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

FORM 10-K

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

For the fiscal year ended December 31, 2014

or

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

For the transition period from _____ to _____ .
Commission File Number: **000-54575**

MRI INTERVENTIONS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**58-2394628**
(State or other jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
5 Musick **Irvine, California** *(Address of principal executive offices)*	**92618** *(Zip Code)*

(949) 900-6833
(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

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

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

As of June 30, 2014, the aggregate market value of the registrant’s common stock held by non-affiliates of the registrant was $63,348,677, based on the closing sale price as reported on OTC Markets.

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

Class	**Outstanding at March 13, 2015**
Common Stock, $.01 par value per share	74,842,428 shares

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III is incorporated by reference from portions of the definitive proxy statement to be filed within 120 days after December 31, 2014, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the annual meeting of stockholders to be held on June 4, 2015.

MRI INTERVENTIONS, INC.

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Trademarks, Trade Names and Service Marks

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

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E the Securities Exchange Act of 1934, as amended. 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 broader market acceptance for our ClearPoint system products;
- future revenues from sales of ClearPoint system products;
- our ability to successfully complete the development of, and obtain regulatory clearance or approval for, our ClearTrace system;
- the anticipated progress of our research and development activities;
- the expected capabilities of our ClearTrace system; 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 Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain.

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

ITEM 1. BUSINESS

Overview

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

We have two product platforms. Our ClearPoint system, which is in commercial use in the United States, is used to perform minimally invasive surgical procedures in the brain. We anticipate that our ClearTrace system, which is still in development, will be used to perform minimally invasive surgical procedures in the heart. Both systems utilize intra-procedural MRI to guide the procedures. Both systems are designed to work in a hospital's existing MRI suite.

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 a neuro-navigation system designed for placing catheters and electrodes across a variety of neurological diseases and conditions and for performing biopsies. Our ClearTrace system is designed to deliver catheter-based therapies to treat certain cardiac diseases. We believe that our two product platforms, subject to appropriate regulatory clearance and approval, will provide better patient outcomes, enhance revenue potential for both physicians and hospitals, and reduce costs to the healthcare system.

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

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

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

Our ClearPoint system is in commercial use. In June 2010, we received 510(k) clearance from the Food and Drug Administration, or FDA, to market our ClearPoint system in the United States for general neurological interventional procedures. In February 2011, we also obtained CE marking approval, which enables us to sell the ClearPoint system in the European Union. In April 2011, we entered into a co-development and distribution agreement with Brainlab, a leader in the image-guided surgery field, under which Brainlab serves as a distribution partner for our ClearPoint system. The ClearPoint system is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within the MRI environment and in conjunction with MRI guidance. It is intended as an integral part of procedures that have traditionally used stereotactic methodologies. Those procedures include placement of electrodes, such as deep brain stimulation leads and depth electrodes, the placement of catheters, such as laser ablation catheters and drug delivery catheters, and biopsies. ClearPoint systems are in clinical use with MRI scanners from the three major manufacturers, Siemens, GE Healthcare and Philips Healthcare, as well as the two major interventional MR/OR platforms that are manufactured by IMRIS and Brainlab.

At present, we are focusing most of our efforts and resources on the commercialization of our ClearPoint system, which we believe can transform the field of minimally invasive neurosurgery. Looking to the future, we hope to achieve a similar outcome for minimally invasive procedures in the heart. Our 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 development agreement with Siemens under which initial work related to the development of hardware and software needed for MRI-guided, catheter-based ablation procedures to treat cardiac arrhythmias, such as atrial fibrillation, was performed. Working closely with us, Siemens created a research version of the software platform specifically for use in MRI-guided cardiac ablation procedures with our catheters. In February 2014, we entered into a new exclusive development agreement with Siemens, which replaced our May 2009 agreement. Under the new development agreement, with cooperation, assistance and technical support from Siemens, we plan to develop the commercial version of the research software platform created by Siemens under our original agreement, and that software will serve as the software component of our ClearTrace system. Our development activities on the ClearTrace system are ongoing. We expect the initial market for our ClearTrace system will be the European Union, but we have not made any filings seeking regulatory clearance or approval for our ClearTrace system and we do not expect to make any such filings within at least the next 12 months.

We have a significant intellectual property portfolio in the field of MRI-guided interventions. As of February 28, 2015, our portfolio included over 50 United States patents and over 40 United States patent applications, which we wholly-own, co-own or have licensed. We also hold various foreign patents and patent applications that correspond with many of our United States patents and patent applications. Our technologies have been the subject of numerous peer-reviewed articles in medical and scientific journals. As a result of our product offerings, collaborative relationships and intellectual property position, we believe that we are well-positioned to remain on the forefront of the emerging market for MRI-guided minimally invasive surgical procedures.

Industry Background

Magnetic Resonance Imaging

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

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

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

There are over 5,000 1.5T and 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 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 MRI guidance. 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 methodologies. 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, and 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. Today, ClearPoint systems are in clinical use with MRI scanners from the three major manufacturers, Siemens, GE Healthcare and Philips Healthcare, as well as the two major interventional MR/OR platforms, which are manufactured by IMRIS and Brainlab.

In April 2011, we entered into a co-development and distribution agreement with Brainlab, which we believe is a leader in the development of software-driven medical technology that supports targeted, less-invasive patient treatment. Under that agreement, we appointed Brainlab as a distributor of our ClearPoint system products, on a non-exclusive basis, in the United States and Europe. We also agreed to collaborate on the potential integration of our ClearPoint system technologies with Brainlab's own interventional MRI technologies, with particular focus on direct delivery of drugs and other therapeutic agents to targets in the brain under MRI guidance, which we call the MRI-guided neurological drug delivery field of use. For that reason, we appointed Brainlab as our exclusive distributor of ClearPoint system products within the MRI-guided neurological drug delivery field of use.

The Need for Minimally Invasive Neurological Interventions

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

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

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.

Our ClearPoint System Solution

We believe the design of our ClearPoint system can significantly simplify how stereotactic neurological interventions are performed. Instead of relying on the indirect guidance of pre-operative imaging, our ClearPoint system is based on a direct approach, in which a physician is guided by high resolution MRI during the procedure, which is designed to be performed in a standard hospital-based MRI scanner instead of a traditional operating room.

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 a head fixation frame, computer workstation and in-room monitor. The head fixation frame immobilizes the patient's head during the procedure, and it is designed to optimize the placement of an imaging head coil in proximity to the patient's head. Our ClearPoint system software is installed on a computer workstation networked with an MRI scanner, for which we use a commercially available laptop computer. The in-room monitor allows the physician to view the display of our ClearPoint system workstation from the scanner room while performing the procedure.

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

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

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

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

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

Regulatory Status

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

Our SmartFlow cannula has received 510(k) clearance and 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. Delivery of other therapeutic agents using our SmartFlow cannula is investigational. The SmartFlow cannula is a disposable device intended for single patient use only and is not intended for implant.

The ClearTrace Cardiac Intervention System

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

General

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

We anticipate that our 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 our ClearTrace system could position it to be the therapy of choice for cardiac ablation procedures to treat cardiac arrhythmias, and the ideal platform for delivering future biologic therapies to treat heart failure and other similar cardiac disorders.

We began preliminary research for an MRI-guided cardiac ablation procedure shortly following our inception in 1998. As a culmination of those research efforts, in May 2009, we entered into an exclusive development agreement with Siemens, under which we and Siemens performed initial work related to the development of hardware and software needed for MRI-guided, catheter-based ablation procedures to treat cardiac arrhythmias. Working closely with us, Siemens created a research version of the software platform specifically for use in MRI-guided cardiac ablation procedures with our catheters. In February 2014, we entered into new exclusive development agreement with Siemens, which replaced our May 2009 agreement. Under the new development agreement, with cooperation, assistance and technical support from Siemens, we plan to develop the commercial version of the research software platform created by Siemens under our original agreement, which software will be necessary for our ClearTrace system. With our agreement with Siemens, the ClearTrace system is designed for procedures that will be performed, at least initially, using certain Siemens MAGNETOM MRI systems. We believe that our exclusive relationship with Siemens secures an important strategic market position for our ClearTrace system.

ClearTrace System Components

We believe our ClearTrace system could 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 cabling system to enable catheter-based procedures in an MRI scanner.

ClearTrace Disposables. The disposable components will include, among other items, an ablation catheter and mapping catheter. 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. 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; tracking prior lesion locations; evaluating ablated cardiac tissue; and monitoring for possible adverse events. The ClearTrace system software will be integrated with our disposable components.

Regulatory Status

Our ClearTrace system is still under development, and, as noted above, we currently are focusing most of our efforts and resources on the commercialization of our ClearPoint system. At present, we are not able to estimate or predict when we expect to complete our development activities or when we expect to make a filing with a regulatory authority seeking approval or clearance for the ClearTrace system. However, we do not expect to make any such filing within at least the next 12 months. We expect the initial market for our ClearTrace system will be the European Union, and, therefore, we intend to seek CE marking approval for the ClearTrace system at the appropriate time. 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, we believe the ablation catheter component may be a Class III medical device and could require FDA approval of a premarket approval application, or PMA.

Licenses and Collaborative Relationships

In addition to our internally-developed technologies and devices, we have established and may continue to pursue licensing and other collaborative relationships with medical device companies and academic institutions to further the development and commercialization of our product platforms and our core technologies. Our current material 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. The agreement contemplates that we and Brainlab could work to potentially integrate our ClearPoint system technologies with Brainlab's own interventional MRI technologies for application in the MRI-guided neurological drug delivery field of use, subject to appropriate regulatory clearance or approval. Brainlab, at its expense, also could explore the integration of our ClearPoint system technologies with Brainlab's interventional MRI technologies for other MRI-guided neurological procedures as well. 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 any co-development activities under the agreement.

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

We entered into a cooperation and development agreement with Siemens in May 2009, under which we and Siemens performed initial work related to the development of hardware and software needed for MRI-guided, catheter-based ablation procedures to treat cardiac arrhythmias. Pursuant to the terms of our agreement, we were generally responsible for developing catheters and other hardware, and Siemens was responsible for developing software, to our specifications. We were responsible for paying Siemens for its software development work, but, under the terms of the agreement, Siemens owned the software. Working closely with us, Siemens created a research version of the software platform specifically for use in MRI-guided cardiac ablation procedures with our catheters, but a commercial version was not developed.

In February 2014, we entered into a new development agreement with Siemens, which replaced our May 2009 agreement. Under the new agreement, with cooperation, assistance and technical support from Siemens, we plan to develop the commercial version of the research software platform created by Siemens under the original agreement. Once the development work is completed, subject to appropriate regulatory clearance or approval, we will sell the software as our own product, and the software will serve as the software component of our ClearTrace system.

Under the development agreement, Siemens developed, at our cost, certain software features, or host features, for certain of Siemens' MAGNETOM MRI systems. The host features will enable the connection of our software and catheters to those MAGNETOM systems. The host features, which are owned by Siemens, run within the MRI scanner system. The host features will then connect to our software, which will operate on a separate computer workstation, and enable the performance of MRI-guided cardiac ablation procedures. Siemens will maintain technical compatibility of the host features with our software for the term of the development agreement.

The development agreement provides for certain commercial exclusivity, generally extending for a period of four years following the European product release date of the host features, in the field of MRI-guided catheter-based cardiac electrophysiology using catheters that are actively tracked by the MRI scanner. During that period and within that field, Siemens agreed that it will not engage in certain actions and activities, the intention being that we will have the exclusive opportunity to commercialize MRI-guided catheter-based cardiac electrophysiology with active catheter tracking with Siemens MRI systems. Likewise, during that period and within that field, we agreed that we will not sell or otherwise provide to any third party actively tracked catheters for commercial use, within the meaning of the development agreement, that are intended to be used with a non-Siemens MRI system.

The development agreement contains a cross-licensing arrangement between us and Siemens. Under that arrangement, each party granted the other party a non-exclusive license to use certain intellectual property rights owned by the granting party and realized in the research software platform developed under the May 2009 agreement. Under our license from Siemens, we may use the licensed intellectual property rights to develop, manufacture and sell software, provided that during the parties' exclusivity period and within the exclusivity field, any such software must be solely for use with Siemens MRI systems. Under its license from us, Siemens may also use the licensed intellectual property rights to develop, manufacture and sell software, provided that during the parties' exclusivity period and within the exclusivity field, any such software must be solely for use with our catheters.

The term of the development agreement will expire four years following the European product release date of the host features for the applicable Siemens MAGNETOM MRI systems.

Boston Scientific

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

In December 2005, we entered into a development agreement and license agreement with Boston Scientific in the neuromodulation field. The development agreement related to the design and development of MRI-compatible and MRI-safe implantable leads for neuromodulation applications, such as implantable DBS leads. Under the license agreement, we granted Boston Scientific an exclusive, worldwide license with respect to certain of our 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. Boston Scientific is responsible for patent prosecution of the intellectual property it licensed and the payment of costs associated with patent prosecution.

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. The development agreement related to feasibility assessment, design and development of certain MRI-compatible, MRI-safe implantable cardiac rhythm management leads. Under the license agreement, we granted Boston Scientific an exclusive, worldwide license with respect to certain of our 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. Boston Scientific is responsible for patent prosecution of the intellectual property it licensed and the payment of costs associated with patent prosecution.

In March 2014, Boston Scientific purchased from us some, but not all, of the intellectual property we had licensed exclusively to Boston Scientific within the fields of neuromodulation and implantable medical leads for cardiac applications. In connection with that purchase transaction, we entered into amendments to our development and license agreements with Boston Scientific to eliminate the milestone-based payments and royalties provided under those agreements. Accordingly, we are no longer entitled to receive future milestone-based payments or royalties under our development and license agreements with Boston Scientific.

The Johns Hopkins University

We have entered into certain exclusive license agreements with The Johns Hopkins University, or Johns Hopkins. For additional information regarding these licenses, see "Business–Intellectual Property."

Sales and Marketing

Commercializing our ClearPoint system involves marketing primarily 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 surgery and who refer patients for surgery; and

- hospitals involved in the treatment of neurological disorders and the opinion leaders at these hospitals.

There are approximately 4,800 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, as well as oncologic neurosurgeons, but we also market our ClearPoint system to other neurosurgeons. We believe that our ClearPoint system represents an attractive platform for a neurosurgery team within a hospital to perform various general neurological procedures.

Our business model for the ClearPoint system is focused on producing high margin revenue from sales of the disposable components. Given that focus on disposable product sales, we sell our reusable components at lower margins in order to secure installations of our system within hospitals. In addition, we may make the reusable ClearPoint components available to hospitals pursuant to our ClearPoint Placement Program, under which we install a system at the hospital but we retain title to the system. Under that program, we may make the reusable ClearPoint components available to a hospital for use during an agreed-upon period of time while the hospital evaluates and processes the purchase opportunity. In addition, under the ClearPoint Placement Program we may permit a hospital to pay for an installed system or its use over an agreed-upon period of time. Our disposable and reusable ClearPoint products are tightly integrated, which allows us to leverage each new installation of a system to generate recurring sales of our disposable products.

Presently, our commercialization efforts for our ClearPoint system are being coordinated primarily through our Vice President, Sales and our Vice President, Marketing. As of February 28, 2015, our sales, clinical support and marketing team consisted of 15 employees.

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 important to our future success. As of February 28, 2015, our research and development team consisted primarily of seven employees. We have assembled an experienced team with recognized expertise in both the development of medical devices and advanced MRI technologies, including interventional MRI microcoils and catheters. We believe that our current research and development team is sufficient for our current needs; however, we may increase the size of our team depending on the progress of our ongoing research and development efforts. Our principal research and development goals are to continue to enhance our ClearPoint system and to complete development of our ClearTrace system.

We have historically spent a significant portion of our capital resources on research and development. Our research and development expenses were approximately $3,297,000 and $2,923,000 for the years ended December 31, 2014 and 2013, 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 key 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 patents and patent applications that we own, whether wholly-owned or co-owned, or license from others. We seek patent protection in the United States and internationally for our products and technologies where and when we believe it is appropriate. United States patents are granted generally for a term of 20 years from the earliest effective priority date of the patent application. The actual protection afforded by a foreign patent, which can vary from country to country, depends on the type of patent, the scope of its claims and the availability of legal remedies in the country.

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

Patents and Patent Applications

We have a significant patent portfolio in the field of MRI-guided interventions. As of February 28, 2015, we wholly-owned, co-owned or licensed over 50 United States patents and over 40 United States patent applications, as well as various foreign patents and foreign patent applications corresponding with many of our United States patents and applications. Our owned, issued patents expire at various dates beginning in 2020. Our licensed, issued patents expire at various dates beginning in 2015. Some of our patents and patent applications are co-owned by Boston Scientific, and, with respect to those patents and patent applications, we have licensing and cross-licensing arrangements in place with Boston Scientific. 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.

Certain License Arrangements

License Arrangements with The Johns Hopkins University

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

In June 2008, we also entered into an exclusive license agreement with Johns Hopkins with respect to certain catheter technology. Under the 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 the sublicense. The license agreement terminates upon the expiration of the last to expire of the licensed patents.

License Arrangements with Merge

In July 2007, we entered into a master services and licensing agreement with Merge Healthcare Canada Corp. (formerly known as Cedara Software Corp.), or Merge, for Merge to develop on our behalf, based on our detailed specifications, a customized software solution for our ClearPoint system. Merge was in the business of providing software development and engineering services on a contract basis to a number of companies. In developing our ClearPoint system software, Merge utilized certain of its own pre-existing software code, or Merge software. Under our agreement with Merge, we received a non-exclusive, worldwide license to the Merge software, in object code form, as an integrated component of our ClearPoint system software. In return, we agreed to pay Merge a license fee for each copy of our ClearPoint system software that we distribute. Except for the Merge software, the work performed by Merge was a "work made for hire" and we exclusively own our ClearPoint system software. Under the master services and licensing agreement, Merge also performed ongoing custom engineering, maintenance and support services with respect to our ClearPoint system software, for which we compensated Merge.

At our request, in July 2013, the master services and licensing agreement was amended to enable us to internally handle development, maintenance and support of our ClearPoint system software going forward. As a result, we now perform the software services which we previously outsourced to Merge. Under the amendment, Merge granted us a non-exclusive, non-transferable, worldwide license to the source code for the Merge software to use in our further development and commercialization of our ClearPoint system software. In return, we agreed to pay Merge a one-time license fee. Merge may terminate the source code license only for cause. We will continue to pay Merge a license fee for each copy of our ClearPoint system software that we distribute, but only for licenses in excess of the licenses we already had purchased or otherwise acquired from Merge prior to the July 2013 amendment. We already have satisfied our minimum license purchase commitments from Merge under the master services and licensing agreement.

License Arrangements with Boston Scientific

In connection with our March 2014 sale of certain MRI-safety technologies to Boston Scientific, we entered into a license agreement with Boston Scientific. Under that license agreement, Boston Scientific granted us an exclusive, royalty-free, fully paid, irrevocable, worldwide license to the transferred intellectual property, with the right to sublicense, within fields of use other than neuromodulation and implantable medical leads for cardiac applications.

Competition

General

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

ClearPoint System

Currently, we are not aware of any other company that offers a direct MRI-guided stereotactic system for neurological interventions, although two companies, Monteris Medical Inc. and Medtronic plc offer devices for laser ablation under direct MRI guidance. In addition, companies such as Brainlab, Medtronic plc, Elekta AB, FHC Inc., Neurologica Corporation, a subsidiary of Samsung Electronics Co., and Mazor Robotics Ltd. offer devices and systems for use in conventional stereotactic neurological procedures, such as surgical navigation workstations, frame-based and frameless stereotactic systems, portable computer tomography scanners and computer-controlled guidance systems, and these devices and systems are competitive with our ClearPoint system. Additionally, we could also face competition from other medical device, biotechnology 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

We are not aware of any company that currently offers a direct MRI-guided cardiac ablation system that has received regulatory clearance or approval. However, at least one company, Imricor Medical Systems, Inc., is in the process of developing such a system, and at least one other company, Philips Healthcare, has a research and development effort in this field. We are not aware of any potential competitive advantages or disadvantages relative to any such system under development; however, if any such company develops, obtains regulatory clearance or approval and achieves commercial success for a direct MRI-guided cardiac ablation system, the ClearTrace system could be rendered non-competitive.

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. Their products include drugs, implantable devices, such as implantable defibrillators and pacemakers, and the devices used in open-heart surgery.

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, Cardio Focus, Inc., Medtronic, Inc. and St. Jude Medical, Inc. These potential competitors have substantially greater financial and other resources than we do, including larger research and development staffs and more experience and greater capabilities in conducting research and development activities, testing products in clinical trials, obtaining regulatory clearances or approvals, and manufacturing, marketing and distributing products.

Regulatory Requirements of the United States Food and Drug Administration

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

- product design, preclinical and clinical development and manufacture;

- product premarket clearance and approval;
- product safety, testing, labeling and storage;
- record keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions and repair or recall of products.

FDA Premarket Clearance and Approval Requirements

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

510(k) Clearance Pathway

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

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

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

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

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 trial, 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 be met, such as conducting a post market clinical trial.

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. Although we believe that most components of our ClearTrace system will fall under the FDA's 510(k) regulatory process, we do believe the ablation catheter component will require the approval of a PMA. Likewise, we could seek to add new indications for use of our existing products that require the approval of a PMA, although we do not have any current plans to do that.

Clinical Trials

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

Pervasive and Continuing Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. In addition to the requirements below, the Medical Device Reporting regulations require that we report to the FDA any incident in which our product 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 medical device 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. 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. Furthermore, 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. 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.

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;
- refusing or delaying requests for 510(k) clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our marketed products; or
- criminal prosecution.

International Marketing Approvals

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

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

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

Healthcare Laws and Regulations

Third-Party Reimbursement

In the United States and elsewhere, healthcare providers that perform surgical procedures using medical devices such as ours generally rely on third-party payors, including governmental payors such as Medicare and Medicaid and private payors, to cover and reimburse all or part of the cost of the products. Consequently, sales of medical devices are dependent in part on the availability of reimbursement to the customer from third-party payors. The manner in which reimbursement is sought and obtained varies based upon the type of payor involved and the setting in which the product is furnished and utilized. In general, third-party payors will provide coverage and reimbursement for medically reasonable and necessary procedures and tests that utilize medical devices. Third-party payors may provide separate payments for implanted or disposable devices themselves, although no such separate payments are currently provided for our ClearPoint disposable products. Most third-party payors will not pay separately for capital equipment. 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.

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.

Medicare and Medicaid

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

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

Because PPS payments are based on predetermined rates and may be less than a hospital's actual costs in furnishing care, and due to payment reforms enacted relatively recently, 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 has been adopted by the Medicare program to describe and develop payment amounts for certain physician services.

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

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, together, the Affordable Care Act, included a number of provisions that will likely result in more coordination between hospitals and physicians and alignment of financial incentives between hospitals and physicians to control hospital costs. Most significantly, the Affordable Care Act provided for a Medicare shared savings program whereby Medicare will share certain savings realized in the delivery of services to Medicare beneficiaries with accountable care organizations, which may be organized through various different legal structures between hospitals and physicians. Other payment reform provisions in the Affordable Care Act included pay-for-performance initiatives, payment bundling and the establishment of an independent payment advisory board.

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

Commercial Insurers

In addition to the Medicare program, many private payors look to CMS policies as a guideline in setting their coverage policies and payment amounts. The current coverage policies of these private payors may differ from the Medicare program, and the payment rates they make may be higher, lower, or the same as the Medicare program. If CMS or other agencies decrease or limit reimbursement payments for hospitals and physicians, this may affect coverage and reimbursement determinations by many private payors. Additionally, some private payors do not follow the Medicare guidelines, and those payors may reimburse only a portion of the costs associated with the use of our products, or none at all.

Fraud and Abuse Laws

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

Anti-Kickback Laws

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

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

Many states have laws that implicate anti-kickback restrictions similar to the federal 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 activities relating to the manner in which we sell our products and document our prices such as the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products, and the sale and marketing of our products, may be subject to scrutiny under these laws.

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

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties 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.

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 healthcare offenses," including healthcare fraud and false statements relating to healthcare matters. The HIPAA healthcare fraud statute prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program, or to obtain by means of false of fraudulent pretenses, any money under the control of any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment and/or exclusion from government-sponsored programs. The Affordable Care Act also provides for civil monetary penalties for knowingly participating in certain federal healthcare offenses and enhances sentences under the Federal Sentencing Guidelines for such offenses. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment. Entities that are found to have aided or abetted in a violation of the HIPAA federal healthcare 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, we expect that many of 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, 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 subject to these standards directly, 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 confidentiality agreement or, when appropriated, business associate agreements. While the government intended this legislation to reduce administrative expenses and burdens for the healthcare industry, our compliance with certain provisions of these standards could entail significant costs for us.

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

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

In addition to federal regulations issued under HIPAA, some states have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. 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, will apply to our receipt of patient identifiable health information in connection with any clinical trials we conduct. In addition, 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 affects our company.

Employees

As of February 28, 2015, we had 37 full time employees, of whom seven were engaged primarily in research and development, eight in manufacturing and quality assurance, 15 in sales, clinical support and marketing, and seven in 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.

We are in the process of consolidating key functions presently performed from our Memphis, Tennessee office into our Irvine, California facility. As a result, we are closing our Memphis, Tennessee office, and we will not retain any of our Memphis-based employees. We expect the transition process and the closure of our Memphis office to be complete by the middle of the second quarter of 2015.

ITEM 1A. RISK FACTORS

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

Risks Related to Our Business

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

As of December 31, 2014, we had an accumulated deficit of approximately $77.3 million. The accumulated deficit has resulted principally from costs incurred in connection with our sales and marketing activities, research and development efforts and manufacturing activities and other general and administrative expenses associated with our operations. We have incurred losses in each year since our inception in 1998, and we may continue to incur losses as we continue to invest capital in the sales and marketing of our ClearPoint products, development of our ClearTrace system and growth of our business generally.

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

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

We expect that sales of our ClearPoint system products will account for the vast majority of our revenues for at least the next few years. Our ClearPoint system may not gain broad market acceptance unless we continue to convince physicians, hospitals and patients of its benefits. Moreover, even if physicians and hospitals understand the benefits of our ClearPoint system, they still may elect not to use our ClearPoint system for a variety of reasons, such as:

- the shift in location of the procedure from the operating room to the MRI suite;
- demand for the MRI suite within the hospital, which may result in limited or no MRI scanner availability for procedures in which our ClearPoint system would be used;
- the familiarity of the physician with other devices and surgical approaches;
- the physician's perception that there are insufficient benefits of our ClearPoint system relative to those other devices and surgical approaches;
- budgetary constraints with respect to the purchase of our ClearPoint system hardware and software;
- the price of our ClearPoint system disposable products, which may be higher than devices used with other surgical approaches; and
- the physician's perception that there is a lack of clinical data on the use of our ClearPoint system.

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.

We have relatively limited experience marketing and selling our ClearPoint system, and if we are unable to expand, manage and maintain our marketing and sales capabilities, we may be unable to generate significant growth in our product revenues.

We started selling our ClearPoint system on a limited basis in August 2010, and we did not begin to meaningfully expand our sales and clinical support capabilities until 2013. As a result, we have relatively limited experience marketing and selling our ClearPoint system. Our operating results are directly dependent upon the marketing and sales efforts of our employees. If our team fails to adequately promote, market and sell our products, our sales will suffer.

We expect to continue building our team to market, sell and support 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 negatively impacted. Our ability to achieve significant revenue growth will depend, in large part, on our success in recruiting, training, motivating and retaining a sufficient number of qualified personnel. New hires require significant training and, in most cases, take significant time before they achieve full productivity. Our recent hires and planned hires may not become as productive as we expect, and we may be unable to hire or retain sufficient numbers of qualified individuals, in which case our business would be harmed.

We have entered into a co-development and distribution agreement with Brainlab pursuant to, among other things, which we appointed Brainlab as a distributor of our ClearPoint system products in the United States and Europe. However, there is no assurance that Brainlab will be successful in marketing and selling our ClearPoint system products. In addition, under our agreement, Brainlab is not subject to any minimum sales or other performance requirements. Therefore, we may not realize the desired benefits from our agreement with Brainlab. To date, we have not generated significant revenues from our distribution relationship with Brainlab.

The existence of adequate coverage and reimbursement is important for sales of our products. If hospitals and physicians believe coverage and reimbursement from third-party payors for procedures utilizing our ClearPoint system products are inadequate, adoption of our products will be adversely affected and our revenues and prospects for profitability will suffer.

Our ClearPoint system products 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 and utilize medical devices such as our ClearPoint system products. Therefore, our ability to successfully commercialize our ClearPoint system depends significantly on the adequacy of coverage and reimbursement from these third-party payors. In the United States, coverage and reimbursement varies among payors.

Medicare pays hospitals a prospectively determined amount for inpatient operating costs. The prospective payment for a patient's stay is determined by the patient's condition and other patient data and procedures performed during the inpatient stay using a classification system known as Medicare Severity Diagnosis Related Groups, or MS-DRGs. Medicare pays a fixed amount to the hospital based on the MS-DRG into which the patient's stay is assigned, regardless of the actual cost to the hospital of furnishing the procedures, items and services provided. Therefore, a hospital must absorb the cost of our products as part of the payment it receives for the procedure in which the products are 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.

For commercial payors, reimbursement to hospitals and physicians generally is dependent upon the specific contract terms between the provider and the payor. Many commercial payors look to Medicare policies as a guideline in setting their coverage policies and payment amounts. However, the current coverage policies of these commercial 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 Medicare reimbursement payments for hospitals and physicians are decreased or limited, coverage and reimbursement determinations by many commercial payors may be affected.

Because hospitals are reimbursed for the procedures in which our ClearPoint system products are used and our products are not separately reimbursed, the additional cost associated with the use of our products could impact hospital profit margins. Some hospitals could believe third-party reimbursement levels are not adequate to cover the cost of our ClearPoint system products. Furthermore, some physicians could believe third-party reimbursement levels are not adequate to compensate them for performing the procedures in which our products are used. Failure by hospitals and physicians to receive an amount that they consider to be adequate reimbursement for procedures in which our products are used will deter them from purchasing or using our products and will limit our sales growth.

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

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

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

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

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

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

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

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

We currently have significant customer concentration, so economic difficulties or changes in the purchasing policies or patterns of our key customers could have a significant impact on our business and operating results.

A small number of our hospital customers account for a substantial portion of our revenues from sales of ClearPoint disposable products. For example, our largest customer, the University of California, San Francisco Medical Center, or UCSF, accounted for 14% of our ClearPoint disposable product revenues for the year ended December 31, 2014. Likewise, Emory University Hospital, or Emory, accounted for 12% of our ClearPoint disposable product revenues for the same period. Sales to almost all of our customers, including UCSF and Emory, are not based on long-term, committed volume purchase contracts, and we may not continue to generate a similar level of revenues from UCSF, Emory or any other customer. Because of our current customer concentration, our revenues could fluctuate, possibly significantly, due to a reduction or delay in orders from any of our significant customers, which could harm our business and results of operations.

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

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

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

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

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

Our ClearTrace system remains under development. We cannot be certain that we will be able to successfully complete development of, and obtain regulatory clearances or approvals for, our ClearTrace system in a timely fashion, or at all.

Our ClearTrace system is still under development, and, to date, we have conducted only animal studies and other preclinical work with respect to that product candidate. Our ClearTrace system will require substantial additional development and testing. There can be no assurance that our development efforts will be successfully completed or that the ClearTrace system will have the capabilities we expect. We may encounter significant difficulties and costs during the course of our development efforts and we may encounter significant delays. Even if we successfully complete development of our ClearTrace system, there can be no assurance that we will obtain the regulatory clearances or approvals to market and commercialize it. If we are unable to obtain regulatory clearances or approvals for our ClearTrace system, or otherwise experience delays in obtaining such regulatory clearances or approvals, the commercialization of the ClearTrace system will be delayed or prevented, which will adversely affect our ability to generate revenues. 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. Delays in developing our ClearTrace system or obtaining regulatory clearances or approvals may also result in the loss of potential competitive advantages that might otherwise be attained by bringing products to market earlier than our competitors. Any of these contingencies could adversely affect our business.

In the United States, unless an exemption applies, we cannot market a new medical device without first receiving either 510(k) clearance 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 anticipate that the initial market for our ClearTrace system will be the European Union and, at the appropriate time, we expect to seek CE marking approval for the ClearTrace system. The ClearTrace system consists of several components, one or more of which may require the submission of a PMA in the United States.

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

At present, our commercialization activities for our ClearPoint system are focused in the United States. However, we do have CE marking approval to market our ClearPoint system in the European Union. In addition, we ultimately intend to market our ClearPoint system in other foreign jurisdictions as well. 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 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.

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. We could seek to obtain additional, more specific indications for use of our ClearPoint system beyond the general neurological intervention claim. To the extent we seek expanded claims for our ClearPoint system, such claims could, depending on their nature, require 510(k) clearance or FDA approval of a PMA. Moreover, some specific ClearPoint system claims could require clinical trials to support regulatory clearance or approval. In the event we seek a new indication for use of, or new claims for, the ClearPoint system that we believe are necessary or desirable for successful commercialization, the FDA may refuse our requests for 510(k) clearance or PMA approval. Likewise, to the extent clinical trials are necessary, we may not successfully complete or have the funds to initiate such clinical trials.

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

Initiating and completing clinical trials necessary to support 510(k) clearance or PMA approval for our 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, would 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 could require the enrollment of large numbers of patients, and suitable patients could 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 could 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 could 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 could cause an increase in costs and delays in the approval and attempted commercialization of our product candidates or result in the failure of the clinical trial. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

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

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

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

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

These companies enjoy significant competitive advantages over us, including:

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

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

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

Our business exposes us to potential product liability risks that are inherent in the manufacturing, marketing and sale of medical devices. We may be held liable if our products cause injury, or death or are found otherwise unsuitable or defective during usage. Our ClearPoint system and our ClearTrace system each incorporates 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 our ClearTrace system are each 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 that we believe is appropriate, this insurance coverage is subject to deductibles and coverage limitations, and may not be adequate to protect us against any future product liability 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.

Risks Related to Funding

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

We have not yet achieved profitability. Accordingly, we have financed our activities principally from sales of equity securities, borrowings and license arrangements. Most recently, in December 2014, we raised $10.2 million, before commissions and offering expenses, from the sale of shares of our common stock and warrants to purchase shares of our common stock in a private placement transaction. Because of the various risks and uncertainties associated with the commercialization of medical devices, there can be no assurance that our cash resources will cover all of our costs until we achieve profitability. Therefore, we could need additional funding. Additional funds, if needed, may not be available on a timely basis or on terms that are acceptable to us, or at all, in which event we could take actions that negatively impact the commercialization of our ClearPoint system, or terminate or delay the development of the ClearTrace system.

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

- the timing of broader market acceptance and adoption of our ClearPoint system products;
- the scope, rate of progress and cost of our ongoing product development activities relating to our ClearPoint system;
- the cost and timing of expanding our sales, clinical support, marketing and distribution capabilities and other corporate infrastructure;
- the cost and timing of establishing inventories at levels sufficient to support our sales;
- the scope, rate of progress and cost of our research and development activities relating to our ClearTrace system;

- the effect of competing technological and market developments;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- the cost and timing of any clinical trials;
- the cost and timing of regulatory filings, clearances and approvals; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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

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

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 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 products or product candidates, or if any protection is reduced or eliminated, others could use the intellectual property covering our products or product candidates, resulting in harm to our competitive business position. In addition, patent and other intellectual property protection may not provide us with a competitive advantage against competitors that devise ways of making competitive products without infringing any patents that we own or have rights to.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Regulatory Compliance

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

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

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

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

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

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

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

We and some of our third-party suppliers are required to comply with the FDA's QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products and product candidates. We and our suppliers will also be subject to the regulations of foreign jurisdictions regarding the manufacturing process to the extent we market our products in these jurisdictions. The FDA enforces the QSR through periodic and unannounced inspections of manufacturing facilities. Our facilities were last inspected by the FDA for QSR compliance in September 2014. We anticipate that we and certain of our third-party suppliers will be subject to future inspections. The failure by us or one of our third-party suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations, could result in enforcement actions against us, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. If we fail to comply with the FDA's QSR or any applicable state equivalent, we would be required to incur the costs and take the actions necessary to bring our operations into compliance, which may have a negative impact on our future sales and our ability to generate a profit.

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

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

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

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

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

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

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

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

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

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

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

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

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

- HIPAA, which established new federal crimes for knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services.

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

- The Affordable Care Act, which imposes certain reporting obligations on manufacturers of drugs, devices and biologics. Specifically, such manufacturers are required to report payments or other transfers of value to or on behalf of a physician or teaching hospital by such manufacturers, as well as any ownership or investment interest held by physicians in such manufacturers. Violations of the reporting requirements are subject to civil monetary penalties.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- HITECH, which strengthens and expands the HIPAA Privacy and Security Rules and its restrictions on use and disclosure of patient identifiable health information, including imposing liability on business associates of covered entities.

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

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

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

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

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

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

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

Risks Related to Facilities, Employees and Growth

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

All of our employees, including the members of our senior management team, are at-will employees, and therefore they may terminate employment with us at any time. Accordingly, there are no assurances that the services of any of our employees will be available to us for any specified period of time. The loss of members of our senior management team, our sales, clinical support and marketing team or our engineering team, or our inability to attract or retain other qualified personnel, could have a material adverse effect on our business, financial condition and results of operations. If the need to replace any of our key employees arises, the replacement process likely would involve significant time and costs, and may significantly delay or prevent the achievement of our business objectives.

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

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

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

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

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

We cannot be certain that our systems, controls, infrastructure and personnel will be adequate to support our future operations. Any failure to effectively manage our growth could impede our ability to successfully develop, market and sell our products and our business will be harmed.

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

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

Risks Related to Our Shares of Common Stock

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

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

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

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

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

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

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

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

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

As of February 28, 2015, almost all of our outstanding shares were freely transferable or could be publicly resold pursuant to Rule 144 under the Securities Act. In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated) who has beneficially owned restricted securities for at least six months, including our affiliates, would be entitled to sell such securities, subject to the availability of current public information about the company. A person who has not been our affiliate at any time during the three months preceding a sale, and who has beneficially owned his shares for at least one year, would be entitled under Rule 144 to sell such shares without regard to any limitations under Rule 144. Under Rule 144, sales by our affiliates are subject to volume limitations, manner of sale provisions and notice requirements. Any substantial sale of common stock pursuant to a prospectus, Rule 144 or otherwise may have an adverse effect on the market price of our common stock by creating an excessive supply. Likewise, the availability for sale of substantial amounts of our common stock could reduce the prevailing market price.

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

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

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

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

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

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 2. PROPERTIES.

We lease approximately 7,400 square feet of space in Irvine, California under a lease that expires in September 2018. Our principal executive office and our principal operations are based at this facility. We believe that our Irvine, California facility is sufficient to meet our needs for the foreseeable future.

We also lease approximately 3,300 square feet of office space in Memphis, Tennessee, which we use for executive offices. We are in the process of closing our Memphis office, a process we expect to complete by the middle of the second quarter of 2015. Our Memphis, Tennessee lease expires in November 2015.

ITEM 3. LEGAL PROCEEDINGS.

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

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Our common stock has been traded on the over-the-counter market since May 21, 2012, under the symbol "MRIC." The following table provides the high and low bid information for our common stock during the periods indicated. This bid information reflects inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

Quarter Ended	High Bid	Low Bid
Fiscal 2014		
Fourth Quarter 2014 (through December 31, 2014)	$ 1.34	$ 0.74
Third Quarter 2014 (through September 30, 2014)	$ 1.28	$ 0.86
Second Quarter 2014 (through June 30, 2014)	$ 1.38	$ 0.65
First Quarter 2014 (through March 31, 2014)	$ 1.58	$ 1.15
Fiscal 2013		
Fourth Quarter 2013 (through December 31, 2013)	$ 1.62	$ 1.28
Third Quarter 2013 (through September 30, 2013)	$ 1.49	$ 1.09
Second Quarter 2013 (through June 30, 2013)	$ 1.31	$ 1.06
First Quarter 2013 (through March 31, 2013)	$ 1.95	$ 1.18

Holders

As of February 28, 2015, we had 74,842,428 shares of common stock outstanding and no shares of preferred stock outstanding. As of February 28, 2015, we had approximately 600 stockholders of record. In addition, as of February 28, 2015, options and warrants to purchase 31,144,945 shares of common stock were outstanding, provided that 9,141,250 shares underlying such options and warrants were subject to derivative restriction agreements.

Dividend Policy

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

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by stockholders [1]	4,477,309	$ 1.29	211,833
Equity compensation plans not approved by stockholders [1][2][3][4][5][6][7]	5,866,000	$ 1.41	275,000
Total	10,343,309	$ 1.36	486,833

(1) The information presented in this table is as of December 31, 2014.

(2) We adopted our 2010 Non-Qualified Stock Option Plan in December 2010. The plan provided for the issuance of non-qualified stock options to purchase up to 2,565,675 shares of our common stock. We ceased making awards under the plan upon the adoption of our 2012 Incentive Compensation Plan. As of December 31, 2014, options to purchase 2,371,000 shares of our common stock were outstanding under the 2010 Non-Qualified Stock Option Plan.

(3) In November 2012 and November 2014, we entered into written compensatory contracts with Robert C. Korn, our Vice President, Sales, pursuant to which we awarded Mr. Korn non-qualified stock options to purchase 150,000 shares and 100,000 shares, respectively, of our common stock.

(4) In December 2013, we entered into written compensatory contracts with an employee and a non-employee director pursuant to which we awarded those individuals non-qualified stock options to purchase 75,000 shares and 125,000 shares, respectively, of our common stock.

(5) In December 2013, we adopted our 2013 Non-Employee Director Equity Incentive Plan. The plan provides for the issuance of awards with respect to an aggregate of 570,000 shares of our common stock. As of December 31, 2014, 295,000 were outstanding under the 2013 Non-Employee Director Equity Incentive Plan.

(6) In October 2014, we entered into a written compensatory contract with Francis P. Grillo pursuant to which we awarded Mr. Grillo non-qualified stock options to purchase 2,400,000 shares of our common stock. Mr. Grillo, who initially joined the company as our President, became our Chief Executive Officer on January 1, 2015.

(7) In December 2014, we entered into a written compensatory contract with Wendelin C. Maners, our Vice President, Marketing, pursuant to which we awarded Ms. Maners non-qualified stock options to purchase 350,000 shares of our common stock.

ITEM 6. SELECTED FINANCIAL DATA.

Not applicable.

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

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

Overview

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

In 2010, we received regulatory clearance from the FDA to market our ClearPoint system in the United States for general neurological procedures. In 2011, we also obtained CE marking approval for our ClearPoint system, which enables us to sell our ClearPoint system in the European Union. The vast majority of our product revenues for the years ended December 31, 2014 and 2013 relate to sales of our ClearPoint system products. We do not have regulatory clearance or approval to sell our ClearTrace system for commercial use; however, we have had an isolated sale of certain ClearTrace system components to a research site for non-commercial use. We have financed our operations and internal growth primarily through the sale of equity securities, the issuance of convertible and other secured notes, and license arrangements. We have incurred significant losses since our inception in 1998 as we devoted substantial efforts to research and development. As of December 31, 2014, we had an accumulated deficit of $77.3 million. We may continue to incur operating losses as we commercialize our ClearPoint system products, continue to develop our ClearTrace system, and expand our business.

Factors Which May Influence Future Results of Operations

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

Revenues

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

Generating recurring revenues from the sale of disposable products is an important part of our business model for our ClearPoint system. We anticipate that, over time, 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 our ClearPoint disposable products.

Our product revenues were $3.4 million and $2.9 million for the years ended December 31, 2014 and 2013, respectively, and were almost exclusively related to our ClearPoint system. Since inception, the most significant source of our revenues has been related to our collaborative agreements with Boston Scientific, principally from recognition of the $13.0 million of licensing fees, which we received in 2008. Revenues associated with these licensing fees were recognized on a straight-line basis over a five year period, which was the period we estimated for our continuing involvement in the development activities, and which period ended in the first quarter of 2013.

Our revenue recognition policies are more fully described in the "Critical Accounting Policies and Significant Judgments and Estimates" section below.

Cost of Product Revenues

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

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 ClearTrace system components. This includes: the salaries, travel, and benefits of research and development personnel, including related share-based compensation; materials and laboratory supplies in research and development activities; consultant costs; sponsored research and product development with third parties; and licensing costs related to technology not yet commercialized. We anticipate that, over time, our research and development expenses may increase as we: (1) continue our ClearTrace system product development efforts; (2) continue to develop enhancements to our ClearPoint system; and (3) expand our research to apply our technologies to additional product applications. From our inception through December 31, 2014, we have incurred approximately $43 million in research and development expenses.

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

Selling, General and Administrative Expenses

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

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 consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these consolidated 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 consolidated financial statements as well as the reported expenses during the reporting periods. The accounting estimates that require our most significant, difficult and subjective judgments have an impact on revenue recognition, computation of the fair value of our derivative liabilities, 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 consolidated financial statements included elsewhere in this Annual Report, 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 are comprised of: (1) product revenues resulting from the sale of ClearPoint system reusable products, disposable products and ClearTrace components; (2) license and development arrangements; (3) development service revenues; and (4) other service revenues. We recognize revenue when persuasive evidence of an arrangement exists, the selling price or fee is fixed or determinable, collection is reasonably assured, and, for product revenues, risk of loss has transferred to the customer. For all sales, we require either a purchase agreement or a purchase order as evidence of an arrangement. We analyze revenue recognition on an agreement by agreement basis. We determine if the deliverables under the arrangement represent separate units of accounting as defined by GAAP. Application of GAAP regarding multiple-element arrangements requires us to make subjective judgments about the values of the individual elements and whether delivered elements are separable from the other aspects of the contractual relationship.

(1) *Product Revenues — Sales of ClearPoint system reusable products*: Generally, revenues related to ClearPoint system reusable product 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 installation. Reusable products include software which is integral to the utility of the ClearPoint system as a whole. Sales of reusable products that have stand-alone value to the customer are recognized when risk of loss passes to the customer. Sales of ClearPoint reusable products to a distributor that has been trained to perform system installations and to conduct physician training are recognized at the time risk of loss passes to the distributor.

Sales of disposable products: Revenues from the sale of disposable products, including ClearPoint system disposable products, are recognized at the time risk of loss passes to the customer, which is generally at shipping point or upon delivery to the customer's location, depending on the agreed upon terms with the customer.

Sales of ClearTrace components: Sales of ClearTrace system components to research sites for non-commercial use are recognized at the time risk of loss passes to the customer, which is generally at shipping point or upon delivery to the customer's location, depending on the agreed upon terms with the customer. The Company does not have regulatory clearance or approval to sell ClearTrace system components for commercial use.

(2) *License and Development Arrangements* — We defer 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 our performance under other elements of the arrangement.

(3) *Development Service Revenues* — We entered into an agreement to provide development services to a third party. Under the agreement, we earned revenue equal to costs incurred for outside expenses related to the development services provided, plus actual direct internal labor costs (including the cost of employee benefits), plus an overhead markup of the direct internal labor costs incurred. Revenue was recognized in the period in which we incurred the related costs.

(4) *Other Service Revenues* — Other service revenues are comprised of installation fees, training fees, shipping fees and service fees charged in connection with ClearPoint system installations and ClearPoint system service agreements. Typically, we will bill upfront for service agreements, which have terms ranging from one to three years. These amounts are recognized as revenues ratably over the term of the related service agreement.

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. Software license inventory that is not expected to be utilized within the next twelve months is classified as a non-current asset. We periodically review our inventory for obsolete items and provide a reserve upon identification of potential obsolete items.

Derivative Liability for Warrants to Purchase Common Stock. Our derivative liabilities for warrants represent the fair value of warrants issued in connection with certain private placements of shares our common stock. The fair values of these warrants are presented as liabilities based on certain net cash settlement and exercise price reset, or "down round," provisions. These derivative liabilities, which are recorded on our consolidated balance sheets, are calculated utilizing the Monte Carlo simulation valuation method. Changes in the fair values of these warrants are recognized as other income or expense in the related statement of operations.

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

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

Results of Operations

Comparison of the Year Ended December 31, 2014 to the Year Ended December 31, 2013

($s in thousands)	Year Ended December 31, 2014	Year Ended December 31, 2013	Percentage Change
Product and other service revenues	$ 3,501	$ 2,997	17%
Development service revenues	104	284	(63)%
License revenues	-	650	NM
Cost of product revenues	1,927	1,421	36%
Research and development costs	3,297	2,923	13%
Selling, general and administrative expenses	8,039	7,061	14%
Gain on sale of intellectual property	(4,339)	-	NM
Other income (expense):			
Gain on change in fair value of derivative liabilities	1,550	1,686	(8)%
Loss on loan modification	-	(1,356)	NM
Other income, net	252	533	(53)%
Interest expense, net	(1,008)	(475)	112%
Net loss	(4,525)	(7,086)	(36)%

NM= not meaningful

Product and Other Service Revenues. Product and other service revenues were $3.5 million for the year ended December 31, 2014, and $3.0 million for the prior year, an increase of $504,000, or 17%. Product and other service revenues included disposable product sales for the year ended December 31, 2014 of $2.6 million, compared with $1.8 million for the same period in 2013, an increase of $831,000, or 47%. The increase reflected customer purchases of disposable products during the year ended December 31, 2014 for a higher number of performed and anticipated procedures compared with the prior year, as well as the sale of drug delivery catheters we manufactured on a contract basis for a third party. Approximately $710,000 of the product and other service revenues for the year ended December 31, 2014 related to the sale of ClearPoint system reusable products, compared with $1.1 million for the prior year, a decrease of $421,000. Product and other service revenues for the year ended December 31, 2014 also included $56,000 in ClearTrace system components sold to a research site for non-commercial use. Other service revenues, mostly related to ClearPoint system service agreements and installation services, were $122,000 for the nine months ended December 31, 2014, and $82,000 for the prior year.

Development Service Revenues. During the years ended December 31, 2014 and 2013, we recorded development service revenues of $104,000 and $284,000, respectively, representing a decrease of $180,000. The decrease reflects the completion of a development project we performed on a contract basis. We do not expect development service revenues to be an ongoing source of revenues.

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

Cost of Product Revenues. Cost of product revenues was $1.9 million for the year ended December 31, 2014, compared to $1.4 million for the prior year, an increase of 36%. The increase in cost of product revenues of 36% was greater than the 17% increase in product revenues as we recorded a higher provision for obsolete and expired products during the year ended December 31, 2014 compared with the prior year. The increase in this provision was approximately $380,000, representing 75% of the increase in cost of product revenues. The increase in this provision related mostly to reserves recorded for ClearPoint system reusable products that are not compatible with procedures requiring patients to be in the prone, or face down, position. This requirement for prone positioning resulted from expanding the range of procedures in which our ClearPoint system may be used. If we excluded the increase related to this provision, cost of product revenues would have grown at a lower rate than the rate of growth in product revenues, which is consistent with the shift in product mix. Revenues related to disposable product sales represented a greater percentage of total product revenues for the year ended December 31, 2014, as compared to the prior year. Margins are generally higher on disposable product sales compared to revenues from sales of ClearPoint system reusable products.

Research and Development Costs. Research and development costs were $3.3 million for the year ended December 31, 2014, compared to $2.9 million for the prior year, an increase of $374,000, or 13%. The increase was driven by a $722,000 increase in expenses related to our ClearTrace system development program, which was partially offset by a decrease in share-based compensation expense of approximately $255,000 and a $133,000 decrease in product development costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $8.0 million for the year ended December 31, 2014, compared with $7.1 million for the prior year, an increase of $978,000, or 14%. The overall increase was driven by an $883,000 increase in sales and marketing expenses, an increase in retention incentives and severance amounts of $252,000, and a $176,000 increase in consulting expenses mostly related to a project performed by a healthcare consulting firm. These increases were partially offset by a $333,000 decrease in share-based compensation expense.

Gain on Sale of Intellectual Property. During the year ended December 31, 2014, we recorded a gain of $4.3 million related to the sale of certain intellectual property to Boston Scientific. The purchase price was satisfied through the cancellation of related party convertible notes payable we previously issued to Boston Scientific in the aggregate principal amount of $4.3 million. We recorded a gain equal to the purchase price, as the assets sold had not been previously recorded on our balance sheet.

Other Income (Expense). During the years ended December 31, 2014 and 2013, we recorded gains of $1.5 million and $1.7 million, respectively, resulting from changes in the fair value of the derivative liability associated with warrants we issued in certain equity private placement transactions.

During the year ended December 31, 2013, we recorded a loss of $1.4 million related to the March 2013 Brainlab loan modification, which modification included a $1.9 million increase to the principal balance of the note, a decrease in the interest rate from 10% to 5.5%, and the elimination of the note's equity conversion feature. The $1.4 million loss we recorded represented the difference between the carrying amount of the note plus the related accrued interest immediately prior to the loan modification and the fair value of the note immediately following the loan modification.

Net other income was $252,000 and $533,000 for the years ended December 31, 2014 and 2013, respectively. Net other income for the year ended December 31, 2014 was attributable mostly to $188,000 in income under certain Small Business Innovation Research, or SBIR, contracts we were awarded and $78,000 in negotiated reductions in amounts payable to service providers. Net other income for the year ended December 31, 2013 was primarily related to $477,000 in negotiated reductions in amounts payable to service providers and $63,000 in income under an SBIR contract.

Net interest expense for the year ended December 31, 2014 was $1.0 million, compared with $475,000 for the prior year. The increase relates mostly to interest on the notes payable we issued in our March 2014 private offering, as well as the amortization of the related debt discount and deferred financing costs associated with that transaction.

Liquidity and Capital Resources

For the years ended December 31, 2014 and 2013, we incurred net losses of $4.5 million and $7.1 million, respectively, and our cumulative net loss from inception through December 31, 2014 was $77.3 million. We believe such losses may continue through at least the year ending December 31, 2015 as we continue to commercialize our ClearPoint system and pursue research and development activities. Net cash used in operations was $7.3 million and $7.8 million for the years ended December 31, 2014 and 2013, respectively. Since inception, we have financed our activities principally from the sale of equity securities, the issuance of notes payable and license arrangements.

Our primary financing activities during the years ended December 31, 2014 and 2013 were:

- a December 2014 equity private placement, which resulted in net proceeds of $9.4 million;
- a March 2014 private offering, which resulted in net proceeds of $3.5 million; and
- a January 2013 equity private placement, which resulted in net proceeds of $9.8 million.

While we expect to continue to use cash in operations, we believe our existing cash and cash equivalents at December 31, 2014 of $9.2 million, combined with cash expected to be generated from product sales, will be sufficient to meet our anticipated cash requirements through at least March 31, 2016. During 2015, we expect to increase revenues from sales of ClearPoint system products as a result of greater utilization at existing installed sites and an increase in the number of installed sites. Certain planned expenditures are discretionary and could be deferred if we are required to do so to fund critical operations.

To the extent our available cash and cash equivalents are insufficient to satisfy our long-term operating requirements, we will need to seek additional sources of funds from the sale of equity or debt securities or through a credit facility, or we will need to modify our current business plan. There can be no assurances that we will be able to obtain additional financing on commercially reasonable terms, if at all. The sale of additional equity or convertible debt securities would likely result in dilution to our current stockholders.

Cash Flows

Cash activity for the years ended December 31, 2014 and 2013 is summarized as follows:

	Years Ended December 31,	
($s in thousands)	**2014**	**2013**
Cash used in operating activities	$ (7,250)	$ (7,778)
Cash used in investing activities	(48)	(174)
Cash provided by financing activities	13,026	9,848
Net increase in cash and cash equivalents	$ 5,728	$ 1,896

Net Cash Flows from Operating Activities. We used $7.3 million and $7.8 million of cash for operating activities during the years ended December 31, 2014 and 2013, respectively. Net cash used in operating activities during the year ended December 31, 2014 primarily reflected our $5.3 million loss from operations, plus the gain on the sale of intellectual property of $4.3 million, plus the $464,000 portion of the increase in accrued expenses related to accrued interest, plus the $346,000 increase in inventory, less a $1.1 million increase in accounts payable and accrued expenses, less $881,000 in share-based compensation, less $411,000 related to expenses paid through the issuance of common stock, and less $377,000 in depreciation and license amortization.

Net cash used in operating activities during the year ended December 31, 2013 primarily reflected our $7.5 million operating loss, plus the $656,000 change from the prior year end deferred revenue balance, plus the $696,000 reduction in accounts payable and accrued expenses, plus the $310,000 growth in inventory, plus the $325,000 increase in accounts receivable, plus a $228,000 increase in accrued expenses related to accrued interest, but less $1.5 million in share-based compensation and $426,000 for depreciation and amortization. All of the changes noted for both years exclude the impact of non-cash changes.

Net Cash Flows from Investing Activities. Net cash flows used in investing activities for the years ended December 31, 2014 and 2013 were $48,000 and $174,000, respectively.

Net Cash Flows from Financing Activities. Net cash provided by financing activities for the year ended December 31, 2014 related primarily to the $9.4 million of net proceeds generated from our December 2014 private placement and the $3.5 million in net proceeds related to our March 2014 private placement. Net cash provided by financing activities for the year ended December 31, 2013 related to $9.8 million in net proceeds from our January 2013 private placement.

Off-balance Sheet Arrangements

We are not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a material current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Operating Capital and Capital Expenditure Requirements

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

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

- the timing of broader market acceptance and adoption of our ClearPoint system products;
- the scope, rate of progress and cost of our ongoing product development activities relating to our ClearPoint system;
- the cost and timing of expanding our sales, clinical support, marketing and distribution capabilities, and other corporate infrastructure;
- the cost and timing of establishing inventories at levels sufficient to support our sales;
- the effect of competing technological and market developments;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- the scope, rate of progress and cost of our research and development activities relating to our ClearTrace system;
- the cost and timing of any clinical trials;
- the cost and timing of regulatory filings, clearances and approvals; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The Report of Independent Registered Public Accounting Firm and Financial Statements are set forth on pages F-1 to F-25 of this Annual Report.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Management's Evaluation of Disclosure Controls and Procedures

We have established disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Exchange Act. Our disclosure controls and procedures are designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others within our organization. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2014 to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure.

Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2014 (the end of the period covered by this Annual Report).

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with United States generally accepted accounting principles. Any system of internal control, no matter how well designed, has inherent limitations, including the possibility that a control can be circumvented or overridden and misstatements due to error or fraud may occur and not be detected. Also, because of changes in conditions, internal control effectiveness may vary over time. Accordingly, even an effective system of internal control will provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2014, based on the criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2014.

Changes in Internal Control over Financial Reporting

During the quarter ended December 31, 2014, there were no changes in our internal control over financial reporting that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2014, pursuant to Regulation 14A under the Exchange Act in connection with our 2015 annual meeting of stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2014, pursuant to Regulation 14A under the Exchange Act in connection with our 2015 annual meeting of stockholders.

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

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2014, pursuant to Regulation 14A under the Exchange Act in connection with our 2015 annual meeting of stockholders.

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

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2014, pursuant to Regulation 14A under the Exchange Act in connection with our 2015 annual meeting of stockholders.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2014, pursuant to Regulation 14A under the Exchange Act in connection with our 2015 annual meeting of stockholders.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)(1) The following documents are filed under “Item 8. Financial Statements and Supplementary Data,” pages F-1 through F-25, and are included as part of this Annual Report:

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

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

(b) Exhibits

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation	10-Q	000-54575	3.1	May 11, 2012
3.2	Amended and Restated Bylaws	10-Q	000-54575	3.2	May 11, 2012
4.1	Reference is made to Exhibits 3.1 and 3.2				
4.2	Specimen of Common Stock Certificate	10-Q	000-54575	4.2	November 14, 2014
4.3	Amended and Restated Subordinated Secured Note Due 2016 issued to Brainlab AG	8-K	000-54575	4.1	March 7, 2013
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	10	000-54575	4.4	December 28, 2011
4.5	Third Omnibus Amendment to the Junior Secured Promissory Notes Due 2020, dated March 25, 2014	S-1	333-201471	4.5	January 13, 2015
4.6	Form of Warrant issued to purchasers in the July 2012 private placement to purchase shares of common stock of MRI Interventions, Inc.	8-K	000-54575	4.1	July 6, 2012
4.7	Form of Warrant issued to purchasers in the January 2013 private placement to purchase shares of common stock of MRI Interventions, Inc.	8-K	000-54575	4.1	January 22, 2013
4.8	Form of 12% Second-Priority Secured Non-Convertible Promissory Note Due 2019 issued in March 2014 private offering	8-K	000-54575	4.1	March 10, 2014
4.9	Form of Warrant to Purchase Common Stock issued in March 2014 private offering	8-K	000-54575	4.2	March 10, 2014
4.10	Form of Warrant to Purchase Common Stock issued in December 2014 private offering	8-K	000-54575	4.1	December 19, 2014
10.1†	Master Security Agreement dated April 5, 2011 by and between SurgiVision, Inc. and Brainlab AG	10	000-54575	10.18	December 28, 2011
10.2	Security Agreement by and between MRI Interventions, Inc. and Landmark Community Bank, in its capacity as collateral agent, dated as of March 25, 2014	S-1	333-201471	10.2	January 13, 2015
10.3	Junior Security Agreement by and between SurgiVision, 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	000-54575	10.6	December 28, 2011
10.4	Third Amendment to Junior Security Agreement by and between MRI Interventions, Inc and Landmark Community Bank, in its capacity as collateral agent, dated March 25, 2014	S-1	333-201471	10.4	January 13, 2015
10.5†	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	000-54575	10.9	December 28, 2011

10.6†	License Agreement by and between SurgiVision, Inc. and The Johns Hopkins University entered into on or around December 7, 2006	10	000-54575	10.10	December 28, 2011

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.7†	License Agreement by and between SurgiVision, Inc. and The Johns Hopkins University entered into on or around June 30, 2008	10	000-54575	10.21	December 28, 2011
10.8†	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	000-54575	10.11	March 15, 2012
10.9†	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	10	000-54575	10.12	March 15, 2012
10.10†	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	10	000-54575	10.38	March 15, 2012
10.11†	Omnibus Amendment No. 4 to Technology License Agreement and System and Lead Development and Transfer Agreement, between MRI Interventions, Inc. and Boston Scientific Neuromodulation Corporation, effective March 19, 2014	10-Q/A	000-54575	10.5	August 29, 2014
10.12†	Technology License Agreement dated as of March 19, 2008 by and between SurgiVision, Inc. and Cardiac Pacemakers, Inc.	10	000-54575	10.13	December 28, 2011
10.13†	Omnibus Amendment No. 1 to Technology License Agreement and Development Agreement between MRI Interventions, Inc. and Cardiac Pacemakers, Inc., dated March 19, 2014	10-Q/A	000-54575	10.4	August 29, 2014
10.14†	Development Agreement dated as of March 19, 2008 by and between SurgiVision, Inc. and Cardiac Pacemakers, Inc.	10	000-54575	10.14	December 28, 2011
10.15†	Asset Purchase Agreement dated March 19, 2014 between MRI Interventions, Inc. and Boston Scientific Neuromodulation Corporation	10-Q/A	000-54575	10.2	August 29, 2014
10.16†	Exclusive License Agreement dated March 19, 2014 between MRI Interventions, Inc. and Boston Scientific Neuromodulation Corporation	10-Q/A	000-54575	10.3	August 29, 2014
10.17†	Development Agreement between MRI Interventions, Inc. and Siemens Medical Solutions USA, Inc., dated February 21, 2014	10-Q/A	000-54575	10.1	August 29, 2014
10.18†	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	000-54575	10.17	March 15, 2012
10.19	Second Amendment to Co-Development and Distribution Agreement, dated March 6, 2013, between MRI Interventions, Inc. and Brainlab AG	8-K	000-54575	10.1	March 7, 2013
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	000-54575	10.2	March 15, 2012

10.21†	Second Amendment to the Master Services and Licensing Agreement, dated as of June 22, 2012, by and between Merge Healthcare Canada Corp. and MRI Interventions, Inc.	8-K	000-54575	10.1	June 26, 2012
10.22†	Third Amendment to the Master Services and Licensing Agreement, dated as of July 28, 2013, by and between Merge Healthcare Canada Corp. and MRI Interventions, Inc.	10-Q	000-54575	10.56	August 14, 2013

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.23	Lease Agreement, dated as of April 21, 2008, by and between Shaw Investment Company, LLC and Surgi-Vision, Inc., as amended by that certain Amendment to Lease dated January 20, 2011, as further amended by that certain Amendment to Lease dated March 26, 2012	10-Q	000-54575	10.27	May 11, 2012
10.24*	Second Amendment to Lease Agreement dated as of February 24, 2015, by and between Shaw Investment Company, LLC and MRI Interventions, Inc.				
10.25	Form of Securities Purchase Agreement by and among MRI Interventions, Inc. and the investors party thereto with respect to January 2013 private offering	8-K	000-54575	10.1	January 22, 2013
10.26	Form of Registration Rights Agreement by and among MRI Interventions, Inc. and the investors party thereto	8-K	000-54575	10.2	January 22, 2013
10.27	Form of Securities Purchase Agreement by and among MRI Interventions, Inc. and the investors party thereto with respect to March 2014 private offering	8-K	000-54575	10.1	March 10, 2014
10.28	Form of Securities Purchase Agreement by and among MRI Interventions, Inc. and the investors party thereto with respect to December 2014 private offering	8-K	000-54575	10.1	December 19, 2014
10.29	Form of Registration Rights Agreement by and among MRI Interventions, Inc. and the investors party thereto	8-K	000-54575	10.2	December 19, 2014
10.30+	2007 Stock Incentive Plan	10	000-54575	10.2	December 28, 2011
10.31+	2007 Stock Incentive Plan Form of Incentive Stock Option Agreement	10-K	000-54575	10.26	March 28, 2014
10.32+	2007 Stock Incentive Place Form of Non-Qualified Stock Option Agreement	10-K	000-54575	10.27	March 28, 2014
10.33+	2010 Incentive Compensation Plan	10	000-54575	10.4	December 28, 2011
10.34+	2010 Non-Qualified Stock Option Plan	10	000-54575	10.5	December 28, 2011
10.35+	2010 Non-Qualified Stock Option Plan Form of Non-Qualified Stock Option Agreement	10-K	000-54575	10.30	March 28, 2014
10.36+	2010 Non-Qualified Stock Option Plan Form of Non-Qualified Stock Option Agreement for Non-Employee Directors	10-K	000-54575	10.31	March 28, 2014
10.37+	MRI Interventions, Inc. 2012 Incentive Compensation Plan	10	000-54575	10.34	February 9, 2012
10.38+	MRI Interventions, Inc. 2012 Incentive Compensation Plan Form of Incentive Stock Option Agreement	10	000-54575	10.35	February 9, 2012
10.39+	MRI Interventions, Inc. 2012 Incentive Compensation Plan Form of Non-Qualified Stock Option Agreement	10	000-54575	10.36	February 9, 2012
10.40+	MRI Interventions, Inc. 2012 Incentive Compensation Plan Form of Non-Qualified Incentive Stock Option Agreement for Non-Employee Directors	10-K	000-54575	10.35	March 28, 2014
10.41+	MRI Interventions, Inc. 2013 Incentive Compensation Plan	Schedule 14A	000-54575	A	May 1, 2013
10.42+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Incentive Stock Option Agreement	10-Q	000-54575	10.53	August 14, 2013

10.43+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Non-Qualified Stock Option Agreement	10-Q	000-54575	10.54	August 14, 2013
10.44+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Non-Qualified Stock Option Agreement for Non-Employee Directors	10-Q	000-54575	10.55	August 14, 2013
10.45+	MRI Interventions, Inc. 2013 Non-Employee Director Equity Incentive Plan	8-K	000-54575	10.1	December 6, 2012
10.46+	MRI Interventions, Inc. 2013 Non-Employee Director Equity Incentive Plan Form of Non-Qualified Stock Option Agreement	10-K	000-54575	10.41	March 28, 2014

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.47+	MRI Interventions, Inc. Non-Employee Director Compensation Plan	8-K	000-54575	10.2	June 14, 2013
10.48+	Form of Indemnification Agreement	10	000-54575	10.8	December 28, 2011
10.49+	Employment Agreement, dated as of June 19, 2012, by and between Kimble L. Jenkins and MRI Interventions, Inc.	8-K	000-54575	10.1	June 21, 2012
10.50+	Employment Agreement, dated as of January 1, 2015, by and between Kimble L. Jenkins and MRI Interventions, Inc.	8-K	000-54575	10.1	December 31, 2014
10.51+	Employment Agreement, dated as of September 9, 2014, by and between Francis P. Grillo and MRI Interventions, Inc.	8-K	000-54575	10.1	September 11, 2014
10.52+	Employment Agreement, dated as of November 10, 2012, by and between Robert C. Korn and MRI Interventions, Inc.	S-1	333-186573	10.47	February 11, 2013
10.53+	Employment Agreement, dated as of September 12, 2014, by and between David W. Carlson and MRI Interventions, Inc.	8-K	000-54575	10.1	September 12, 2014
10.54+	Employment Agreement, dated as of September 12, 2014, by and between Oscar L. Thomas and MRI Interventions, Inc.	S-1	333-201471	10.53	January 13, 2015
10.55+	Second Amended and Restated Key Personnel Incentive Program	10-Q	000-54575	10.3	August 14, 2013
10.56+	Second Amended and Restated Key Personnel Incentive Award Agreement, dated June 13, 2013, by and between MRI Interventions, Inc. and Paul A. Bottomley	10-Q	000-54575	10.31	August 14, 2013
10.57+	Amended and Restated Key Personnel Incentive Award Agreement, dated June 13, 2013, by and between MRI Interventions, Inc. and Paul A. Bottomley	10-Q	000-54575	10.32	August 14, 2013
10.58+	Second Amended and Restated Key Personnel Incentive Award Agreement, dated June 13, 2013, by and between MRI Interventions, Inc. and Parag V. Karmarkar	10-Q	000-54575	10.33	August 14, 2013
10.59+	SurgiVision, Inc. Cardiac EP Business Participation Plan	10	000-54575	10.29	December 28, 2011
10.60+	Cardiac EP Business Participation Plan Award Agreement, dated June 3, 2010, by and between SurgiVision, Inc. and Nassir F. Marrouche	10	000-54575	10.30	December 28, 2011
10.61+	Non-Qualified Stock Option Agreement, effective as of November 10, 2012, granted by MRI Interventions, Inc. to Robert C. Korn	S-8	333-191908	99.3	October 25, 2013
10.62+	Non-Qualified Stock Option Agreement, effective as of December 5, 2013, granted by MRI Interventions, Inc. to Parag Karmarkar	10-K	000-54575	10.56	March 28, 2014
10.63+	Non-Qualified Stock Option Agreement, effective as of December 5, 2013, granted by MRI Interventions, Inc. to Paul A. Bottomley	10-K	000-54575	10.57	March 28, 2014
10.64+	Non-Qualified Stock Option Agreement, effective as of October 6, 2014, granted by MRI Interventions, Inc. to Francis P. Grillo	S-1	333-201471	10.63	January 13, 2015
10.65+	Non-Qualified Stock Option Agreement, effective as of November 10, 2014, granted by MRI Interventions, Inc. to Robert C. Korn	S-1	333-201471	10.64	January 13, 2015
10.66+	Non-Qualified Stock Option Agreement, effective as of	S-1	333-201471	10.65	January 13, 2015

	December 1, 2014, granted by MRI Interventions, Inc. to Wendelin C. Maners
21*	Subsidiaries of MRI Interventions, Inc.
23.1*	Consent of Cherry Bekaert LLP
24.1*	Power of Attorney (included on the signature pages hereto)
31.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934
31.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
32++	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Rule 13a-14(b) Under the Securities Exchange Act of 1934 and Section 1350 of Chapter 60 of Title 18 of the United States Code				
101.INS*	XBRL Instance				
101.SCH*	XBRL Taxonomy Extension Schema				
101.CAL*	XBRL Taxonomy Extension Calculation				
101.DEF*	XBRL Taxonomy Extension Definition				
101.LAB*	XBRL Taxonomy Extension Labels				
101.PRE*	XBRL Taxonomy Extension Presentation				

* Filed herewith.

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

\+ Indicates management contract or compensatory plan.

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

SIGNATURES

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

MRI INTERVENTIONS, INC.

Date: March 17, 2015

/s/ Francis P. Grillo
Francis P. Grillo
Chief Executive Officer and President
(Principal Executive Officer)

POWER OF ATTORNEY

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Francis P. Grillo **Francis P. Grillo**	*President and Chief Executive Officer* *(Principal Executive Officer)*	March 17, 2015
/s/ David W. Carlson **David W. Carlson**	*Chief Financial Officer* *(Principal Financial Officer and Principal Accounting Officer)*	March 17, 2015
/s/ Kimble L. Jenkins **Kimble L. Jenkins**	*Chairman and Director*	March 17, 2015
/s/ Pascal E.R. Girin **Pascal E.R. Girin**	*Director*	March 17, 2015
/s/ Charles E. Koob **Charles E. Koob**	*Director*	March 17, 2015
/s/ Philip A. Pizzo **Philip A. Pizzo**	*Director*	March 17, 2015
/s/ Timothy T. Richards **Timothy T. Richards**	*Director*	March 17, 2015
/s/ Andrew K. Rooke **Andrew K. Rooke**	*Director*	March 17, 2015
/s/ Michael J. Ryan **Michael J. Ryan**	*Director*	March 17, 2015
/s/ Maria Sainz **Maria Sainz**	*Director*	March 17, 2015
/s/ John N. Spencer, Jr. **John N. Spencer, Jr.**	*Director*	March 17, 2015

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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 consolidated balance sheets of MRI Interventions, Inc. and subsidiary (the "Company") as of December 31, 2014 and 2013, and the related consolidated statements of operations, stockholders' deficit and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the accompanying consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of MRI Interventions, Inc. and subsidiary as of December 31, 2014 and 2013 and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the consolidated financial statements, the Company recognized net losses of approximately $4.5 million, and $7.1 million during 2014 and 2013, respectively. At December 31, 2014 the Company had incurred cumulative net losses of approximately $77.3 million. Management's plans in regard to this matter are described in Note 1.

/s/ Cherry Bekaert LLP
Charlotte, North Carolina
March 17, 2015

MRI INTERVENTIONS, INC.

Consolidated Balance Sheets

	December 31,	
	2014	**2013**
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 9,244,006	$ 3,516,244
Accounts receivable	468,949	770,352
Inventory, net	1,965,039	1,477,161
Prepaid expenses and other current assets	29,220	174,870
Total current assets	11,707,214	5,938,627
Property and equipment, net	482,970	903,160
Software license inventory	910,000	927,500
Other assets	285,498	103,783
Total assets	$ 13,385,682	$ 7,873,070
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 997,090	$ 1,376,627
Accrued compensation	323,644	210,359
Other accrued liabilities	1,297,712	310,317
Derivative liabilites	2,198,162	3,747,858
Deferred product and service revenues	102,710	106,859
Related party convertible notes payable	-	4,338,601
Total current liabilities	4,919,318	10,090,621
Accrued interest	876,025	531,830
Senior note payable, net of unamortized discount of $271,306 and $437,261 at December 31, 2014 and December 31, 2013, respectively	4,018,139	3,852,183
2010 junior secured notes payable, net of unamortized discount of $2,683,171 and $2,767,595 at December 31, 2014 and December 31, 2013, respectively	316,829	232,405
2014 junior secured 12% notes payable, net of unamortized discount of $369,299 at December 31, 2014	3,355,701	-
Total liabilities	13,486,012	14,707,039
Commitments and contingencies (Notes 5, 6, 7, 8 , 9, 10, and 11)		
Stockholders' deficit:		
Common stock, $0.01 par value; 100,000,000 shares authorized; 74,842,428 shares issued and outstanding at December 31, 2014; and 58,536,972 issued and outstanding, at December 31, 2013	748,424	585,369
Additional paid-in capital	76,428,580	65,333,264
Accumulated deficit	(77,277,334)	(72,752,602)
Total stockholders' deficit	(100,330)	(6,833,969)
Total liabilities and stockholders' deficit	$ 13,385,682	$ 7,873,070

See notes to consolidated financial statements.

MRI INTERVENTIONS, INC.

Consolidated Statements of Operations

	Years Ended December 31,	
	2014	**2013**
Revenues:		
Product revenues	$ 3,378,765	$ 2,914,774
Development service revenues	103,846	283,764
Other service revenues	121,871	82,037
Related party license revenues	-	650,000
Total revenues	3,604,482	3,930,575
Cost of product revenues	1,927,138	1,421,148
Research and development costs	3,297,112	2,922,912
Selling, general, and administrative expenses	8,039,455	7,061,286
Gain on sale of intellectual property	(4,338,601)	-
Operating loss	(5,320,622)	(7,474,771)
Other income (expense):		
Gain on change in fair value of deriviative liabilities	1,549,696	1,686,478
Gain on forgiveness of amounts in accounts payable	77,837	477,263
Loss on note payable modification	-	(1,356,177)
Other income, net	175,547	56,228
Interest income	11,617	24,544
Interest expense	(1,018,807)	(499,839)
Net loss	$ (4,524,732)	$ (7,086,274)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.08)	$ (0.12)
Weighted average shares outstanding:		
Basic and diluted	59,240,848	57,261,713

See notes to consolidated financial statements.

MRI INTERVENTIONS, INC.

Consolidated Statements of Stockholders' Deficit
Years Ended December 31, 2013 and 2014

	Common Stock		Additional Paid-in	Treasury	Accumulated	
	Shares	Amount	Capital	Stock	Deficit	Total
Balances, January 1, 2013	48,093,000	$ 484,187	$ 58,995,972	$ (1,679,234)	$ (65,666,328)	$ (7,865,403)
January 2013 Private Placement	9,201,684	92,017	6,407,533	-	-	6,499,550
Share-based compensation	-	-	1,458,271	-	-	1,458,271
Warrant exercises	1,127,829	11,278	8,347	-	-	19,625
Issuance of common stock in payment of director fees	114,459	1,145	139,117	-	-	140,262
Retirement of treasury stock	-	(3,258)	(1,675,976)	1,679,234	-	-
Net loss for the year	-	-	-	-	(7,086,274)	(7,086,274)
Balances, December 31, 2013	58,536,972	585,369	65,333,264	-	(72,752,602)	(6,833,969)
Share-based compensation	-	-	880,765	-	-	880,765
Issuance of common stock in payment of accounts payable	189,752	1,898	260,170	-	-	262,068
Issuance of common stock in payment of director fees	140,396	1,403	147,988	-	-	149,391
Warrants issued in connection with March 2014 Debt Private Placement	-	-	443,267	-	-	443,267
Option exercises	162,500	1,625	141,375	-	-	143,000
December 2014 Private Placement	15,812,808	158,129	9,221,751	-	-	9,379,880
Net loss for the year	-	-	-	-	(4,524,732)	(4,524,732)
Balances, December 31, 2014	74,842,428	$ 748,424	$ 76,428,580	$ -	$ (77,277,334)	$ (100,330)

See notes to consolidated financial statements.

MRI INTERVENTIONS, INC.

Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2014	**2013**
Cash flows from operating activities:		
Net loss	$ (4,524,732)	$ (7,086,274)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and license amortization	377,261	426,183
Share-based compensation	880,765	1,458,271
Expenses paid through the issuance of common stock	411,459	140,262
Gain on change in fair value of derivative liabilities	(1,549,696)	(1,686,478)
Gain on negotiated reductions in account payable	(77,837)	(477,263)
Gain on sale of intellectual property	(4,338,601)	-
Loss on loan modification	-	1,356,177
Amortization of debt issuance costs and and original issue discounts	330,987	143,418
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	301,403	(324,920)
Inventory	(345,988)	(309,551)
Prepaid expenses and other current assets	145,650	(63,997)
Other assets	-	(2,550)
Accounts payable and accrued expenses	1,143,175	(695,343)
Deferred revenue	(4,149)	(655,866)
Net cash flows from operating activities	(7,250,303)	(7,777,931)
Cash flows from investing activities:		
Purchases of property and equipment	(48,129)	(74,469)
Acquisition of license	-	(100,000)
Net cash flows from investing activities	(48,129)	(174,469)
Cash flows from financing activities:		
Net proceeds from equity private placements	9,379,880	9,829,014
Net proceeds from debt private placement	3,503,314	-
Proceeds from stock option and warrant exercises	143,000	19,625
Net cash flows from financing activities	13,026,194	9,848,639
Net change in cash and cash equivalents	5,727,762	1,896,239
Cash and cash equivalents, beginning of year	3,516,244	1,620,005
Cash and cash equivalents, end of year	$ 9,244,006	$ 3,516,244
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ -	$ -
Interest	$ 223,500	$ 11,168

See notes to consolidated financial statements.

MRI INTERVENTIONS, INC.

Consolidated Statements of Cash Flows

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

- During the years ended December 31, 2014 and 2013, a net amount of ClearPoint system reusable components with costs of $221,021 and $143,372, respectively, and accumulated depreciation of $96,631 and $115,952, respectively, were transferred from loaned systems to inventory at the net carrying cost.

- In March 2014, the Company entered into an asset purchase agreement to sell certain intellectual property. The asset purchase price was satisfied through the cancellation of related party convertible notes payable in the aggregate amount of $4,338,601.

- In recording the March 2014 debt private placement transaction, the Company recorded the fair value of the warrants issued to the placement agent, in the amount of $30,210, as a deferred financing cost, and the Company recorded a corresponding amount to additional paid-in capital. In addition, warrants with a relative fair value of $413,057 were issued to investors in the debt private placement transaction (see Note 6). The relative fair value of these warrants was recorded as additional paid-in capital which resulted in a corresponding debt discount.

- In March 2013, in connection with a loan modification, accrued interest in the amount of $389,444 was rolled into the principal balance of a note payable and the principal balance of the note was increased by an additional $1,900,000.

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

See notes to consolidated financial statements.

1. Description of the Business and Liquidity

MRI Interventions, Inc. (the "Company") is a medical device company focused on the development and commercialization of technology that enables physicians to see inside the brain and heart using direct, intra-procedural magnetic resonance imaging ("MRI") guidance while performing minimally invasive surgical procedures. The Company was incorporated in the state of Delaware in March 1998. The Company's principal executive office and principal operations are located in Irvine, California. The Company established MRI Interventions (Canada) Inc., a wholly-owned subsidiary incorporated in Canada, in August 2013. This subsidiary was established primarily for the purpose of performing software development, and its activities are reflected in these consolidated financial statements.

The Company's ClearPoint system, an integrated system comprised of reusable and disposable products, is designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. The Company received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") in 2010 to market the ClearPoint system in the United States for general neurological interventional procedures. The Company's ClearTrace system is a product candidate under development that is designed to allow catheter-based minimally invasive procedures in the heart to be performed in an MRI suite.

Liquidity and Management's Plans

For the years ended December 31, 2014 and 2013, the Company incurred net losses of $4,524,732 and $7,086,274, respectively, and the cumulative net loss since the Company's inception through December 31, 2014 was $77,277,334. The Company believes such losses may continue through at least the year ending December 31, 2015, as the Company continues to commercialize its ClearPoint system and pursue research and development activities. Net cash used in operations was $7,250,303 and $7,777,931 for the years ending December 31, 2014 and 2013, respectively. Since inception, the Company has financed its activities principally from the sale of equity securities, the issuance of notes payable and license arrangements.

The Company's primary financing activities during the years ended December 31, 2014 and 2013 were:

- a December 2014 equity private placement (see Note 7), which resulted in net proceeds of $9,379,880;
- a March 2014 private offering (see Note 6), which resulted in net proceeds of $3,503,314; and
- a January 2013 equity private placement (see Note 7), which resulted in net proceeds of $9,829,014.

While the Company expects to continue to use cash in operations, the Company believes its existing cash and cash equivalents at December 31, 2014 of $9,244,006, combined with cash expected to be generated from product sales, will be sufficient to meet its anticipated cash requirements through at least March 31, 2016.

During 2015, the Company expects to increase revenues from sales of ClearPoint system products as a result of greater utilization at existing installed sites and an increase in the number of installed sites. Certain planned expenditures are discretionary and could be deferred if the Company is required to do so to fund critical operations.

To the extent the Company's available cash and cash equivalents are insufficient to satisfy its long-term operating requirements, the Company will need to seek additional sources of funds from the sale of equity or debt securities or through a credit facility, or the Company will need to modify its current business plan. There can be no assurances that the Company will be able to obtain additional financing on commercially reasonable terms, if at all. The sale of additional equity or convertible debt securities would likely result in dilution to the Company's current stockholders.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

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

Cash and Cash Equivalents

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

Derivative Liability for Warrants to Purchase Common Stock

Derivative liabilities for warrants represents the fair value of warrants issued in connection with certain private placements of shares of the Company's common stock (see Note 7). The fair values of these warrants are presented as liabilities based on certain net cash settlement and exercise price reset, or "down round," provisions. These derivative liabilities, which are recorded on the accompanying consolidated balance sheets, are calculated utilizing the Monte Carlo simulation valuation method. Changes in the fair values of these warrants are recognized as other income or expense in the related statement of operations.

Other Derivative Financial Instruments

The Company adjusts its derivative financial instruments to fair value at each balance sheet date (see Note 6). Changes in the fair values of derivatives are recorded each reporting period as gains or losses in the statements of operations unless the derivatives qualify for hedge accounting. At December 31, 2014 and 2013, the Company did not have any derivative instruments that were designated as hedges.

Fair Value Measurements

The Company measures and records certain financial assets and liabilities at fair value on a recurring basis. GAAP provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority, referred to as Level 1, to quoted prices in active markets for identical assets and liabilities. The next priority, referred to as Level 2, is given to quoted prices for similar assets or liabilities in active markets or quoted prices for identical or similar assets or liabilities in markets that are not active; that is, markets in which there are few transactions for the asset or liability. The lowest priority, referred to as Level 3, is given to unobservable inputs. The table below reflects the level of the inputs used in the Company's fair value calculation for instruments carried at fair value at (see Note 7):

	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value
December 31, 2014				
Derivative liabilities - warrants	$ -	$ -	$ 2,198,162	$ 2,198,162
December 31, 2013				
Derivative liabilities - warrants	$ -	$ -	$ 3,747,858	$ 3,747,858

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

The table below reflects the carrying values and the estimated fair values, based on Level 3 inputs, of the Company's outstanding notes payable including the related accrued interest at December 31, 2014:

	Carrying Values	Estimated Fair Value
Senior secured note payable, including accrued interest	$ 4,456,665	$ 4,456,665
2014 junior secured notes payable, including accrued interest	3,475,826	3,845,125
2010 junior secured notes payable, including accrued interest	754,328	2,305,171

Inventory

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

Property and Equipment

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

Impairment of Long-Lived Assets

The Company evaluates the recoverability of its long-lived assets (finite-lived intangible assets and property and equipment). Whenever events or changes in circumstances indicate that the carrying amount of such assets may not be fully recoverable, the expected undiscounted future cash flows are compared to the net book value of the related assets. If the net book value of the related assets exceeds the undiscounted expected future cash flows of the assets, the carrying amount would be reduced to the present value of the expected future cash flows and an impairment loss would be recognized. The Company has not recorded any impairment losses for the years ended December 31, 2014 or 2013.

Revenue Recognition

The Company's revenues are comprised of: (1) product revenues resulting from the sale of ClearPoint system reusable products, disposable products and ClearTrace system components; (2) license and development arrangements; (3) development service revenues; and (4) other service revenues. The Company recognizes revenue when persuasive evidence of an arrangement exists, the selling price or fee is fixed or determinable, collection is reasonably assured and, for product revenues, 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. The Company analyzes revenue recognition on an agreement by agreement basis. The Company determines whether the deliverables under the arrangement represent separate units of accounting as defined by GAAP. Application of GAAP regarding multiple-element arrangements requires management to make subjective judgments about the values of the individual elements and whether delivered elements are separable from the other aspects of the contractual relationship.

(1) Product Revenues

Sales of ClearPoint system reusable products: Generally, revenues related to the sale of ClearPoint system reusable products 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 installation. Reusable products include software which is integral to the utility of the system as a whole. Sales of reusable products that have stand-alone value to the customer are recognized when risk of loss passes to the customer. Sales of ClearPoint reusable products to a distributor that has been trained to perform system installations and to conduct ClearPoint physician training are recognized at the time risk of loss passes to the distributor.

Sales of disposable products: Revenues from the sale of disposable products, including ClearPoint system disposable products, are recognized at the time risk of loss passes to the customer, which is generally at shipping point or upon delivery to the customer's location, depending on the agreed upon terms with the customer.

Sales of ClearTrace components: Sales of ClearTrace system components to research sites for non-commercial use are recognized at the time risk of loss passes to the customer, which is generally at shipping point or upon delivery to the customer's location, depending on the agreed upon terms with the customer. The Company does not have regulatory clearance or approval to sell ClearTrace system components for commercial use.

(2) License and Development Arrangements —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.

(3) *Development Service Revenues* — The Company entered into an agreement to provide development services to a third party. Under the agreement, the Company earned revenue equal to costs incurred for outside expenses related to the development services provided, plus actual direct internal labor costs (including the cost of employee benefits), plus an overhead markup of the direct internal labor costs incurred. Revenue was recognized in the period in which the Company incurred the related costs.

(4) *Other Service Revenues* — Other service revenues are comprised of installation fees, training fees, shipping fees and service fees charged in connection with ClearPoint system installations and ClearPoint service agreements. Typically, the Company will bill upfront for service agreements, which have terms ranging from one to three years. These amounts are recognized as revenues ratably over the term of the related service agreement.

Product Warranties

The Company's standard policy is to warrant ClearPoint system reusable products against defects in material or workmanship for one year following installation. The Company's estimate of costs to service the warranty obligations is based on historical experience and continues to be an immaterial amount. A periodic review of warranty obligations is performed to determine the adequacy of the reserve and adjustments, recorded to cost of product revenues, are made to the estimated warranty liability (included in other accrued liabilities) as appropriate.

Research and Development Costs

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

Income Taxes

Deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective income tax basis. Such assets and liabilities are measured using enacted tax rates expected to apply to taxable income or loss 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. The Company provides a valuation allowance against net deferred income tax assets unless, based upon available evidence, it is more likely than not the deferred income tax assets will be realized. The Company recognizes interest and penalties related to unrecognized tax benefits as a component of income tax expense. As of December 31, 2014 and 2013, the Company had no accrued interest or penalties related to uncertain tax positions.

Net Loss Per Share

Basic loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without giving consideration to common stock equivalents. Diluted loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. The calculation of diluted net loss per share does not include the weighted average number of common stock equivalents outstanding for the period because to do so would be anti-dilutive. Accordingly, 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 of the anti-dilutive result:

	As of December 31,	
	2014	**2013**
Stock options	10,343,309	7,430,225
Warrants	20,759,136	12,136,865
Shares under convertible note agreements	-	542,325
	31,102,445	20,109,415

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

Fair Value Determination of Share-Based Transactions

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

Determining the fair value of shares of privately held companies requires making complex and subjective judgments. Prior to the time the Company's common stock was publicly traded, the Company used the income approach, the market approach, and the probability weighted expected return method to estimate the enterprise values for the dates on which these transactions occurred. The assumptions used in each of the different valuation methods take into account certain discounts such as selecting the appropriate discount rate and control and lack of marketability discounts. The discount rates used in these valuations ranged from 22% to 35%. The discounts for lack of marketability ranged from 15% to 35% and the discounts for lack of control ranged from 20% to 30%. If different discount rates or lack of marketability and control discounts had been used, the valuations would have been different. The enterprise value under each valuation method was allocated to preferred and common shares taking into account the enterprise value available to all stockholders and allocating that value among the various classes of stock based on the rights, privileges, and preferences of the respective classes in order to provide an estimate of the fair value of a share of the Company's common stock. There is inherent uncertainty in these estimates.

Concentration Risks 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. At December 31, 2014, the Company had bank balances in excess of the insured limits of approximately $514,000, most of which was held on deposit to satisfy outstanding checks.

Accounts receivable at December 31, 2014 and 2013, and all product revenues recognized for the years ended December 31, 2014 and 2013, relate to sales and services to customers located in the United States ("U.S.") and to one distributor. At December 31, 2014, two customers in the U.S. represented 20% and 17% of the Company's accounts receivable balance. At December 31, 2013, three customers in the U.S. represented 28%, 18% and 15% of the Company's accounts receivable balance. No other customer represented more that 8.5% of total accounts receivable at December 31, 2014 or 2013. For the year ended December 31, 2014, sales to one customer represented 10.4% of product revenues. For the year ended December 31, 2013, sales to one customer represented 20% of product revenues. No other single customer represented greater than 9% of product revenues for the years ended December 31, 2014 or 2013. The Company performs credit evaluations of its customers' financial condition and, generally, requires no collateral from its customers. The Company will provide an allowance for doubtful accounts when collections become doubtful, but the Company has not experienced any credit losses or recorded any allowances to date.

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; uncertainty of widespread market acceptance of products; access to credit for capital purchases by customers; and product liability claims. Certain components used in manufacturing have relatively few alternative sources of supply, and establishing additional or replacement suppliers for such components cannot be accomplished quickly. The inability of any of these suppliers to fulfill the Company's supply requirements may negatively impact future operating results.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers," which creates a new Topic, Accounting Standards Codification ("ASC") Topic 606. The standard is principle-based and provides a five-step model to determine when and how revenue is recognized. The core principle is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This standard is effective for the Company beginning in 2017 and allows for either full retrospective adoption or modified retrospective adoption. The Company is currently evaluating the impact of the adoption of ASC Topic 606 on its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, "Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern," which provides guidance on determining when and how to disclose going-concern uncertainties in financial statements. The new standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued. An entity must provide certain disclosures if "conditions or events raise substantial doubt about the entity's ability to continue as a going concern." The ASU applies to all entities and is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The adoption of this guidance is not expected to have any impact on the Company's consolidated results of operations or financial position. The Company is currently evaluating the impact of this update on future disclosures concerning its liquidity position.

3. Inventory

Inventory consists of the following as of December 31:

	2014	2013
Work in process	$ 899,014	$ 673,860
Software license inventory	350,000	385,000
Finished goods	716,025	418,301
Inventory included in current assets	1,965,039	1,477,161
Software license inventory	910,000	927,500
	$ 2,875,039	$ 2,404,661

4. Property and Equipment

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

	2014	2013
Equipment	$ 1,112,377	$ 1,081,056
Furniture and fixtures	108,983	106,054
Leasehold improvements	157,236	157,236
Computer equipment and software	148,164	134,285
Loaned systems	699,384	920,406
	2,226,144	2,399,037
Less accumulated depreciation and amortization	(1,743,174)	(1,495,877)
Total property and equipment, net	$ 482,970	$ 903,160

Depreciation and amortization expense related to property and equipment for the years ended December 31, 2014 and 2013 was $343,929 and $400,516, respectively. The Company may loan the reusable components of a ClearPoint system to a customer. Any such customer can then use the loaned ClearPoint system to perform procedures using ClearPoint disposable products which are generally purchased from the Company.

5. Sale of Intellectual Property in Exchange for Cancellation of the Boston Scientific Notes

In March 2014, the Company entered into an Asset Purchase Agreement (the "BSC Purchase Agreement") with Boston Scientific. Pursuant to the BSC Purchase Agreement, Boston Scientific purchased from the Company certain MRI-safety technology for implantable medical leads (the "Transferred Intellectual Property") for an aggregate purchase price of $4,338,601. The Transferred Intellectual Property includes some, but not all, of the intellectual property the Company previously licensed exclusively to Boston Scientific within the fields of neuromodulation and implantable medical leads for cardiac applications. The purchase price was satisfied through the cancellation of three convertible notes payable issued by the Company to Boston Scientific, which were scheduled to mature in 2014, in the aggregate principal amount of $4,338,601 (the "Boston Scientific Notes"). Accordingly, all obligations of the Company under the Boston Scientific Notes were discharged and the liens that secured the Company's obligations under the Boston Scientific Notes were terminated and released. The Company recorded a gain in its consolidated statement of operations equal to the aggregate purchase price for the assets sold under the BSC Purchase Agreement.

In connection with the BSC Purchase Agreement, the parties entered into a license agreement pursuant to which Boston Scientific granted the Company an exclusive, royalty-free, fully paid up, irrevocable, worldwide license to the Transferred Intellectual Property, with the right to sublicense, within fields of use other than neuromodulation and implantable medical leads for cardiac applications.

In addition, Boston Scientific and the Company entered into amendments to their pre-existing development and license agreements (the "Pre-existing Agreements"), in the fields of neuromodulation and implantable medical leads for cardiac applications, to eliminate the milestone-based payments and royalties provided under those agreements. As such, the Company is no longer entitled to receive any potential future milestone-based payments or royalties under its development and license agreements with Boston Scientific.

Pursuant to one of the Pre-existing Agreements, the Company received a non-refundable licensing fee of $13,000,000 from Boston Scientific in 2008. The Company recorded the $13,000,000 payment as deferred revenue and recognized the revenue on a straight-line basis over the five year period estimated by the Company for its continuing involvement in the development effort (see Note 2, Revenue Recognition), which period ended on March 31, 2013. The Company reevaluated its estimated remaining period of continuing involvement at each reporting period until all of the revenue that had been deferred was recognized.

The transactions contemplated by the BSC Purchase Agreement do not impact the Company's ability to continue to commercialize its ClearPoint system or to continue the development of its ClearTrace system.

6. Notes Payable

Senior Note Payable

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

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

The Company calculated the fair value of the Amended Brainlab Note, as of the loan modification date, based on the amended terms. On the date of the loan modification, the fair value of the Amended Brainlab Note, with its principal balance of $4,289,444, was $3,745,621. The difference between the fair value of the Amended Brainlab Note on the date of the loan modification and the carrying value of the April 2011 Note and related accrued interest immediately prior to the loan modification, resulted in a charge to other expense of $1,356,177 in the consolidated statement of operations during the year ended December 31, 2013. The $543,823 difference between the principal amount of the Amended Brainlab Note and the fair value of the Amended Brainlab Note on the date of the loan modification was recorded as a debt discount and is being amortized to interest expense using the effective interest method over the term of the Amended Brainlab Note.

2010 Junior Secured Notes Payable

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 and other existing security holders of the Company. 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 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 interests that secure the Amended Brainlab Note and the 2014 Secured Notes. All outstanding principal and interest on the junior secured notes will be due and payable in a single payment upon maturity.

Under GAAP, 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 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 in the offering for $158,816.

2014 Junior Secured 12% Notes Payable

In March 2014, the Company entered into securities purchase agreements for the private placement of (i) 12% second-priority secured non-convertible promissory notes maturing in 2019 (the "2014 Secured Notes") and (ii) warrants to purchase 0.3 share of the Company's common stock for each dollar in principal amount of the 2014 Secured Notes sold by the Company. Pursuant to those securities purchase agreements, the Company sold 2014 Secured Notes in a total aggregate principal amount of $3,725,000, together with warrants to purchase up to 1,117,500 shares of common stock, for aggregate gross proceeds of $3,725,000, before placement agent commissions and other expenses.

The 2014 Secured Notes have a five-year term, and they bear interest at a rate of 12% per year, payable semi-annually, in arrears, on each six-month and one-year anniversary of the issuance date. The 2014 Secured Notes are not convertible into shares of the Company's common stock. Following the third anniversary of the issuance date, the 2014 Secured Notes may be prepaid, without penalty or premium, provided that all principal and unpaid accrued interest under all 2014 Secured Notes is prepaid at the same time. Prior to the third anniversary of the issuance date, the Company may prepay all, but not less than all, of the principal and unpaid accrued interest under the 2014 Secured Notes at any time, subject to the Company's payment of the additional prepayment premium stated in the notes. The 2014 Secured Notes are secured by a security interest in the Company's property and assets, which security interest is junior and subordinate to the security interest that secures the senior secured note payable previously issued by the Company to Brainlab AG, which is discussed below.

The warrants issued to the investors are exercisable, in full or in part, at any time prior to the fifth anniversary of the issuance date, at an exercise price of $1.75 per share, subject to adjustment from time to time for stock splits or combinations, stock dividends, stock distributions, recapitalizations and other similar transactions. Assumptions used in calculating the fair value of the warrants using the Black-Scholes valuation model were:

Dividend yield	0%
Expected Volatility	47.5% - 47.7%
Risk free Interest rates	1.73% - 1.76%
Expected life (in years)	5.0

Under GAAP, the Company allocated the $3,725,000 in proceeds proportionately between the 2014 Secured Notes and the warrants issued to investors based on their relative fair values, with $413,057 being recorded as equity. The 2014 Secured Notes were recorded at the principal amount less a discount equal to the $413,057 amount recorded as equity. This discount is being amortized to interest expense over the five year term of the notes using the effective interest method.

Non-employee directors of the Company invested a total of $1,100,000, either directly or through a trust. The Company's placement agents earned cash commissions of $145,500 as well as warrants to purchase 72,750 shares of the Company's common stock. The placement agent warrants have the same terms and conditions as the investor warrants. The placement agent cash commissions, the $30,210 fair value of the placement agent warrants, and other offering expenses totaling $76,186 were recorded as deferred financing costs and are classified as other assets. These deferred financing costs are being amortized to interest expense over the term of the 2014 Secured Notes using the effective interest method.

Scheduled Notes Payable Maturities

Scheduled principal payments with respect to notes payable is summarized as follows:

Years ending December 31,	
2015	$ -
2016	4,289,445
2017	-
2018	-
2019	3,725,000
Thereafter	3,000,000
Total scheduled principal payments	11,014,445
Less unamortized discounts at December 31, 2014	(3,323,776)
	$ 7,690,669

7. Stockholders' Equity

December 2014 Private Placement

In December 2014, the Company entered into a securities purchase agreement for the private placement of shares of the Company's common stock and warrants to purchase shares of the Company's common stock, at a purchase price of $0.6435 per unit (the "December 2014 Financing Transaction"). Each unit consisted of one share of common stock and a warrant to purchase 0.4 share of common stock.

In the December 2014 Financing Transaction, the Company sold to the investors (the "Investors") 15,812,808 shares of common stock, together with warrants to purchase 6,325,125 shares of common stock (the "Investor Warrants"), for aggregate gross proceeds of $10,175,550, before commissions and offering expenses. One non-employee director of the Company invested $15,000 in the December 2014 Financing Transaction. The Company's placement agents earned cash commissions of $709,839, and the Company incurred other transaction costs of $85,831 related to the financing. In addition to the cash commission, the Company also issued warrants to the placement agents to purchase 1,106,896 shares of common stock (the "Placement Agent Warrants").

The Investor Warrants and the Placement Agent Warrants are exercisable for five years from the date of issuance and have an exercise price of $0.858 per share, subject to adjustment from time to time for stock splits or combinations, stock dividends, stock distributions, recapitalizations and other similar transactions. The Investor Warrants contain a provision permitting the Company to redeem the warrants, to the extent then outstanding as of the redemption date, in the event the closing sale price of the Company's common stock equals or exceeds twice the exercise price of the Investor Warrants for 20 consecutive trading days. Neither the Investor Warrants nor the Placement Agent Warrants contain any down round exercise price reset provision. Both the Investor Warrants and the Placement Agent Warrants are deemed to be indexed to the Company's stock, and as such, the Company recorded the $9,379,880 of net proceeds from the December 2014 Financing Transaction as equity.

At the closing of the December 2014 Financing Transaction, the Company also entered into a registration rights agreement (the "Registration Rights Agreement") with the Investors. Pursuant to the Registration Rights Agreement, the Company was required to prepare and file a registration statement (the "Registration Statement") with the SEC under the Securities Act covering the resale of the shares of common stock issued to the Investors under the securities purchase agreement and the shares of common stock underlying the Investor Warrants and the Placement Agent Warrants. The Company filed the Registration Statement on January 13, 2015 and the Registration Statement was declared effective on January 26, 2015. If the Company fails to continuously maintain the effectiveness of the Registration Statement (with certain permitted exceptions), the Company will incur certain liquidated damages to the Investors. The Registration Rights Agreement also contains mutual indemnifications by the Company and each Investor, which the Company believes are customary for transactions of this type.

In connection with the December 2014 Financing Transaction, the Company entered into derivative restriction agreements with each of its directors and executive officers. Under the derivative restriction agreements, each director and executive officer is prohibited from exercising his or her outstanding options and warrants for shares of common stock until the Company's certificate of incorporation has been amended to provide a number of authorized shares sufficient to permit the Company to reserve shares of common stock for exercise of such options and warrants. Derivative restriction agreements were entered into with respect to 9,141,250 shares underlying outstanding options and warrants held by the Company's directors and executive officers. The purpose of the derivative restriction agreements was to ensure a sufficient number of authorized, unissued and unreserved shares of common stock to enable the Company to consummate the December 2014 Financing Transaction.

January 2013 Private Placement

In January 2013, the Company entered into a securities purchase agreement for the private placement of shares of the Company's common stock and warrants to purchase shares of the Company's common stock, at a purchase price of $1.20 per unit (the "January 2013 Financing Transaction"). Each unit consisted of one share of common stock and a warrant to purchase 0.5 share of common stock.

In the January 2013 Financing Transaction, the Company sold to the investors 9,201,684 shares of common stock, together with warrants to purchase 4,600,842 shares of common stock, for aggregate gross proceeds of $11,042,021, before commissions and offering expenses. The Company's placement agents earned commissions of $1,104,202, and the Company incurred other transaction costs of $133,024 related to the financing. Non-employee directors of the Company invested a total of $402,000 in the January 2013 Financing Transaction.

The warrants issued in the January 2013 Financing Transaction are exercisable for five years from the date of issuance and had an initial exercise price of $1.75 per share, subject to adjustment from time to time for stock splits or combinations, stock dividends, stock distributions, recapitalizations and other similar transactions. The warrants contain a down round exercise price reset provision stating that, in the event the Company issues shares of its common stock or common stock equivalents in a subsequent financing transaction at a price below the then prevailing warrant exercise price, then the exercise price of the warrants will be adjusted downward to the price at which the Company issues the common stock or common stock equivalents. As a result of the December 2014 Financing Transaction, the exercise price of the warrants issued in the January 2013 Financing Transaction has been adjusted to $0.64 per share.

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

Common Stock Warrants Requiring Liability Accounting

The net-cash settlement and down round provisions contained in the warrants issued in the January 2013 Financing Transaction require derivative liability accounting treatment for the warrants. Likewise, a down round provision contained in the terms of warrants issued by the Company in a 2012 financing transaction also requires derivative liability accounting treatment for those warrants. The fair value of all such warrants was calculated using the Monte Carlo simulation valuation method.

Assumptions used in calculating the fair value of the warrants are noted below:

	December 31,		Transaction Date January 2013 Financing
	2014	2013	
Dividend yield	0%	0%	0%
Expected volatility	39.3% - 100.0%	40.4% - 100.0%	47.1% - 100.0%
Risk free interest rates	0.67% - 1.12%	1.01% - 1.27%	0.91%
Expected remaining term (in years)	2.51 to 3.07	3.51 to 4.07	5.00

In addition to the assumptions above, the Company also takes into consideration whether or not it would participate in another round of equity financing and, if so, what that stock price would be for such a financing at that time.

The fair values and the changes in fair values of the warrants accounted for as derivative liabilities are reflected below:

Balance at January 1, 2013	$	2,128,302
Fair value of January 2013 warrants at transaction date		3,305,245
Gain on change in fair value		(1,685,689)
Balance at December 31, 2013		3,747,858
Gain on change in fair value		(1,549,696)
Balance at December 31, 2014	$	2,198,162

Stock Incentive Plans

The Company has various share-based compensation plans and share-based compensatory contracts (collectively, 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, and some of the Plans provide for cash-based awards. Awards may be subject to a vesting schedule as set forth in each individual award agreement.

In June 2013, the stockholders of the Company approved the 2013 Incentive Compensation Plan (the "2013 Plan"). Upon stockholder approval of the 2013 Plan, the Company ceased making awards under a previous plan. A total of 1,250,000 shares of the Company's common stock are reserved for issuance under the 2013 Plan, of which awards as to 1,038,167 shares were outstanding as of December 31, 2014. Thus, awards as to 211,833 shares remained available for grants under the 2013 Plan as of December 31, 2014.

In December 2013, the Company's board of directors approved the 2013 Non-Employee Director Equity Incentive Plan (the "Director Plan"). A total of 570,000 shares of the Company's common stock are reserved for issuance under the Director Plan. The shares reserved for issuance under the Director Plan are intended to be used to cover the stock options granted pursuant to the terms of the Company's Non-Employee Director Compensation Plan. As of December 31, 2014, awards for 295,000 shares had been issued under the Director Plan. Therefore, 275,000 shares remained available for awards under the Director Plan as of December 31, 2014.

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

	Options Outstanding	Options Exercisable (1)	Range of Exercise Prices	Weighted-average Exercise price per share	Intrinsic Value (2)
Balance at January 1, 2013	6,432,127		$ 0.88 - $ 9.64	$ 1.58	$ 1,846,040
Exercisable at January 1, 2013		2,386,909	0.88 - 9.64	2.13	205,000
Granted (3)	1,219,500		1.09 - 1.75	1.43	
Cancelled or forfeited	(221,402)		1.00 - 9.64	4.33	
Outstanding at December 31, 2013	7,430,225		0.88 - 9.64	1.47	1,493,368
Exercisable at December 31, 2013		4,416,292	0.88 - 9.64	1.68	566,589
Granted (3)	3,284,500		0.80 - 1.46	1.09	
Exercised	(162,500)		0.88 - 0.88	0.88	
Cancelled or forfeited	(208,916)		0.88 - 9.64	1.42	
Outstanding at December 31, 2014	10,343,309		0.80 - 9.64	1.36	4,800
Exercisable at December 31, 2014		5,627,505	1.00 - 9.64	1.56	600

(1) Certain of these options are subject to the derivative restriction agreements entered into by the Company's directors and executive officers.

(2) 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.

(3) All options granted during the years ended December 31, 2013 and 2014 were granted with exercise prices which were deemed to be equal to the fair market value of the Company's stock on the date of grant, except for 200,000 options granted in December 2013 that have an exercise price of $1.75, which was deemed to be above fair market value on the date of grant.

The following table summarizes information about stock options at December 31, 2014 (contractual life expressed in years):

	Options Outstanding			Options Exercisable (1)		
Range of Exercise Prices	Number Outstanding	Weighted - Average Remaining Contractual Life	Weighted - Average Exercise Price	Number Exercisable	Weighted - Average Remaining Contractual Life	Weighted - Average Exercise Price
$ 0.80 - $1.13	5,997,567	8.37	$ 1.05	2,055,433	6.71	$ 1.01
1.16 - 2.13	4,252,117	7.37	1.70	3,478,447	6.76	1.76
3.20 - 9.64	93,625	3.14	6.04	93,625	3.14	6.04
	10,343,309	7.91	1.36	5,627,505	6.68	1.56

(1) Certain of these options are subject to the derivative restriction agreements entered into by the Company's directors and executive officers.

The weighted average grant date fair value of options granted during the years ended December 31, 2013 and 2014 was $0.63 and $0.54, respectively. A summary of the status of the Company's nonvested stock options during the years ended December 31, 2013 and 2014 is presented below:

Nonvested Stock Options	Shares	Weighted - Average Grant Date Fair Value
Nonvested January 1, 2013	4,045,218	$ 0.56
Granted	1,219,500	0.63
Forfeited	(94,833)	0.76
Vested	(2,155,952)	0.58
Nonvested December 31, 2013	3,013,933	0.52
Granted	3,284,500	0.54
Forfeited	(46,416)	0.58
Vested	(1,536,213)	0.50
Nonvested December 31, 2014	4,715,804	0.54

As of December 31, 2014, there was a total of approximately $2,045,000 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 2.3 years.

The assumptions used in calculating the fair value under the Black-Scholes option-pricing model are set forth in the following table for options issued by the Company during the:

	Years Ended December 31,	
	2014	2013
Dividend yield	0%	0%
Expected Volatility	49.4% to 51.8%	43.4% to 46.0%
Risk free Interest rates	1.73% to 2.71%	0.92% to 2.10%
Expected lives (in years)	5.5 - 6.0	5.0 - 6.0

Warrants

Outstanding warrants relate primarily to warrants issued in connection with financings. Warrants have been issued for terms of up to five years. Common stock warrants issued, expired and outstanding during the years ended December 31, 2013 and 2014 are as follows:

	Shares	Weighted - Average Exercise Price
Outstanding at January 1, 2013	8,763,836	$ 0.95
Expired	(41,666)	1.00
Issued	4,643,842	1.75
Shares withheld on net settled exercises	(101,318)	0.85
Exercised	(1,127,829)	0.08
Outstanding at December 31, 2013	12,136,865	1.33
Issued	8,622,271	0.98
Outstanding at December 31, 2014	20,759,136	0.91(1)

(1) This weighted-average exercise price reflects the impact of warrant exercise price adjustments triggered by the December 2014 private placement.

The following table summarizes information about outstanding warrants at December 31, 2014 (contractual life expressed in years):

Exercise Price	Number Outstanding	Weighted - Average Remaining Contractual Life	Intrinsic Value (1)
$ 0.60	458,977	3.14	$ 105,565
0.64	4,600,842	2.16	874,160
0.75	2,577,750	2.11	206,220
0.86	7,432,021	4.98	-
0.97	343,578	2.50	-
1.00	1,360,000	2.35	-
1.19	2,727,274	2.50	-
1.75	1,233,250	4.23	-
8.00	25,444	0.24	-
	20,759,136	3.37	$ 1,185,945

(1) Intrinsic value is calculated as the estimated fair value of the Company's stock at December 31, 2014 less the warrant exercise price of in-the-money warrants.

8. Income Taxes

The Company had no income tax expense for the years ended December 31, 2014 and 2013. Due to uncertainties surrounding the realization of its deferred income tax assets in future periods, the Company has recorded a 100% valuation allowance against its net deferred income tax assets. If it is determined in the future that it is more likely than not that any deferred income tax assets are realizable, the valuation allowance will be reduced by the estimated net realizable amounts. For the years ended December 31, 2014 and 2013, the valuation allowance increased by $1,247,481 and $3,022,506, respectively.

The tax effect of temporary differences and net operating losses that give rise to components of deferred income tax assets and liabilities consist of the following:

	As of December 31, 2014	As of December 31, 2013
Deferred income tax assets (liabilities):		
Property and equipment	$ (79,190)	$ (153,864)
Deferred revenue	38,989	40,564
Accrued expenses	50,613	223,022
Share based compensation related	1,738,280	1,554,048
Other	334,217	208,266
Net operating loss carryforwards	24,125,719	23,089,111
	26,208,628	24,961,147
Less valuation allowance	(26,208,628)	(24,961,147)
	$ -	$ -

The Company had a cumulative federal net operating loss of approximately $63,000,000 as of December 31, 2014, which begins to expire in 2015. Under Sections 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 an ownership change has occurred. However, given the equity transactions in which the Company has engaged, the Company believes that the use of the net operating losses shown as deferred tax assets will be significantly limited.

Management has evaluated the effect of guidance provided by GAAP regarding accounting for uncertainty in income taxes and determined the Company has no uncertain tax positions that could have a significant impact on its consolidated financial statements. The Company’s income tax returns after 2010 remain open for examination.

9. Commitments

Leases

The Company leases office space in Tennessee and California under non-cancellable operating leases. The leases expire in 2015. At December 31, 2014, future minimum lease payments under non-cancellable operating leases were $117,638.

Rent expense under all operating leases was approximately $166,000 and $149,000 for the years ended December 31, 2014 and 2013, respectively

Licenses

Certain license arrangements require minimum royalty payments. As of December 31, 2014, future minimum payments under these arrangements are as follows:

Years ending December 31,	
2015	$ 100,000
2016	105,000
2017	115,000
2018	95,000
2019	95,000
Thereafter	795,000
Total minium payments	$ 1,305,000

Royalty payment amounts may be greater than the minimum required payment amounts based on the negotiated royalty rates. If the Company sublicenses the intellectual property that is licensed from the licensor and the Company receives any royalty payment under or with respect to such sublicense, the Company is obligated to pay the licensor an agreed upon percentage of any such payments. Under the terms of these license agreements, the Company is required to reimburse the licensor for costs incurred by the licensor associated with patent filing, prosecution and maintenance. 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.

Co-Development Agreement

In February 2014, the Company and Siemens Medical Solutions USA, Inc. (“Siemens Medical”) entered into a Development Agreement (the “New Siemens Agreement”), which replaced and supersedes the Company’s Cooperation and Development Agreement with Siemens Aktiengesellschaft, Healthcare Sector (“Siemens AG”) entered into in 2009 (the “Original Siemens Agreement”). References below to “Siemens” will mean Siemens Medical or Siemens AG, as applicable.

Under the New Siemens Agreement, the Company, with cooperation, assistance and technical support from Siemens, plans to develop the commercial version of the research software platform created by Siemens under the Original Siemens Agreement. In addition, under the New Siemens Agreement, Siemens developed certain software features (the “Host Features”) for a planned software release for certain Siemens MAGNETOM MRI systems. The Host Features will enable the connection of the Company’s software and catheters to those MAGNETOM MRI systems, and the Company paid Siemens to perform the development work for the Host Features. The Host Features, which are owned by Siemens, will run within the MRI scanner system. The Host Features will then connect to the Company’s software, which will operate on a separate computer workstation, and enable the performance of MRI-guided cardiac ablation procedures. At December 31, 2014, all amounts required to be paid by the Company to Siemens for software development under the New Siemens Agreement had been expensed.

Technical Service and Training Agreements

The Company entered into technical service and training service agreements with a university whereby the Company committed to pay for certain services to be provided. Under the agreements, the Company is obligated to make payments totaling approximately $87,000 during 2015. No payment obligation exists under the agreements beyond 2015.

Master Services and Software License Agreement

In July 2007, the Company entered into a Master Services and Licensing Agreement (the "Master Software Agreement") with Merge Healthcare Canada Corp. f/k/a Cedara Software Corp. ("Merge") for Merge to develop on the Company's behalf, based on the Company's detailed specifications, a customized software solution for the Company's ClearPoint system. Merge was in the business of providing software development and engineering services on a contract basis to a number of companies. In developing the Company's ClearPoint system software, Merge utilized certain of its own pre-existing software code. Under the Master Software Agreement, the Company received a non-exclusive, worldwide license to the pre-existing software code, in object code form, as an integrated component of the Company's ClearPoint system software. In return, the Company agreed to pay Merge a license fee for each copy of the ClearPoint system software that the Company distributes, subject to certain minimum license purchase commitment by the Company.

In July 2013, the Company and Merge entered into an amendment to the Master Software Agreement (the "2013 Software Amendment"). At the Company's request, the parties entered into the 2013 Software Amendment to enable the Company to internally perform development, maintenance and support of its ClearPoint system software going forward. As a result, the services which the Company had been outsourcing to Merge are now performed by the Company itself. Under the 2013 Software Amendment, Merge granted the Company a non-exclusive, non-transferable, worldwide license to the source code for certain Merge software, which as mentioned above had been utilized in Merge's original development work, to use in the Company's further development and commercialization of its ClearPoint system software. In return, the Company agreed to pay Merge a one-time license fee. Merge may terminate the source code license only for cause. The Company will continue to pay Merge a license fee for each copy of the ClearPoint system software that the Company distributes, but only for licenses in excess of those licenses already purchased or otherwise acquired by the Company prior to the 2013 Software Amendment. The Company had already satisfied its minimum license purchase commitments from the Master Software Agreement. The portion of the licenses purchased by the Company that is not expected to be sold or placed in service in the next 12 months has been recorded as a non-current asset, called software license inventory.

Cardiac EP Business Participation Plan

In June 2010, the Company adopted a plan to provide a key product development advisor and consultant with financial rewards in the event that the Company sells its business operations relating to catheter-based MRI-guided cardiac ablation to treat cardiac arrhythmias, which the Company refers to as its cardiac EP operations. In the event the Company sells its cardiac EP operations, whether on a stand-alone basis or as part of the sale of the Company, the participant will receive a payment under the plan equal to (i) the transaction value paid for or allocated to the cardiac EP operations in the sale, multiplied by (ii) the participant's "participation interest" at the time of the sale. The participant was initially awarded a participation interest of 6.6%. However, pursuant to the terms of the plan, the participation interest is equitably reduced from time to time to take into account equity financing transactions in which the Company issues shares of its common stock, or securities convertible into shares of its common stock, in exchange for cash proceeds. At December 31, 2014, the participation interest was 2.5%. The plan will terminate in June 2025.

Employment Agreements

The Company has employment agreements (each, an "Employment Agreement," and collectively, the "Employment Agreements") with seven executive officers (each, an "Executive"). Among other provisions customary for agreements of this nature, the Employment Agreements provide for severance in the event the Company terminates the Executive's employment without cause. Likewise, the Employment Agreements provide for certain payments in connection with a change of control transaction and a termination of employment following a change of control transaction. The Employment Agreements for two of the Executives provide for a retention bonus in the amount of $166,667 to be paid to each of the two Executives if such Executive is still employed by the Company on July 31, 2015. The retention bonus is payable on the earlier of July 31, 2015 or the date on which the Executive's employment is terminated without cause.

Key Personnel Incentive Program

The Company adopted its Key Personnel Incentive Program to provide a consultant and an employee (collectively, the "Participants"), who at the time of adoption of the program were key to the Company's development and licensing activities, with the opportunity to receive incentive bonus payments based on the performance of future services to the Company or upon a consummation of a transaction involving the sale of the Company. In June 2012, the Participants voluntarily and irrevocably relinquished their rights to receive, and the Participants discharged the Company from its obligations to make, any and all incentive bonus payments under the Key Personnel Incentive Program based on the performance of services.

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

10. Legal Proceeding

In June 2013, Custom Equity Research, Inc. d/b/a Summer Street Research Partners ("Summer Street") commenced an arbitration proceeding alleging breach of contract and quantum meruit claims against the Company. Summer Street claimed that the Company owed it additional cash commissions and common stock warrants in connection with the Company's previous engagement of Summer Street to serve as its financial advisor and placement agent. In the arbitration, the Company filed counter-claims against Summer Street alleging fraud and misrepresentation, abuse of process and malicious prosecution. In July 2014, the Company and Summer Street entered into a settlement agreement, which resulted in the dismissal of the arbitration. Pursuant to the settlement agreement, the Company paid Summer Street $20,000.

11. Subsequent Events

Restructuring

In March 2015, the Company announced that it will consolidate all major business functions into its Irvine, California office. In connection with this consolidation, the Company will close its Memphis, Tennessee office in May of this year. The Company will not retain any of its Memphis-based employees. A total of seven employees will be impacted by the consolidation, including three current executive officers of the Company. In addition to the retention bonuses described in Note 9 that the Company will pay upon termination of the two applicable executive officers, the Company expects to incur approximately $450,000 of costs, consisting of severance and other related compensation, related payroll taxes, and certain office closure costs. Most of these costs are expected to be recorded to expense during the first quarter of 2015 and paid during the second quarter of 2015.

In connection with the consolidation, the Company entered into an employment agreement in March 2015 to hire a new chief financial officer. Under the terms of this employment agreement, the Company will grant an option to purchase 450,000 shares of the Company's common stock on the date employment begins. In addition, upon each of the first and second anniversaries of the start date, the new chief financial officer will receive additional stock options to purchase 150,000 shares of the Company's common stock. The exercise price of such options will be equal to the fair market value of the Company's common stock on the date of grant. The stock options will vest and become exercisable in three equal annual installments, conditioned on continued employment.

Lease Extension

In March 2015, the Company's lease agreement for its Irvine, California facility was amended to extend the term by three years. The term of the lease agreement was previously scheduled to end in September 2015. Lease payments for the term of the three year extension total approximately $275,000.

Exhibit 10.24

Second Amendment to Lease Agreement

This Second Amendment to Lease Agreement ("Amendment") is dated as of February 24, 2015, and amends that certain Standard Industrial/Commercial Single-Tenant Lease –Net, dated April 21, 2008 (the "Original Lease") by and between Surgi-Vision, Inc. (whose name has been changed to MRI Interventions, Inc.), (Lessee"), and Shaw Investment Company, LLC ("Lessor") as further amended by that certain Amendment dated March 26, 2012. The Original Lease concerns that certain property known as 5 Musick, Irvine, California. Initially capitalized terms used and not defined herein shall have the meanings given them in the Original Lease.

Lessor and Lessee now desire to amend the Lease to reflect their agreement with respect to the following:

The current Lease term expires on September 30, 2015. Lessee wishes to extend the term of the Lease by Three (3) Years commencing October 1, 2015 and terminating September 30, 2018.

October 1, 2015 through September 30, 2016	$	7,255.92
October 1, 2016 through September 30, 2017	$	7,626.12
October 1, 2017 through September 30, 2018	$	7,996.32

Lessor shall, at Lessor's sole cost provide a Tenant Improvement Allowance in the amount of Seven Thousand Five Hundred Dollars, ($7,500.00) available to Lessee upon the submittal of invoices from a licensed general contractor and Lessor's verification of the completion of the work. Lessee shall provide Lessor or Lessor's representative with the scope of work to be completed. Lessee shall be required to receive approval from Lessor prior to the commencement of the work. Lessor's approval shall not be unreasonably withheld.

Except as amended hereby, and in prior Amendment(s) to the Lease, the Original Lease remains in full force and effect in accordance with its terms. In the event of any conflict between the provisions of the Original Lease and the Amendment(s), the provisions of this Amendment shall control. This Second Amendment shall be governed by California law and may be executed in counterparts, and all counterparts shall constitute but one and the same document.

IN WITNESS WHEREOF, Lessor and Lessee have executed this Amendment as of the day first above written.

Lessor:

Shaw Investment Company, LLC,

By /s/ Charles E. Crookall

Title Manager Date 3-10-2015

Lessee:

MRI Interventions, Inc.

By /s/ David Carlson

Title CFO Date 3/5/15

EXHIBIT 21

List of Subsidiaries

Name of Subsidiary	**Jurisdiction of Formation**
MRI Interventions (Canada) Inc.	Canada (New Brunswick)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion or incorporation by reference of our report, dated March 17, 2015, with respect to the consolidated balance sheets of MRI Interventions, Inc. and subsidiary (the "Company") as of December 31, 2014 and 2013 and the related consolidated statements of operations, stockholders' deficit and cash flows for the years then ended, in (i) the Company's Registration Statement on Form S-8 (No. 333-183382), (ii) the Company's Registration Statement on Form S-8 (No. 333-191908), and (iii) the Company's Registration Statement on Form S-1 (No. 333-201471) and the related Prospectus.

/s/ Cherry Bekaert LLP

Charlotte, North Carolina
March 17, 2015

EXHIBIT 31.1

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

I, Francis P. Grillo, certify that:

1. I have reviewed this annual report on Form 10-K for the fiscal year ended December 31, 2014, of MRI Interventions, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 17, 2015

/s/ Francis P. Grillo
Francis P. Grillo
Chief Executive Officer

EXHIBIT 31.2

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

I, David W. Carlson, certify that:

1. I have reviewed this annual report on Form 10-K for the fiscal year ended December 31, 2014, of MRI Interventions, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 17, 2015

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

EXHIBIT 32

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13a-14(b) UNDER THE SECURITIES EXCHANGE ACT OF 1934 AND SECTION 1350 OF CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE

Each of the undersigned, Francis P. Grillo and David W. Carlson, certifies pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and Section 1350 of Chapter 63 of Title 18 of the United States Code, that (1) this annual report on Form 10-K for the fiscal year ended December 31, 2014, of MRI Interventions, Inc. (the "Company") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, and (2) the information contained in this report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 17, 2015

/s/ Francis P. Grillo
Francis P. Grillo
Chief Executive Officer

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