008 by and between SurgiVision, Inc. and Cardiac Pacemakers, Inc.
- 10.14†\*\* Development Agreement dated as of March 19, 2008 by and between SurgiVision, Inc. and Cardiac Pacemakers, Inc.
- 10.15†\*\* Cooperation and Development Agreement, dated as of May 4, 2009, by and between SurgiVision, Inc. and Siemens Aktiengesellschaft, Healthcare Sector
- 10.16 Consulting Agreement with Dr. Paul Bottomley
- 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
- 10.18†\*\* Master Security Agreement dated April 5, 2011 by and between SurgiVision, Inc. and Brainlab AG
- 10.19†\*\* Patent License Agreement – Nonexclusive entered into on or around April 27, 2009 by and between SurgiVision, Inc. and National Institutes of Health
- 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
- 10.21†\*\* Exclusive License Agreement entered into on or around June 30, 2008 by and between SurgiVision, Inc. and The Johns Hopkins University
- 10.22†\*\* Exclusive License Agreement entered into on or around June 30, 2008 by and between SurgiVision, Inc. and The Johns Hopkins University
- 10.23†\*\* Exclusive License Agreement entered into on or around June 30, 2008 by and between SurgiVision, Inc. and The Johns Hopkins University
- 10.24\*\* Loan Agreement dated as of October 16, 2009 by and between SurgiVision, Inc. and Boston Scientific Corporation
- 10.25†\*\* Patent Security Agreement dated as of October 16, 2009 by and between SurgiVision, Inc. and Boston Scientific Corporation
- 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
- 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
- 10.28\*\* Separation Agreement, dated as of April 30, 2010, by and between John Thomas and SurgiVision, Inc.

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- 10.29\*\* SurgiVision, Inc. Cardiac EP Business Participation Plan
- 10.30\*\* Cardiac EP Business Participation Plan Award Agreement, dated June 3, 2010, by and between SurgiVision, Inc. and Nassir F. Marrouche
- 10.31\*\* Amended and Restated Key Personnel Incentive Award Agreement, dated June 2, 2010, by and between SurgiVision, Inc. and Paul A. Bottomley
- 10.32\*\* Key Personnel Incentive Award Agreement, dated June 2, 2010, by and between SurgiVision, Inc. and Paul A. Bottomley
- 10.33\*\* Amended and Restated Key Personnel Incentive Award Agreement, dated June 2, 2010, by and between SurgiVision, Inc. and Parag V. Karmarkar
- 10.34\*\* MRI Interventions, Inc. 2012 Incentive Compensation Plan
- 10.35\*\* MRI Interventions, Inc. 2012 Incentive Compensation Plan Form of Incentive Stock Option Agreement
- 10.36\*\* MRI Interventions, Inc. 2012 Incentive Compensation Plan Form of Non-Qualified Stock Option Agreement
- 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
- 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

\* To be filed by amendment.

\*\* Previously filed.

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

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**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, 2011 and 2010, and the related statements of operations, stockholders' deficit and cash flows for the years ended December 31, 2011, 2010 and 2009. 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 of America). 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, 2011 and 2010 and the results of its operations and its cash flows for the years ended December 31, 2011, 2010 and 2009 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company incurred net losses during the three years ended December 31, 2011 of approximately \$24.9 million and had an accumulated stockholders' deficit at December 31, 2011 of approximately \$59.8 million and will require additional financing to fund the continued development of products subject to its technologies. The availability of such financing cannot be assured. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans with regard to these matters are described in Note 1. The financial statements do not include any adjustments with respect to the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

As discussed in Note 14, the accompanying 2010 balance sheet has been restated.

/s/ Cherry, Bekaert & Holland, L.L.P.  
Tampa, Florida  
February 27, 2012

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## MRI INTERVENTIONS, INC.

## Balance Sheets

	December 31,	
	2011	2010
		(Restated)
<b>ASSETS</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 145,478	\$ 1,577,314
Accounts receivable	401,580	31,540
Inventory	968,818	1,610,442
Prepaid expenses and other current assets	19,773	16,540
Total current assets	1,535,649	3,235,836
<b>Property and equipment, net</b>	1,218,830	979,509
<b>Deferred costs</b>	214,469	263,495
<b>Licenses, net</b>	27,000	45,000
<b>Other assets</b>	34,481	39,001
Total assets	<u>\$ 3,030,429</u>	<u>\$ 4,562,841</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 4,037,168	\$ 3,495,283
Accrued compensation	1,011,413	124,792
Accrued interest	971,733	344,395
Other accrued liabilities	2,015,046	2,079,574
Related party deferred revenue	2,600,000	2,600,000
2010 unsecured convertible notes payable, net of unamortized discount of \$117,405	3,953,595	—
Total current liabilities	14,588,955	8,644,044
<b>Related party deferred revenue</b>	1,396,374	3,996,374
<b>Related party accrued interest</b>	799,102	410,425
<b>Other accrued liabilities</b>	209,143	278,060
<b>Related party BSC convertible notes payable, net of unamortized discount of \$0 and \$653,236 at December 30, 2011 and 2010, respectively</b>	3,500,000	2,846,764
<b>2010 unsecured convertible notes payable, net of unamortized discount of \$571,275</b>	—	3,499,725
<b>Related party 2011 unsecured convertible notes payable, net of unamortized discount of \$432,706</b>	877,294	—
<b>2011 junior secured convertible note payable</b>	2,000,000	—
<b>2011 junior secured convertible notes payable, net of unamortized discount of \$316,610</b>	1,308,390	—
<b>2010 junior secured notes payable, net of unamortized discount of \$2,805,686 and \$2,775,300 at December 31, 2011 and 31, 2010, respectively</b>	194,314	224,700
Total liabilities	<u>24,873,572</u>	<u>19,900,092</u>
<b>Commitments and contingencies (Note 12)</b>	—	—
<b>Stockholders' deficit</b>		
Series A convertible preferred stock; \$.01 par value; 8,000,000 authorized and 7,965,000 shares issued and outstanding	7,965,000	7,965,000
Common stock, \$.01 par value; 70,000,000 shares authorized; 16,410,820 (2011) and 16,185,820 (2010) issued; 16,084,990 (2011) and 15,859,990 (2010) outstanding	164,108	161,858
Additional paid-in capital	31,495,593	29,692,324
Treasury stock, at cost, 325,830 common shares	(1,679,234)	(1,679,234)
Accumulated deficit	(59,788,610)	(51,477,199)
Total stockholders' deficit	<u>(21,843,143)</u>	<u>(15,337,251)</u>
Total liabilities and stockholders' deficit	<u>\$ 3,030,429</u>	<u>\$ 4,562,841</u>

See notes to financial statements.

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**MRI INTERVENTIONS, INC.**  
**Statements of Operations**

	Years Ended December 31		
	2011	2010	2009
<b>Revenues:</b>			
Related party license and service revenues	\$ 2,663,328	\$ 2,600,000	\$ 2,600,000
Product revenues	1,154,838	69,450	—
Total revenues	<u>3,818,166</u>	<u>2,669,450</u>	<u>2,600,000</u>
<b>Costs and operating expenses:</b>			
Cost of product revenues	656,414	16,314	—
Research and development	4,251,476	5,681,031	6,067,617
Selling, general, and administrative	4,831,814	4,698,786	3,595,917
Costs of withdrawn IPO	—	1,788,609	—
Total costs and operating expenses	<u>9,739,704</u>	<u>12,184,740</u>	<u>9,663,534</u>
Operating loss	(5,921,538)	(9,515,290)	(7,063,534)
<b>Other income (expense):</b>			
Gain on change in fair value of derivative liability	—	1,227,500	—
Other income, net	104,850	413,623	—
Interest income	3,481	10,403	106,197
Interest expense	(2,498,204)	(1,590,471)	(152,473)
<b>Loss before taxes</b>	(8,311,411)	(9,454,235)	(7,109,810)
<b>Income tax expense</b>	—	—	49,250
<b>Net loss</b>	<u>\$ (8,311,411)</u>	<u>\$ (9,454,235)</u>	<u>\$ (7,159,060)</u>
<b>Net loss per share attributable to common stockholders:</b>			
Basic and diluted	<u>\$ (0.52)</u>	<u>\$ (1.40)</u>	<u>\$ (1.34)</u>
<b>Weighted average shares outstanding:</b>			
Basic and diluted	<u>15,961,371</u>	<u>6,773,714</u>	<u>5,336,633</u>

See notes to financial statements.



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	<u>7,965,000</u>	<u>\$7,965,000</u>	<u>16,084,990</u>	<u>\$164,108</u>	<u>\$31,495,593</u>	<u>\$(1,679,234)</u>	<u>—</u>	<u>\$(59,788,610)</u>	<u>\$(21,843,143)</u>

See notes to financial statements.

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**MRI INTERVENTIONS, INC.**  
**Statements of Cash Flows**

	Years Ended December 31		
	2011	2010	2009
<b>Cash flows from operating activities</b>			
Net loss	\$(8,311,411)	\$(9,454,235)	\$(7,159,060)
Adjustments to reconcile net loss to net cash flows from operating activities:			
Depreciation and license amortization	354,885	266,223	168,710
Expenses paid through the issuance of common stock	—	29,749	
Share-based compensation	989,902	245,462	130,587
Gain on change in fair value of derivative liability	—	(1,227,500)	—
Amortization of debt issuance costs and original issue discount	1,359,687	889,624	98,500
Write-off of costs of withdrawn IPO	—	1,788,609	—
Increase (decrease) in cash resulting from changes in:			
Accounts receivable	(370,040)	(31,540)	—
Inventory	91,519	(1,214,962)	(569,350)
Prepaid expenses and other current assets	(3,233)	38,487	(83,049)
Deposits	4,520	19,520	4,775
Accounts payable and accrued expenses	2,244,575	3,543,310	418,970
Related party deferred revenue	(2,600,000)	(2,600,000)	(2,488,725)
<b>Net cash flows from operating activities</b>	<b>(6,239,596)</b>	<b>(7,707,253)</b>	<b>(9,478,642)</b>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(26,101)	(61,704)	(282,362)
<b>Net cash flows from investing activities</b>	<b>(26,101)</b>	<b>(61,704)</b>	<b>(282,362)</b>
<b>Cash flows from financing activities:</b>			
Purchase of treasury stock for cash	—	—	(547,835)
Issuance of note receivable, stockholder	—	—	(500,000)
Deferred offering costs paid	—	—	(53,496)
Proceeds from related party convertible notes	—	—	3,500,000
Proceeds from sale of unit securities	—	3,000,000	—
Proceeds from 2010 unsecured convertible notes payable, net of issuance costs	—	3,777,142	—
Proceeds from related party 2011 unsecured convertible notes payable and common stock warrants	1,310,000	—	—
Proceeds from 2011 unsecured convertible notes payable and common stock warrants, net of issuance costs	1,521,610	—	—
Proceeds from 2011 junior secured note payable	2,000,000	—	—
Proceeds from warrant and option exercises	2,250	—	10,663
<b>Net cash flows from financing activities</b>	<b>4,833,860</b>	<b>6,777,142</b>	<b>2,409,332</b>
<b>Net change in cash and cash equivalents</b>	<b>(1,431,837)</b>	<b>(991,815)</b>	<b>(7,351,672)</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>1,577,314</b>	<b>2,569,129</b>	<b>9,920,801</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 145,477</b>	<b>\$ 1,577,314</b>	<b>\$ 2,569,129</b>
<b>SUPPLEMENTAL CASH FLOW INFORMATION</b>			
<b>Cash paid for:</b>			
Income taxes	\$ —	\$ 49,250	\$ —
Interest	—	—	—

See notes to financial statements.

**MRI INTERVENTIONS, INC.**

**Statements of Cash Flows**

**NON-CASH TRANSACTIONS:**

- In December 2009, related party notes receivable and accrued interest in the amount of \$1,131,399 were cancelled in exchange for 195,868 shares of treasury stock.
- At December 31, 2009, deferred offering costs in the amount of \$313,007 were included in accrued expenses.
- 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.
- Both the, \$163,633 fair value of warrants and the \$163,633 intrinsic value of the beneficial conversion feature associated with notes issued in the 2011 junior secured convertible notes (see Note 8) were recorded as additional paid-in capital and a discount to the convertible notes payable.
- ClearPoint reusable components were transferred from inventory to loaned systems, which is a component of property and equipment, during the years ended December 31, 2011 and 2010 with costs of \$550,105 and \$173,870, respectively.
- At December 31, 2011, placement agent fees recorded as deferred costs associated with the 2011 Unit Offering (see Note 8) in the amount of \$66,500 were included in accrued expenses.

See notes to financial statements.

**MRI INTERVENTIONS, INC.**

**Notes to Financial Statements**

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

MRI Interventions, Inc. (the "Company"), formerly SurgiVision, Inc., was formed on March 12, 1998. The Company registered its name change with the state of Delaware, where the Company is incorporated, in May 2011.

The Company operates in the medical device industry and is focused on the development and commercialization of technology that enables physicians to see inside the brain and heart using direct, intra-procedural magnetic resonance imaging, or MRI, guidance while performing minimally invasive surgical procedures.

The Company'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, or the FDA, to market the ClearPoint system in the United States for general neurological interventional procedures. The Company's ClearTrace system is a product candidate 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.

*Liquidity and Management's Plans*

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. For the years ended December 31, 2011, 2010 and 2009, the Company incurred net losses of \$8,311,410, \$9,454,235, and \$7,159,060, respectively, and the cumulative net loss since the Company's inception through December 31, 2011 is \$59,788,609, which has resulted in a negative working capital position of \$13,053,306 at December 31, 2011. In view of these matters, the ability of the Company to continue as a going concern is dependent upon its ability to generate additional financing sufficient to commercialize its developed products, support its research and development activities and obtain future regulatory clearances or approvals, and ultimately to generate revenues sufficient to cover all costs.

Since inception, the Company has financed its activities principally from the sale of equity securities, borrowings, and license arrangements. The Company recently completed a private offering of its securities (see Note 8) in which it received net proceeds, before expenses, of approximately \$4,887,000, of which approximately \$3,425,000 was received subsequent to December 31, 2011. The Company intends to finance its future commercialization and development activities and its working capital needs largely from borrowings and from the sale of equity securities until funds provided by operations are sufficient to meet working capital requirements. In December 2011, the Company filed a Form 10 registration statement with the Securities and Exchange Commission (the "SEC") to register the Company's common stock as a class of equity securities under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Upon the effectiveness of the Form 10 registration statement, the Company will become a public reporting company subject to the periodic reporting requirements of the Exchange Act. There can be no assurance that the Company will be successful in achieving its financing goals on reasonable commercial terms, if at all, or that the Company will generate revenues sufficient to cover its costs.

**MRI INTERVENTIONS, INC.**  
**Notes to Financial Statements**

**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, 2011 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, product liability and the need to obtain additional financing. The Company’s products include components subject to rapid technological change. 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. While the Company has ongoing programs to minimize the adverse effect of such uncertainty and considers technological change in estimating the net realizable value of its inventory, uncertainty continues to exist.

Receivables at December 31, 2011 and all product revenues for 2011 relate to sales to a limited number of hospital customers located in the United States (“U.S.”) and to one distributor outside of the U.S. Sales to five of these hospital customers each represented between 12% and 17% of total product sales. Product revenues for 2010 all related to sales to two U.S. hospitals. 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 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*

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including its derivative liability. Generally accepted accounting principles for fair value measurement provide a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to quoted prices in active markets for identical assets and liabilities (“Level 1”) and the lowest priority to unobservable inputs (“Level 3”). The Company measures the fair value of its derivative liability (see Note 6) on a recurring basis using Level 3 inputs. The fair value of the Company’s derivative liability was \$0 at December 31, 2011 and 2010.

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.

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The fair values of the Company's notes payable differ from their carrying values primarily as the result of certain unamortized debt discounts that have been recorded as it relates to those debt instruments as well as a less than market contract interest rate associated with the 2010 junior secured notes payable issued by the Company in 2010. The fair values of all outstanding notes payable other than the 2010 junior secured notes payable were determined to be equal to the face value of the notes payable as the contractual interest rate approximated the market interest rate. Since the contractual interest rate on the 2011 junior secured notes payable is 3.5% per year, the Company determined the fair value of these notes by discounting the face value utilizing an estimated market interest rate of 10%. The carrying values and estimated fair values of notes payable are as follows at December 31, 2011:

	<u>Carrying Value</u>	<u>Estimated Fair Value</u>
Related party BSC convertible notes payable	\$ 3,500,000	\$3,500,000
2010 unsecured convertible notes payable	3,953,595	4,071,000
2010 junior secured notes payable	194,314	1,746,222
2011 related party unsecured convertible notes payable	877,294	1,310,000
2011 junior secured note payable	2,000,000	2,000,000
2011 junior secured convertible notes payable	1,308,390	1,625,000

*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. 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 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.

*Licenses*

Licenses are recorded at cost and are amortized using the straight-line method over their estimated useful lives. The carrying value of licenses at December 31, 2011 and 2010 was \$27,000 and \$45,000, respectively, net of accumulated amortization of \$63,000 and \$45,000 at those respective dates. Future amortization under licenses is expected to be approximately \$18,000 annually through June 2013. One of the licenses contains a requirement to pay the licensor an additional \$40,000 upon the issuance of a certain patent. The license arrangements also require certain minimum royalty payments to the licensor (see Note 12).

*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. When this occurs, 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 to date.

*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 Accounting Standards Codification ("ASC") 605-10-S99,

**MRI INTERVENTIONS, INC.**

**Notes to Financial Statements**

Revenue Recognition, when persuasive evidence of an arrangement exists, the fee is fixed or determinable, collection of the fee is probable and risk of loss has transferred to the customer. For all sales, the Company requires 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 incidental to the utility of the ClearPoint system as a whole, and as such, the provisions of ASC 985-605, Software Revenue Recognition, are not applicable.

(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 delivery to the customer's location, based on the specific terms with that customer.

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

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

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

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

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

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

**MRI INTERVENTIONS, INC.**

**Notes to Financial Statements**

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 are recognized upon receipt in accordance with the Company's revenue recognition policy. Future product royalty income related to the agreement will be recognized as the related products are sold and amounts are due to the Company.

*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 costs for research and development personnel, costs for materials used in research and development activities and costs for outside services.

*Costs of Withdrawn IPO*

In December 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 September 2010 the Company made the decision to withdraw its registration statement and to cancel the planned IPO. Costs which had been deferred during 2009 totaling \$366,503 and costs incurred during 2010 related to the IPO effort are recorded as costs of withdrawn IPO in the statement of operations for the year ended December 31, 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 for the year ended December 31, 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 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 bases. 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 uncertainty surrounding realization of the deferred income tax assets in future periods, the Company has recorded a 100% valuation allowance against its net deferred 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.

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**Notes to Financial Statements**

*Net Loss Per Share*

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

	<u>Years Ended December 31,</u>		
	<u>2011</u>	<u>2010</u>	<u>2009</u>
Stock options	3,679,977	3,762,477	669,777
Warrants	1,922,944	435,986	410,542
Convertible preferred shares	1,991,250	1,991,250	1,991,250
Shares under convertible note agreements	1,046,263	997,678	444,247
	<u>8,640,434</u>	<u>7,187,391</u>	<u>3,515,816</u>

The table above excludes the potential impact of convertible notes payable issued by the Company in 2011 (see Notes 7, 8, and 9) that have conversion features which are contingent upon the occurrence of a future event. In addition, the conversion ratios related to the convertible preferred shares and convertible notes reflected in the table above will be different upon the effectiveness of the Company’s Form 10 registration statement (see Notes 7 and 9).

**MRI INTERVENTIONS, INC.**

**Notes to Financial Statements**

*Share-Based Compensation*

The Company accounts for compensation for all arrangements under which employees and others receive shares of stock or other equity instruments (including options and warrants) in accordance with ASC Topic 718 “Compensation – Stock Compensation.” Under ASC Topic 718, the fair value of each award is estimated and amortized as compensation expense over the requisite service period. The fair value of the Company’s share-based options and warrants is estimated on the grant date using the Black-Scholes valuation model. This valuation model requires the input of highly subjective assumptions, including the estimated stock price volatility, estimated option term and risk free interest rate during the expected term. To estimate the expected term, the Company utilizes the “simplified” method for “plain vanilla” options as discussed within the Securities and Exchange Commission’s Staff Accounting Bulletin 107, or SAB 107. The Company believes that all factors listed within SAB 107 as pre-requisites for utilizing the simplified method are true for the Company and for the Company’s share-based compensation arrangements. As the Company has been operating as a private company, it was unable to use actual price volatility and option life data as input assumptions within its Black-Scholes valuation model. Prior to October 2009, the Company used expected volatilities based on the historical volatility of the industry sector in which the Company operates, in accordance with the guidance set forth in ASC Topic 718. Beginning in October 2009, the Company based its estimate of expected volatility on the average of historical volatilities of publicly traded companies it deemed similar 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 price becomes available. The Company utilizes risk-free interest rates based on a zero-coupon U.S. treasury instrument, the term of which is consistent with the expected term of the stock options. The Company has not paid and does not anticipate paying cash dividends on its shares of common stock; therefore, the expected dividend yield is assumed to be zero.

*Fair Value Determination of Privately-Held Equity Securities*

The fair values of the common stock, as well as the common stock underlying options and warrants, granted as compensation, or issued in connection with the settlement of liabilities, were estimated by management, with input from a third-party valuation specialist.

Determining the fair value of stock requires making complex and subjective judgments. The Company has used the income approach, the market approach, and the probability weighted expected return method to estimate the value of the enterprise for the dates on which securities are issued/granted and outstanding. The income approach was based on estimated future cash flows that utilized the Company’s forecasts of revenue and costs. The assumptions underlying the revenue and cost estimates were consistent with the Company’s business plan. The market approach was based on recent sales of the Company’s common stock in privately negotiated transactions between stockholders or the once anticipated IPO price of the Company’s common stock. Once the Company began the process of preparing for its IPO, the Company 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 thereafter used the income and market approaches previously discussed. The assumptions used in each of the different valuation methods take into account certain discounts such as selecting the appropriate discount rate and control and lack of marketability discounts. The discount rates used in these valuations ranged from 22% to 35%. The discounts for lack of marketability ranged from 15% to 35% and the discount for lack of control ranged from 20% to 30%. If different discount rates or lack of marketability and control discounts had been used, the valuations would have been different. The enterprise value under each valuation method was allocated to preferred and common shares taking into account the enterprise value available to all stockholders and allocating that value among the various classes of stock based on the rights, privileges, and preferences of the respective classes in order to provide an estimate of the fair value of a share of the Company’s common stock. There is inherent uncertainty in these estimates.

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[Table of Contents](#)**MRI INTERVENTIONS, INC.****Notes to Financial Statements***Derivative Financial Instruments*

The Company accounts for derivative instruments in accordance with ASC Topic 815, 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 statement of operations unless the derivatives qualify for hedge accounting. At December 31, 2011 and 2010, the Company did not have any derivative instruments that were designated as hedges.

*New Accounting Pronouncements*

In April 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2010-17 (“ASU 2010-17”) which provided guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. ASU 2010-17 is effective prospectively for milestones achieved in fiscal years and interim periods within those years beginning on or after June 15, 2010. The adoption of this standard on January 1, 2011 did not have any impact on the Company’s financial statements.

In May 2011, the FASB, issued additional guidance on fair value measurements. The updated guidance provides a consistent definition of fair value and aligns the fair value measurement and disclosure requirements between U.S. GAAP and International Financial Reporting Standards, or IFRS, amends certain guidance primarily related to fair value measurements for financial instruments, and enhances disclosure requirements particularly for Level 3 fair value measurements. The guidance is effective prospectively for fiscal years beginning after December 15, 2011 and interim periods within those years. Early adoption is permitted. The Company does not expect the adoption of this guidance will have a material impact on its financial statements.

In June 2011, the FASB issued new accounting guidance related to the presentation of comprehensive income that increases comparability between U.S. GAAP and IFRS. This guidance will require 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. Nonpublic entities should begin applying these requirements for fiscal years ending after December 15, 2012, and interim and annual periods thereafter. The Company does not believe the adoption of this guidance will have a material impact on its results of operations or financial position.

**3. Inventory**

Inventory consists of the following as of December 31:

	<u>2011</u>	<u>2010</u>
Work in process	\$454,366	\$ 662,988
Software (Note 11)	467,000	664,300
Finished goods	47,452	283,154
	<u>\$968,818</u>	<u>\$1,610,442</u>

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**MRI INTERVENTIONS, INC.**  
**Notes to Financial Statements**

**4. Property and Equipment**

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

	<u>2011</u>	<u>2010</u>
Equipment	\$ 934,253	\$ 906,485
Furniture and fixtures	106,054	106,053
Leasehold improvements	157,236	157,236
Computer equipment and software	101,482	103,150
Loaned systems	<u>723,975</u>	<u>173,870</u>
	2,023,000	1,446,794
Less accumulated depreciation and amortization	<u>(804,170)</u>	<u>(467,285)</u>
Total property and equipment, net	<u>\$1,218,830</u>	<u>\$ 979,509</u>

Depreciation and amortization expense for the years ended December 31, 2011, 2010, and 2009 was \$336,885, \$246,331, and \$150,710, respectively.

The Company may loan the reusable components of a ClearPoint system to a customer. Any such customer uses the loaned ClearPoint system to perform procedures using ClearPoint disposable products which are purchased from the Company. Accordingly, the \$723,975 and \$173,870 of loaned systems at December 31, 2011 and 2010, 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, 2011, accumulated depreciation on loaned systems was \$73,846; at December 31, 2010 no depreciation expense had been recorded on loaned systems as these systems had been shipped to customers, but were not yet installed.

**5. Related Party License Agreements**

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

*BSC Neuro Agreement*

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

Under the BSC Neuro Agreement, in addition to prospective royalty payments on net sales of licensed products, the Company could receive up to \$1,600,000 in future milestone-based payments associated with successful development and regulatory approval of the leads (see Note 13 for modification of these terms). The Company did not receive any up-front license payments pursuant to this agreement. In addition, 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. This agreement requires specified milestones in the development of an MRI-safe implantable lead to be achieved by December 31, 2012. If the milestones are not achieved by that date and

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**MRI INTERVENTIONS, INC.**

**Notes to Financial Statements**

this failure is not the result of BSC Neuro's failure to reasonably cooperate with the Company in pursuing the milestones, the Company will be required to repay BSC Neuro certain amounts, including any development expenses and milestone payments previously made to the Company under this agreement and any patent prosecution costs incurred by BSC Neuro with respect to the intellectual property licensed under this agreement. As of December 31, 2011, the Company has received approximately \$750,000 of payments from BSC Neuro which would be subject to the repayment obligation described above. In addition, the Company would be responsible to reimburse BSC Neuro for out of pocket costs incurred by BSC Neuro in prosecuting patent applications and maintaining issued patents for the licensed technologies. As discussed in Note 2, Revenue Recognition, all amounts received have been recorded as deferred revenue.

*BSC Cardiac Agreement*

Effective March 19, 2008, the Company entered into definitive license and development agreements (collectively the "BSC Cardiac Agreement") with Cardiac Pacemakers, Inc. ("BSC Cardiac"), an affiliate of 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 non-refundable licensing fees totaling \$13,000,000 in 2008, and the Company could receive up to \$20,000,000 in future milestone-based payments associated with the successful development and regulatory approval of the implantable cardiac leads, subject to certain patents being issued on patent applications licensed to BSC Cardiac. The Company initially recorded the payment 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.

Remaining related party deferred revenue is presently expected to be recognized as revenue as follows:

<u>Years ending December 31,</u>	
2012	2,600,000
2013	<u>1,396,374</u>
	<u>\$3,996,374</u>

**MRI INTERVENTIONS, INC.**  
**Notes to Financial Statements**

**6. Related Party Notes Payable**

*Related Party BSC Convertible Notes Payable*

In October 2009, the Company entered into a convertible note payable arrangement with BSC. During October, November and December of 2009, the Company borrowed an aggregate of \$3,500,000 from BSC under this arrangement. 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. At December 31, 2011 BSC had extended the due dates of the notes to January 16, 2012 (see Note 13 for subsequent modification of the terms of the BSC Notes).

The Company will be required to prepay all or a portion of the convertible notes payable (the "BSC Notes") upon the consummation of any 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 principal and accrued interest 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 principal and accrued interest of the BSC Notes. The Company has not conducted a qualified financing since entering into the agreement related to the BSC Notes. The Company can prepay the BSC Notes at any time. The principal and interest outstanding on 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 (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 preferred stock financing conducted by the Company prior to the qualified public offering. The terms of the preferred stock into which BSC may elect to convert the BSC Notes, other than in the context of a qualified financing, must be agreed upon between the Company and BSC. 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 and determined, based upon the conversion price reset provision that the conversion feature should be accounted for as a derivative liability (see Note 2, Fair Value Measurements). Under this guidance the conversion feature was initially measured at fair value upon the issuance of the BSC Notes and will be adjusted to the current fair value at the end of each reporting period. Changes in fair value will be recorded as other income (expense) in the related statement of operations. The Company calculated the fair value of this derivative liability utilizing the Black-Scholes pricing model. The assumptions used in calculating the fair value of the derivative liability using this model as of the transaction date and December 31, 2011 and 2010 were as follows:

	December 31,		Transaction Date
	2011	2010	
Dividend yield	0%	0%	0%
Expected volatility	46.58%	44.84%	38.28%
Risk free interest rate	0.25%	0.61%	1.14%
Expected remaining term	0.15 years	0.75 years	2 years
Common stock price	\$ 0.60	\$ 1.80	\$ 9.64

There was no adjustment of the derivative liability of \$1,227,500 at December 31, 2009 because the change in its fair value from the transaction date was insignificant. At December 31, 2011 and 2010, the fair value of the derivative liability was \$0 (using Level 3 Inputs). Accordingly, the \$1,227,500 decrease in fair value during the year ended December 31, 2010 was recorded as a gain in the 2010 statement of operations.

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The proceeds from the transaction were allocated as follows:

<b>Financial Instrument:</b>	
Related party convertible notes payable	\$2,272,500
Derivative liability	<u>1,227,500</u>
	<u>\$3,500,000</u>

The discount on the BSC Notes was amortized through charges to interest expense based upon the effective interest method through the date of maturity. The unamortized discount at December 31, 2011 and 2010 was \$0 and \$653,236, respectively.

*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 mature June through September 2013, unless earlier converted, and accrue interest at 15% per year. The warrants vest immediately, have a term of five years, and have an exercise price of \$0.01 per share. The original terms of the Summer 2011 Notes provide 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 provide 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. To the extent not previously converted, the original terms of the Summer 2011 Notes provide for automatic conversion of the notes in the event the Company completes a reverse merger transaction with a public shell company and thereafter closes an equity financing that results in gross proceeds of at least \$5,000,000, based on a conversion price equal to 60% of the price paid by investors in the equity financing. The Summer 2011 Notes were amended in December 2011 to provide that the principal and all accrued interest under the notes will automatically convert into shares of the Company's common stock on the effective date of a Form 10 registration statement filed with the SEC under the Exchange Act, based on a conversion price of \$0.60 per share. The Company filed a Form 10 registration statement with the SEC in December 2011, and the Company expects that its Form 10 registration statement will be effective on February 27, 2012. At that time, the Summer 2011 Notes will convert into shares of the Company's common stock.

The Company analyzed the terms of the warrants based on the provisions of ASC Topic 480 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 is 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 assumptions used in calculating the fair value of the warrants were a dividend yield of 0%, expected volatility of approximately 43%, risk free interest rates between 0.21% and 0.45%, an expected term of 2 years, and a \$0.60 per share price of the Company's common stock. 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.

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**7. 2010 Senior 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 provide a mandatory conversion feature upon the closing of an initial public offering of the Company's common stock that automatically converts 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 permit 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 mature in March 2012, unless earlier converted, and accrue interest at the rate of 10% per annum. 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 with the SEC under the Exchange Act, based on a conversion price of \$1.00 per share. The Company filed a Form 10 registration statement with the SEC in December 2011, and the Company expects that its Form 10 registration statement will be effective on February 27, 2012. At that time, the March 2010 Notes will convert into shares of the Company's common stock.

The Company applied the guidance in ASC 815-40, "Derivatives and Hedging Contracts in an Entity's Own Equity," in determining that the conversion features of the March 2010 Notes did not require derivative liability accounting treatment. The Company relied upon guidance in ASC 470-20, "Debt with Conversion and Other Options," in determining that the non-mandatory conversion feature represented a beneficial conversion feature ("BCF") that should be recorded as equity based on its intrinsic value. Upon the issuance of the March 2010 Notes, the intrinsic value of the BCF was \$834,555, which represented the difference between the estimated fair value at the date of issuance of \$9.64 per common share and the conversion price of \$8.00 per share multiplied by the number of conversion shares. This BCF was recorded as debt discount, which is being amortized to interest expense using the effective interest method over the term of the March 2010 Notes.

The Company incurred approximately \$293,000 of costs related to the issuance of the March 2010 Notes, comprised of placement agent commissions and legal fees. In addition, warrants with a five year term were issued to the placement agent exercisable for 25,444 shares of the Company's common stock at a price equal to the lesser of \$8.00 per share or 80% of the public offering price in the Company's initial public offering, subject to a minimum \$4.00 per share conversion price. The estimated fair value of the placement agent warrants at the date of issuance was \$120,218 (Note 8). The total costs incurred in connection with the issuance of the March 2010 Notes of approximately \$413,000 were capitalized as deferred financing costs and are being amortized using the effective interest method over the term of the March 2010 Notes. The unamortized balance at December 31, 2011 was \$44,579.

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**8. Unit Offerings**

*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, as well as the April 2011 and the 2011 Unit Offering Notes. All outstanding principal and interest on the notes will be due and payable in a single payment upon maturity.

Under guidance in 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.

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, these five non-employee directors were not able to purchase units. All funds advanced to the Company by the five non-employee directors were returned, without interest, \$90,000 of which was returned prior to December 31, 2010 and \$100,000 of which was returned in January 2011. This \$100,000 is included in other accrued liabilities at December 31, 2010.

*2011 Junior Secured Convertible Notes*

In October 2011, the Company began a private placement of securities in which the Company offered units, with 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 mature three years from the date of issuance (October through December 2014), unless earlier converted, and accrue interest at 10% per year. The notes are secured by a security interest in the assets of the Company, which security interest is junior and subordinate to the security interest that secures the BSC Notes (Note 6) and *pari passu* with the security interest that secures the April 2011 Note (Note 9). The 2011 Unit Offering Notes, including the principal and all accrued interest, convert automatically into shares of the Company's common stock on the effective date of a Form 10 registration statement filed with the SEC under the Exchange Act, based on a conversion price of \$0.60 per share. In addition, a note holder may elect at any time to convert the note into shares of the Company's common stock, based on a conversion price of \$0.60 per share. The warrants vest immediately, have a term of five years, and have an exercise price of \$0.75 per share. At December 31, 2011, the Company had sold 16.25 units, resulting in the issuance of convertible notes in the aggregate principal amount of \$1,625,000 and warrants to purchase 812,500 shares of common stock under the terms described above. The offering period for the Company's sale of units extended beyond December 31, 2011. See Note 13 for additional information regarding units sold after December 31, 2011. The Company's placement agent for the unit offering receives a cash fee equal to 10% of the gross proceeds, as well as a warrant to purchase that number of shares of the Company's common stock equal to 8% of the number of shares of common stock issuable upon conversion of the notes and exercise of the warrants issued in the offering, at an exercise price of \$0.60 per share. At December 31, 2011 the Company had \$66,500 included in other accrued liabilities related to cash fees due to the placement agent, and none of the placement agent warrants had yet been issued as of December 31, 2011.

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Utilizing guidance in ASC 470, the Company allocated the \$1,625,000 in proceeds from the sale of the units on a relative fair value basis between the convertible notes and the warrants issued. Using the relative fair value of the notes, an effective conversion price was determined which resulted in a BCF. The fair value of the warrants issued was calculated using the Black-Scholes pricing model (see Note 10). The relative fair value of the 812,500 warrants issued and the intrinsic value of the BCF were each \$163,633, and these amounts were recorded as increases to additional paid-in capital and a discount to the carrying value of the convertible notes. The Company's management estimated the fair value of the Company's common stock to be \$0.60 at the time the convertible notes were issued, and the Company's management believes the 10% stated interest rate to be a market rate. The effective conversion price of the conversion feature was \$0.54 per common share. The total discount of \$327,266 is being amortized to interest expense over the three year term of the notes using the effective interest method. The unamortized balance of the discount was \$316,610 at December 31, 2011.

At December 31, 2011, the Company had incurred approximately \$170,000 of costs related to the issuance of the units, comprised of placement agent cash fees and professional fees. These costs were capitalized as deferred financing costs, and, along with the fair value of the placement agent warrants once issued, will be amortized using the effective interest method over the three year term of the 2011 Unit Offering Notes.

**9. 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 (Note 6) and *pari passu* with security interest that secures the 2011 Unit Offering Notes (Note 8). 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 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). In addition, in September 2011, the terms of the April 2011 Note were amended to establish a maximum conversion price of \$0.60 per share. Accordingly, the conversion price under the April 2011 Note will be the lesser of the price paid by investors in a qualified financing or \$0.60 per share (again, contingent upon the completion of a qualified preferred stock financing). A further amendment to the April 2011 Note was executed in February 2012 that removed the acceleration provision mentioned above related to not consummating a qualified financing and that provides the Strategic Partner the option to convert principal and accrued interest into shares of the Company's common stock at a conversion price of \$0.60 per share at any time on or before February 24, 2013.

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 neurological drug delivery field and as a non-exclusive distributor of the Company's ClearPoint system products for other 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

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Company licensed certain ClearPoint system technology to the Strategic Partner and will work together to potentially integrate the Company's ClearPoint product line into the Strategic Partner's interventional MRI product line, particularly for a neurological drug delivery application.

Relying upon guidance in ASC 605-25, 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. The conversion feature associated with the note was not accorded any accounting treatment since this a contingent feature completely 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 has been recorded as a liability related to the April 2011 Note.

**10. Stockholders' Equity**

*Series A Preferred Stock*

In 2006, the Company issued 7,965,000 shares of Series A Convertible Preferred Stock for net proceeds of \$7,335,787 (\$7,965,000 net of \$629,213 in transaction expenses). Additionally, the placement agent received detachable warrants to acquire up to 141,500 shares of the Company's common stock at \$4.00 per share with a fair value of \$28,696 on the date of issuance. The warrants expired on December 31, 2011. The holders of the Series A Convertible Preferred Stock have the following rights and privileges:

**Voting.** Each holder of Series A Convertible Preferred Stock is entitled to vote on all matters presented to holders of common stock, with each holder entitled to the number of votes equal to the number of shares of common stock into which his or her shares of Series A Convertible Preferred Stock could be converted.

**Dividend Rights.** There is no dividend rate on the Series A Convertible Preferred Stock; however, the Company will pay holders of Series A Convertible Preferred Stock any dividend it declares with respect to the common stock on an as converted basis.

**Conversion.** The holders of Series A Convertible Preferred Stock have the right to convert such shares, at any time, into shares of common stock at the then applicable conversion rate. In addition, the Series A Convertible Preferred Stock automatically converts 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

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stock, subject to adjustment for certain corporate events, including stock splits, stock dividends, and recapitalizations. However, on December 15, 2011, the Company's Board of Directors approved an amendment to the terms of the Series A Convertible Preferred Stock providing for the automatic conversion of all outstanding shares of Series A Convertible Preferred Stock into shares of common stock, on a 1-for-1 basis, on the effective date of a Form 10 registration statement filed 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.

**Liquidation.** In the event of the liquidation, dissolution or winding-up of the Company, the holders of Series A Convertible Preferred Stock would be entitled to receive \$1.00 per share before any liquidation distributions may be paid to holders of the Company's common stock.

**Redemption.** Shares of Series A Convertible Preferred Stock are not redeemable by the Company.

*Registration Rights Agreement*

The Company has an agreement with many of its current stockholders pursuant to which the Company has granted those stockholders certain registration rights. The stockholders who are parties to the agreement generally have two demand registration rights, which rights become effective as of the date that is six months after the Company's initial public offering (as such these registration rights are contingent upon the successful completion of an initial public offering). A requisite percentage of holders is required to exercise a demand registration right, and certain other restrictions apply. The stockholders who are parties to the agreement also have the right to participate on a "piggyback basis" in certain registrations by the Company under the Securities Act of 1933, subject to certain restrictions, including underwriter holdbacks. Notwithstanding the demand and piggyback registration rights described in the agreement, the Company is not obligated under the agreement to register shares to the extent the stockholder can sell all of its shares under the Securities Act of 1933 in a single transaction without registration or any other restrictions.

In addition, the Company has granted certain piggyback registration rights to purchasers of the 2011 Unit Offering Notes (with respect to the shares of common stock issuable upon conversion of the notes or exercise of the warrants issued with the notes – see Note 8) in connection with registrations by the Company under the Securities Act of 1933 for secondary offerings of shares of common stock by any of the Company's stockholders.

*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 have been reserved for issuance under the 2010 Plans. At December 31, 2011, 3,246,450 awards have been issued 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"). A total of 3,000,000 shares of the Company's common stock have been reserved for issuance under the 2012 Plan. With the adoption of the 2012 Plan, no additional grants under the 2010 Plans will be made subsequent to December 31, 2011.

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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, 2009	599,875		\$ 0.88 - \$24.00	\$ 3.62	\$3,742,700
Options exercisable at January 1, 2009		<u>432,083</u>	0.88 - 24.00	2.70	3,133,667
Options granted (2)	93,402		9.64	9.64	
Options exercised	(3,333)		3.20	3.20	
Options cancelled or forfeited	<u>(20,167)</u>		1.64 - 20.00	9.60	
Balance at December 31, 2009	669,777		0.88 - 24.00	4.28	3,694,400
Options exercisable at December 31, 2009		<u>483,364</u>	0.88 - 24.00	2.78	3,424,333
Options granted (2)	3,246,450		1.80	1.80	
Options cancelled or forfeited	<u>(153,750)</u>		3.20 - 24.00		
Outstanding at December 31, 2010	3,762,477		0.88 - 24.00	2.11	262,500
Options exercisable at December 31, 2010		<u>433,746</u>	0.88 - 24.00	3.03	262,500
Options cancelled or forfeited	<u>(82,500)</u>		1.80 - 24.00	4.93	
Outstanding at December 31, 2011	<u>3,679,977</u>		0.88 - 9.64	2.05	—
Options exercisable at December 31, 2011		<u>1,501,659</u>	0.88 - 9.64	2.15	—

- (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, 2009 and 2010 were granted with exercise prices of \$9.64 and \$1.80 per share, respectively, which was 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, 2011:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted - Average Remaining Contractual Life	Weighted - Average Exercise Price	Number Exercisable	Weighted - Average Exercise Price
\$ 0.88 - 0.96	287,500	2.33	\$ 0.89	287,500	\$ 0.89
1.80	3,195,950	8.96	1.80	1,065,318	1.80
3.20 - 9.64	196,527	4.75	7.74	148,841	7.13
	<u>3,679,977</u>	8.21	2.05	<u>1,501,659</u>	2.15

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The weighted average grant date fair value of options granted during the years ended December 31, 2010 and 2009 was \$0.83 and \$2.83, 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, 2009, 2010, and 2011 is presented below:

<u>Nonvested Stock Options</u>	<u>Shares</u>	<u>Weighted - Average Grant Date Fair Value</u>
Nonvested January 1, 2009	167,792	\$ 1.67
Granted	93,402	2.83
Forfeited/cancelled	(7,250)	2.84
Vested	(67,531)	1.11
Nonvested December 31, 2009	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	<u>2,178,318</u>	0.87

As of December 31, 2011 there was a total of approximately \$1,783,000 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 1.9 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 2010 and 2009 (no options were issued in 2011):

	<u>Year Ended December 31,</u>	
	<u>2010</u>	<u>2009</u>
Dividend yield	0%	0%
Expected Volatility	44.81%	23.45% to 38.28%
Risk free Interest rates	2.36%	1.48% to 2.43%
Expected lives	6.0 years	3.25 to 5.75 years

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*Warrants*

Warrants have been issued for terms of up to five years. Common stock warrants issued, expired, and outstanding during the years ended December 31, 2009, 2010 and 2011 are as follows:

	<u>Shares</u>	<u>Weighted - Average Exercise Price</u>
Warrants outstanding at January 1, 2009	828,502	\$ 1.74
Warrants that expired during 2009	<u>(417,960 )</u>	0.04
Warrants outstanding at December 31, 2009	410,542	0.42
Warrants issued during 2010	<u>25,444</u>	8.00
Warrants outstanding at December 31, 2010	435,986	3.74
Warrants that expired during 2011	(410,542 )	3.48
Warrants issued during 2011	2,122,500	0.29
Warrants exercised during 2011	<u>(225,000 )</u>	0.01
Warrants outstanding at December 31, 2011	<u>1,922,944</u>	0.43

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

	<u>Year Ended December 31,</u>	
	<u>2011</u>	<u>2010</u>
Dividend yield	0%	0%
Expected Volatility	48.67% to 49.36%	44.81%
Risk free Interest rates	0.81% to 1.13%	2.36%
Expected lives	5.0 years	5.0 years

*Other Stock Transactions with Related Parties*

- During January 2009, the Company loaned \$500,000 under an 8% note receivable to a stockholder with an original maturity date in July 2010. The note was collateralized by 125,000 shares of the Company's common stock owned by the stockholder. In addition, during January 2009, the Company purchased 125,000 shares of the Company's common stock from that same stockholder for \$500,000 in cash (accounted for as a treasury stock purchase). During December 2009, the Company purchased 134,178 additional shares of the Company's common stock from this stockholder in exchange for cancellation of the aforementioned \$500,000 note receivable plus \$36,712 of accrued interest thereon.
- The Company had a note receivable from its Chief Executive Officer ("CEO") related to the sale of common stock. The note bore interest at 4.5%. Interest income related to this note was approximately \$21,000 for the year ended December 31, 2009. On December 22, 2009, the Company purchased 66,652 shares of common stock from the CEO, for an aggregate purchase price of \$642,525. The Company paid a portion of the aggregate purchase price (\$594,687) by cancelling the aforementioned promissory note plus accrued interest, with the remainder paid in cash. Also, on December 22, 2009, the Company issued to the CEO options to purchase 66,652 shares of its common stock at an exercise price of \$9.64 per share, which represented the estimated fair market value per share.

**MRI INTERVENTIONS, INC.**  
**Notes to Financial Statements**

**11. Income Taxes**

The Company had no income tax expense for the years ended December 31, 2011 and 2010 and recorded income tax expense of \$49,250 for the year ended December 31, 2009 related to state income taxes which could not be offset by net operating loss carryforwards. As the Company has incurred net operating losses, it has recognized valuation allowances for all deferred income tax assets. The tax effect of temporary differences and net operating losses that give rise to components of deferred tax assets and liabilities consist of the following:

	<u>As of December 31,</u>	
	<u>2011</u>	<u>2010</u>
Deferred tax assets (liabilities):		
Property and equipment	\$ (144,185)	\$ (193,617)
Deferred revenue	1,517,024	2,503,984
Accrued expenses	1,138,800	1,518,400
Other	727,207	297,309
Net operating loss carryforwards	<u>18,509,210</u>	<u>14,758,835</u>
	21,748,056	18,884,911
Less valuation allowance	<u>(21,748,056)</u>	<u>(18,884,911)</u>
	<u>\$ —</u>	<u>\$ —</u>

The Company has a cumulative federal net operating loss of approximately \$48,800,000 as of December 31, 2011. The first of these net operating loss carryforwards is set to expire beginning 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 the financial statements at December 31, 2011 or 2010. The Company’s returns after 2006 remain open for examination.

**12. Commitments**

*Leases*

The Company leases office space in Maryland, California and Tennessee under non-cancellable operating leases. Leases expire in 2012 and 2014.

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

<u>Years ending December 31,</u>	
2012	\$ 137,571
2013	62,272
2014	<u>58,399</u>
Total minimum payments	<u>\$ 258,242</u>

Rent expense under all operating leases was approximately \$174,000, \$181,000 and \$190,000 for the years ended December 31, 2011, 2010, and 2009, respectively.

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### **MRI INTERVENTIONS, INC.** **Notes to Financial Statements**

#### *Licenses*

Certain license arrangements require minimum royalty payments. As of December 31, 2011, future minimum royalty payments are as follows:

<u>Years Ending December 31,</u>	
2012	70,000
2013	95,000
2014	95,000
2015	95,000
2016	95,000
Thereafter	1,010,000
	<u>\$ 1,460,000</u>

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. One of the licenses is cancelable by the licensor if, by the fourth anniversary of the effective date (June 30, 2012), there have been no commercial sales of a product subject to the license.

#### *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, 2011, the Company has made a total of \$850,000 in milestone payments and the Company's accounts payable balance includes approximately \$524,000 related to these milestones. Based on negotiations between the Company and the co-developer, the parties have agreed in principle to modify the terms of the co-development agreement such that the co-developer would fund the future remaining development work it performs under the agreement. However, the negotiations between the Company and the co-developer are ongoing with respect to any modification of the co-development agreement.

#### *Shared Research Agreements*

The Company has entered into research agreements with certain universities whereby the Company has committed to pay certain research-related expenses. At December 31, 2011, the Company's other accounts payable and accrued liabilities includes approximately \$1,301,000 related to these agreements. As of December 31, 2011 the Company does not have any additional commitments under any such agreements.

#### *Software License Agreement*

The Company is obligated under a master services and license agreement to purchase a minimum number of licenses for software code that is incorporated in the Company's ClearPoint system software. The minimum future purchase obligation is \$87,500 per calendar quarter in 2012, 2013 and 2014, with an aggregate remaining commitment at December 31, 2011 totaling \$1,050,000. At December 31, 2011, the Company had purchased licenses under this agreement totaling \$675,000, of which \$525,000 had not yet been paid and is included in accounts payable at December 31, 2011. The cost of each license will be charged to cost of sales as each ClearPoint system is sold or amortized over a five year period for licenses used in loaned systems.

**MRI INTERVENTIONS, INC.**

**Notes to Financial Statements**

*Cardiac EP Business Participation Plan*

In June 2010, the Company adopted a plan that provides 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%. That participation interest is 6.5% at December 31, 2011. The participation interest, expressed as a percentage, will be equitably reduced from time to time to take into account future 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. The plan will terminate in June 2025.

*Key Personnel Incentive Program*

In June 2010, the Company amended its Key Personnel Incentive Program, which provides a key employee and a key consultant, who is also a non-employee director of the Company, 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 the event of a sale transaction, each participant will receive a bonus payment under the program if the participant continues to provide services to the Company as its employee or consultant as of the date of the transaction. Until the occurrence of a sale transaction, each participant will be entitled to receive semi-annual service bonuses beginning in June 2012 and continuing through December 2015, if the participant continues to provide services to the Company as its employee or consultant as of the respective scheduled payment dates. Pursuant to their awards, the two participants would receive service bonuses totaling up to \$1,700,000 and \$1,000,000, respectively, payable in eight equal semi-annual installments. At December 31, 2011, the Company has approximately \$762,000 recorded as accrued compensation, approximately \$87,000 of which is included in other accrued liabilities as a long-term liability.

If the participant's employment or consultancy is (i) terminated due to the participant's death or disability, or (ii) involuntarily terminated by the Company other than for cause, then the participant will be deemed vested, as of the termination date, in all future scheduled service bonus payments, and the Company will be required to pay that aggregate amount no later than March 15 of the year following the year in which the termination occurred. If the participant's employment or consultancy is involuntarily terminated by the Company for cause, or if the participant voluntarily terminates his employment or consultancy, the participant thereafter will not be entitled to any payments under the program. The program will terminate on the earlier of December 31, 2015 or the occurrence of a transaction involving the sale of the Company.

*Legal Settlement*

On April 22, 2010, SurgiVision Consultants, Inc. and Guy M. Kezirian, or the plaintiffs, filed a lawsuit against the Company in the United States District Court, Central District of California, alleging trademark infringement, unfair competition, trademark dilution and violation of the Anti-Cybersquatting Protection Act, all relating to the Company's use of its SURGI-VISION and SURGIVISION trademarks and the Company's www.surgivision.com domain name. On February 16, 2011, the parties entered into a settlement agreement which resulted in the dismissal of the litigation. Pursuant to the settlement agreement, the Company agreed to discontinue use of any form of the SURGIVISION name and agreed to pay the plaintiffs \$425,000 for reimbursement of out of pocket legal expenses incurred by the plaintiffs in connection with the litigation. The Company accrued the full amount of the settlement at December 31, 2010 as selling, general and administrative expenses and the liability is included in other accrued liabilities. The \$425,000 was payable in twelve equal monthly installments of \$35,417 beginning in March of 2011. At December 31, 2011, the balance of \$70,834 is included in other accrued liabilities.

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### MRI INTERVENTIONS, INC. Notes to Financial Statements

#### 13. Subsequent Events

##### *2011 Unit Offering (Note 8)*

On February 24, 2012, the Company ended its unit offering. In the unit offering, the Company sold approximately 54.3 units in the aggregate, of which approximately 38 units were sold subsequent to December 31, 2011. In connection with the approximately 38 units sold subsequent to year-end, the Company issued 2011 Unit Offering Notes in the aggregate principal amount of \$3,805,500 and warrants to purchase 1,902,750 shares of common stock.

##### *Modification of Terms of BSC Notes (Note 6)*

Effective February 2, 2012, the Company entered into a loan modification with BSC 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 annum to 0%, and (iii) the maturity date of each of the BSC Notes was extended by three years (until October through December 2014). As such, relying upon guidance in ASC 470-10, the outstanding aggregate loan balance and the related accrued interest, as of December 31, 2011 have been classified as long-term liabilities in the accompanying balance sheets. As of February 2, 2012, the outstanding aggregate loan balance, including principal and interest, owed to Boston Scientific was \$4,338,601.

##### *Modification of Terms of BSC Neuro Agreement (Note 5)*

In connection with the February 2012 modification of the BSC Notes, the Company and BSC Neuro also amended the terms of the BSC Neuro Agreement. The amended BSC Neuro Agreement reduces the aggregate future milestone-based payments the Company could receive from \$1,600,000 to \$800,000, and it reduces the prospective royalty payments the Company could receive on net sales of licensed products. In addition, 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.

#### 14. Restatements

The Company previously classified accrued interest of \$410,425 as a current liability as of December 31, 2010. This amount should have been classified as a long-term liability pursuant to the modification of the related party BSC Notes described in Note 6. The table below summarizes the impact of this restatement to the audited balance sheet as of December 31, 2010 that was included in the Company's Form 10 registration statement filed with the Securities and Exchange Commission on December 28, 2011:

	December 31, 2010		
	As previously reported	Adjustment	As Restated
<b>Balance Sheet:</b>			
Total assets	\$ 4,562,841	\$ —	\$ 4,562,841
Accrued interest	754,820	(410,425)	344,395
Total current liabilities	9,054,469	(410,425)	8,644,044
Related party accrued interest (long term)	—	410,425	410,425
Total liabilities	19,900,092	—	19,900,092
Total liabilities and stockholders' deficit	4,562,841	—	4,562,841

In addition to the restatement above, the December 31, 2010 balance sheet information included in the September 30, 2011 unaudited condensed financial statements included in the Company's Form 10 registration statement filed with the Securities and Exchange Commission on December 28, 2011 incorrectly classified related party notes payable, net of unamortized discount of \$3,414,223, as a current liability instead of a long-term liability. The impact of these classification errors described above is limited to the classification of liabilities in the balance sheet between current and long-term and had no effect on any amounts previously reported in the statements of operations, changes in stockholders' deficit, or cash flows.

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**SIGNATURES**

Pursuant to the requirements of the Section 12 of the Securities Exchange Act of 1934, MRI Interventions, Inc. has duly caused this Amendment No. 2 to The Registration Statement on Form 10 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Memphis, State of Tennessee, on the 27th day of February, 2012.

**MRI Interventions, Inc.**

By: /s/ KIMBLE L. JENKINS \_\_\_\_\_

**Kimble L. Jenkins**  
*Chief Executive Officer*  
*(principal executive officer)*

**AMENDED AND RESTATED  
CERTIFICATE OF INCORPORATION  
OF  
MRI INTERVENTIONS, INC.**

**MRI INTERVENTIONS, INC.**, a corporation organized and existing under the General Corporation Law of the State of Delaware (the "Corporation"), does hereby certify as follows:

FIRST: The name of the Corporation is MRI Interventions, Inc.

SECOND: The original Certificate of Incorporation of the Corporation was filed with the Secretary of State of the State of Delaware on March 12, 1998, and was amended on September 18, 1998, January 18, 2000, September 30, 2002, April 28, 2004, July 6, 2004, September 20, 2006, May 31, 2007, November 12, 2008, December 14, 2009, July 13, 2010, October 21, 2010, May 13, 2011 and February 10, 2012.

THIRD: At a meeting of the Board of Directors of the Corporation a resolution was duly adopted pursuant to Sections 242 and 245 of the Delaware General Corporation Law ("DGCL"), setting forth this Amended and Restated Certificate of Incorporation and declaring this Amended and Restated Certificate of Incorporation to be advisable. The stockholders of the Corporation duly approved and adopted this Amended and Restated Certificate of Incorporation at an annual meeting of the Corporation's stockholders held on February 10, 2012 in accordance with Sections 242 and 245 of the DGCL.

FOURTH: The Amended and Restated Certificate of Incorporation of the Corporation is hereby amended and restated in its entirety to read as follows:

**ARTICLE I**

The name of the Corporation is MRI Interventions, Inc.

**ARTICLE II**

The address of the registered office of this Corporation in the State of Delaware is 1209 Orange Street, City of Wilmington, County of New Castle, Zip Code 19801, and the name of the registered agent of this Corporation in the State of Delaware at such address is The Corporation Trust Company.

**ARTICLE III**

The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the DGCL.

**ARTICLE IV**

**A. Authorized Stock.** The total number of shares which the Corporation shall have authority to issue is One Hundred Twenty Five Million (125,000,000), consisting of One Hundred Million (100,000,000) shares of Common Stock, par value \$0.01 per share (the "Common Stock"), and Twenty Five Million (25,000,000) shares of Preferred Stock, par value \$0.01 per share (the "Preferred Stock").

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**B. Preferred Stock.** The Preferred Stock may be issued from time to time in one or more series. The Board of Directors is hereby expressly authorized at any time and from time to time to provide for the issuance of all or any of the shares of the Preferred Stock in one or more series, and to fix the number of shares and to determine or alter for each such series, such voting powers, full or limited, or no voting powers, and such designation, preferences, and relative, participating, optional, or other rights and such qualifications, limitations, or restrictions thereof, as shall be stated and expressed in the resolution or resolutions adopted by the Board of Directors providing for the issuance of such shares to the fullest extent as may now or hereafter be permitted by the DGCL. The Board of Directors is also expressly authorized to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series.

**C. Common Stock.**

1. **Voting Rights.** Each outstanding share of Common Stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders of the Corporation for their vote; provided, however, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (which as used herein, shall mean the certificate of incorporation of the Corporation, as amended from time to time, including any certificate of designation filed with respect to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon by law or pursuant to this Certificate of Incorporation.

2. **Dividends.** Subject to the rights of the holders of any series of Preferred Stock then outstanding, the holders of shares of Common Stock shall be entitled to receive, when and if declared by the Board of Directors, out of the assets of the Corporation which are by law available therefor, dividends payable either in cash, in property or in shares of capital stock.

3. **Dissolution, Liquidation or Winding Up.** In the event of any dissolution, liquidation or winding up of the affairs of the Corporation, after distribution in full of the preferential amounts, if any, to be distributed to the holders of shares of any series of Preferred Stock then outstanding, the holders of Common Stock shall be entitled, unless otherwise provided by law or this Certificate of Incorporation, to receive all of the remaining assets of the Corporation of whatever kind available for distribution to stockholders ratably in proportion to the number of shares of Common Stock held by them respectively.

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## ARTICLE V

**A. Management of Business.** The business and affairs of the Corporation shall be managed by or under the direction of its Board of Directors.

**B. Number of Directors.** The authorized number of directors of the Corporation shall be determined from time to time exclusively by resolution adopted by the affirmative vote of a majority of the authorized number of directors at any regular or special meeting of such Board of Directors, within any limits prescribed in the Bylaws of the Corporation.

**C. Vacancies.** Subject to the rights of the holders of any series of Preferred Stock then outstanding, any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors, shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders, except as otherwise provided by law, be filled only by the affirmative vote of a majority of the directors then in office, even if less than a quorum of the Board of Directors, and not by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified or until his or her death, resignation, disqualification or removal.

**D. Elections.** The directors of the Corporation need not be elected by written ballot unless the Bylaws of the Corporation so provide.

## ARTICLE VI

**A. No Action by Stockholders.** No action required or permitted to be taken by the stockholders of the Corporation shall be taken except at a duly called annual or special meeting of stockholders of the Corporation, and no action shall be taken by the stockholders by written consent; provided, however, that the foregoing shall not apply with respect to any action that requires the vote or consent only of holders of one or more series of Preferred Stock then outstanding.

**B. Special Meetings of Stockholders.** Special meetings of stockholders of the Corporation may be called only by the Chairman of the Board, the Chief Executive Officer or by the Board of Directors acting pursuant to a resolution adopted by a majority of the authorized number of directors, and any power of stockholders to call a special meeting is specifically denied. Only such business shall be considered at a special meeting of stockholders as shall have been stated in the notice for such meeting.

**C. Advance Notice.** Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Corporation shall be given in the manner provided in the Bylaws of the Corporation.

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## ARTICLE VII

The Board of Directors is expressly empowered to adopt, amend or repeal the Bylaws of the Corporation. Any adoption, amendment or repeal of the Bylaws of the Corporation by the Board of Directors shall require the approval of a majority of the directors then in office. The stockholders shall also have power to adopt, amend or repeal the Bylaws of the Corporation; provided, however, that, in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by this Certificate of Incorporation, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to adopt, amend or repeal any provision of the Bylaws of the Corporation.

## ARTICLE VIII

**A. Limitation of Liability.** A director of the Corporation shall not be liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent such exemption from liability or limitation thereof is not permitted under the DGCL as it presently exists or may hereafter be amended. Any amendment, modification or repeal of the foregoing sentence shall not adversely affect any right arising prior to the time of such amendment, modification or repeal.

**B. Right of Indemnification.** The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (a "Covered Person") who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding"), by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such Covered Person. Notwithstanding the preceding sentence, except as otherwise provided in section D of this Article VIII, the Corporation shall not be required to indemnify a Covered Person in connection with a Proceeding (or part thereof) commenced by such Covered Person unless the commencement of such Proceeding (or part thereof) by the Covered Person was authorized in the specific case by the Board of Directors.

**C. Prepayment of Expenses.** The Corporation shall to the fullest extent not prohibited by applicable law pay the expenses (including attorneys' fees) incurred by a Covered Person in defending any Proceeding in advance of its final disposition, provided, however, that, to the extent required by law, such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the Covered Person to repay all amounts advanced if it should be ultimately determined that the Covered Person is not entitled to be indemnified under this Article VIII or otherwise.

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**D. Claims.** If a claim for indemnification (following the final disposition of the Proceeding with respect to which indemnification is sought, including any settlement of such Proceeding) or advancement of expenses under this Article VIII is not paid in full within thirty days after a written claim therefor by the Covered Person has been received by the Corporation, the Covered Person may file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim to the fullest extent permitted by applicable law. In any such action the Corporation shall have the burden of proving that the Covered Person is not entitled to the requested indemnification or advancement of expenses under this Article VIII and applicable law.

**E. Non-Exclusivity of Rights.** The rights conferred on any Covered Person by this Article VIII shall not be exclusive of any other rights which such Covered Person may have or hereafter acquire under any statute, any other provision of this Certificate of Incorporation, the Bylaws of the Corporation, or any agreement, vote of stockholders or disinterested directors or otherwise.

**F. Insurance.** The Corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the Corporation would have the power to indemnify such person against such liability under this Article VIII, the DGCL or otherwise.

**G. Amendment or Repeal.** Any right to indemnification or to advancement of expenses of any Covered Person arising hereunder shall not be eliminated or impaired by an amendment to or repeal of this Article VIII after the occurrence of the act or omission that is the subject of the civil, criminal, administrative or investigative action, suit or proceeding for which indemnification or advancement of expenses is sought.

**H. Other Indemnification and Advancement of Expenses.** This Article VIII shall not limit the right of the Corporation, to the extent and in the manner permitted by law, to indemnify and to advance expenses to persons other than Covered Persons when and as authorized by appropriate corporate action.

## ARTICLE IX

**A. Reservation of Rights.** The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute, except as provided in section B of this Article IX, and all rights conferred upon the stockholders herein are granted subject to this reservation.

**B. Requisite Vote.** Notwithstanding any other provisions of this Certificate of Incorporation or any provision of law which might otherwise permit a lesser vote or no vote, but in addition to any affirmative vote of the holders of any particular class or series of the voting stock of the Corporation required by law, this Certificate of Incorporation or any certificate of

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designation of Preferred Stock, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to alter, amend or repeal Articles V, VI, VII, VIII and IX of this Certificate of Incorporation.

**IN WITNESS WHEREOF**, this Certificate of Incorporation, which restates, integrates and amends the amended and restated certificate of incorporation of the Corporation, and which has been duly adopted in accordance with Sections 242 and 245 of the DGCL, has been executed on behalf of MRI Interventions, Inc. by the undersigned officer, thereunto duly authorized, this \_\_\_\_\_ day of \_\_\_\_\_, 2012.

**MRI INTERVENTIONS, INC.**

By: \_\_\_\_\_  
Kimble L. Jenkins  
Chief Executive Officer

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE UNITED STATES SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”), AND MAY NOT BE SOLD, ASSIGNED, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED EXCEPT IN A TRANSACTION WHICH IS REGISTERED UNDER THE SECURITIES ACT, OR IN A TRANSACTION WHICH IS EXEMPT FROM OR NOT SUBJECT TO THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT. ADDITIONALLY, THE TRANSFER OF THIS NOTE IS SUBJECT TO THE CONDITIONS SPECIFIED IN THIS NOTE, AND MAKER HEREOF RESERVES THE RIGHT TO REFUSE THE TRANSFER OF THIS NOTE UNTIL SUCH CONDITIONS HAVE BEEN FULFILLED WITH RESPECT TO SUCH TRANSFER.

**SURGIVISION, INC.**

**10% SUBORDINATED SECURED CONVERTIBLE NOTE DUE 2016**

Issue Date: April 5, 2011

Principal Amount: U.S. \$2,000,000

SURGIVISION, INC., a Delaware corporation (the “**Company**”), for value received, hereby promises to pay to BRAINLAB AG., a corporation organized under the laws of the Federal Republic of Germany (“**Brainlab**”), the principal amount of U.S. \$2,000,000 on April 5, 2016 (the “**Maturity Date**”). This Note is subject to the following terms and conditions:

**1. DEFINITIONS**

“**Bankruptcy Law**” means Title 11, U.S. Code or any similar federal, state or foreign law for the relief of debtors.

“**Brainlab**” means Brainlab AG., a corporation organized under the laws of the Federal Republic of Germany or its successors or assigns.

“**Business Day**” means each day of the year on which banking institutions are not required or authorized to close in Germany or New York.

“**Capital Stock**” means, with respect to any Person, any and all shares, interests, participations or other equivalents (however designated and whether or not voting) of corporate stock, limited liability company interests, partnership interests or any other participation, right or other interest in the nature of an equity interest in such Person including, without limitation, common stock and preferred stock of such Person, or any option, warrant or other security convertible into any of the foregoing.

“**Collateral Agent**” means Landmark Community Bank, in its capacity as collateral agent for the ratable benefit of the Junior Lender.

“**Company**” means SurgiVision, Inc., a Delaware corporation.

“**Conversion Date**” has the meaning specified in Section 4(b)(iii) of this Note.

“**Conversion Notice**” has the meaning specified in Section 4(b)(i) of this Note.

“**Conversion Price**” has the meaning specified in Section 4(a)(iv) of this Note.

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“**Conversion Shares**” means shares of Qualified Financing Stock to be issued in connection with the conversion of this Note.

“**Default**” means any event which is, or after notice or passage of time or both would be, an Event of Default.

“**Event of Default**” has the meaning specified in Section 9(a) of this Note.

“**Indebtedness**” of any Person means at any date, without duplication, (i) all obligations of such Person for borrowed money, (ii) all obligations of such Person evidenced by bonds, debentures, notes or other similar instruments, (iii) all obligations of such Person to pay the deferred purchase price of property or services, except trade accounts payable arising in the ordinary course of business, (iv) all obligations of such Person as lessee which are capitalized in accordance with United States generally accepted accounting principles, (v) all reimbursement obligations of such Person (whether contingent or otherwise) in respect of letters of credit, banker’s acceptances, surety or other bonds and similar instruments, (vi) all Indebtedness of others secured by a lien on any asset of such Person, whether or not such Indebtedness is assumed by such Person, and (vii) all Indebtedness of others guaranteed by such Person or for which such Person is otherwise liable.

“**Issue Date**” of this Note means the date on which this Note was originally issued or deemed issued as set forth on the face of this Note.

“**Junior Debt**” means any obligations of the Company under the Junior Debt Documents, including, without limitation, obligations with respect to the payment of principal, interest (including without limitation interest accruing at the then applicable rate provided in the Junior Notes after the commencement of any Proceeding by, against or relating to the Company, whether or not a claim for such interest is allowed in such Proceeding), fees, costs and expenses before or after the commencement of any Proceeding, in each instance, without regard to whether or not an allowed claim in any such Proceeding.

“**Junior Debt Documents**” means the Junior Notes, the Junior Security Agreement, and any and all other documents or instruments evidencing or further guarantying or securing, directly or indirectly, any of the Junior Debt, whether now existing or hereafter amended or created.

“**Junior Lender**” means, collectively, the holders of the Junior Notes.

“**Junior Notes**” means those certain Junior Secured Promissory Notes due 2020 issued by the Company, and any amendments thereto or extensions thereof.

“**Junior Security Agreement**” means that certain Junior Security Agreement dated November 5, 2010, by and between the Company and the Collateral Agent, and any amendments thereto.

“**Legend**” has the meaning specified in Section 10(c) of this Note.

“**Lien**” shall mean any mortgage, deed of trust, pledge, hypothecation, assignment, security interest, encumbrance, lien or other security interest or security agreement of any kind or nature whatsoever.

“**Maturity Date**” means April 5, 2016.

“**Note**” means this 10% Subordinated Secured Convertible Note Due 2016 issued by the Company.

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“**Person**” means any individual, corporation, partnership, limited liability company, joint venture, association, joint-stock company, trust, unincorporated organization or government, or any agency or political subdivision thereof.

“**Qualified Financing**” means any bona fide, third-party, arms-length negotiated equity financing with net proceeds to the Company of at least \$10,000,000, pursuant to a single transaction or series of related transactions, occurring after the Issue Date in which shares of the Company’s preferred stock are issued in exchange for cash proceeds.

“**Qualified Financing Stock**” means shares of a series of the Company’s preferred stock issued in a Qualified Financing after the Issue Date.

“**Securities Act**” means the Securities Act of 1933, as amended, and the rules and regulations of the Securities Exchange Commission promulgated thereunder.

“**Senior Debt**” means any obligations of the Company under the Senior Debt Documents, including, without limitation, obligations with respect to the payment of principal, interest (including without limitation interest accruing at the then applicable rate provided in the Senior Notes after the commencement of any Proceeding by, against or relating to the Company, whether or not a claim for such interest is allowed in such Proceeding), fees, costs and expenses before or after the commencement of any Proceeding, in each instance, without regard to whether or not an allowed claim in any such Proceeding.

“**Senior Debt Documents**” means the Senior Notes, the Loan Agreement dated as of October 16, 2009 between the Company and Boston Scientific Corporation, the Patent Security Agreement dated October 16, 2009 between the Company and Boston Scientific Corporation, and any and all other documents or instruments evidencing or further guarantying or securing, directly or indirectly, any of the Senior Debt, whether now existing or hereafter amended or created.

“**Senior Lender**” means the holder of the Senior Debt.

“**Senior Notes**” means those certain Secured Convertible Promissory Notes issued by the Company to Boston Scientific Corporation dated as of October 16, 2009, November 17, 2009 and December 18, 2009, respectively, in the aggregate original principal amount of \$3,500,000, and any amendments thereto or extensions thereof.

“**Shares**” means the shares of Capital Stock in the Company, or any other securities into which such shares of Capital Stock shall be reclassified or changed.

“**Subsidiary**” of any specified Person means any corporation, partnership, joint venture, limited liability company, association, trust or other business entity, whether now existing or hereafter organized or acquired, (i) in the case of a corporation, of which more than 50% of the total voting power of the Capital Stock entitled (without regard to the occurrence of any contingency) to vote in the election of directors, officers or trustees thereof is held by such specified Person or any of its Subsidiaries or (ii) in the case of a partnership, joint venture, limited liability company, association, trust or other business entity, with respect to which such specified Person or any of its Subsidiaries has the power to direct or cause the direction of the management and policies of such entity by contract or otherwise.

“**Tax or Taxes**” means any present or future tax, duty, levy, impost, assessment or other government charge (including penalties and interest related thereto) imposed or levied by or on behalf of any Taxing Authority.

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“**Taxing Authority**” means any government or political subdivision or territory or possession of any government or agency therein or thereof having the power to tax.

“**Term**” means the period of time from the Issue Date until all amounts owing by the Company under this Note have been paid in full in cash or converted into equity of the Company as contemplated herein.

“**Transfer Restricted Security**” has the meaning specified in Section 10(c) of this Note.

## **2. INTEREST; PRINCIPAL**

(a) Accrual and Payment of Interest. The outstanding principal amount of this Note shall accrue interest at a rate per annum (calculated on the basis of the actual number of days elapsed over a year of 360 days) equal to ten percent (10%) from the Issue Date to but excluding the Maturity Date. All accrued but unpaid interest shall be due and payable on the Maturity Date. Notwithstanding the foregoing, in the event that the principal balance of this Note is converted pursuant to Section 4 hereof on or prior to the Maturity Date, all accrued but unpaid interest shall also be converted in accordance with Section 4 hereof.

(b) Defaulted Interest. If the Company defaults in a payment of principal or interest on this Note, it shall pay interest on overdue principal and on overdue installments of interest (without regard to any applicable grace periods) from time to time on demand at the rate per annum equal to fifteen percent (15%), to the extent lawful, until such time as the Company has paid such overdue principal and interest.

(c) Principal. If this Note has not previously been converted as provided in Section 4 hereof, all principal and all accrued, but unpaid interest shall be immediately due and payable by the Company to Brainlab on the Maturity Date.

(d) Prepayment. Amounts owing under this Note may not be pre-paid, in whole or in part, by the Company prior to the delivery of a Financing Notice (as defined below) from the Company to Brainlab without the prior written consent of Brainlab. In the event that the Company delivers a Financing Notice and conversion is not automatic, the Company may thereafter, pre-pay, in whole or in part, amounts owing under this Note prior to the the Maturity Date, upon at least 10 days prior notice to Brainlab.

## **3. METHOD OF PAYMENT**

All principal and interest owing by the Company to Brainlab under this Note shall be paid in United States Dollars. The Company shall pay all principal and interest owing under this Note by wire transfer of immediately available funds, in accordance with the wiring instructions provided from time to time by Brainlab to the Company in writing, provided that if any applicable law (as determined by the Company) requires the deduction of withholding of any Tax from any such payment, then the Company shall make such deduction and timely pay the full amount deducted to the relevant governmental authority in accordance with applicable law and remit the balance of the payment to Brainlab.

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#### 4. CONVERSION

##### (a) Conversion of Note.

(i) The Company shall provide written notice to Brainlab setting forth the fact that a Qualified Financing has occurred, the applicable Conversion Price, the number of Conversion Shares issued/to be issued upon conversion and the calculation thereof and the rights, preferences and responsibilities of the Conversion Shares, not more than 10 days following the consummation of a Qualified Financing, as well as a representation as to the then current capitalization of the Company (“**Financing Notice**”).

(ii) Subject to the further provisions of this Section 4, in the event that the Conversion Shares to be issued to Brainlab in connection with the Qualified Financing shall represent at least 10% of the outstanding Shares of the Company, on a fully diluted basis, the principal and accrued interest existing pursuant to this Note shall automatically be converted into Conversion Shares simultaneous upon the closing of the Qualified Financing. Subject to the further provisions of this Section 4, in the event that the Conversion Shares to be issued to Brainlab in connection with the Qualified Financing shall represent less than 10% of the outstanding Shares of the Company, on a fully diluted basis, Brainlab may, at its sole option, cause all but not less than all of the principal and accrued interest existing pursuant to this Note to be converted into Conversion Shares at any time following the closing of a Qualified Financing but prior to the time all amounts owing by the Company under this Note have been paid in full, at the Conversion Price in effect on the Conversion Date.

(iii) The number of Conversion Shares issuable upon conversion of this Note shall equal the number determined by dividing (a) the outstanding principal amount of this Note plus all accrued but unpaid interest by (b) the Conversion Price in effect on the Conversion Date.

(iv) Subject to the adjustments provided by this Section 4, the “**Conversion Price**” shall be the price per share paid by investors in the Qualified Financing for one share of Qualified Financing Stock.

(v) Notwithstanding any of the foregoing to the contrary, the Company shall not issue or cause to be issued fractional Conversion Shares on conversion of this Note. If any fraction of a share would, except for the provisions of this Section 4(a)(v), be issuable upon conversion of this Note, the number of Conversion Shares to be issued will be rounded up to the nearest whole share.

##### (b) Conversion Procedure

(i) In the case of an optional conversion by Brainlab, Brainlab shall deliver to the Company a written notice of Brainlab’s election to convert all of the principal and accrued interest existing pursuant to this Note into Conversion Shares (a “**Conversion Notice**”).

(ii) In the case of any conversion of this Note, Brainlab must (a) surrender this Note to the Company, and (b) furnish appropriate endorsements and transfer documents if required by the Company. As soon as practicable after Brainlab fulfills these obligations the Company shall deliver to Brainlab (or any affiliate of Brainlab as designated in writing by Brainlab) a certificate (or, if so designated in writing by Brainlab, multiple certificates in the name of Brainlab or its affiliates in such denominations as Brainlab may request) for the number of Conversion Shares issuable upon the conversion.

(iii) For purposes of this Note, the “**Conversion Date**” shall be (a) in the case of an automatic conversion upon a Qualified Financing, the closing date of a Qualified Financing, or (b) in the case of an optional conversion by Brainlab, the date on which the Conversion Notice is delivered to the Company in accordance with Section 11(a) hereof.

(iv) The Person(s) in whose name the Conversion Shares are registered shall be deemed to be a shareholder of record as of the Conversion Date.

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(c) Taxes on Conversion. If Brainlab converts this Note, the Company shall pay any documentary, stamp, transfer or similar Tax, but excluding any foreign Tax, due on the issuance of Conversion Shares upon such conversion. Nothing herein shall preclude any Tax withholding required by law or regulation.

(d) Obligation to Provide Conversion Shares.

(i) All Conversion Shares delivered upon conversion of this Note shall be (a) duly authorized and validly issued, (b) free from preemptive rights and free of any lien or adverse claim and (c) subject to the terms of the Company's Certificate of Incorporation.

(ii) The Company will promptly comply with all federal and state securities laws regulating the offer and delivery of Conversion Shares, upon conversion of this Note, if any.

(e) Adjustment of Conversion Price. The Conversion Price shall be adjusted from time to time by the Company as follows:

(i) In the event that the Company experiences a Qualified Financing and, prior to Brainlab's election to convert, another Qualified Financing shall occur, the Conversion Price shall be adjusted based upon the most recent Qualified Financing.

(ii) In the event of any stock subdivision, stock combination or other similar event, the Conversion Price shall be appropriately and equitably adjusted to reflect such event. An adjustment made pursuant to this Section shall become effective immediately after the effectiveness of such event.

(f) Notice of Adjustment. Whenever the Conversion Price is adjusted, the Company shall promptly deliver to Brainlab a notice of the adjustment briefly stating the facts requiring the adjustment and the manner of computing it.

(g) Notice of Certain Transactions. In the event that:

(i) the Company takes any action which would require an adjustment in the Conversion Price;

(ii) the Company consolidates or merges with, or transfers all or substantially all of its assets to, another corporation and the Company's stockholders must approve the transaction; or

(iii) there is a dissolution or liquidation of the Company;

the Company shall deliver to Brainlab a notice stating the proposed record or effective date, as the case may be, at least 10 days before such date; provided, however, that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice. Additionally, in the event of any other occurrence which causes any of the representations and warranties of the Company contained herein to be untrue or incorrect in any material respect, the Company shall deliver to Brainlab a written notice describing such occurrence within 10 days of the Company becoming aware thereof.

(h) Effect of Reclassification, Consolidation, Merger or Sale on Conversion Right. If any of the following shall occur, namely: (a) any reclassification or change of shares of Capital Stock issuable upon conversion of this Note (other than a change as a result of a subdivision or combination, any other change for which an adjustment is provided in Section 4(e), or any change in par value); (b) any

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consolidation or merger to which the Company is a party other than a consolidation or merger in which the Company is the continuing corporation and which does not result in any reclassification or change of shares of Capital Stock issuable upon conversion of this Note (other than a change in name or as a result of a subdivision or combination); or (c) any sale or conveyance of all or substantially all of the assets of the Company as an entirety, then the Company, or such successor or purchasing corporation, as the case may be, shall, as a condition precedent to such reclassification, change, consolidation, merger, sale or conveyance, deliver a notice to Brainlab that Brainlab shall have the right to convert this Note into the kind and amount of securities and property (including cash) receivable upon such reclassification, change, consolidation, merger, sale or conveyance by a holder of the number of Conversion Shares deliverable upon conversion of this Note immediately prior to such reclassification, change, consolidation, merger, sale or conveyance. Such notice shall provide for adjustments of the Conversion Price which shall be as nearly equivalent as may be practicable to the adjustments of the Conversion Price provided for in Section 4(e). If, in the case of any such consolidation, merger, sale or conveyance, the stock or other securities and property (including cash) receivable thereupon by a holder of shares of Capital Stock include shares of stock or other securities and property of a corporation other than the successor or purchasing corporation, as the case may be, in such consolidation, merger, sale or conveyance, then the Company shall use commercially reasonable efforts to cause such notice to be executed by such other corporation and contain such additional provisions to protect the interests of Brainlab as the directors of the Company shall reasonably consider necessary by reason of the foregoing. The provisions of this Section 4(h) shall similarly apply to successive consolidations, mergers, sales or conveyances.

## 5. SECURITY

The Company hereby grants to Brainlab a continuing second priority security interest in and Lien on, second only to the Liens of Senior Lender under the Senior Debt Documents, all of the properties, assets, and rights of the Company, wherever located and whether now owned or hereafter acquired or arising, and all proceeds and products thereof (all such properties, assets, rights, proceeds and products hereinafter sometimes called, collectively, the “**Collateral**”). This security interest and Lien shall be evidenced the parties entering into a Master Security Agreement, the terms of which shall be incorporated herein by reference. Upon the request of Brainlab, the Company will execute and deliver such further instruments and do such further acts as may be reasonably necessary or proper to carry out and perfect the security interest granted hereby.

## 6. SUBORDINATION

(a) Subordination of this Note. Brainlab agrees that, until such time as all amounts owing by the Company under the Senior Debt have been indefeasibly converted into equity of the Company or paid in full in cash, any Lien it may acquire against any assets or property of the Company to secure any obligations of the Company to Brainlab in connection herewith shall be subordinate and inferior to the Liens of Senior Lender under the Senior Debt Documents. The priorities set forth in this section are applicable irrespective of the order or time of attachment, or the order, time or manner of perfection, or the order or time of filing or recordation of any document or instrument, or other method of perfecting the Lien, and notwithstanding any conflicting terms or conditions which may be contained in any of the Senior Debt Documents or any other documents.

(b) Subordination of Other Indebtedness. The Company and the Collateral Agent, on behalf of the Junior Lender, agree that, until such time as all amounts owing by the Company under this Note have been indefeasibly converted into equity of the Company or paid in full in cash (a) the Junior Debt is subordinate in priority and subject in right and priority of payment to the prior performance of any and all obligations of the Company to Brainlab or its successor or assignee, pursuant to this Note, including, but not limited to, any interest accruing thereon after the commencement of an insolvency proceeding,

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without regard to whether or not such interest is an allowed claim and (b) any Liens the Collateral Agent has or may acquire, on behalf of and for the ratable benefit of the Junior Lender, against any assets or property of the Company to secure any obligations of the Company to the Junior Lender shall be subordinate and inferior to the Liens of Brainlab under this Note and the related Master Security Agreement. The priorities set forth in this section are applicable irrespective of the order or time of attachment, or the order, time or manner of perfection, or the order or time of filing or recordation of any document or instrument, or other method of perfecting the Lien, and notwithstanding any conflicting terms or conditions which may be contained in the Master Security Agreement in favor of Brainlab or any other documents.

7. **REPRESENTATIONS AND WARRANTIES OF THE COMPANY** The Company hereby represents and warrants to Brainlab as of the Issue Date, and, if applicable, as of the Conversion Date, as follows, each of which shall survive for the Term of this Note:

(a) **Organization and Qualification**. The Company is a corporation duly incorporated and validly existing under the laws of the State of Delaware. The Company has all requisite power and authority to carry on its business as currently conducted, other than such failures that, individually or in the aggregate, would not have a material adverse effect on the Company's business, properties or financial condition taken as a whole (a "**Material Adverse Effect**"). The Company is duly qualified to transact business in each jurisdiction in which the failure to be so qualified would reasonably be expected to have a Material Adverse Effect.

(b) **Capitalization**.

(i) As of the Issue Date, the authorized Capital Stock of the Company consists of: (a) 30,000,000 shares of Preferred Stock, of which 8,000,000 shares have been designated Series A Convertible Preferred Stock and of which 7,965,000 shares of Series A Convertible Preferred Stock are issued and outstanding; and (b) 70,000,000 shares of Common Stock, of which 15,859,981 shares are issued and outstanding. As of the Conversion Date, the capitalization of the Company shall be as set forth in the Financing Notice.

(ii) As of the Issue Date, other than as set forth on Schedule 7(b), (a) there is not outstanding, nor is the Company bound by, any subscriptions, options, preemptive rights, warrants, calls, commitments or agreements or rights, rights of first offer or first refusal, or rights of any character requiring the Company to issue or entitling any Person to acquire any shares of Capital Stock or any other equity security of the Company, including any right of conversion or exchange under any outstanding security or other instrument, and the Company is not obligated to issue or transfer any shares of Capital Stock or other equity interest for any purpose; (b) there are no outstanding obligations of the Company to repurchase, redeem or otherwise acquire any outstanding shares of Capital Stock or other equity interests in the Company; and (c) no plan, purchase agreement, option or other agreement or understanding between the Company and any holder of any shares of Capital Stock or other equity interests or securities or rights exercisable or convertible for shares of Capital Stock or other equity interests or securities provides for acceleration or other changes in the vesting provisions or other terms of such agreement or understanding as the result of the occurrence of any event.

(c) **Subsidiaries**. The Company has no Subsidiaries. The Company is not a participant in any joint venture, partnership, or similar arrangement.

(d) **Authorization**. All action for or on the part of the Company, its officers and directors necessary, including without limitation, all action required by the Company's stockholders, for the authorization, execution and delivery of this Note and the performance of all obligations of the Company

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hereunder shall have been taken, and this Note will constitute a valid and legally binding obligation of the Company, enforceable in accordance with its terms, subject to: (i) judicial principles limiting the availability of specific performance, injunctive relief, and other equitable remedies and (ii) bankruptcy, insolvency, reorganization, moratorium or other similar laws now or hereafter in effect generally relating to or affecting creditors' rights.

(e) Valid Issuance of Conversion Shares Upon Conversion. Upon conversion in accordance with the terms hereof, Brainlab will obtain good and valid title to the Conversion Shares to be issued upon conversion free and clear of any liens, restrictions, claims, equities, options, charges, rights of first refusal, or encumbrances or other restrictions, except restrictions on transfer and other rights and limitations contained in the Company's Certificate of Incorporation and except for restrictions imposed by applicable state and federal securities laws.

(f) Required Consents. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any Person, including, without limitation any, federal, state or local governmental authority on the part of the Company is required in connection with the offer, sale or issuance of this Note or the issuance of Conversion Shares upon conversion as provided for herein, except for the following: (i) the filing of such notices as may be required under the Securities Act; (ii) the filing of such notices as may be required under any applicable state securities laws, which, in the case of each of (i) and (ii), shall be filed by the Company (with the cooperation of Brainlab) following conversion within the applicable required timeframes; and (iii) the compliance with any other applicable state and/or federal securities laws, which compliance the Company (with the cooperation of Brainlab) will arrange within the appropriate time periods therefore.

(g) Litigation. Other than as set forth on Schedule 7(g), there is no claim, action, suit, proceeding, arbitration, complaint, charge or investigation ("**Action**") pending (i) by, or to the best of the Company's knowledge, against (A) the Company or (B) to the best of the Company's knowledge, any officer or director of the Company arising out of such officer's or director's employment or service to the Company; or (ii) that questions the validity of, or may materially and adversely impact Brainlab's rights under, this Note. Other than as set forth on Schedule 7(g), neither the Company, nor, to the best of the Company's knowledge, any officer or director of the Company, is a party to or is named as subject to the provisions of any order, writ, injunction, judgment or decree of any governmental authority (collectively, an "**Order**") (in the case of officers or directors, such as would affect the Company). Other than as set forth on Schedule 7(g), to the best of the Company's knowledge, (i) the Company has not received written notice of a threatened Action or Order against the Company, and (ii) no event has occurred or circumstance exists that may give rise to or serve as a basis for the commencement or imposition of any such Action or Order. For purposes of this Note, "**Company's knowledge**" shall mean the actual knowledge, following due inquiry, of each of Kimble Jenkins, the Company's Chief Executive Officer, and Oscar Thomas, the Company's Vice President, Business Affairs.

(h) Intellectual Property.

(i) For purposes of this Note, "**Company Intellectual Property**" shall mean all patents, patent rights, patent applications, trademarks and service marks, trademark rights, trademark applications, service mark rights, service mark applications, trade names, registered copyrights, copyright rights, domain names and proprietary rights and trade secrets, technology and know-how, owned or used by the Company, that the Company reasonably believes to be necessary to or used in connection with the business of the Company as presently conducted or as proposed to be conducted, in each case together with any amendments, modifications and supplements thereto.

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(ii) The Company owns or possesses sufficient legal rights to all Company Intellectual Property for the conduct of its business as presently conducted or as presently proposed to be conducted without, to the best of the Company's knowledge, conflict with, or infringement of, the rights of others. To the best of the Company's knowledge, no service marketed or sold, or presently proposed to be marketed or sold, by the Company violates or will violate any license or infringes or will infringe any intellectual property rights of any Person. Other than as set forth on Schedule 7(h)(ii) hereto, and other than with respect to commercially available software products under standard end-user object code license agreements, as of the Issue Date there are no outstanding options, licenses, agreements, claims, encumbrances or shared ownership interests of any kind relating to the Company Intellectual Property, nor is the Company bound by or a party to any options, licenses or agreements of any kind with respect to the patents, trademarks, service marks, trade names, copyrights, trade secrets, licenses, information, proprietary rights and processes of any other Person. Except as set forth on Schedule 7(h)(ii) hereto, the Company has not received any communications alleging that the Company has violated or, by conducting its business, would violate any of the patents, trademarks, service marks, tradenames, copyrights, trade secrets, mask works or other proprietary rights or processes of any other Person. The Company has obtained and possesses valid licenses to use all of the software programs present on the computers and other software-enabled electronic devices that it owns or leases or that it has otherwise provided to its employees for their use in connection with its business. To the best of the Company's knowledge, except as set forth in Schedule 7(h)(ii) hereto, the Company does not use any inventions of any of the officers, employees or consultants of the Company (or Persons the Company currently intends to hire) made prior to their employment with or engagement by the Company. Except as set forth in Schedule 7(h)(ii) hereto, each officer, employee and consultant of the Company has assigned to the Company all intellectual property rights he or she creates in the performance of services for the Company that are related to the business of the Company as now conducted and as presently proposed to be conducted by execution of a binding agreement with the Company.

(i) No Violation of Law. Other than as set forth in Schedule 7(i), (i) the Company is not in violation, in any material respect, of any applicable local, state or federal law, ordinance, regulation, order, injunction or decree, or any other requirement of any governmental body, agency or authority or court binding on it, or relating to its property or business or its advertising, sales or pricing practices (including, without limitation, any state or federal banking laws and regulations, antitrust laws and regulations, or consumer protection laws or regulations), and (ii) the Company has not, in any event, received any written notice of the existence of any of the foregoing.

(j) Compliance with Other Instruments. The Company is not in violation or default of any provision of its Certificate of Incorporation or Bylaws. The Company is not in violation or default of any provision of any material instrument, mortgage, deed of trust, loan, contract, commitment, judgment, decree, order or obligation to which it is a party or by which it or any of its properties or assets are bound which would reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The execution, delivery and performance of and compliance with this Note and the issuance of Conversion Shares upon conversion as provided herein, will not result in any such violation, be in conflict with or constitute, with or without the passage of time or giving of notice, a default under any such provision, require any consent or waiver under any such provision (other than any consents or waivers that have been obtained), or result in the creation of any mortgage, pledge, lien, encumbrance or charge upon any of the properties or assets of the Company pursuant to any such provision.

(k) Permits. The Company has all permits, licenses, and any similar authority necessary for the conduct of its business as now being conducted by it, the lack of which would reasonably be expected to have a Material Adverse Effect. The Company is not in default in any material respect under any of such permits, licenses, or other similar authority.

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(l) **Environmental and Safety Laws.** The operations of the Company have been and are in compliance in all respects with all Environmental Laws (defined below) applicable to the Company and with all licenses required by Environmental Laws applicable to the Company, except, in each case, such non-compliance as would not have a Material Adverse Effect. For purposes of this Note, the term “**Environmental Laws**” shall mean all present federal, state and local laws, statutes, ordinances, regulations, codes, published policies, rules, directives, orders, decrees, permits, licenses, approvals, authorizations, published guidelines, covenants, deed restrictions, treaties, conventions, and rules of common law in effect, and in each case as amended, and any judicial or administrative judgment, opinion or interpretation thereof, relating to the regulation or protection of human health, safety, natural resources or the environment, including, without limitation, laws and regulations (and all other items recited above) relating to the use, treatment, storage, management, handling, manufacture, generation, processing, recycling, distribution, transport, release or threatened release of or exposure to any hazardous material.

(m) **Title to Property and Assets.** The Company has good and marketable title to all of the material properties and assets owned by it, free and clear of any and all mortgages, liens, encroachments, easements, restrictions, claims, equities, options, charges, rights of first refusal, encumbrances, defects of title or other conflicting ownership or security interests whatsoever (collectively, “**Encumbrances**”), except (i) Liens for current taxes and assessments not yet due, (ii) Liens under the Senior Debt Documents, (iii) Liens under the Junior Debt Documents, (iv) Liens in favor of Brainlab as contemplated hereunder, and (v) possible minor Encumbrances which do not, in any case, materially detract from the value of the property subject thereto or materially impair the operations of the Company (collectively, “**Permitted Encumbrances**”). With respect to any material property and assets it leases, the Company is in material compliance with such leases and, to the best of its knowledge, holds a valid leasehold interest free of any and all Encumbrances, except for Permitted Encumbrances. The Company’s material properties and assets are in good condition and repair, in all material respects, for the purposes for which they are currently used, ordinary wear and tear excepted.

(n) **Financial Statements.** The unaudited financial statements of the Company for the fiscal year ended December 31, 2010 (consisting of a balance sheet and statement of operations) (collectively, the “**Financial Statements**”) have been provided to Brainlab. The Financial Statements (i) were prepared on an accrual basis, in accordance with the Company’s past practices, applied on a consistent basis throughout the period indicated, (ii) are derived from and were prepared in accordance with the books and records of the Company, and (iii) fairly present in all material respects the financial position of the Company at the date therein indicated and the results of operations of the Company for the period therein specified. The Company has no material liabilities of a kind that would be required under United States generally accepted accounting principles to be reflected on the face of the Company’s balance sheet, other than (i) those set forth or adequately provided for in the December 31, 2010 balance sheet included in the Financial Statements, (ii) those incurred in the conduct of the Company’s business since January 1, 2011 in the ordinary course, consistent with past practice, which are of the type that ordinarily occur or recur and, individually or in the aggregate, are not material in nature or amount and do not result from any breach of contract, tort or violation of law, (iii) those set forth on Schedule 7(n) and (iv) liabilities arising pursuant to this Note. Except for liabilities reflected in the Financial Statements, the Company has no off balance sheet liability of any nature to, or any financial interest in, any third party or entities, the purpose or effect of which is to defer, postpone, reduce or otherwise avoid or adjust the recording of debt expenses incurred by the Company. Except as set forth on Schedule 7(n), since January 1, 2011, there have not been any materially adverse changes in the assets, liabilities, condition (financial or otherwise), relationships (including with its customers, suppliers and employees), operations or prospects of the Company.

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(o) Agreements; Actions.

(i) Except for agreements set forth on Schedule 7(o)(i) hereto, there are no agreements, understandings or proposed transactions between the Company and any of its officers, directors, affiliates, or any affiliate thereof.

(ii) Except as set forth on Schedule 7(o)(ii), there are no agreements, understandings, instruments, contracts, judgments, orders, writs or decrees to which the Company is a party or by which it is bound that involve (i) provisions restricting the development, manufacture or distribution of the Company's products or services or (ii) the payment of indemnification by the Company with respect to infringement of proprietary rights.

(iii) Since January 1, 2011, the Company has not (i) incurred indebtedness for money borrowed, or (ii) sold, exchanged or otherwise disposed of any of its assets or rights having an aggregate value of more than \$50,000, other than the sale of its inventory and license agreements in the ordinary course of business.

(p) Changes. Other than as set forth on Schedule 7(p), since January 1, 2011, there has not been:

(i) any adverse change in the assets, liabilities, financial condition or operating results of the Company, from that reflected in the Financial Statements, except for changes arising in the ordinary course of business that, individually or in the aggregate, could not reasonably be expected to have a Material Adverse Effect;

(ii) any damage, destruction or loss of any asset or property of the Company having an aggregate value in excess of \$50,000, whether or not covered by insurance;

(iii) any waiver by the Company of a valuable right or of a debt owed to it in excess of \$50,000;

(iv) any satisfaction or discharge of any Encumbrance or payment of any obligation by the Company, except in the ordinary course of business and the satisfaction or discharge of which would not have a Material Adverse Effect;

(v) any material change or amendment to any contract or agreement that could reasonably be expected to be material to the Company either in terms of revenue generated thereby or the liabilities incurred by the Company thereunder;

(vi) any material change in any compensation arrangement or agreement with any key employee;

(vii) any sale, assignment or transfer of any patents, trademarks, copyrights, trade secrets or other intangible assets;

(viii) any resignation or termination of employment of any key employee or officer of the Company (and to the best of Company's knowledge, there is no impending resignation or termination of employment of any such key employee or officer);

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(ix) the loss of any customer or the cancellation of any order of the Company which has historically represented, or is expected to represent, revenue to the Company in excess of \$5,000 per month or \$50,000 in the aggregate nor any written notice thereof;

(x) any mortgage, pledge, grant of a security interest in, or Encumbrance created by the Company, with respect to any of its material properties or assets, except for Permitted Encumbrances;

(xi) any loans or guarantees made by the Company to or for the benefit of any related party, or any members of their immediate families, other than travel advances and other advances made in the ordinary course of business;

(xii) any declaration, set aside, payment or other distribution in respect of any of the Capital Stock of the Company, or any direct or indirect redemption, purchase or other acquisition of any of such Capital Stock by the Company;

(xiii) any other event or condition of any character that would have a Material Adverse Effect; or

(xiv) any agreement or commitment by the Company to do any of the things described in this Section 7(p).

(q) Employee Benefit Plans.

(i) Except as set forth in Schedule 7(q) hereto, the Company does not maintain, sponsor, or make contributions to: any “employee pension benefit plan” or “employee welfare benefit plan,” as such terms are defined in the Employee Retirement Income Security Act of 1974, as amended, and all regulations promulgated thereunder (“**ERISA**”); any collective bargaining agreement; any severance agreement or plan, or any medical, life or disability benefit plan or arrangement; any excess benefit plan, bonus or incentive plan, top hat plan or deferred compensation plan, salary reduction agreement, or change-of-control agreement; whether or not written with respect to any employee, former employee, director, independent contractor, or any beneficiary or dependent thereof (all such plans, policies, programs, arrangements, agreements and contracts, including those that are set forth on Schedule 7(q) hereto are referred to in this Note as “**Scheduled Plans**”).

(ii) To the best of the Company’s knowledge, each Scheduled Plan has been operated and administered in compliance in all material respects, and each Scheduled Plan currently complies in form and in operation in all material respects, with all applicable requirements of ERISA, the Internal Revenue Code of 1986, as amended, and all regulations promulgated thereunder (the “**Code**”), and all other applicable laws. Neither the Company nor any controlled group affiliate, as described in Sections 414(b) or (c) of the Code, has ever sponsored, maintained, contributed to or had any obligation to contribute to any plan subject to Section 412 of the Code or Title IV of ERISA.

(r) Tax Returns, Payments and Elections. The Company has filed all material tax returns and reports (including information returns and reports) as the Company is required by law to have filed, and such returns and reports are true and correct in all material respects. The Company has paid all material taxes and other assessments that have become due and payable. The Company has not made any elections pursuant to the Code (other than elections that relate solely to methods of accounting, depreciation or amortization) that would have a Material Adverse Effect. Except as set forth in Schedule 7(r), the Company has never had any material tax deficiency proposed or assessed against it and the Company has not executed any waiver of any statute of limitations on the assessment or collection of any tax or governmental charge. Except as set forth in Schedule 7(r), none of the federal income tax returns,

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state income or franchise tax or sales or use tax returns of the Company has ever been audited by governmental authorities. Since January 1, 2011, the Company has not incurred any taxes, assessments or governmental charges other than in the ordinary course of business and the Company has made adequate provisions on its books of account for all material taxes, assessments and governmental charges with respect to its business, properties and operations that have accrued but not yet been paid. Except as set forth in Schedule 7(r) hereto, the Company has withheld or collected from each payment made to each of its employees, the amount of all taxes (including, but not limited to, federal income taxes, Federal Insurance Contribution Act taxes and Federal Unemployment Tax Act taxes) required to be withheld or collected therefrom, and has paid the same to the proper tax receiving officers or authorized depositories.

(s) Labor Agreements and Actions: Employee Compensation. The Company is not bound by or subject to (and none of its assets or properties is bound by or subject to) any written or oral, express or implied, contract, commitment or arrangement with any labor union, and no labor union has requested or, to the best of the Company's knowledge, has sought to represent any of the employees, representatives or agents of the Company. There is no strike or other labor dispute involving the Company pending, or to the best of the Company's knowledge, threatened, that could have a Material Adverse Effect, nor is the Company aware of any labor organization activity involving its employees. To the best of the Company's knowledge none of its officers or key employees or any group of key employees intends to terminate their employment with the Company, nor does the Company have a present intention to terminate the employment of any of the foregoing. The Company has complied in all material respects with all applicable state and federal equal employment opportunity laws.

(t) Brokers or Finders. The Company has not agreed to incur, directly or indirectly, any liability for brokerage or finders' fees, agents' commissions or other similar charges in connection with this Note or any of the transactions contemplated hereby.

(u) Disclosure. Neither this Note nor any and all written statements furnished or made to Brainlab by or on behalf of the Company in connection with this Note, taken as a whole, and including any corrective materials furnished or made available to Brainlab, contains any untrue statement of a material fact or omits or will omit to state a material fact necessary in order to make the statements contained herein and therein not materially misleading in light of the circumstances under which they were made.

## **8. COVENANTS AND OTHER AGREEMENTS**

(a) Payment of Note. The Company shall promptly make all payments in respect of this Note on the dates and in the manner provided in this Note. The Company shall, to the extent permitted by law, pay interest on overdue amounts at the rate set forth in Section 2 of this Note, which interest on overdue amounts (to the extent that the payment of such interest shall be legally enforceable) shall accrue from the date such amounts become overdue.

(b) No Additional Indebtedness. During the Term of this Note, other than the Senior Debt, the Company shall incur no new Indebtedness for borrowed money in excess of \$250,000 individually or in the aggregate, except with the prior written consent of Brainlab which consent, in the case of Indebtedness that is, by its terms, subordinate to Indebtedness owed to Brainlab, shall not unreasonably be withheld or delayed.

(c) Financial Reporting. As long as any amounts remain outstanding under this Note or, if this Note is converted, as long as Brainlab continues to hold at least 50% of the Conversion Shares issued upon such conversion, the Company shall deliver to Brainlab (i) as soon as practicable after the end of each fiscal year of the Company, and in any event within 120 days thereafter, a balance sheet of the

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Company and statement of stockholders' equity as of the end of such year and statements of income and cash flow for such year, such year-end financial reports to be in reasonable detail, prepared in accordance with generally accepted accounting principles, consistently applied (subject however to the absence of footnotes in the event the Company does not engage an independent certified public accounting firm to audit and certify such financial statements); and (ii) as soon as practicable after the end of each fiscal quarter (except the last quarter of each fiscal year), and in any event within forty-five (45) days thereafter, an unaudited balance sheet of the Company as of the end of such fiscal quarter, and an unaudited statement of income for each fiscal quarter and for the current fiscal year to date.

(d) Information and Inspection Rights. During the Term of this Note or, if this Note is converted, as long as Brainlab continues to hold at least 50% of the Conversion Shares issued upon such conversion, in addition to any rights that may be available under Delaware or other applicable law, subject to the execution of a standard confidentiality agreement, Brainlab shall have the right, at its sole expense and upon reasonable prior notice to the Company, to inspect and examine the Company's properties, operations and books of account; provided, however, that any such inspection or examination shall be conducted in a manner that is reasonably designed to minimize any interference with the operations of the Company's business; provided, further, that the Company shall be under no obligation to provide, give access to or discuss with Brainlab any information regarding the Company's properties, operations or books of account to the extent necessary to comply with the terms and conditions of confidentiality agreements between the Company and any third parties or to the extent the Company has determined that there exists an actual or potential conflict of interest between Brainlab and the Company.

(e) Board Observation Rights. During the Term of this Note or, if this Note is converted, as long as Brainlab continues to hold at least 50% of the Conversion Shares issued upon such conversion, Brainlab shall be entitled to appoint one individual who shall be invited to attend and observe all meetings of the Company's board of directors or any committees created by the board; provided, however, that such board observer agrees to hold in confidence and trust, to act in a fiduciary manner with respect to and not to disclose any information provided to or learned by the board observer acting in such capacity. Notwithstanding the provisions of this Section 8(e), the Company reserves the right to exclude the board observer from portions of any meeting where and to the extent that the Company reasonably believes that excluding the board observer from attending such portion of the meeting is reasonably necessary (i) to preserve attorney-client, work product or similar privilege between the Company and its counsel with respect to any matter, (ii) to comply with the terms and conditions of confidentiality agreements between the Company and any third parties, or (iii) because the Company has determined, in good faith, that there exists, with respect to the subject of such deliberation or such information, an actual or potential conflict of interest between Brainlab and the Company. Furthermore, the members of the Company's board of directors shall be entitled to hold reasonable executive sessions which the board observer may not be invited to attend. Brainlab's board observer shall use the same degree of care to protect the Company's confidential and proprietary information as Brainlab uses to protect its confidential and proprietary information of like nature, but in no circumstances with less than reasonable care.

(f) Further Instruments and Acts. Upon the reasonable request of Brainlab, the Company will execute and deliver such further instruments and do such further acts as may be reasonably necessary or proper to carry out more effectively the provisions of this Note.

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## 9. DEFAULTS AND REMEDIES

(a) Events of Default. Each of the following shall be an “**Event of Default**” for purposes of this Note:

(1) unless this Note is converted pursuant to Section 4 hereof, failure to pay principal of or interest on this Note on the dates specified in Section 2 hereof, to and including the Maturity Date;

(2) failure to perform any other covenant, representation, warranty or agreement of the Company under this Note, continued for 30 days or more after written notice to the Company by Brainlab;

(3) there shall be, with respect to any issue or issues of Indebtedness (other than Indebtedness created or as a result of this Note) of the Company or any of its Subsidiaries, whether such Indebtedness now exists or shall hereafter be created, (x) an event of default that has caused the holders thereof (or their representatives) (i) to declare such Indebtedness to be due and payable prior to its scheduled maturity and such Indebtedness has not been discharged in full or such acceleration has not been rescinded or annulled within 45 days following such acceleration and/or (ii) to commence judicial proceedings to exercise remedies under applicable law and such judicial proceedings have not been dismissed or stayed within 45 days following such commencement and/or (y) the failure to make a principal payment at the final (but not any interim) fixed maturity and such defaulted payment shall not have been made, waived or extended within 45 days of such payment default;

(4) except for judgments related to matters disclosed on the schedules to this Note, the rendering of a final judgment or judgments against the Company or any of its Subsidiaries in an amount that exceeds \$500,000 in excess of insurance coverage, which judgment remains in force, undischarged, unsatisfied, unbonded or unstayed for a period of 60 days;

(5) the Company or any of its Subsidiaries pursuant to or within the meaning of any Bankruptcy Law:

(A) admits in writing its inability to pay its debts generally as they become due,

(B) commences a voluntary case or proceeding,

(C) consents to the entry of an order for relief against it in an involuntary case or proceeding,

(D) consents or acquiesces in the institution of a bankruptcy or insolvency proceeding against it,

(E) consents to the appointment of a custodian of it or for all or substantially all of its property, or

(F) makes a general assignment for the benefit of its creditors, or any of them takes any action to authorize or effect any of the foregoing;

(6) a court of competent jurisdiction enters an order or decree under any Bankruptcy Law that:

(A) is for relief against the Company or any of its Subsidiaries in an involuntary case or proceeding,

(B) appoints a custodian for the Company or any of its Subsidiaries or for all or substantially all of their property, or

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(C) orders the liquidation of the Company or any of its Subsidiaries, and in each case the order or decree remains unstayed and in effect for 60 days; provided, however, that if the entry of such order or decree is appealed and dismissed on appeal, then the Event of Default hereunder by reason of the entry of such order or decree shall be deemed to have been cured;

(7) failure to consummate a Qualified Financing within 180 days following the date of this Note;

(8) failure to issue Conversion Shares when such Conversion Shares are required to be delivered, upon conversion of this Note and such failure is not remedied for a period of 10 Business Days;

(9) a breach of any the representations and warranties contained in this Note that is not remedied within 30 days following the Company's receipt of a notice of such breach from Brainlab; or

(10) a breach or default by the Company of or under any of the terms of any other agreement between the Company and Brainlab or any affiliate of Brainlab that is not remedied within 30 days following the Company's receipt of a notice of such breach from Brainlab.

(b) Acceleration. If an Event of Default with respect to this Note (other than an Event of Default specified in clause (5) or (6) of Section 9(a) with respect to the Company) occurs and is continuing, Brainlab by notice in writing to the Company may declare the unpaid principal of and accrued interest to the date of acceleration on this Note to be due and payable immediately and, upon any such declaration, such principal amount and accrued interest, notwithstanding anything contained in this Note to the contrary, will become immediately due and payable. If an Event of Default specified in clause (5) or (6) of Section 9(a) with respect to the Company occurs, this Note will ipso facto become immediately due and payable without any declaration or other act on the part of Brainlab.

(c) Remedies. If an Event of Default occurs and is continuing, Brainlab may pursue any available remedy by proceeding at law or in equity to collect the payment of principal of or interest on this Note or to enforce the performance of any provision of this Note. A delay or omission by Brainlab in exercising any right or remedy maturing upon an Event of Default shall not impair the right or remedy or constitute a waiver of or acquiescence in the Event of Default. No remedy is exclusive of any other remedy. All available remedies are cumulative to the extent permitted by law.

(d) Waiver of Usury, Stay or Extension Laws. The Company covenants (to the extent that it may lawfully do so) that it will not at any time insist upon, or plead, or in any manner whatsoever claim or take the benefit or advantage of, any usury, stay or extension law wherever enacted, now or at any time hereafter in force, which may affect the covenants or the performance of this Note; and the Company (to the extent that it may lawfully do so) hereby expressly waives all benefit or advantage of any such law and covenants that it will not hinder, delay or impede the execution of any power herein granted to the Company, but will suffer and permit the execution of every such power as though no such law had been enacted.

#### 10. EXCHANGE; TAXES; LEGEND; REPLACEMENT

(a) Exchange. For so long as this Note is outstanding and unless this Note is converted pursuant to Section 4, at the option of Brainlab, and subject to the other provisions of this Note, this Note may be exchanged for other promissory notes of a like aggregate principal amount and subject to substantially the same terms and conditions as set forth in this Note, executed by the Company, upon surrender of this Note to the Company.

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(b) Payment of Taxes. Notwithstanding any other provision of this Section 10, no transfer of this Note shall be permitted, and no registration of transfer shall be effected unless, prior to the time of such transfer or registration of transfer, Brainlab has made arrangements reasonably satisfactory to the Company for payment or reimbursement of any and all Taxes which would, in the absence of payment by the transferor, be required to be paid by the Company as a result of such transfer. No service charge shall be made for any registration of transfer or exchange.

(c) Legend. Except as permitted by Section 10(e), this Note (and all promissory notes issued in exchange therefor or substitution of this Note) shall, so long as appropriate, bear a legend (the “**Legend**”) to substantially the following effect (each, a “**Transfer Restricted Security**”):

**THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE UNITED STATES SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”), AND MAY NOT BE SOLD, ASSIGNED, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED EXCEPT IN A TRANSACTION WHICH IS REGISTERED UNDER THE SECURITIES ACT, OR IN A TRANSACTION WHICH IS EXEMPT FROM OR NOT SUBJECT TO THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT. ADDITIONALLY, THE TRANSFER OF THIS NOTE IS SUBJECT TO THE CONDITIONS SPECIFIED IN THIS NOTE, AND THE MAKER HEREOF RESERVES THE RIGHT TO REFUSE THE TRANSFER OF THIS NOTE UNTIL SUCH CONDITIONS HAVE BEEN FULFILLED WITH RESPECT TO SUCH TRANSFER.**

(d) Removal of Legend. At such time as any Transfer Restricted Security may be freely transferred without registration under the Securities Act and without being subject to transfer restrictions pursuant to the Securities Act, the Company shall permit the holder of such Transfer Restricted Security to exchange such Transfer Restricted Security for a new Note which does not bear the applicable portion of the Legend upon receipt of an appropriate certification from such holder and, at the request of the Company, upon receipt of an opinion of counsel, reasonably acceptable to the Company, that the transfer restrictions contained in the Legend are no longer applicable.

(e) Replacement of Lost, Stolen or Destroyed Note. Upon receipt of an executed lost note affidavit in form and substance satisfactory to the Company regarding the loss, theft, destruction, or mutilation of this Note and, if requested by the Company in the case of any such loss, theft or destruction, upon delivery of an indemnity bond or other agreement or security reasonably satisfactory to the Company, or, in the case of any such mutilation, upon surrender and cancellation of this Note, the Company will issue a new Note, of like tenor, in the amount of unpaid principal of this Note, in lieu of such lost, stolen, destroyed or mutilated Note.

## 11. MISCELLANEOUS

(a) Notices. All notices (including the Conversion Notice, if any), consents, waivers and other communications required or permitted by this Note shall be in writing and shall be deemed given to a party when (a) delivered to the appropriate address by hand, (b) one (1) Business Day following delivery to a nationally recognized overnight courier service (costs prepaid), or (c) received or rejected by

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the addressee, if sent by certified mail, return receipt requested, in each case to the following addresses and marked to the attention of the person (by name or title) designated below (or to such other address or person as a party may designate by notice to the other party):

the Company: SurgiVision, Inc.  
Attention: Chief Financial Officer  
One Commerce Square  
Suite 2550  
Memphis, TN 38103

With copy to: SurgiVision, Inc.  
Attention: VP, Business Affairs  
One Commerce Square  
Suite 2550  
Memphis, TN 38103

Brainlab: Brainlab AG.  
Attention: Chief Financial Officer  
Kapellenstr. 12,  
85622 Feldkirchen, Germany

With copy to: Legal Department  
Attention: General Counsel, Brainlab AG  
Kapellenstr. 12,  
85622 Feldkirchen, Germany

(b) Successors. All agreements of the Company in this Note shall bind its successor.

(c) Severability. Each provision of this Note shall be considered separable and if for any reason any provision which is not essential to the effectuation of the basic purpose of this Note shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

(d) Applicable Law; Dispute Resolution. This Note shall be construed and enforced in accordance with, and all questions concerning the construction, validity, interpretation and performance of this Note shall be governed by, the internal laws of the State of Delaware, without giving effect to provisions thereof regarding conflict of laws. The parties hereby submit to the exclusive jurisdiction of any state or federal court located within the State of Delaware, over any dispute arising out of or relating to this Note or any of the transactions contemplated hereby, and further agree that venue for all such matters shall lie exclusively in those courts and that process for any such action or proceeding may be served on any party anywhere in the world. The parties hereby irrevocably waive, to the fullest extent permitted by applicable law, any objection which they may now or hereafter have, including, but not limited to, any claim of forum non conveniens, to venue in the courts noted above. Each of the parties agrees that a judgment in any such dispute may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law. Each of the parties hereto hereby agrees that this Note involves at least One Hundred Thousand Dollars (\$100,000), and that it has been entered into in express reliance on 6 Del. C. § 2708. **EACH OF THE PARTIES HEREBY KNOWINGLY, VOLUNTARILY AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY** in any dispute, and consents to any and all relief ordered by the court, after the time for appeal has expired.

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(e) Time is of the Essence. The Company hereby agrees that time is of the essence in the performance of this Note.

(f) No Third Party Beneficiaries. This Note is for the sole benefit of the parties hereto and nothing herein, express or implied, is intended to or shall confer upon any other Person any legal or equitable benefit, claim, cause of action, remedy or right of any kind.

**[Signature Page Follows]**

IN WITNESS WHEREOF, the Company has caused this instrument to be duly executed this as of the date first written above.

**SURGIVISION, INC.**

By: /s/ Kimble Jenkins

Name: Kimble Jenkins

Title: CEO

Acknowledged, accepted and agreed to as of the date set forth above:

**BRAINLAB AG**

By: /s/ Joseph Doyle

Name: Joseph Doyle

Title: CFO

Acknowledged, accepted and agreed to as of the date set forth above with respect to Section 6(b) hereof on behalf of the Junior Lender:

**LANDMARK COMMUNITY BANK**

as collateral agent for the ratable benefit of the Junior Lender

By: /s/ William Bryan Jones

Name: William Bryan Jones

Title: S.V.P.

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DISCLOSURE SCHEDULES  
AS MADE PART OF THE  
10% SUBORDINATED SECURED  
CONVERTIBLE NOTE DUE 2016  
ISSUED BY  
SURGIVISION, INC.  
IN FAVOR OF  
BRAINLAB AG.  
DATED AS OF APRIL 5, 2011

Except as otherwise defined herein, capitalized terms in these schedules shall have the meanings ascribed to those terms in the above-referenced 10% Subordinated Secured Convertible Note Due 2016 (the "Note").

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Schedule 7(b)  
Capitalization

There are presently 3,759,977 shares of SurgiVision's common stock, par value \$0.01 per share (the "Common Stock"), issuable upon exercise of outstanding options. The options issued by SurgiVision provide for acceleration of the applicable vesting schedules upon the occurrence of a "Change of Control" event. The circumstances that constitute a "Change of Control" are set forth in the applicable option agreement or the applicable stock option plan under which the option was granted. Certain options issued to SurgiVision's directors and executive officers will become exercisable only if SurgiVision closes one or more equity financings that result in certain minimum cash proceeds.

There are presently 435,984 shares of Common Stock issuable upon exercise of outstanding warrants.

As provided in the Company's certificate of incorporation (as amended and restated to date, the "COI"), shares of SurgiVision's Series A Convertible Preferred Stock are convertible into shares of Common Stock.

The Senior Notes are convertible into shares of Capital Stock in accordance with the terms thereof.

In March 2010, SurgiVision issued certain unsecured convertible notes in the aggregate principal amount of \$4,071,000 in a private placement transaction. Such notes are convertible into shares of Common Stock.

The Note is convertible into shares of Capital Stock in accordance with the terms thereof.

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Schedule 7(g)  
Litigation

On April 22, 2010, SurgiVision Consultants, Inc. and Guy M. Kezirian (collectively, the "Plaintiffs") filed a lawsuit against SurgiVision in the United States District Court, Central District of California, alleging trademark infringement, unfair competition, trademark dilution and violation of the Anti-Cybersquatting Protection Act, all relating to SurgiVision's use of its "SURGI-VISION" and "SURGIVISION" trademarks and its "surgivision.com" domain name. SurgiVision and the Plaintiffs entered into a binding settlement agreement on February 16, 2011, and an order dismissing the litigation was entered on February 18, 2011.

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Schedule 7(h)(ii)  
Intellectual Property

SurgiVision has in place five exclusive license agreements with The Johns Hopkins University.

In December 2005, SurgiVision entered into a development agreement and license agreement with an affiliate of Boston Scientific Corporation in the implantable neurological field.

In July 2007, SurgiVision entered into a master service and license agreement with Cedara Software Corp. (d/b/a Merge OEM).

In July 2007, we entered into a research agreement with The University of Utah ("Utah"). In return for the funding provided by SurgiVision for Utah's research activities, Utah granted SurgiVision a non-exclusive, worldwide license to any intellectual property created or conceived by Utah personnel in the performance of the research. In addition, SurgiVision also received the first option to license exclusively any such intellectual property.

In August 2007, SurgiVision entered into a research agreement with the University of California, San Francisco ("UCSF"). In return for SurgiVision's financial support of UCSF's research, SurgiVision received the first option to license, exclusively or non-exclusively, any intellectual property conceived or created by UCSF personnel under the research project.

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

In April 2009, we entered into a patent license agreement with the National Institutes of Health, or NIH, that covers techniques for three dimensional renderings of the patient's anatomy from MRI data in real time. The techniques underlying this patent may be used in the development of SurgiVision's ClearTrace system.

In May 2009, SurgiVision entered into a license agreement with Georg Thieme Verlag with respect to an electronic brain atlas.

In May 2009, SurgiVision entered into a cooperation and development agreement with Siemens Healthcare to develop the hardware and MRI software systems for MRI-guided, catheter-based ablation to treat cardiac arrhythmias.

On April 22, 2010, SurgiVision Consultants, Inc. and Guy M. Kezirian (collectively, the "Plaintiffs") filed a lawsuit against SurgiVision in the United States District Court, Central District of California, alleging trademark infringement, unfair competition, trademark dilution and violation of the Anti-Cybersquatting Protection Act, all relating to SurgiVision's use of its "SURGI-VISION" and "SURGIVISION" trademarks and its "surgivision.com" domain name. SurgiVision and the Plaintiffs entered into a binding settlement agreement on February 16, 2011, and an order dismissing the litigation was entered on February 18, 2011.

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Schedule 7(i)  
No Violation of Law

None

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Schedule 7(n)  
Financial Statements

On April 22, 2010, SurgiVision Consultants, Inc. and Guy M. Kezirian (collectively, the "Plaintiffs") filed a lawsuit against SurgiVision in the United States District Court, Central District of California, alleging trademark infringement, unfair competition, trademark dilution and violation of the Anti-Cybersquatting Protection Act, all relating to SurgiVision's use of its "SURGI-VISION" and "SURGIVISION" trademarks and its "surgivision.com" domain name. SurgiVision and the Plaintiffs entered into a binding settlement agreement on February 16, 2011, and an order dismissing the litigation was entered on February 18, 2011. The amount of the financial settlement is not reflected in the balance sheet included in the Financial Statements.

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Schedule 7(o)(i)  
Agreements; Actions

SurgiVision has adopted certain compensation practices for its non-employee directors.

Each of SurgiVision's officers is an employee of the company.

SurgiVision has issued stock options to each of its directors and officers.

In April 2010, SurgiVision entered into a separation agreement with Mr. John C. Thomas, Jr., who previously served as our Chief Financial Officer. Under the separation agreement, Mr. Thomas ceased to be a SurgiVision employee, SurgiVision agreed to pay Mr. Thomas certain severance, and Mr. Thomas agreed to consult and cooperate with SurgiVision in connection with the orderly transition of his business responsibilities to a new Chief Financial Officer. Mr. Thomas continues to serve as a director of the company.

SurgiVision adopted its Key Personnel Incentive Program to provide a key employee and consultant with the opportunity to receive incentive bonus payments based on future performance of services to the company or upon a consummation of a sale transaction. The compensation committee of SurgiVision's Board of Directors is responsible for administering the program, and the only participants in the program are Paul A. Bottomley and Parag Karmarkar. Dr. Bottomley is a director of the company.

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Schedule 7(o)(ii)  
Agreements; Actions

None

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Schedule 7(p)  
Changes

On April 22, 2010, SurgiVision Consultants, Inc. and Guy M. Kezirian (collectively, the “Plaintiffs”) filed a lawsuit against SurgiVision in the United States District Court, Central District of California, alleging trademark infringement, unfair competition, trademark dilution and violation of the Anti-Cybersquatting Protection Act, all relating to SurgiVision’s use of its “SURGI-VISION” and “SURGIVISION” trademarks and its “surgivision.com” domain name. SurgiVision and the Plaintiffs entered into a binding settlement agreement on February 16, 2011, and an order dismissing the litigation was entered on February 18, 2011. The amount of the financial settlement is not reflected in the Financial Statements. Pursuant to the settlement agreement, SurgiVision also abandoned the registrations for its “SURGI-VISION” and “SURGIVISION” trademarks, and it transferred to the Plaintiffs the “surgivision.com” domain name.

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Schedule 7(q)  
Employee Benefit Plans

SurgiVision utilizes ADP Total Source as a Professional Employer Organization. As such, SurgiVision's employees are co-employed through ADP. ADP administers and maintains the benefit plans in which SurgiVision's employees participate. The benefits made available to SurgiVision's employees through ADP include a 401(k) plan, medical insurance, life insurance, long-term disability coverage, and flexible spending accounts for health care and dependent care costs. SurgiVision does not match contributions made by participants in the 401(k) plan.

In April 2010, SurgiVision entered into a separation agreement with Mr. John C. Thomas, Jr., who previously served as our Chief Financial Officer. Under the separation agreement, Mr. Thomas ceased to be a SurgiVision employee, SurgiVision agreed to pay Mr. Thomas certain severance, and Mr. Thomas agreed to consult and cooperate with SurgiVision in connection with the orderly transition of his business responsibilities to a new Chief Financial Officer. Mr. Thomas continues to serve as a director of the company.

SurgiVision adopted its Key Personnel Incentive Program to provide a key employee and consultant with the opportunity to receive incentive bonus payments based on future performance of services to the company or upon a consummation of a sale transaction. The compensation committee of SurgiVision's Board of Directors is responsible for administering the program, and the only participants in the program are Paul A. Bottomley and Parag Karmarkar. Dr. Bottomley is a director of the company.

SurgiVision adopted its Cardiac EP Business Participation Plan to enable it to provide a key product development advisor and consultant with financial rewards in the event SurgiVision sells its cardiac EP business operations. SurgiVision's cardiac EP business operations include its operations relating to the ClearTrace system for MRI-guided cardiac ablation to treat cardiac arrhythmias, but it does not include SurgiVision's operations relating to its ClearPoint system, its SafeLead Development Program or any other product or product candidate. The sole participant in the plan is Dr. Nassir F. Marrouche.

SurgiVision has two plans under which it is currently issuing stock option awards, the 2010 Incentive Compensation Plan and the 2010 Non-Qualified Stock Option Plan. Although there are options outstanding under SurgiVision's 2007 Stock Incentive Plan and 1998 Stock Option Plan, no new awards may be granted under those plans.

SurgiVision has implemented a ClearPoint Sales Incentive Program that covers SurgiVision's Vice President, Sales and Sales Representatives.

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Schedule 7(r)  
Tax Returns, Payments and Elections

None

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**FIRST AMENDMENT TO  
10% SUBORDINATED SECURED CONVERTIBLE NOTE DUE 2016**

This **FIRST AMENDMENT** (this "Amendment") is made effective as of September 30, 2011 and is made in reference to that certain 10% Subordinated Secured Convertible Note Due 2016 (the "Note") issued by MRI Interventions, Inc. f/k/a SurgiVision, Inc., a Delaware corporation (the "Company"), and payable to Brainlab AG, a corporation organized under the laws of the Federal Republic of Germany ("Brainlab").

**WHEREAS**, the Company previously issued the Note to Brainlab; and

**WHEREAS**, the Company and Brainlab desire to amend the terms of the Note;

**NOW, THEREFORE**, the Note is hereby amended as set forth below:

1. Defined Terms. Capitalized terms used in this Amendment without definition shall have the same meanings ascribed to such terms in the Note.

2. Amendment to Section 4 (Conversion). Section 4 of the Note (Conversion) is hereby amended by deleting paragraph (a)(iv) in its entirety and substituting the following therefor:

“(iv) Subject to the adjustments provided by this Section 4, the “**Conversion Price**” shall be the lesser of (A) the price per share paid by investors in the Qualified Financing for one share of Qualified Financing Stock, or (B) \$0.60 per share.

3. Amendment to Section 9 (Defaults and Remedies). Section 9 of the Note (Defaults and Remedies) is hereby amended by deleting clause (7) of paragraph (a) thereof and substituting the following therefor:

“(7) failure to consummate a Qualified Financing within 360 days following the date of this Note;”

4. Miscellaneous. On and after the date hereof, reference in the Note to “this Note”, “hereunder”, “hereof”, “herein” or words of like import referring to such Note shall mean and be a reference to the Note as amended by this Amendment. Except as expressly provided in this Amendment, all other terms, conditions and provisions of the Note shall continue in full force and effect as provided therein.

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**IN WITNESS WHEREOF**, the Company has executed, acknowledged and delivered this Amendment as of the day and year first above written.

**MRI INTERVENTIONS, INC.**

By: /s/ Oscar Thomas

Name: Oscar Thomas

Title: Vice President, Business Affairs

Acknowledged, accepted and agreed to  
as of the date set forth above:

**BRAINLAB AG**

By: /s/ Joseph Doyle

Name: Joseph Doyle

Title: CFO

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**SECOND AMENDMENT TO  
10% SUBORDINATED SECURED CONVERTIBLE NOTE DUE 2016**

This **SECOND AMENDMENT** (this "Amendment") is made effective as of February 23, 2012 and is made in reference to that certain 10% Subordinated Secured Convertible Note Due 2016 issued by MRI Interventions, Inc. f/k/a SurgiVision, Inc., a Delaware corporation (the "Company"), and payable to Brainlab AG, a corporation organized under the laws of the Federal Republic of Germany ("Brainlab"), as amended by that certain First Amendment made effective as of September 30, 2011 (as amended, the "Note").

**WHEREAS**, the Company previously issued the Note to Brainlab; and

**WHEREAS**, the Company and Brainlab desire to amend the terms of the Note as hereinafter provided;

**NOW, THEREFORE**, the Note is hereby amended as set forth below:

1. Defined Terms. Capitalized terms used in this Amendment without definition shall have the same meanings ascribed to such terms in the Note.

2. Amendment to Section 1 (Definitions).

(a) Section 1 of the Note (Definitions) is hereby amended by deleting the definitions of the terms "Conversion Shares" and "Senior Notes" and substituting the following therefor:

"**Conversion Shares**" means shares of Common Stock or Qualified Financing Stock, as applicable, to be issued in connection with the conversion of this Note.

"**Senior Notes**" means those certain Amended and Restated Secured Convertible Promissory Notes issued by the Company to Boston Scientific Corporation dated as of October 16, 2009, November 17, 2009 and December 18, 2009, respectively, and restated as of February 2, 2012, in the aggregate original principal amount of \$4,338,601.24, and any amendments thereto or restatements or extensions thereof.

(b) Section 1 of the Note (Definitions) is hereby further amended by adding the following new defined terms thereto:

"**Common Stock**" means the Company's common stock, par value \$0.01 per share.

"**Subordination Agreement**" means the subordination agreement dated as of February 23, 2012, among the Senior Lender, Brainlab and the Company.

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3. Amendment to Section 4 (Conversion).

(a) Section 4 of the Note (Conversion) is hereby amended by deleting paragraph (a)(iv) in its entirety and substituting the following therefor:

“(iv) Subject to the adjustments provided by this Section 4, the “**Conversion Price**” shall be (a) in the case of Section 4(a)(ii), the lesser of (1) the price per share paid by investors in the Qualified Financing for one share of Qualified Financing Stock, or (B) \$0.60 per share, or (b) in the case of Section 4(a)(vi), \$0.60 per share.

(b) Section 4 of the Note (Conversion) is hereby amended by adding the following a new paragraph (a)(vi) thereto:

“(vi) Notwithstanding any of the foregoing to the contrary, subject to earlier payment or conversion as provided for elsewhere in this Note, the entire outstanding principal amount of this Note, together with all accrued but unpaid interest thereon, may be converted into shares of Common Stock at the option of Brainlab at any time on or before February 23, 2013.”

4. Amendment to Section 6 (Subordination). Section 6 of the Note (Subordination) is hereby amended by deleting paragraph (a) in its entirety and substituting the following therefor:

“(a) Notwithstanding any provision herein to the contrary, Brainlab hereby agrees that the obligations of the Company to Brainlab hereunder shall be subordinated in all respects, including in right of payment, to the Senior Debt and that Brainlab shall not be entitled to receive any payment from the Company hereunder until the Senior Debt has been discharged in full. The holder of this Note, whether upon original issue or upon transfer or assignment hereof, by such holder’s acceptance hereof, agrees that this Note shall be subject to the provisions of the Subordination Agreement.”

5. Amendment to Section 9 (Defaults and Remedies).

(a) Section 9 of the Note (Defaults and Remedies) is hereby amended by deleting clause (7) of paragraph (a) in its entirety.

(b) Section 9 of the Note (Defaults and Remedies) is hereby further amended by deleting paragraph (b) in its entirety and substituting the following therefor:

“(b) Acceleration. If an Event of Default with respect to this Note (other than an Event of Default specified in clause (5) or (6) of Section 9(a) with respect to the Company) occurs and is continuing, Brainlab by notice in writing to the Company may declare the unpaid principal of and accrued interest to the date of acceleration on this Note to be due and payable immediately and, upon any such declaration, such principal amount and accrued interest, notwithstanding anything contained in this Note to the contrary, will become immediately due and payable, subject, however, to Section 6(a) and the Subordination Agreement. If an Event of Default specified in clause (5) or (6) of Section 9(a) with respect to the Company occurs, this

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Note will ipso facto become immediately due and payable without any declaration or other act on the part of Brainlab, subject, however, to Section 6(a) hereof and the Subordination Agreement.”

(c) Section 9 of the Note (Defaults and Remedies) is hereby further amended by deleting the first sentence of paragraph (c) in its entirety and substituting the following therefor:

“Subject to Section 6(a) and the Subordination Agreement, if an Event of Default occurs and is continuing, Brainlab may pursue any available remedy by proceeding at law or in equity to collect the payment of principal of or interest on this Note or to enforce the performance of any provision of this Note.”

6. Miscellaneous. On and after the date hereof, reference in the Note to “this Note”, “hereunder”, “hereof”, “herein” or words of like import referring to such Note shall mean and be a reference to the Note as amended by this Amendment. Except as expressly provided in this Amendment, all other terms, conditions and provisions of the Note shall continue in full force and effect as provided therein.

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**IN WITNESS WHEREOF**, the Company has executed, acknowledged and delivered this Amendment as of the day and year first above written.

**MRI INTERVENTIONS, INC.**

By: /s/ Kim Jenkins

Name: Kim Jenkins

Title: CEO

Acknowledged, accepted and agreed to  
as of the date set forth above:

**BRAINLAB AG**

By: /s/ Stefan Vilsmeier

Name: Stefan Vilsmeier

Title: CEO

**CONSULTING AGREEMENT**

THIS CONSULTING AGREEMENT (this "Agreement") is made effective as of May 1, 2011, by and between SurgiVision, Inc., a Delaware corporation (the "Company"), and Dr. Paul Bottomley ("Consultant").

The Company and Consultant hereby agree that Consultant will advise the Company on matters relating to the field of internal MRI coils including advances in MRI hardware and software, in vivo and/or implantable MRI/RF safe probes, leads, electrodes, coils, catheters, and implantable interventional or diagnostic medical devices, such as implantable pulse generators, implantable leads, neuromodulation and/or deep brain stimulation devices and related operational MRI compatible software and hardware (the "Field"), under the following terms and conditions:

1. Consulting Services. Consultant's responsibilities shall include the following activities (collectively referred to as the "Services"):

- a) informing the Company of new developments in the Field, subject to the provisions set forth in Section 2 below regarding non-disclosure under this Agreement;
- b) advising the Company on the Company's research and development projects relating to the Field;
- c) advising the Company regarding development of prototype devices;
- d) assisting with technical evaluation of the Company's methods, processes, devices, products and prototypes;
- e) participating in scientific advisory committee meetings in relation to the Field, as the Company may request,
- f) timely disclosing to the Company patentable ideas, conceptions, and/or inventions resulting from services rendered under this Agreement ("Inventions"), whether conceived or reduced to practice by Consultant alone or with employees or other advisors or consultants to Company, and cooperating with the Company to prepare, file and prosecute patent applications for Inventions as are deemed necessary by the Company to publish or protect Inventions, by patent or otherwise, and to vest title to Inventions in the Company or its nominees, their successors or assigns; and
- g) cooperating with the Company to provide expert technical advice based on Consultant's know-how for commercializing products in the Field, upon reasonable request from Company.

The Services shall be performed via telephone and correspondence and/or onsite at the Company's facilities, and they may include meetings with personnel and other consultants at times and locations to be mutually agreed upon. In each instance, Consultant shall perform the Services only upon Company's request and after the scope of the Services has been approved by Company.

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2. Consultant's Obligations to JHU. The parties acknowledge that the Johns Hopkins University, its Schools and Divisions, and the Johns Hopkins Hospital and Health System and its affiliated hospitals ("JHU") is not a party to this Agreement, which is a private contract between Consultant and the Company. Therefore, JHU shall have no liability under this Agreement. The office address of Consultant may be identified in this Agreement for the purpose of convenient communication between the Company and Consultant. Consultant shall not use the facilities, equipment, materials, funds, or resources owned or administered by JHU or located on any of the premises of JHU, excluding those such materials, resources, or space that the Company is granted use of by JHU via formal institutional transactions, including rent of incubator space, hourly charges to the Company by JHU for services, and the like. Consultant shall not engage or employ students, trainees, post-doctoral fellows or other employees of JHU to provide services under this Agreement. JHU policies and Consultant's obligations to JHU shall govern and be afforded primacy in the event a conflict arises between such obligations and policies in this Agreement. Consultant shall not disclose under this Agreement: (a) any invention, improvement, or other information that is proprietary to JHU and not generally available to the public without permission from the Johns Hopkins Technology Transfer Office, other than through formal institutional transactions; or (b) unpublished results of, or unpublished data from, research or clinical activity conducted at, by, or on behalf of JHU, except where said unpublished results or data are posted or made openly available to the scientific community, for example via electronic means, web-sites, on-line methods, on-line courses, and the like or except with the permission of Johns Hopkins Technology Transfer Office. Nothing in this Agreement shall in any way inhibit Consultant's ability to conduct research and other academic activities at, through, or on behalf of JHU, or to lecture upon, submit for publication, publish, or otherwise disclose the results of such activities, regardless of the sponsor or field of such activities, during or at any time after the term of this Agreement.

3. Confidentiality. "Confidential Information" means all oral, written, graphic, or physical information, disclosed to Consultant under this Agreement, not generally available to the public, including without limitation, information related to Company's products, processes, techniques, technology, formulae, research data, manufacturing methods, know-how, and trade secrets. All Confidential Information is and will be the exclusive property of Company and its affiliates. Consultant agrees not to use Confidential Information for any purposes other than the performance of the Services. Nothing in this Agreement shall limit or be construed to limit Consultant's right to use, disseminate, or publish any information that: (a) is or becomes available to the public through no breach of this Agreement by Consultant; (b) was or is obtained by Consultant from a third party who had the legal right to disclose the information to Consultant; (c) is already in the possession of Consultant at the time it is communicated to Consultant under this Agreement (or any predecessor agreement hereto); (d) was developed by Consultant independently of and without reference to any information communicated to Consultant under this Agreement (or any predecessor agreement hereto); or (e) is required to be disclosed by law, government regulation, or court order.

4. Speaking, Non-Endorsement, and Publications. Consultant and Company agree that Company will not use Consultant's name or likeness for the purpose of endorsement,

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promotion or marketing of the Company or its products. Consultant shall not under this Agreement speak with or to any third parties in any context or manner that could reasonably constitute endorsement, promotion, or marketing of any product or technology. In speaking with or to any third parties or if citing Consultant in any context, format, or document, the following disclaimer must be presented: “Participation by Dr. Bottomley *[in the development of this product or as an advisor, consultant, speaker, or member of the Scientific Advisory Board]* does not constitute or imply endorsement by the Johns Hopkins University or the Johns Hopkins Hospital and Health System.” Consultant shall not publish, nor submit for publication, any work resulting from the Services provided hereunder without prior written approval from Company. If Consultant is listed as an author on any publication resulting from performance of Services under this Agreement, the following form of acknowledgement must be added to the body of the publication:

a) If Consultant’s contributions to the work result wholly from the Services performed under this Agreement, Consultant’s position, address, and contact information will be listed as at the Company, and JHU will not be mentioned in this reference (with the exception that, in the event that JHU’s name is included in the official mailing address of a biotechnology park and the Company’s premises are located therein, then JHU’s name may be included as a legitimate mailing address); or

b) If Consultant’s contributions to the work include materials arising out of both the Services performed under this Agreement and work done at JHU: “Dr. Bottomley is a paid consultant to SurgiVision, Inc. This arrangement has been approved by Johns Hopkins University in accordance with its conflict of interest policies.”

5. No Conduct of Clinical Research. Consultant shall be engaged by the Company to provide consulting services only as set forth in Section 1 above, and shall not direct or conduct clinical trials for or on behalf of the Company under this Agreement. Data provided to Consultant under this Agreement will not include any identifying information regarding patients or human subjects and Consultant will not have access to this information, either directly or indirectly through coding systems that link de-identified data to individual persons.

6. Ownership of Intellectual Property. All discoveries, inventions, improvements, or processes (whether patentable or not) conceived or first reduced to practice by Consultant, whether alone or in collaboration with employees of or other consultants or advisors to the Company, resulting from the Services rendered under this Agreement will be owned exclusively by the Company. Consultant shall assign to the Company all rights, title, and interest thereto and agrees to execute any documents attesting to the ownership thereof as requested by the Company. Consultant shall reasonably assist the Company in obtaining or perfecting the Company’s rights, title, and interest, including, without limitation, the filing and prosecution of any patent applications. The Company shall have no rights under this Agreement to any publication, invention, discovery, improvement, or other intellectual property whatsoever, whether or not publishable, patentable, or copyrightable, which is developed as a result of a program of research a) financed in whole or in part by funds provided by or under the control of JHU, or b) using the facilities, resources, or employees of JHU (which for this purpose does not include any materials, resources, or space that the Company is granted use of by JHU via formal institutional transactions, including rent of incubator space, hourly charges to the Company by JHU for services, and the like).

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7. Compensation. In consideration for Consultant's Services hereunder, the Company shall pay Consultant as follows:

a) \$60,000 per year, payable in equal monthly installments; and

b) Reasonable out-of-pocket expenses (upon presentation of appropriate receipts) incurred by Consultant, including all travel, food and lodging in connection with the Services provided hereunder.

Payment shall be made within forty-five (45) days of receipt of an invoice of itemized services and submission of appropriate vouchers and receipts as may be reasonably necessary to substantiate Consultant's out-of-pocket expenses.

Consultant shall not be paid vacation, holiday, or sick time during the term of the Agreement. In the event of premature termination of this Agreement, the Company shall pay Consultant for the Services performed and expenses incurred through the date of termination. In the event of any overpayment by the Company, Consultant shall, upon submission by the Company of documents evidencing such overpayment, remit the same to the Company within thirty (30) days after termination. Consultant shall also cooperate with Company in producing documents as evidence of overpayment of either party.

8. Term and Termination. This Agreement shall be effective for a period of twenty-four (24) months, beginning May 1, 2011 and ending April 30, 2013.

This Agreement may be extended by written agreement signed by both parties. Either party may terminate this Agreement with or without cause upon giving thirty (30) days prior written notice to the other party. Termination or expiration of this Agreement shall not affect any rights or obligations which have accrued prior thereto or in connection therewith. Any written agreements altering the term and/or conditions of this agreement may be subject to advance review and approval by the Johns Hopkins University School of Medicine's Office of Policy Coordination.

9. Compliance. In the performance of the Services hereunder, Consultant shall comply with all applicable federal, state, and local laws, regulations, and guidelines. Consultant shall also comply with the Company's policies while on the Company premises.

10. Independent Contractor. Consultant's status under this Agreement is that of an independent contractor. Consultant shall not be deemed an employee, agent, partner, or joint venturer of the Company for any purpose whatsoever, and Consultant shall have no authority to bind or act on behalf of the Company. This Agreement shall not entitle Consultant to participate in any benefit plan or program of Company. Consultant shall be responsible for, and agrees to comply with, obligations under federal and state tax laws for payment of income and, if applicable, self-employment tax.

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11. Assignment. Consultant may not assign this Agreement or any interest herein, or delegate any of his duties hereunder, to any third party without the Company's prior written consent, which consent is within the Company's sole discretion to grant or withhold. Any attempted assignment or delegation by Consultant without such consent shall be null and void.

12. Debarment. Consultant warrants and represents that Consultant has never been, is not currently, and during the term of this Agreement, will not become:

a) an individual who has been debarred by the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. 335a (a) or (b) ("Debarred Individual") from providing services in any capacity to a person that has an approved or pending drug product application, or an employer, employee or partner of a Debarred Individual; or

b) a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. 335a (a) or (b) ("Debarred Entity") from submitting or assisting in the submission of any abbreviated drug application, or an employee, partner, shareholder, member, subsidiary or affiliate of a Debarred Entity.

Consultant further warrants and represents that no Debarred Individual or Debarred Entity has performed or rendered, or will perform or render, any services or assistance relating to activities taken pursuant to this Agreement. Consultant further warrants and represents that Consultant has no knowledge of any circumstances which may affect the accuracy of the foregoing warranties and representations, including, but not limited to, FDA investigation of, or debarment proceedings against Consultant or any person or entity performing services or rendering assistance relating to activities taken pursuant to this Agreement, and Consultant will immediately notify the Company if Consultant becomes aware of any such circumstances during the term of this Agreement.

13. Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the matters herein contained and supersedes all previous agreements and undertakings with respect thereto. This agreement may be modified only by written agreement signed by the parties.

This Agreement shall be governed by and construed in accordance with the laws of the State of Maryland without regard to its conflicts of laws rules.

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IN WITNESS WHEREOF, the parties have executed this Consulting Agreement as of the date(s) set forth below, but with an effective date as of May 1, 2011.

COMPANY:

SurgiVision, Inc.

By: /s/ Kimble Jenkins  
Name: Kimble Jenkins  
Title: CEO

Date: effective May 1, 2011

Address:  
One Commerce Square  
Suite 2550  
Memphis, TN 38103

CONSULTANT:

/s/ Dr. Paul Bottomley  
Dr. Paul Bottomley

Date: effective May 1, 2011