PROSPECTUS SUPPLEMENT NO. 9
(to Prospectus dated July 7, 2017)

Filed Pursuant to Rule 424(b)(3)
Registration No. 333-218960

MRI Interventions, Inc.

13,807,533 Shares of Common Stock

This prospectus supplement relates to the prospectus dated July 7, 2017, as supplemented by prospectus supplement no. 1 dated August 11, 2017, prospectus supplement no. 2 dated August 18, 2017, prospectus supplement no. 3 dated September 5, 2017, prospectus supplement no. 4 dated October 3, 2017, prospectus supplement no. 5 dated October 10, 2017, prospectus supplement no. 6 dated November 6, 2017, prospectus supplement no. 7 dated November 7, 2017 and prospectus supplement no. 8 dated December 14, 2017, which permits the resale of up to 6,693,333 outstanding shares of our common stock and 7,114,200 shares of our common stock issuable upon the exercise of outstanding warrants, by the selling securityholders identified in the prospectus, as amended and supplemented from time to time. We will pay the expenses of registering the shares of our common stock, but we are not selling any shares of common stock in this offering and therefore will not receive any proceeds from this offering. We will, however, receive the exercise price of the warrants, if and when the warrants are exercised for cash by the securityholders.

This prospectus supplement is being filed to update, amend and supplement the information previously included in the prospectus with the information contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 21, 2018 (the "10-K"). Accordingly, we have attached the 10-K to this prospectus supplement. You should read this prospectus supplement together with the prospectus, which is to be delivered with this prospectus supplement.

Our common stock is traded in the over-the-counter market and is quoted on the OTCQB Marketplace and the OTC Bulletin Board under the symbol MRIC. On March 19, 2018, the last reported sale price of our common stock was $3.31 per share.

Investing in our common stock involves risk. See "Risk Factors" beginning on page 12 of the prospectus to read about factors you should consider before buying shares of our common stock.

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

The date of this prospectus supplement is March 21, 2018.

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

FORM 10-K

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

For the fiscal year ended December 31, 2017

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: **001-34822**

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, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth 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 ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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, 2017, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $37,780,637, based on the closing sale price as reported on the OTCQB Marketplace.

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 February 28, 2018**
Common Stock, $.01 par value per share	10,693,851 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, 2017, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the 2017 annual meeting of stockholders.

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 AG, Healthcare Sector, and its affiliates, Boston Scientific refers to Boston Scientific Corporation and its affiliates, Brainlab refers to Brainlab AG and its affiliates, and Voyager refers to Voyager Therapeutics, Inc. and its affiliates.

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains "forward-looking statements" as defined under the United States federal securities laws. 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 may include, but are not limited to, statements about:

- future revenues from sales of ClearPoint system products;
- our ability to market, commercialize and achieve broader market acceptance for our ClearPoint system products; and
- estimates regarding the sufficiency of our cash resources and our ability to obtain additional financing, to the extent necessary or advisable.

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. From our inception in 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 portfolio. 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 a product candidate still in development, will be used to perform minimally invasive surgical procedures in the heart. However, further development of ClearTrace has been suspended, as we devote our resources to the continued development and commercialization of ClearPoint. Both systems utilize intra-procedural MRI to guide the procedures.

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, electrodes and laser fibers to treat 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, further discussed as follows:

- *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 and effectively perform a surgical intervention in the brain or heart. We believe that our product platforms 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 guidance. We believe that these capabilities will translate directly into better outcomes for the patients undergoing the procedures due to improved efficiency and 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 the use of our products may result in more efficient utilization of healthcare resources and physician time. Our product platforms are designed to work in a hospital's existing MRI suite, which facilitates additional utility for an infrastructure investment that has already been made by the hospital. Further, if patient outcomes and procedure efficiencies are improved through use of our products, we believe that the result will be a reduction in overall healthcare costs.

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;
- the ability to directly acquire volumetric (three dimensional) data sets;
- the ability to evaluate both the structure and certain functions of internal organs; and
- no harmful ionizing radiation exposure for either the patient or the physician.

There are approximately 12,000 MRI scanners installed 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. There are approximately 4,800 1.5T scanners and 900 3.0T scanners located within hospitals in the U.S. which potentially can be utilized for surgical procedures.

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. It 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, electrodes and fiber lasers, which have traditionally been performed using stereotactic methodologies. It 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.

The Need for Minimally Invasive Neurological Interventions

Market Overview

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 ablation, 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.

U.S. Market Opportunities

We believe there are over 55,000 potential neurosurgical procedures per year in the United States in which our ClearPoint system could be used as a navigational platform. The potential procedures include:

- *Electrode Placement* – The current standard of care for the placement of the DBS electrodes requires the patient to be awake during surgery, in order to verify proper placement. Since our ClearPoint system provides real-time visualization of the placement, patients can be asleep during the procedure, which we believe will drive growth in the number of potential procedures. Both St. Jude Medical (now part of Abbott Laboratories) and Boston Scientific received FDA clearances for new DBS systems. Abbott Laboratories began marketing the Infinity® DBS system in 2017 and Boston Scientific launched the Vercise™ Deep Brain Stimulation System in 2018. DBS is used to treat the symptoms of Parkinson's Disease, a degenerative condition that affects more than one million people in the United States and 10 million people worldwide. DBS works by stimulating a targeted region of the brain through implanted leads that are powered by a device called an implantable pulse generator. We estimate 12,500 Parkinson's disease and essential tremor patients per year are potential candidates for the implantation of deep brain stimulation electrodes utilizing our ClearPoint system. In addition, patients suffering from essential tremor, dystonia, obsessive compulsion disorder or severe depression may create additional potential procedure opportunities.

- *Laser ablation of the hippocampus* – Currently, approximately 260,000 people suffer from drug treatment resistant Epilepsy. We estimate laser ablation of the hippocampus and amygdala, a small structure in the brain that may serve as the foci of certain types of epileptic seizures, is a viable therapeutic option for approximately 28,000 patients annually.

- *Brain tumor biopsy and laser ablation* – For smaller, harder to reach brain tumors or those near critical structures (the brain stem or large blood vessels), navigating the surgical field so that the biopsy needle reaches the brain tumor and accurately acquires a representative sample of the tumor is paramount. For small, deep-seated tumors, navigating the laser ablation device to the exact target is challenging and necessary to avoid the inadvertent destruction of healthy brain tissue. We estimate these brain tumor applications represent the potential for approximately 15,000 procedures per year.

- *Brain direct drug delivery* – The blood-brain barrier prevents large-molecule, and nearly all small-molecule, neurotherapeutics from reaching the brain. Several pharmaceutical and biotech companies are developing methods to deliver a wide variety of molecules, genes or proteins to targeted brain tissue or structures that would need to bypass the blood-brain barrier, which may enable the development of treatments for Parkinson's disease, Huntington's disease and certain types of cancers. If our ClearPoint system were to become the standard approach to local drug delivery in the brain, we believe the impact on our financial performance could be significant. However, these treatments are subject to FDA-mandated clinical trial requirements, which are expensive and time consuming to conduct, and thus, it is too early in the development cycle to estimate the potential of, and our ability to capitalize on, this market opportunity with a reasonable amount of certainty.

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 guide 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 for 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

Our second product platform, the ClearTrace system, is a product candidate designed to allow catheter-based minimally invasive procedures in the heart to be performed using continuous, intra-procedural MRI guidance. However, further development of ClearTrace has been suspended, as we devote our resources to the continued development and commercialization of ClearPoint.

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.

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 new imaging capability is required for the next generation of interventional cardiac therapies. In addition, 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 and require intravenous contrast dye which, in large quantities, is toxic to the kidneys. 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 a new exclusive development agreement with Siemens, which replaced our May 2009 agreement. The new development agreement contemplates that, with cooperation, assistance and technical support from Siemens, we would develop the commercial version of the research software platform created by Siemens under our original agreement, which software would serve as the software component of our ClearTrace system. In 2015, we suspended our development activities on the ClearTrace system so that we could focus our resources on the ClearPoint system, and we have not made any filings seeking regulatory clearance or approval 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. The ablation catheter will be used to perform MRI-guided delivery of ablative energy to create cardiac lesions. The 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

We have suspended development of our ClearTrace system so that we could focus our resources on the ClearPoint system, and to date we have conducted only animal studies and other preclinical work with respect to the ClearTrace system. We have not made any filing with any regulatory authority seeking approval or clearance for the ClearTrace system. 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 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 expired in April 2016; however, Brainlab continues to serve as a distributor on a purchase order basis.

As part of the closing of the restructuring of a note payable to Brainlab, we entered into a worldwide, non-exclusive, non-transferable license with Brainlab on April 4, 2016, which allows Brainlab to develop proprietary software to support our SmartFrame device, for use in neurosurgery. The License Agreement will not affect our ability to continue to independently develop, market and sell our own software for the SmartFrame device.

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. The new development agreement contemplates that, with cooperation, assistance and technical support from Siemens, we would develop the commercial version of the research software platform created by Siemens under our original agreement, which software would serve as the software component of our ClearTrace system. Upon completion of development, subject to appropriate regulatory clearance or approval, we would then sell the software as our own product, and the software would 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 agreed to 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, which occurred in October 2014, 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, or the exclusivity 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 exclusivity period and within the exclusivity 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. However, the development agreement provides that, as a condition of continued exclusivity, we must release the software and catheters for our ClearTrace system in the United States or European Union by the end of June 2016. In 2015, we suspended our development activities on our ClearTrace system to enable us to focus our resources on our ClearPoint system, and we have not made any filings seeking regulatory clearance or approval for our ClearTrace system. As a result, we did not meet the June 2016 milestone, and Siemens elected to terminate the exclusivity provisions of the development agreement.

The development agreement also 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. Under its license from us, Siemens may also use the licensed intellectual property rights to develop, manufacture and sell software.

The term of the development agreement will expire in the third quarter of 2018.

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."

Mayo Clinic

In April 2017, we entered into a joint development agreement with Mayo Clinic for the design and development of MRI-guided therapies for stroke. The initial focus of the collaboration is the development and commercialization of a novel, MRI-guided, minimally invasive neurosurgical aspiration system, utilizing our ClearPoint platform, for the treatment of conditions such as intra cerebral hemorrhage.

Acoustic MedSystems, Inc.

In April 2017, we entered into a license and collaboration agreement with Acoustic MedSystems, Inc. ("AMS"). The agreement calls for our collaboration with AMS on the development of real-time, MRI-guided ultrasonic ablation therapies, with an initial focus on the treatment of pancreatic cancer. As part of the agreement, we received an exclusive license to AMS's technology in the field of pancreatic cancer.

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, including 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.

As of February 28, 2018, our sales, clinical support and marketing team consisted of 15 employees. We believe that our current sales, clinical support and marketing team is sufficient for our current needs; however, we expect the size of our team to vary with size of the ClearPoint installed base and the volume of procedures utilizing the ClearPoint system.

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, 2018, our research and development team consisted of 6 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, resources permitting, to complete development of our ClearTrace system.

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.

Customers

A small number of our hospital customers account for a substantial portion of our revenues from sales of ClearPoint disposable products. Our two largest customers account for a disproportionately large portion of our ClearPoint product revenues.

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, 2018, we wholly-owned, co-owned or licensed a total of 79 United States patents and 27 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. 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., Integra Life Sciences, and Neurologica Corporation, a subsidiary of Samsung Electronics Co., 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

At least one company, Imricor Medical Systems, Inc., has received CE mark for the Advantage-MR EP Recorder/Stimulator System and Vision-MR Ablation Catheter, which are in clinical trials in Europe. 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 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 may drive physician preference will be 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 (a subsidiary of Auris Surgical Robotics) and Stereotaxis, Inc., which currently market, or have marketed, 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, PLC and St. Jude Medical. 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.

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. A de novo classification 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 classification 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 we have 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 to a device 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 to a device, we may be required to cease marketing and/or recall the modified device, if already in distribution, until 510(k) clearance or PMA approval is obtained and we could be subject to significant regulatory fines or penalties.

The FDA is currently considering proposals to reform its 510(k) marketing clearance process, and such proposals could include increased requirements for clinical data and a longer review period. Specifically, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the 510(k) program, and in July 2014, published a new guidance document governing the review process for the clearance of medical devices. Specifically, the FDA has adopted new practices related to the acceptance of 510(k) applications which could place a higher standard on data and evidence provided to the FDA and a reduced ability to definitionally (i.e. same intended use, same technological characteristics) consider other devices as potential predicates. The FDA intends these reform actions to improve the efficiency and transparency of the 510(k) clearance process, as well as bolster patient safety.

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 so.

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 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 actions 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, 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 physicians' 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.

On April 16, 2015, President Obama signed into law, the Medicare Access and CHIP Reauthorization Act of 2015, or the Medicare Access Act, which removed the sustainable growth rate or SGR, methodology applicable to fees for physician services. The Medicare Access Act provides for a transition from the fee-for-service payment system to a more value-based system. In this process, reimbursements from the Medicare program may be reduced. As noted above, 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.

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 that, 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, 2018, we had 34 full time employees, of whom 6 were engaged primarily in research and development, 9 in manufacturing and quality assurance, 15 in sales, clinical support and marketing, and 4 in administrative and finance functions. None of our employees are covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

ITEM 1A. RISK FACTORS

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

Risks Related to Our Business and Industry

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 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.

Federal legislation and other payment and policy changes may have a material adverse effect on our business.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, together, the Affordable Care Act, includes a number of provisions that 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.

On April 16, 2015, President Obama signed into law, the Medicare Access and CHIP Reauthorization Act, or the Medicare Access Act, which removed the sustainable growth rate or SGR, methodology applicable to fees for physician services. The Medicare Access Act provides for a transition from the fee-for-service payment system to a more value-based system. In this process, reimbursements from the Medicare program may be reduced. As noted above, 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.

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 recently promulgated or 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 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.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained or maintained if obtained.

Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government-managed systems.

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, whether in the United States or abroad, 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 revenues 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. Our two largest customers account for a disproportionately large portion of our ClearPoint product revenues. Sales to almost all our customers, including our two largest customers, are not based on long-term, committed volume purchase contracts, and we may not continue to generate a similar level of revenues from these customers, 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 a product candidate in 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 a product candidate in development, although we suspended our ClearTrace development program in 2015 to enable us to focus resources on our ClearPoint system. At the time we suspended our ClearTrace development work, we had 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 we will resume our ClearTrace development program, or that, if resumed, our development efforts will be successfully completed, or that the ClearTrace system will have the capabilities we expect. If we resume our work, we may encounter significant difficulties and costs during the course of our development efforts and we may encounter significant additional 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. 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. Likewise, in lieu of resuming our ClearTrace development program and undertaking the remaining development work, we may explore collaborations with one or more third parties pursuant to which the technologies underlying our ClearTrace system would be further developed and potentially commercialized. If we enter into any such collaboration with a third party, we may have to relinquish valuable rights to our ClearTrace system and its underlying technologies.

It is likely that we will not realize anticipated benefits from our collaborative agreement with Siemens regarding our ClearTrace system.

As discussed elsewhere in this Annual Report under "Business—Licenses and Collaborative Relationships—Siemens," in February 2014 we entered into a development agreement with Siemens that relates to our ClearTrace system. That development agreement provides for certain commercial exclusivity in the field of MRI-guided catheter-based cardiac electrophysiology using catheters that are actively tracked by the MRI scanner. During the exclusivity period and within that particular exclusivity field, Siemens agreed not to engage in certain actions and activities, the intention being that we would have the exclusive opportunity to commercialize MRI-guided catheter-based cardiac electrophysiology with active catheter tracking with Siemens MRI systems. Likewise, during the exclusivity period and within the exclusivity field, we agreed not to sell or otherwise provide to any third party actively tracked catheters for commercial use that are intended to be used with a non-Siemens MRI system. However, the development agreement provides that, as a condition of continued exclusivity, we must release software and catheters for our ClearTrace system in the United States or European Union by the end of June 2016. Given the stage and status of our ClearTrace development program, we did not meet that milestone, and, as a result, Siemens has informed us that it has terminated the exclusivity provisions of the agreement. Based on Siemens' termination of exclusivity, it is likely we will not realize some of the anticipated benefits from our development agreement with Siemens.

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 premarket approval application ("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.

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.

Risks Related to Our Financial Position

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.

We have incurred losses in each year since our inception in 1998 that have resulted principally from costs incurred in connection with our sales and marketing activities, research and development efforts, manufacturing activities and other general and administrative expenses associated with our operations, 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 and working capital and could result in a decline in our stock price or cause us to cease operations.

Our level of indebtedness and debt service obligations could adversely affect our financial condition, and may make it more difficult for us to fund our operations.

We have a significant amount of debt, including: (i) a senior secured note payable to Brainlab, or the Brainlab Note, which was originally issued to Brainlab on April 5, 2011, and subsequently amended and restated on March 6, 2013 and on April 4, 2016, that matures in December 2018, with an aggregate principal amount of $2.0 million bearing interest at 5.5% annum, compounded simply, paid quarterly in arrears; (ii) notes payable to certain holders that mature in March 2019, with an aggregate principal amount of approximately $2.0 million payable at maturity and interest accruing at 12% per annum payable semi-annually, or the 2014 Secured Notes; and (iii) notes payable to certain holders that mature in November 2020 with both principal of $3.0 million and interest accruing at 3.5% per annum payable in a single installment upon maturity, or the 2010 Secured Notes, and together with the Brainlab Note and the 2014 Secured Notes, the Notes. Our obligations under the Notes are secured by all our existing property and assets, with the Brainlab Note having a first priority followed in order by the 2014 Secured Notes and the 2010 Secured Notes. The Notes may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. The Notes will require us to repay our indebtedness by making payments of interest and principal, which will reduce the amount of money available to finance our operations, our commercialization efforts and other general corporate activities. To the extent additional debt is added to our current debt levels, the risk described above could increase.

We may need additional funding for our business, and 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.

The cumulative net loss from our inception through December 31, 2017 was approximately $101 million. Net cash used in operations was $6.0 million for the year ended December 31, 2017. Since our inception, we have financed our operations principally from the sale of equity securities, the issuance of notes payable and license arrangements. Recent such financing activities consist of: (i) a May 2017 private placement of equity, which resulted in net proceeds of $12.0 million; (ii) a September 2016 private placement of equity, which resulted in net proceeds of $4.1 million; (iii) along with the September 2016 private placement, a simultaneous sale of units (consisting of common stock and warrants to purchase common stock) to certain existing holders of the Company's convertible promissory notes and common stock warrants issued by the Company in connection therewith, resulting in the conversion of notes into units and the adjustment of the exercise price of existing warrants (the transactions described in this clause (iii) are also referred to herein as the Note Conversion); (iv) an April 2016 restructuring of our existing debt to Brainlab, or the Restructuring Transaction, including the issuance to Brainlab of shares of our common stock and warrants to purchase additional shares of our common stock; (v) a December 2015 private placement of equity, which resulted in net proceeds of $4.7 million; (vi) a December 2014 private placement of equity, which resulted in net proceeds of $9.4 million; and (vii) a March 2014 private placement of debt and warrants, which resulted in net proceeds of $3.5 million. In addition, in March 2014, we completed a transaction with Boston Scientific that resulted in the cancellation of $4.3 million in related party convertible notes payable held by Boston Scientific which were scheduled to mature in 2014.

Our plans reflect our anticipation of increases in revenues from sales of the ClearPoint system and related disposable products as a result of greater utilization at existing installed sites and the installation of the ClearPoint system at new sites. We also anticipate maintaining recurring operating expenses at historical levels, with expected decreases in general and administrative expenses being offset by increases in selling and marketing expenses associated with the anticipated growth in revenues. However, there is no assurance that we will be able to achieve anticipated results, and even in the event such results are achieved, we expect to continue to consume cash in operations over at least the next twelve months.

As a result of the foregoing, we believe it may be necessary to seek additional sources of funds from the sale of equity or debt securities, which likely would result in dilution to existing ownership interests, or from the establishment of a credit facility. There is no assurance, however, that we will be able to obtain such additional financing on commercially reasonable terms, if at all, and there is no assurance that any additional financing we do obtain will be sufficient to meet our needs. If we are not able to obtain the additional financing on a timely basis, we may be unable to achieve anticipated results, and may not be able to meet other obligations as they become due. An inability to obtain a sufficient amount of additional funding would create substantial doubt as to our ability to continue as a going concern.

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, existing ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect such existing stockholders' rights. 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 to which we have rights.

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 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.

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.

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 Legal and 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.

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.

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.

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.

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

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

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

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

- The federal Health Insurance Portability and Accountability Act of 1996, as amended, or 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: (i) anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; and (ii) the Foreign Corrupt Practices Act, which may apply to interactions with foreign government officials, including physician employees of a foreign government entity, by our employees and third-party business partners.

- 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 which 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.

- The federal Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which strengthens and expands the HIPAA Privacy and Security Rules and its restrictions on use and disclosure of patient identifiable health information, including imposing liability on business associates of covered entities.

- Both HITECH and 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. Any such violations could lead to sanctions that could adversely affect our business.

Changes in U.S. tax laws could have a material adverse effect on our business, cash flow, results of operations and financial conditions.

On December 22, 2017, the U.S. government enacted comprehensive Federal tax legislation commonly referred to as the Tax Cuts and Jobs Act of 2017 (the "Tax Act"). The Tax Act introduces significant changes to U.S. income tax law that could have a meaningful impact on our provision for income taxes. Accounting for the income tax effects of the Tax Act requires significant judgments and estimates in the interpretation and calculations of the provisions of the Tax Act.

Due to the timing of the enactment and the complexity involved in applying the provisions of the Tax Act, we made reasonable estimates of the effects and recorded provisional amounts in our financial statements for the year ended December 31, 2017. The U.S. Treasury Department, the Internal Revenue Service ("IRS"), and other standard-setting bodies may issue guidance on how the provisions of the Tax Act will be applied or otherwise administered that is different from our interpretation. As we collect and prepare necessary data and interpret the Tax Act and any additional guidance issued by the IRS or other standard-setting bodies, we may make adjustments to the provisional amounts that could materially affect our financial position and results of operations as well as our effective tax rate in the period in which the adjustments are made.

Risks Related to Our 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 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.

Damage to our reputation could harm our businesses, including our competitive position and business prospects.

Our ability to attract and retain customers, supplier, investors and employees is impacted by our reputation. Harm to our reputation can arise from various sources, including employee misconduct, security breaches, unethical behavior, litigation or regulatory outcomes, the suitability or harm, which could, among other consequences, increase the size and number of litigation claims and damages asserted or subject us to enforcement actions, fines and penalties and cause us to incur related costs and expenses.

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. We conduct substantially all 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.

Our corporate headquarters is leased, and if we are unable to renew the lease on similar terms, we could be materially and adversely affected.

Our corporate headquarters is leased, and the lease is set to expire in September 2018. We can provide no assurances that we will be able to renew our lease upon expiration on similar terms, or at all. If we are unable to renew our lease on similar terms, it may have a material and adverse effect on our business and operations.

Risks Related to Our Common Stock

Our common stock may be traded infrequently and in low volumes, so stockholders may be unable to sell their shares of common stock at or near the quoted bid prices if they wish to sell their 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 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 no assurance that stockholders will be able to sell their shares at or near bid prices or at all if they need money or otherwise desire to liquidate their shares. As a result, investors could lose all or part of their investment.

Our common stock has historically been treated as a "penny stock," which places restrictions on broker-dealers recommending the stock for purchase, and it may be treated as a "penny stock" in the future.

Our common stock has historically been defined as a "penny stock" under the Securities Exchange Act of 1934, as amended, 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 once again becomes 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.

The market price of our common stock may be highly volatile, and a stockholder may not be able to resell their shares at or above the price at which the shares were purchased.

Companies trading in the stock market in general have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The market price of our common stock may be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- Failure to develop successfully our products;
- Changes in laws or regulations applicable to future products;
- Inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- Adverse regulatory decisions;
- Introduction of new products, services or technologies by our competitors;
- Failure to meet or exceed financial projections we may provide to the public;
- Inability to obtain additional funding;
- Failure to meet or exceed the financial projections of the investment community;
- Disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- Additions or departures of key personnel;
- Significant lawsuits, including patent or stockholder litigation;
- Changes in the market valuations of similar companies;
- Sales of our common stock by us or our stockholders in the future; and
- Trading volume of our common stock.

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, 2018, almost all of our outstanding shares were freely transferable or could be publicly resold pursuant to Rule 144 under the Securities Act of 1933, as amended, or 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 this 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.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. Our existing NOLs may be subject to substantial limitations arising from previous ownership changes. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs. Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U.S. federal taxable income. We have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. federal taxable income necessary to utilize our NOLs.

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 our stockholders' 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.

We have 200,000,000 shares of common stock authorized. As a result, our Board will be able to issue a substantial number of additional shares of common stock, without seeking stockholder approval. In addition, 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.

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.

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, giving retroactive effect to a 1:40 reverse split of our common stock effectuated in July 2016 (the "Reverse Split"). This bid information reflects inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions. Prior to May 21, 2012, there was no established public trading market for our common stock.

Quarter Ended	High Bid	Low Bid
Fiscal 2017		
Fourth Quarter 2017 (through December 31, 2017)	$3.35	$2.33
Third Quarter 2017 (through September 30, 2017)	$3.64	$1.76
Second Quarter 2017 (through June 30, 2017)	$7.40	$2.57
First Quarter 2017 (through March 31, 2017)	$6.00	$2.10
Fiscal 2016		
Fourth Quarter 2016 (through December 31, 2016)	$6.30	$1.99
Third Quarter 2016 (through September 30, 2016)	$14.00	$4.00
Second Quarter 2016 (through June 30, 2016)	$20.00	$6.00
First Quarter 2016 (through March 31, 2016)	$19.20	$10.40

Holders

As of February 28, 2018, we had 10,693,851 shares of common stock outstanding and no shares of preferred stock outstanding. As of February 28, 2018, we had 569 stockholders of record. In addition, as of February 28, 2018, options and warrants to purchase 10,187,277 shares of common stock were outstanding.

Dividend Policy

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

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by stockholders (1)	744,199	$9.08	1,096,496
Equity compensation plans not approved by stockholders (1)(2)(3)(4)(5)(6)	494,000	$17.56	-
Total	1,238,199	$12.47	1,096,496

(1) The information presented in this table is as of December 31, 2017, and after giving effect to the Reverse Split.

(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 64,141 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, 2017, options to purchase 53,625 shares of our common stock were outstanding under the 2010 Non-Qualified Stock Option Plan.

(3) 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 14,250 shares of our common stock. As of December 31, 2017, awards with respect to 10,375 shares of our common stock were outstanding under the 2013 Non-Employee Director Equity Incentive Plan.

(4) In October 2014, we entered into a written compensatory contract with Francis P. Grillo, our Chief Executive Officer, pursuant to which we awarded Mr. Grillo non-qualified stock options to purchase 60,000 shares of our common stock.

(5) 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 8,750 shares of our common stock.

(6) In March 2015, we entered into a written compensatory contract with Harold A. Hurwitz, our Chief Financial Officer, pursuant to which we awarded Mr. Hurwitz non-qualified stock options to purchase 11,250 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 a product candidate, will be used to perform minimally invasive surgical procedures in the heart. In 2015, we suspended development of the ClearTrace system so that we could focus our resources on the ClearPoint system. Both systems utilize intra-procedural MRI to guide the procedures and 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 U.S. 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. Substantially all our product revenues for the years ended December 31, 2017 and 2016 relate to sales of our ClearPoint system products. We do not have regulatory clearance or approval to sell our ClearTrace system for 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 have devoted substantial efforts to research and development. As of December 31, 2017, we had accumulated losses of approximately $101 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 2010, we received 510(k) clearance from the FDA to market our ClearPoint system in the U.S. 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 functional neurological 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 installations of our ClearPoint system to generate recurring sales of our functional neurological products. Our product revenues were approximately $7.0 million and $5.6 million for the years ended December 31, 2017 and 2016 and were almost entirely related to our ClearPoint system.

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

Cost of Revenues

Cost of revenues includes the direct costs associated with the assembly and purchase of components for functional neurological products, drug delivery and biologic products, and ClearPoint capital equipment 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 provisions for obsolete, impaired, or excess inventory.

Research and Development Costs

Our research and development costs consist primarily of costs associated with the conceptualization, design, testing, and prototyping of our ClearPoint system products (and, prior to its suspension of development in 2015, of our ClearTrace system components). Such costs include salaries, travel, and benefits for 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 costs may increase as we: (i) continue to develop enhancements to our ClearPoint system; (ii) resume our ClearTrace system product development efforts; and (iii) seek to expand the application of our technological platforms. From our inception through December 31, 2017, we have incurred approximately $51 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 either the further development of our ClearTrace system for commercialization, or in our efforts to expand the application of our technological platforms.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of salaries, incentive-based and share-based compensation, and travel and benefits; marketing costs; professional fees, including fees for attorneys and outside accountants; occupancy costs; insurance; and other general and administrative expenses, which include, but are not limited to, 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 the increased headcount necessary to support 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 functional neurological products and drug delivery and biologic products; (2) product revenues resulting from the sale of ClearPoint capital equipment; and (3) revenues resulting from the rental, service, installation, training and shipping related to ClearPoint capital equipment. 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 individual 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.

- *Sales of functional neurology products and biologics and drug delivery systems products*: Revenues from the sale of functional neurology products (consisting of disposable products sold commercially and related to cases utilizing our ClearPoint system), and biologics and drug delivery systems (consisting primarily of disposable products related to customer-sponsored clinical trials utilizing our ClearPoint system), are recognized at the time risk of loss passes to the customer, which is generally upon delivery to the customer's location.

- *Sales of capital equipment*: The predominance of capital equipment sales (consisting of integrated computer hardware and software that are integral components of our ClearPoint system) are preceded by customer evaluation periods of generally 90 days. During these evaluation periods, installation of, and training of customer personnel on, the systems have been completed and the systems have been in operation. Accordingly, capital equipment sales following such evaluation periods are recognized upon receipt of an executed purchase agreement or purchase order that provide for risk of loss to pass to the customer. Sales of capital equipment not having been preceded by an evaluation period are recognized on an individual agreement basis as described above.

- *Rental, service and other revenues:* Revenues from rental of our ClearPoint capital equipment are recognized over the term of the rental agreement, which is less than one year. Revenues from service of ClearPoint capital equipment previously sold to customers are based on agreements with terms ranging from one to three years. Typically, we bill and collect service fees at the inception of the agreement and recognize revenue ratably over the term of the related service agreement. Other revenues consist primarily of installation, training and shipping fees in connection with sales of ClearPoint capital equipment and is recognized as the related services are performed.

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 functional neurological products, drug delivery and biologic products, and ClearPoint capital equipment. 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 potentially obsolete items.

Derivative Liabilities. Our derivative liabilities arise from: (a) a conversion feature related to the Brainlab Note; and (b) warrants issued in connection with certain private placements of shares our common stock. The fair values of the conversion feature and the warrants are presented as liabilities based on the terms of the conversion feature that allow for potential conversion at a price that may be less than market value on the date of conversion, and the terms of the warrants that bear 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 prerequisites 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 incurred under the terms of collaborative agreements, costs for materials used in research and development activities, and costs for outside services.

Results of Operations

Comparison of the Year Ended December 31, 2017 to the Year Ended December 31, 2016

	Year Ended December 31,		Percentage
	2017	2016	Change
Product revenues	$ 7,024,010	$ 5,600,453	25%
Service and other revenues	355,515	149,001	139%
Total revenues	7,379,525	5,749,454	28%
Cost of revenues	2,898,808	2,642,763	10%
Research and development costs	2,813,733	2,628,179	7%
Sales and marketing expenses	3,956,455	3,777,119	5%
General and administrative expenses	4,046,366	4,190,131	(3)%
Other income (expense):			
Gain on change in fair value of derivative liabilities	24,728	1,065,935	(98)%
Loss on debt restructuring	-	(811,909)	NM
Other income, net	16,682	216,075	(92)%
Interest expense, net	(872,926)	(1,051,258)	(17)%
Net loss	$ (7,167,353)	$ (8,069,895)	(11)%

NM= not meaningful

Revenue. Total revenues were $7.4 million for the year ended December 31, 2017, and $5.7 million for the year ended December 31, 2016, an increase of $1.6 million, or 28%.

Functional neurology revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 34% to $5.3 million from $4.0 million in 2016. This increase was due primarily to the utilization of the ClearPoint system in 629 cases during 2017, an increase of 25% from 504 cases in 2016. There were no increases in functional neurology product prices during 2017 that would be reasonably expected to affect a typical customer order.

Biologics and drug delivery systems revenue, which consists primarily of disposable product sales related to customer-sponsored clinical trials utilizing the ClearPoint system, were $563,000, as compared with $771,000 in 2016. This fluctuation arose from $222,000 in purchases of such products by Voyager in late 2016, which have been subsequently used in Voyager's clinical trials. Biologics and drug delivery product price increases were implemented in 2017, but such increases did not extend to the entire biologics and drug delivery product line and averaged less than 1% for a typical customer order.

Capital equipment revenue, consisting of sales, rentals and service of ClearPoint reusable hardware and software, increased 50%, to $1.5 million, from $980,000 in 2016. This increase was due primarily to increases from 2016 to 2017 of : (a) $284,000 of equipment sales due to the sale of a greater number of ClearPoint systems in 2017, relative to 2016; (b) $131,000 of equipment rental revenue arising from agreements with terms of less than one year to two customers in 2017 (there was no equipment rental revenue in 2016); and (c) $49,000 related to equipment service contracts due to an increase in the number of such contracts in 2017, relative to 2016. Capital equipment price increases were implemented in 2017, but such increases did not extend to the entire capital equipment product line and averaged approximately 3% for a typical customer order for either new equipment or a new service contract.

Cost of Revenue. Cost of revenue was $2.9 million for the year ended December 31, 2017, representing gross margin of 61%, compared to $2.6 million for the same period in 2016, representing gross margin of 54%. The increase in gross margin was due primarily to: (a) a larger portion of capital equipment service and rental revenues, which bear higher margins relative to product sales, in relationship to total revenues in 2017, relative to 2016; (b) lower costs for scrap, expired product and reserves for inventory obsolescence during 2017, relative to 2016; and (c) a favorable mix of functional neurology and capital equipment products sold in 2017, relative to 2016.

Research and Development Costs. Research and development costs were $2.8 million for year ended December 31, 2017, compared to $2.6 million for the same period in 2016, an increase of $186,000, or 7%. The increase was due primarily to: (a) payments aggregating $661,000, the majority of which was in the form of shares of our common stock, required under certain license and product co-development agreements entered into in April 2017; and (b) an increase of $87,000 in regulatory legal fees related to increased filing activity in 2017, relative to 2016, that were partially offset by: (c) an aggregate decrease of $373,000 in software development and intellectual property-related costs; and (c) a decrease of $168,000 in personnel costs related to a lower headcount during 2017, relative to 2016.

Sales and Marketing Expenses. Sales and marketing expenses were $4.0 million for the year ended December 31, 2017, compared to $3.8 million for the same period in 2016, an increase of $179,000, or 5%. This increase was primarily due to an increase of $143,000 in personnel-related expenses due to increased headcount during 2017, relative to 2016.

General and Administrative Expenses. General and administrative expenses were $4.0 million for the year ended December 31, 2017, compared to $4.2 million for the same period in 2016, a decrease of $144,000, or 3%. The decrease was due primarily to: (a) a decrease of $629,000 in professional fees, primarily related to financing activities undertaken in 2016 that did not recur during 2017; and (b) a decrease of $246,000 in stock-based compensation, due to the suspension during 2017 of stock-based grants pending stockholder approval of the Second Amended and Restated Incentive Compensation Plan in October 2017. These decreases were partially offset by: (a) an increase of $235,000 in recruiting and hiring costs related to the November 2017 change in our Chief Executive Officer; (b) an increase of $167,000 in general corporate legal fees; (c) an increase of $49,000 in investor relations costs; (d) an increase of $32,000 in insurance premiums.

Other Income (Expense). During the years ended December 31, 2017 and 2016, we recorded gains of $25,000 and $1.1 million, respectively, resulting from changes in the fair value of our derivative liabilities. Such derivative liabilities related to: (a) warrants issued with either or both net-cash settlement and down-round price protection provisions in connection with 2012 and 2013 private placement transactions; (b) the June 2016 Amendment of the New Brainlab Note as discussed in Note 5 to the Consolidated Financial Statements included elsewhere in the Annual Report and as discussed below; and (c) the August 2016 Amendments, entered into with the 2014 Convertible Note Holders, as discussed in Note 5 to the Consolidated Financial Statements included elsewhere in the Annual Report and as discussed below.

In April 2016, we entered into the 2016 Purchase Agreement with Brainlab under which the Brainlab Note was restructured and reissued as the New Brainlab Note. As a result, we recorded a debt restructuring gain of $941,000.

In June 2016, we entered into the June 2016 Amendments with Brainlab, with respect to the New Brainlab Note, and with the 2014 Convertible Note Holders. Based on the provisions of the June 2016 Amendments, on June 30, 2016, we recorded a debt restructuring loss of $820,000 resulting from the restructuring of the New Brainlab Note and those 2014 Secured Notes subject to the June 2016 Amendments.

In August 2016, we entered into the August 2016 Amendments with the 2014 Convertible Note Holders. Based on the provisions of the August 2016 Amendments, on August 30, 2016 we recorded a debt restructuring loss of approximately $933,000, representing the aggregate difference in the fair value of the derivative liabilities created by the June 2016 Amendments between the points in time (i) immediately preceding, and (ii) immediately subsequent to, the execution of the August 2016 Amendments.

During the year ended December 31, 2017, we recorded other income of $17,000, as compared with other income of $216,000 recorded during the same period in 2016, representing a decrease of $199,000, or 92%. This decrease was due primarily to grant income from a U.S. federal agency of $203,000 earned from a project in process during the 2016, which was discontinued by the agency later in 2016. We have not since undertaken any additional such projects.

Net interest expense for the year ended December 31, 2017 was $873,000, compared with $1.1 million for the same period in 2016. The decrease was due primarily to the conversion of an aggregate $1.74 million in principal balance of the 2014 Secured Convertible Notes held by the 2014 Convertible Note Holders in connection with the 2016 PIPE and pursuant to the terms of the August 2016 Amendments, as discussed in Note 5 to the Consolidated Financial Statements included elsewhere in this Annual Report.

Liquidity and Capital Resources

At December 31, 2017, we had cash and cash equivalent balances aggregating $9.3 million, resulting primarily from completion of the 2017 PIPE discussed in Note 6 to the Consolidated Financial Statements included elsewhere in this Annual Report. Net cash used in operating activities was $6.0 million and $5.8 million for the years ended December 31, 2017 and 2016, respectively.

Our plans for the next twelve months reflect management's anticipation of increases in revenues from sales of the ClearPoint system and related disposable products resulting from greater utilization at existing installed sites and the installation of the ClearPoint system at new sites. Management also anticipates increases over the next twelve months in operating expenses to support the expected increase in revenues, with resulting decreases in loss from operations and in cash flow used in operations. There is no assurance, however, that we will be able to achieve our anticipated results, and even in the event such results are achieved, we expect to continue to consume cash in our operations over at least the next twelve months.

As a result of the foregoing, we believe we will have sufficient cash resources to support our operations for at least the next twelve months.

Cash Flows

Cash activity for the years ended December 31, 2017 and 2016 is summarized as follows:

	Years Ended December 31,	
($s in thousands)	**2017**	**2016**
Cash used in operating activities	$ (5,992)	$ (5,820)
Cash used in investing activities	(27)	(101)
Cash provided by financing activities	11,993	3,828
Net change in cash and cash equivalents	$ 5,974	$ (2,093)

Net Cash Flows from Operating Activities. We used $6.0 million and $5.8 million of cash for operating activities in 2017 and 2016, respectively.

In 2017, uses of cash in operating activities consisted of: (i) our $7.2 million loss; (ii) increases in accounts receivable of $83,000, inventory of $470,000, prepaid expenses and other current assets of $58,000, and other assets of $1,000; and (iii) a decrease in accounts payable and accrued expenses of $512,000. These uses were partially offset by: (a) an increase in deferred revenue of $33,000; and (b) non-cash expenses included in our net loss aggregating $2.3 million and consisting of depreciation and amortization, share-based compensation, expenses paid through the issuance of common stock, and amortization of debt issuance costs and original issue discounts, partially offset by a $24,000 decrease in the fair value of our derivative liabilities.

In 2016, uses of cash in operating activities primarily consisted of: (i) our $8.1 million loss; and (ii) a $38,000 increase in prepaid expenses and other current assets. These uses were partially offset by: (a) decreases in accounts receivable of $352,000 and in inventory of $72,000; (b) increases in accounts payable and accrued expenses of $178,000, and in deferred revenue of $107,000; (c) non-cash expenses included in our net loss aggregating $2.6 million and consisting of depreciation and amortization, share-based compensation, expenses paid through the issuance of common stock, loss on debt restructuring, loss on retirement of equipment, and amortization of debt issuance costs and original issue discounts, partially offset by a $1.1 million decrease in the fair value of our derivative liabilities.

Net Cash Flows from Investing Activities. Net cash flows used in investing activities in 2017 and 2016 were $27,000 and $101,000, respectively, and consisted primarily of equipment purchases.

Net Cash Flows from Financing Activities. Net cash provided by financing activities in 2017 of $12.0 million reflected primarily net proceeds received from the 2017 PIPE. Net cash provided by financing activities in 2016 of $3.8 million reflected primarily net proceeds received from the 2016 PIPE.

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 continue our efforts to expand the commercialization of our ClearPoint system products, develop our ClearTrace system, and pursue additional applications for our technology platforms. Our cash balances are typically held in a variety of demand accounts 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 ClearPoint system products, complete the development of our ClearTrace system and pursue additional applications for our technology platforms. 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 cost of pursuing additional applications of our technology platforms under current collaborative arrangements, and 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 (prior to the suspension of such development);
- 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 [●] to [●] 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 Securities Exchange Act of 1934, or the Exchange Act. Our disclosure controls and procedures are designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others within our organization. Under their 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, 2017, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2017.

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, 2017, 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, 2017.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's assessment was not subject to attestation by our independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management's assessment in this Annual Report.

Changes in Internal Control over Financial Reporting

During the year ended December 31, 2017, 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, 2017, pursuant to Regulation 14A under the Exchange Act in connection with our 2018 annual meeting of stockholders.

Our Board of Directors has adopted a Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics applies to all of our employees, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions), agents and representatives, including directors and consultants. The Code of Business Conduct and Ethics is posted on our website at www.mriinterventions.com. We will provide a copy of this document to any person, without charge, upon request, by writing to our Investor Relations Department, 5 Musick, Irvine, CA 92618. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics, or waivers of such provisions, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors on our website identified above. The inclusion of our website address in this Annual Report does not include or incorporate by reference the information on our website into this Annual Report.

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, 2017, pursuant to Regulation 14A under the Exchange Act in connection with our 2018 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, 2017, pursuant to Regulation 14A under the Exchange Act in connection with our 2018 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, 2017, pursuant to Regulation 14A under the Exchange Act in connection with our 2018 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, 2017, pursuant to Regulation 14A under the Exchange Act in connection with our 2018 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 [●] through [●], 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

		Incorporation by Reference			
Exhibit Number	**Exhibit Description**	**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	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of MRI Interventions, Inc.	8-K	000-54575	3.1	June 8, 2015
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of MRI Interventions, Inc.	S-1	333-211647	3.3	August 2, 2016
3.4	Amended and Restated Bylaws	10-Q	000-54575	3.2	May 11, 2012
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4				
4.2	Specimen of Common Stock Certificate	S-1	333-211647	4.3	July 6, 2016
4.3	Form of Second Amended and Restated 5.5% Promissory Note, Due December 31, 2018, issued to Brainlab AG by MRI Interventions, Inc.	8-K	000-54575	4.3	March 22, 2016
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

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
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
4.11	Form of Series A Warrant to Purchase Common Stock issued in 2015 private offering	8-K	000-54575	4.1	December 15, 2015
4.12	Form of Series B Warrant to Purchase Common Stock issued in 2015 private offering	8-K	000-54575	4.2	December 15, 2015
4.13	Form of Series A Warrant to Purchase Common Stock issued to Brainlab AG	8-K	000-54575	4.1	March 22, 2016
4.14	Form of Series B Warrant to Purchase Common Stock issued to Brainlab AG	8-K	000-54575	4.2	March 22, 2016
4.15	Form of Omnibus Amendment dated June 30, 2016 by and among MRI Interventions, Inc., and certain holders of MRI Interventions, Inc.'s 12% Second-Priority Secured Non-Convertible Promissory Notes Due 2019	8-K	000-54575	10.1	July 1, 2016
4.16	Form of Omnibus Amendment dated June 30, 2016 to Second Amended and Restated Secured Note Due 2018	8-K	000-54575	10.2	July 1, 2016
4.17	Form of Warrant to Purchase Common Stock issued in connection with August 2016 note conversion	8-K	001-34822	4.1	September 1, 2016
4.18	Form of Second Omnibus Amendment dated August 31, 2016 by and among MRI Interventions, Inc., and certain holders of the Company's 12% Second-Priority Secured Non-Convertible Promissory Notes Due 2019	8-K	001-34822	10.3	September 1, 2016
4.19	Form of Warrant to Purchase Common Stock issued in 2017 private offering	8-K	001-34822	4.1	May 25, 2017
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	10	000-54575	10.9	December 28, 2011

	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				
10.6†	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
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

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
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.	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	10.20	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	10-Q	000-54575	10.56	August 14, 2013

	Healthcare Canada Corp. and MRI Interventions, Inc.				
10.23	License and Collaboration Agreement, dated April 25, 2017, by and between MRI Interventions, Inc. and Acoustic Medsystems, Inc.	10-Q	001-34822	10.1	May 9, 2017
10.24	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

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.25	Second Amendment to Lease Agreement dated as of February 24, 2015, by and between Shaw Investment Company, LLC and MRI Interventions, Inc.	10-K	000-54575	10.24	March 17, 2015
10.26	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
10.27	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
10.28	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
10.29	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
10.30	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
10.31	Form of Securities Purchase Agreement by and among MRI Interventions, Inc. and the investors party thereto with respect to December 2015 private offering	8-K	000-54575	10.1	December 15, 2015
10.32	Form of Registration Rights Agreement by and among MRI Interventions, Inc. and the investors party thereto	8-K	000-54575	10.2	December 15, 2015
10.33	Form of Securities Purchase Agreement by and between MRI Interventions, Inc. and Brainlab AG with respect to March 2016 private offering	8-K	000-54575	10.1	March 22, 2016
10.34	Form of Registration Rights Agreement by and between MRI Interventions, Inc. and Brainlab AG with respect to March 2016 private offering	8-K	000-54575	10.2	March 22, 2016
10.35	Form of Patent and Technology License Agreement by and between MRI Interventions, Inc. and Brainlab AG	8-K	000-54575	10.3	March 22, 2016
10.36	Form of Securities Purchase Agreement by and between the Company and the investors party thereto with respect to the August 2016 private offering	8-K	001-34822	10.1	September 1, 2016
10.37	Form of Registration Rights Agreement by and between the Company and the investors party thereto with respect to the August 2016 private offering	8-K	001-34822	10.2	September 1, 2016
10.38	Form of Securities Purchase Agreement by and between the Company and the investors party thereto with respect to the May 2017 private offering	8-K	001-34822	10.1	May 25, 2017
10.39	Form of Registration Rights Agreement by and between the Company and the investors party thereto with respect to the May 2017 private offering	8-K	001-34822	10.2	May 25, 2017
10.40+	2007 Stock Incentive Plan	10	000-54575	10.2	December 28, 2011
10.41+	2007 Stock Incentive Plan Form of Incentive Stock Option Agreement	10-K	000-54575	10.26	March 28, 2014
10.42+	2007 Stock Incentive Place Form of Non-Qualified Stock Option Agreement	10-K	000-54575	10.27	March 28, 2014
10.43+	2010 Incentive Compensation Plan	10	000-54575	10.4	December 28, 2011

10.44+	2010 Non-Qualified Stock Option Plan	10	000-54575	10.5	December 28, 2011
10.45+	2010 Non-Qualified Stock Option Plan Form of Non-Qualified Stock Option Agreement	10-K	000-54575	10.30	March 28, 2014

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.46+	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
10.47+	MRI Interventions, Inc. 2012 Incentive Compensation Plan	10	000-54575	10.34	February 9, 2012
10.48+	MRI Interventions, Inc. 2012 Incentive Compensation Plan Form of Incentive Stock Option Agreement	10	000-54575	10.35	February 9, 2012
10.49+	MRI Interventions, Inc. 2012 Incentive Compensation Plan Form of Non-Qualified Stock Option Agreement	10	000-54575	10.36	February 9, 2012
10.50+	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
10.51+	MRI Interventions, Inc. Amended and Restated 2013 Incentive Compensation Plan	Schedule 14A	000-54575	B	April 17, 2015
10.52+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Incentive Stock Option Agreement	10-Q	000-54575	10.53	August 14, 2013
10.53+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Non-Qualified Stock Option Agreement	10-Q	000-54575	10.54	August 14, 2013
10.54+	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
10.55+	MRI Interventions, Inc. 2013 Non-Employee Director Equity Incentive Plan	8-K	000-54575	10.1	December 6, 2013
10.56+	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
10.57+	MRI Interventions, Inc. Non-Employee Director Compensation Plan, as amended and restated by the Board of Directors of MRI Interventions, Inc. on December 12, 2017	8-K	001-34822	10.1	December 14, 2017
10.58+	Form of Indemnification Agreement	10	000-54575	10.8	December 28, 2011
10.59+	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
10.60+	Employment Offer Letter between MRI Interventions, Inc. and Harold A. Hurwitz	10-Q	000-54575	10.1	May 7, 2015
10.61+	Non-Competition Agreement between Harold A. Hurwitz and MRI Interventions, Inc.	10-Q	000-54575	10.2	May 7, 2015
10.62+	Non-Disclosure and Proprietary Rights Agreement between Harold A. Hurwitz and MRI Interventions, Inc.	10-Q	000-54575	10.3	May 7, 2015
10.63+	Consulting Agreement dated April 1, 2015 between MRI Interventions, Inc. and Kimble L. Jenkins	10-Q	000-54575	10.4	May 7, 2015
10.64+	Omnibus Amendment dated April 1, 2015 between MRI Interventions, Inc. and Kimble L. Jenkins	10-Q	000-54575	10.5	May 7, 2015
10.65+	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
10.66+	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
10.67+	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

10.68+	Second Amended and Restated Key Personnel Incentive Program	10-Q	000-54575	10.3	August 14, 2013
10.69+	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

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.70+	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
10.71+	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
10.72+	SurgiVision, Inc. Cardiac EP Business Participation Plan	10	000-54575	10.29	December 28, 2011
10.73+	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
10.74+	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
10.75+	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
10.76+	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
10.77+	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
10.78+	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
10.79+	Non-Qualified Stock Option Agreement, effective as of December 1, 2014, granted by MRI Interventions, Inc. to Wendelin C. Maners	S-1	333-201471	10.65	January 13, 2015
10.80+	Non-Qualified Stock Option Agreement, effective as of March 30, 2015 granted by MRI Interventions, Inc. to Harold A. Hurwitz	10-Q	000-54575	10.1	August 10, 2015
10.81*+	Amendment No. 1 dated December 15, 2016 to Consulting Agreement dated April 1, 2015 between MRI Interventions, Inc. and Kimble L. Jenkins	10-K	001-34822	10.78	March 9, 2017
10.82+	Amendment No. 2, dated April 1, 2017, to Consulting Agreement dated April 1, 2015 between MRI Interventions, Inc. and Kimble L. Jenkins	10-Q	001-34822	10.2	May 9, 2017
10.83+	Separation, Transition and Consulting Agreement, dated as of October 6, 2017 by and between MRI Interventions, Inc. and Francis P. Grillo	8-K	001-34822	10.1	October 10, 2017
10.84+	Employment Agreement, dated as of October 6, 2017, by and between MRI Interventions, Inc. and Joseph Michael Burnett	8-K	001-34822	10.2	October 10, 2017
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
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 21, 2018

/s/ Joseph M. Burnett
Joseph M. Burnett
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 Joseph M. Burnett and Harold A. Hurwitz, 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/ Joseph M. Burnett **Joseph M. Burnett**	*President and Chief Executive Officer (Principal Executive Officer)*	March 21, 2018
/s/ Harold A. Hurwitz **Harold A. Hurwitz**	*Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)*	March 21, 2018
/s/ Kimble L. Jenkins **Kimble L. Jenkins**	*Chairman and Director*	March 21, 2018
/s/ R. John Fletcher **R. John Fletcher**	*Director*	March 21, 2018
/s/ Pascal E.R. Girin **Pascal E.R. Girin**	*Director*	March 21, 2018
/s/ Timothy T. Richards **Timothy T. Richards**	*Director*	March 21, 2018
/s/ Maria Sainz **Maria Sainz**	*Director*	March 21, 2018
/s/ John N. Spencer, Jr. **John N. Spencer, Jr.**	*Director*	March 21, 2018

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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements
We have audited the accompanying consolidated balance sheets of MRI Interventions, Inc. (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Cherry Bekaert LLP

We have served as the Company's auditor since 2008.

Charlotte, North Carolina
March 21, 2018

MRI INTERVENTIONS, INC.

Consolidated Balance Sheets

	December 31,	
	2017	**2016**
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 9,289,831	$ 3,315,774
Accounts receivable, net	949,415	865,943
Inventory, net	2,314,184	1,768,382
Prepaid expenses and other current assets	192,727	134,996
Total current assets	12,746,157	6,085,095
Property and equipment, net	267,667	328,249
Software license inventory	871,900	976,900
Other assets	11,641	10,641
Total assets	$ 13,897,365	$ 7,400,885
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 759,445	$ 1,546,926
Accrued compensation	806,445	666,060
Other accrued liabilities	480,159	450,424
Derivative liabilities	95,786	131,173
Deferred product and service revenues	256,178	223,117
Senior secured note payable	2,000,000	-
Total current liabilities	4,398,013	3,017,700
Accrued interest	752,500	647,500
Senior secured note payable	-	2,000,000
2010 junior secured notes payable, net of unamortized discount of $1,956,458 and $2,302,472 at December 31, 2017 and 2016, respectively	1,043,542	697,528
2014 junior secured 12% notes payable, net of unamortized discount and deferred issuance costs aggregating $100,430 and $180,774 at December 31, 2017 and 2016, respectively	1,874,570	1,794,226
Total liabilities	8,068,625	8,156,954
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.01 par value; 25,000,000 shares authorized at December 31, 2017 and 2016; none issued and outstanding at December 31, 2017 and 2016	-	-
Common stock, $0.01 par value; 200,000,000 shares authorized at December 31, 2017 and 2016; 10,693,851 and 3,622,032 shares issued and outstanding at December 31, 2017 and 2016, respectively	106,937	36,220
Additional paid-in capital	106,757,920	93,076,475
Accumulated deficit	(101,036,117)	(93,868,764)
Total stockholders' equity (deficit)	5,828,740	(756,069)
Total liabilities and stockholders' equity (deficit)	$ 13,897,365	$ 7,400,885

See notes to consolidated financial statements.

MRI INTERVENTIONS, INC.

Consolidated Statements of Operations

	Years Ended December 31,	
	2017	**2016**
Revenues:		
Product revenues	$ 7,024,010	$ 5,600,453
Service and other revenues	355,515	149,001
Total revenues	7,379,525	5,749,454
Cost of revenues	2,898,808	2,642,763
Research and development costs	2,813,733	2,628,179
Sales and marketing expenses	3,956,455	3,777,119
General and administrative expenses	4,046,366	4,190,131
Operating loss	(6,335,837)	(7,488,738)
Other income (expense):		
Gain on change in fair value of derivative liabilities	24,728	1,065,935
Loss on debt restructuring	-	(811,909)
Other income, net	16,682	216,075
Interest expense, net	(872,926)	(1,051,258)
Net loss	$ (7,167,353)	$ (8,069,895)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.93)	$ (2.93)
Weighted average shares outstanding:		
Basic and diluted	7,738,343	2,754,803

See notes to consolidated financial statements.

MRI INTERVENTIONS, INC.

Consolidated Statements of Stockholders' Equity (Deficit)
Years Ended December 31, 2017 and 2016

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balances, December 31, 2015	2,284,537	$ 22,845	$ 83,722,596	$ (85,726,580)	$ (1,981,139)
Share-based compensation	29,117	291	1,186,809	-	1,187,100
Issuances of common stock:					
In payment of expenses	4,375	44	62,686	-	62,730
In connection with debt restructuring	99,310	993	1,347,727	-	1,348,720
Creation of derivative liabilities in connection with note and warrant restructuring	-	-	-	(72,289)	(72,289)
Cash paid in lieu of issuing fractional shares in reverse split of common stock	(552)	(5)	(4,755)	-	(4,760)
September 2016 private placement, net of offering costs of $140,749	1,201,000	12,010	5,635,350	-	5,647,360
Transfer of fair value of derivative liabilities upon conversion of related debt in connection with September 2016 private placement	-	-	1,088,432	-	1,088,432
Warrant exercise	4,245	42	37,630	-	37,672
Net loss for the year	-	-	-	(8,069,895)	(8,069,895)
Balances, December 31, 2016	3,622,032	36,220	93,076,475	(93,868,764)	(756,069)
Issuances of common stock:					
Share-based compensation	354,391	3,544	1,242,057	-	1,245,601
In payment of expenses	88,333	883	501,149	-	502,032
Warrant exercise	4,095	40	11,169	-	11,209
May 2017 private placement, net of offering costs of $1,244,581	6,625,000	66,250	11,927,070	-	11,993,320
Net loss for the year	-	-	-	(7,167,353)	(7,167,353)
Balances, December 31, 2017	10,693,851	$ 106,937	$106,757,920	$(101,036,117)	$ 5,828,740

See notes to consolidated financial statements.

MRI INTERVENTIONS, INC.

Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$ (7,167,353)	$ (8,069,895)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	116,454	155,707
Share-based compensation	1,245,601	1,187,100
Expenses paid through the issuance of common stock	502,032	62,730
Gain on change in fair value of derivative liabilities	(24,178)	(1,065,935)
Loss on debt restructuring	-	811,909
Loss on retirement of equipment	-	1,689
Amortization of debt issuance costs and original issue discounts	426,358	424,431
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(83,472)	352,100
Inventory	(469,922)	72,342
Prepaid expenses and other current assets	(57,731)	(37,748)
Other assets	(999)	-
Accounts payable and accrued expenses	(512,362)	178,419
Deferred revenue	33,061	107,108
Net cash flows from operating activities	(5,992,511)	(5,820,043)
Cash flows from investing activities:		
Purchases of property and equipment	(26,752)	(101,002)
Net cash flows from investing activities	(26,752)	(101,002)
Cash flows from financing activities:		
Net proceeds from equity private placements and exercise of warrants	11,993,320	3,833,052
Cash paid in lieu of issuing fractional shares in reverse split of common stock	-	(4,756)
Net cash flows from financing activities	11,993,320	3,828,296
Net change in cash and cash equivalents	5,974,057	(2,092,749)
Cash and cash equivalents, beginning of year	3,315,774	5,408,523
Cash and cash equivalents, end of year	$ 9,289,831	$ 3,315,774
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ -	$ -
Interest	$ 348,528	$ 976,295

See notes to consolidated financial statements.

MRI INTERVENTIONS, INC.

Consolidated Statements of Cash Flows

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

- During the year ended December 31, 2017 the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of $29,121 from inventory to loaned systems, which are included in property and equipment in the accompanying consolidated balance sheets. During the year ended December 31, 2016, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of $55,963 from loaned systems to inventory.

- Costs, amounting to $74,000, were incurred and unpaid at December 31, 2016, respectively, in connection with the Company's 2016 private placement (see Note 6), are included in accounts payable and were charged to stockholders' deficit in the accompanying December 31, 2016 consolidated balance sheet.

- As discussed in Note 7:

    - On June 30, 2016, the fair value of derivatives, amounting to $72,289 and arising from the June 2016 Amendments (as defined in Note 5) entered into with certain note holders, was established as a liability with a corresponding charge to stockholders' equity.

    - On September 2, 2016, certain notes payable, accounted for as derivatives, were converted into shares of the Company's common stock, and related warrants with down round price protection and accounted for as derivatives, were assigned a fixed strike price. As a result, derivative liabilities were reduced by $1,207,813, with a corresponding amount being recorded as an increase to stockholders' equity.

- During the years ended December 31, 2017 and 2016, exercise of warrants accounted for as derivatives resulted in reductions in the balance of derivative liabilities and corresponding increases to stockholders' equity amounting to $10,659 and $37,672, respectively.

See notes to consolidated financial statements.

1. Description of the Business and Financial Condition

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 capital equipment 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 that is designed to allow catheter-based minimally invasive procedures in the heart to be performed in an MRI suite. Although still a product candidate, the Company has suspended its efforts to commercialize the ClearTrace system.

Liquidity and Management's Plans

The Company has incurred net losses since its inception which has resulted in a cumulative deficit at December 31, 2017 of $101 million. As a result, management historically has expressed substantial doubt as to the Company's ability to continue as a going concern. As discussed in Note 6, in May 2017, the Company completed a private offering of equity units (the "2017 PIPE") through which the Company received aggregate gross proceeds of approximately $13.25 million, before deducting placement agents' fees and offering expenses aggregating approximately $1.3 million. As a result, the Company's cash and cash equivalent balances at December 31, 2017 aggregated $9.3 million, which, in management's opinion, is sufficient to support the Company's operations for at least the next twelve months and to alleviate doubt as to the Company's ability to continue as a going concern.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, MRI Interventions (Canada) Inc. All significant inter-company accounts and transactions have been eliminated.

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.

Reverse Stock Split

As discussed in Note 6, on July 21, 2016, the Company's Board of Directors approved a 1-for-40 reverse stock split of its issued common stock, which was effectuated on July 26, 2016. All disclosures of common shares and per share data in the accompanying consolidated financial statements and related notes have been adjusted retroactively to reflect the reverse stock split for all periods presented.

Cash and Cash Equivalents

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

Derivative Liabilities

Derivative liabilities represent the fair value of conversion features of certain notes and of certain warrants to purchase common stock (see Note 7). These derivative liabilities 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 consolidated statements of operations.

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, or inputs other than quoted prices that are observable 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 calculations:

	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value
December 31, 2017				
Derivative liabilities - warrants	$ -	$ -	$ 79,286	$ 79,286
Derivative liabilities – debt conversion feature	$ -	$ -	$ 16,500	$ 16,500
December 31, 2016				
Derivative liabilities - warrants	$ -	$ -	$ 91,173	$ 91,173
Derivative liabilities – debt conversion feature	$ -	$ -	$ 40,000	$ 40,000

Inputs used in the Company's Level 3 calculation of fair value include the assumed dividend rate on the Company's common stock, risk-free interest rates stock price volatility and the likelihood of a future equity financing transaction, all of which are further discussed in Note 7.

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, 2017 and 2016:

	Carrying Value	Estimated Fair Value
December 31, 2017		
Senior secured note payable, including accrued interest	$ 2,028,111	$ 2,028,111
2014 junior secured notes payable, including accrued interest	$ 1,942,195	$ 2,042,625
2010 junior secured notes payable, including accrued interest	$ 1,796,042	$ 3,752,500
December 31, 2016		
Senior secured note payable, including accrued interest	$ 2,028,111	$ 2,028,111
2014 junior secured notes payable, including accrued interest	$ 1,861,851	$ 2,042,625
2010 junior secured notes payable, including accrued interest	$ 1,345,028	$ 2,789,257

Inventory

Inventory is carried at the lower of cost (first-in, first-out method) or net realizable value. Items in inventory relate predominantly 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 ClearPoint capital equipment on loan to customers for evaluation purposes, 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 periodically 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 were to exceed 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, 2017 or 2016.

Revenue Recognition

The Company's revenues are comprised of: (1) product revenues resulting from the sale of functional neurological products, and drug delivery and biologic products; (2) product revenues resulting from the sale of ClearPoint capital equipment; and (3) revenues resulting from the rental, service, installation, training and shipping related to ClearPoint capital equipment. 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 individual agreement basis. The Company determines if the deliverables under the arrangement represent separate units of accounting as defined by GAAP. Application of GAAP regarding multiple-element arrangements requires the Company 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.

- *Sales of functional neurology products, and biologics and drug delivery systems products*: Revenues from the sale of functional neurology products (consisting of disposable products sold commercially and related to cases utilizing our ClearPoint system), and biologics and drug delivery systems (consisting primarily of disposable products related to customer-sponsored clinical trials utilizing our ClearPoint system), are recognized at the time risk of loss passes to the customer, which is generally upon delivery to the customer's location.

- *Sales of capital equipment*: The predominance of capital equipment sales (consisting of integrated computer hardware and software that are integral components of the Company's ClearPoint system) are preceded by customer evaluation periods of generally 90 days. During these evaluation periods, installation of, and training of customer personnel on, the systems have been completed and the systems have been in operation. Accordingly, capital equipment sales following such evaluation periods are recognized upon receipt of an executed purchase agreement or purchase order that provide for risk of loss to pass to the customer. Sales of capital equipment not having been preceded by an evaluation period are recognized on an individual agreement basis as described above.

- *Rental, service and other revenues:* Revenues from rental of ClearPoint capital equipment are recognized over the term of the rental agreement, which is less than one year. Revenues from service of ClearPoint capital equipment previously sold to customers are based on agreements with terms ranging from one to three years. Typically, the Company bills and collects service fees at the inception of the agreement and recognizes revenue ratably over the term of the related service agreement. Other revenues consist primarily of installation, training and shipping fees in connection with sales of ClearPoint capital equipment and is recognized as the related services are performed.

Product Warranties

The Company's standard policy is to warrant ClearPoint system capital equipment against defects in material or workmanship for one year following installation. The Company periodically reviews its estimate of costs to service warranty obligations based primarily on historical experience, which has been nominal. Such estimates are included in accrued liabilities in the accompanying consolidated balance sheets, and changes in such estimates are recorded as costs of product revenues in the accompanying consolidated statements of operations.

Research and Development Costs

Costs related to research, design and development of products are charged to research and development expense as incurred.

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 bases. 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, 2017 and 2016, the Company had no accrued interest or penalties related to uncertain tax positions.

Net Loss Per Share

The Company computes net loss per share using the weighted-average number of common shares outstanding during the period. Basic and diluted net loss per share are the same because the conversion, exercise or issuance of all potential common stock equivalents, which comprise the entire amount of the Company's outstanding common stock options and warrants as described in Note 6, would be anti-dilutive.

Share-Based Compensation

The Company accounts for compensation for all arrangements under which employees, directors 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 its 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: (i) historical volatilities of publicly traded companies it deemed similar to the Company; and (ii) the Company's historical volatility, which is limited, and will consistently apply this methodology until its own sufficient relevant historical data is exists. 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

The Company's common stock is traded in the over-the-counter market and is quoted on the OTCQB Marketplace and the OTC Bulletin Board under the symbol "MRIC." Quoted closing stock prices are used as a key input in determining the fair value for share-based transactions.

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 U.S. insured by the Federal Deposit Insurance Corporation. At December 31, 2017, the Company had approximately $103,559 in bank balances that were in excess of the insured limits.

For the year ended December 31, 2017, sales to no customers represented in excess of 10% of the Company's product revenues. For the year ended December 31, 2016, sales to one customer represented 10% of the Company's product revenues.

Information with respect to accounts receivable from those customers who comprised more than 10% of accounts receivable at December 31, 2017 and 2016 is as follows:

	December 31,	
	2017	**2016**
Customer – 1	10%	20%
Customer – 2	-	13%
Customer – 3	-	10%

Prior to granting credit, the Company performs credit evaluations of its customers' financial condition, and generally does not require collateral from its customers. The Company will provide an allowance for doubtful accounts when collections become doubtful. The allowance for doubtful accounts at December 31, 2017 and 2016 was $29,000 and $25,000, respectively.

The Company is subject to risks common to emerging companies in the medical device industry, including, but not limited to: new technological innovations; acceptance and competitiveness of its products; 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 August 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2015-14 as an amendment to ASU 2014-09, "Revenue from Contracts with Customers," which created 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, and ASUs 2016-10, 2016-12, 2016-20 and 2017-13 discussed below, are effective for the Company beginning in 2018.

- In April 2016, the FASB issued ASU 2016-10, "Revenues from Contracts With Customers (Topic 606): Identifying Performance Obligations and Licensing," which clarified guidance related to identifying performance obligations and licensing implementation guidance contained in ASC Topic 606 as promulgated by ASU 2015-14 discussed above.

- In May 2016, the FASB issued ASU 2016-12, "Revenues from Contracts With Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients," which address narrow-scope improvements to the guidance on collectability, noncash consideration, and completed contracts at transition. Additionally, the amendments in this ASU provide a practical expedient for contract modifications at transition and an accounting policy election related to the presentation of sales taxes and other similar taxes collected from customers.

- In December 2016, the FASB issued ASU 2016-20, "Technical Corrections and Improvements to Topic 606, Revenue from Contracts With Customers," which provided for minor corrections and minor improvements to previously issued Topic 606 guidance.

- In September 2017, the FASB issued ASU 2017-13, "Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842)," which added and deleted paragraphs pursuant to SEC Staff Announcements and SEC Observer Comments.

- In November 2017, the FASB issued ASU 2017-14, "Income Statement – Reporting Comprehensive Income (Topic 220), Revenue Recognition (Topic 605), and Revenue from Contracts with Customers (Topic 606)," which amends SEC paragraphs pursuant to the SEC Staff Accounting Bulletin No. 116 and SEC Release No. 33-10403, which bring existing guidance into conformity with Topic 606

The Company has assessed the potential impact of the provisions ASU 2015-14 and the subsequently issued related ASUs discussed above (collectively, "Topic 606") on its consolidated financial statements. In its assessment, the Company has considered such factors as the following:

- *Economic factors:*
    - The Company's revenues are comprised of the product and service lines described below. With respect to each of these product and service lines:
        - The Company's customers are predominantly large, well-known hospitals. Accounts receivable are due in a range of 30-60 days from the date of product delivery. The Company establishes an allowance for doubtful accounts, which historically has not been material.
        - Due to the short-term nature of the Company's performance obligations, the Company has no remaining post-transaction performance obligations.
    - Based on the foregoing, the Company has concluded that the nature, amount and certainty of revenue recognition for each of the product and service lines described below are not affected by economic factors.

- *Sales of functional neurology products, and biologics and drug delivery systems products*: Revenues are recognized generally upon delivery to the customer's location, consistent with the Topic 606 criterion related to the point in time at which the customer obtains control of the product.

- *Sales of capital equipment*: As discussed above, under the heading "Revenue Recognition," the predominance of capital equipment sales is preceded by customer evaluation periods of generally 90 days. During these evaluation periods, installation of, and training of customer personnel on, the systems have been completed (recognition of revenue from such installation and training is discussed below) and the systems have been in operation. Accordingly, capital equipment sales following such evaluation periods are recognized upon receipt of an executed purchase agreement or purchase order that provide for risk of loss to pass to the customer. Sales of capital equipment not having been preceded by an evaluation period are generally recognized upon delivery to the customer's location, consistent with the Topic 606 criterion related to the point in time at which the customer obtains control of the product.

- *Rental, service and other revenues:*
    - Revenues from rental of capital equipment are recognized over the term of the rental agreement, which is less than one year, and which is consistent with the Topic 606 criterion of recognizing revenue for such contracts on a straight-line basis.
    - Revenues from service of capital equipment previously sold to customers are based on agreements with terms ranging from one to three years. The Company's performance obligations with respect to such service agreements consists predominantly of being available to service the equipment and the Company's historical cost of performing service on capital equipment has been nominal. Typically, the Company bills and collects service fees at the inception of the agreement and recognizes revenue ratably over the term of the related service agreement, which the Company believes is consistent with the Topic 606 criterion of recognizing revenue for such contracts on a straight-line basis.

- Other revenues consist primarily of installation, training and shipping fees in connection with sales of capital equipment. Such fees are recognized as revenue at the point in time at which the related sale of the capital equipment is recognized, as discussed above, which the Company has concluded is consistent with the Topic 606 criterion related to the satisfaction of performance obligations.

Based on the foregoing assessment, the Company concluded that adoption of Topic 606 will not have a material effect on its consolidated financial statements. The Company adopted the provisions of Topic 606 on January 1, 2018 under the modified retrospective method permitted by such provisions.

In February 2016, the FASB issued ASU 2016-02, "Leases," which created a new Topic, ASC Topic 842 and established the core principle that a lessee should recognize the assets, representing rights-of-use, and liabilities to make lease payments, that arise from leases. For leases with a term of 12 months or less, a lessee is permitted to make an election under which such assets and liabilities would not be recognized, and lease expense would be recognized generally on a straight-line basis over the lease term. This standard is effective for the Company beginning in 2019, and early application is permitted. The Company currently has two leases for manufacturing and office space that would be subject to the provisions of ASU 2016-02. The Company believes that adoption of ASC Topic 842 (as amended by ASC 2017-13 described above) will result in the establishment on the Company's consolidated balance sheet of an asset and liability for each such lease, but that neither such assets and liabilities nor the resulting lease expense recognition will have a material effect on the Company's consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments," which addresses eight specific cash flow issues with the objective of reducing existing diversity in practice. The standard is effective for the Company beginning in 2018, and early adoption is permitted. The Company believes that adoption of ASU 2016-15 will not have a material effect on its consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, "Compensation – Stock Compensation (Topic 718)," which clarifies and reduces both (i) diversity in practice and (ii) cost and complexity when a company changes the terms or conditions of a share-based payment award. The standard is effective for the Company beginning in 2018, and early adoption is permitted. The Company believes that adoption of ASU 2017-09 will not have a material effect on its consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, "Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception," which, among other items, changes the classification of certain equity-linked financial instruments (or embedded features) with down round features. The standard is effective for the Company beginning in 2019, and early adoption is permitted. Because the terms of the Company's currently existing derivative liabilities described in Note 7, all of which the Company believes are included in the scope of the standard, will have expired prior to the standard's effective date, the Company believes that adoption of the standard on its effective date will not have a material effect on the Company's consolidated financial statements.

2016 Fourth Quarter Adjustment

In August 2016, the Company elected to suspend its efforts to sell equity units through a public offering then underway, and instead commenced a private placement of equity units through the 2016 PIPE (see Note 6). Upon suspension of its public offering efforts, the Company capitalized certain related legal and other costs, amounting to $459,000, in anticipation of resuming public offering efforts within an estimated six-month time frame. In December 2016, the Company determined that a future public offering it might consider was not likely to be commenced within this six-month time frame, and accordingly, in the fourth quarter of 2016, the Company recorded a charge of $459,000 to general and administrative expense.

3. Inventory

Inventory consists of the following as of December 31:

	2017	2016
Raw materials and work in process	$ 1,167,142	$ 1,025,368
Software licenses	52,500	70,000
Finished goods	1,094,542	673,014
Inventory included in current assets	2,314,184	1,768,382
Software licenses – non-current	871,900	976,900
	$ 3,186,084	$ 2,745,282

4. Property and Equipment

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

	2017	2016
Equipment	$ 1,151,543	$ 1,165,076
Furniture and fixtures	112,143	112,143
Leasehold improvements	179,999	179,999
Computer equipment and software	148,017	150,304
Loaned systems	348,473	431,608
	1,940,175	2,039,130
Less accumulated depreciation and amortization	(1,672,508)	(1,710,881)
Total property and equipment, net	$ 267,667	$ 328,249

Depreciation and amortization expense related to property and equipment for the years ended December 31, 2017 and 2016 was $116,454 and $155,707, respectively. Loaned systems are ClearPoint systems that are in operation at customer sites on an evaluation basis.

5. Notes Payable

Senior Secured Note Payable

The indebtedness outstanding under the senior secured note payable to Brainlab, originally issued to Brainlab on April 5, 2011, and subsequently amended and restated on March 6, 2013 (the "Brainlab Note"), at December 31, 2015 was approximately $5.0 million, including approximately $740,000 of accrued interest which accrued at a rate of 5.5% and was payable in a single aggregate installment upon maturity of the indebtedness. The Brainlab Note was to mature in April 2016.

On April 4, 2016 (the "Closing Date"), the Company and Brainlab finalized a securities purchase agreement (the "2016 Purchase Agreement"), as discussed below.

2016 Purchase Agreement

Under the 2016 Purchase Agreement, the Company: (i) paid to Brainlab all accrued and unpaid interest on the Brainlab Note, in the amount of approximately $740,000; (ii) amended and restated the Brainlab Note on the terms described below; (iii) entered into a patent and technology license agreement with Brainlab (the "License Agreement") for software relating to the Company's SmartFrame device, in consideration for the cancellation of $1.0 million of the principal amount of the Brainlab Note; (iv) issued to Brainlab, in consideration for the cancellation of approximately $1.3 million of the principal amount of the Brainlab Note, 99,310 units, consisting of: (a) one share of the Company's common stock; (b) warrants to purchase 0.4 share of common stock (the "2016 Series A Warrants"); and (c) warrants to purchase 0.3 shares of common stock (the "2016 Series B Warrants") (collectively, the "Equity Units"); and (v) entered into a Registration Rights Agreement, pursuant to which the Company agreed to file a registration statement with the SEC covering the resale of the shares of common stock issued to Brainlab under the 2016 Purchase Agreement, as well as the shares of common stock that are issuable upon exercise of the 2016 Series A Warrants and 2016 Series B Warrants.

The 2016 Purchase Agreement contains covenants, representations and warranties by the Company and Brainlab (including indemnification from the Company in the event of breaches of its representations and warranties), which the Company believes are customary for transactions of this type.

As a result of the foregoing, on the Closing Date, the Company recorded a debt restructuring gain of approximately $941,000 representing the difference between (a) the aggregate fair value of the License Agreement, which had no cost basis on the Company's consolidated balance sheets, and the Equity Units, and (b) the aggregate principal amount of the Brainlab Note cancelled as consideration.

2016 Warrants

The 2016 Series A Warrants and 2016 Series B Warrants are exercisable, in full or in part, at any time prior to the fifth anniversary of their issuance, at an exercise price of $16.23 per share (before giving effect to the Note Conversion as defined below) and $21.10 per share, respectively, subject to provisions for: (a) adjustments in the case of certain corporate transactions; (b) consideration to be received in lieu of shares of the Company's common stock in the case of certain fundamental transactions; and (c) a "cashless exercise" feature.

Amended and Restated Promissory Note

On the Closing Date and pursuant to the 2016 Purchase Agreement, the Company issued Brainlab an unregistered, amended and restated secured note (the "New Brainlab Note"), which has the same terms and conditions as the Brainlab Note, except that: (i) the principal amount of the New Brainlab Note is $2 million; (ii) interest will be paid quarterly in arrears; and (iii) the maturity date of the New Brainlab Note is December 31, 2018.

Non-Exclusive License Agreement

On the Closing Date and pursuant to the 2016 Purchase Agreement, the Company and Brainlab entered into the License Agreement, for software relating to the Company's SmartFrame device, for use in neurosurgery. The License Agreement does not affect the Company's ability to continue to independently develop, market and sell its own software for the SmartFrame device.

The New Brainlab Note is collateralized by a senior security interest in all the assets of the Company.

2014 Junior Secured Notes Payable

In March 2014, the Company entered into securities purchase agreements for the private placement of: (i) second-priority secured non-convertible promissory notes (the "2014 Secured Notes); and (ii) warrants to purchase 0.01 shares of the Company's common stock for each dollar in principal amount of the 2014 Secured Notes sold by the Company (the "investor warrants"). 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 27,937 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 bear interest at a rate of 12% per year, payable semi-annually, in arrears. 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. The 2014 Secured Notes are collateralized by a security interest in all the Company's assets, which security interest is junior and subordinate to the security interest that collateralizes the New Brainlab Note.

The investor warrants are exercisable, in full or in part, at any time prior to the fifth anniversary of the issuance date, at an original exercise price of $70.00 per share, subject to provisions for: (a) adjustments in the case of certain corporate transactions; (b) consideration to be received in lieu of shares of the Company's common stock in the case of certain fundamental transactions; and (c) a "cashless exercise" feature.

Under GAAP, the Company allocated the $3,725,000 in proceeds proportionately between the 2014 Secured Notes and the investor warrants based on their relative fair values, with $413,057 being allocated to the fair value of the investor warrants, recorded as equity and as a discount to the carrying amount at the date of issuance. After giving effect to the conversions discussed below under the heading *"August 31, 2016 Amendments,"* the unamortized discount at December 31, 2017 and 2016 was $67,770 and $121,985, respectively. This discount is being amortized to interest expense over the five-year term of the 2014 Secured Notes using the effective interest method. The carrying amount of the 2014 Secured Notes in the accompanying condensed consolidated balance sheets is also presented net of issuance costs, as discussed further below.

Non-employee directors of the Company purchased a total of $1,100,000 of the 2014 Secured Notes, either directly or through a trust. The Company's placement agents earned cash commissions of $145,500 as well as warrants (the "placement agent warrants") to purchase 1,818 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, aggregating $76,186, were recorded as deferred financing costs and are presented as reductions of the carrying amount of the 2014 Secured Notes in the accompanying condensed consolidated balance sheets. These deferred financing costs, having an unamortized balance of $32,660 and $58,789 at December 31, 2017 and 2016, respectively, are being amortized to interest expense over the term of the 2014 Secured Notes using the effective interest method.

2010 Junior Secured Notes Payable

In November 2010, the Company issued units consisting of a junior secured note (the "2010 Secured Notes") and one share of the Company's common stock. An aggregate of 267,857 units were issued, and the Company received proceeds of $3,000,000 representing the aggregate principal amount of the 2010 Secured Notes. The 2010 Secured Notes mature in November 2020, accrue interest at the rate of 3.5% per year, and are collateralized by a security interest in all the assets of the Company, which security interest is junior and subordinate to the security interests that collateralize the New Brainlab Note and the 2014 Secured Notes. All outstanding principal and interest on the 2010 Secured Notes will be due and payable in a single payment upon maturity.

Under GAAP, the Company allocated the $3 million in proceeds from the sale of the units between the 2010 Secured Notes and the shares of common stock based on their relative fair values that resulted in $2,775,300 being allocated to the value of the shares of common stock, which was recorded as equity and as a discount to the carrying value of the 2010 Secured Notes at their date of issuance. The unamortized discount at December 31, 2017 and 2016 was $1,956,458 and $2,302,472, respectively. This discount is being amortized to interest expense over the 10-year term of the notes using the effective interest method.

Four then-serving officers of the Company purchased an aggregate of 22,068 units in the offering for $247,164. In addition, three non-employee directors of the Company also purchased an aggregate of 14,180 units in the offering for $158,816.

June 30, 2016 Amendments

On June 30, 2016, the Company entered into amendments (the "June 2016 Amendments") with: (a) Brainlab, with respect to the New Brainlab Note; and (b) two holders of the 2014 Secured Notes (the "2014 Convertible Note Holders"), one of which is a trust for which one of the Company's then non-employee directors serves as a trustee, having an aggregate principal balance of $3 million. Pursuant to the June 2016 Amendments, the parties agreed that, in the event the Company closes a qualified public offering: (i) $500,000 of the principal balance of the New Brainlab Note and an aggregate $1.5 million of the principal balance of the 2014 Secured Notes, plus all unpaid accrued interest on such principal amounts, would automatically convert into the security offered in the qualified public offering, based on the public offering price of that security; and (ii) the exercise price for 34,957 shares of common stock underlying warrants issued in connection with the New Brainlab Note and 11,250 shares of common stock underlying warrants issued in connection with the 2014 Secured Notes would be reduced to equal the greater of (x) the public offering price of the security offered in the qualified public offering, or (y) if the security offered in the qualified public offering is or includes convertible stock or common stock warrants, the highest price per whole share for which the Company's common stock is issuable upon conversion of such convertible stock or upon exercise of such common stock warrants. As discussed under the heading "*August 31, 2016 Amendments,*" the 2014 Convertible Note Holders subsequently entered into the August 2016 Amendments (defined below), which superseded the June 2016 Amendments, and converted the 2014 Principal (defined below), under the terms of the August 2016 Amendments.

The provisions of the June 2016 Amendments created: (a) a conversion feature allowing for the principal balances described above, plus all unpaid related accrued interest, to be converted into the security offered in the qualified public offering, and at a price that may be less than the market value per share of the Company's common stock; and (b) down round strike price protection with respect to the warrants, both of which the Company has accounted for as derivatives, the calculation for which is described in Note 7.

In addition, based on the provisions of the June 2016 Amendments, the Company recorded a debt restructuring loss of approximately $820,000 resulting from the restructuring of the New Brainlab Note and the 2014 Secured Notes subject to the June 2016 Amendments.

August 31, 2016 Amendments

On August 31, 2016, the Company entered into second amendments (the "August 2016 Amendments") with the 2014 Convertible Note Holders.

Pursuant to the August 2016 Amendments, the parties agreed that, in the event the Company closes a PIPE Transaction (as that term is defined in the August 2016 Amendments; the "2016 PIPE"): (i) an aggregate $1.75 million of aggregate principal balance of the 2014 Convertible Note Holders' 2014 Secured Notes (the "2014 Principal") would automatically convert into the security offered by the Company in the 2016 PIPE, based on the offering price of that security in the 2016 PIPE (the "Note Conversion"); and (ii) the exercise price for 13,125 shares of common stock that may be purchased upon exercise of warrants issued in connection with the issuance of the 2014 Secured Notes (the "2014 Warrants") will be reduced to equal the greater of (x) the offering price of the security offered in the 2016 PIPE, or (y) if the security offered in the 2016 PIPE is or includes convertible stock or common stock warrants, the highest price per whole share for which the Company's common stock is issuable upon conversion of such convertible stock or upon exercise of such common stock warrants. These provisions maintained but modified: (a) the conversion feature allowing for the 2014 Principal to be converted into the security offered in the 2016 PIPE, and at a price that may be less than the market value per share of the Company's common stock; and (b) the down round strike price protection with respect to the 2014 Warrants, both of which the Company has accounted for as derivatives, the calculation for which is described in Note 7.

Execution of the August 2016 Amendments constituted a debt extinguishment under GAAP, necessitating the Company to record a debt restructuring loss of approximately $933,000, representing the aggregate difference in the fair value of the derivatives described in the preceding paragraph between the points in time (i) immediately preceding, and (ii) immediately subsequent to, the execution of the August 2016 Amendments.

As described in Note 6, the 2016 PIPE was completed on September 2, 2016, resulting in (i) conversion of the 2014 Principal, and (ii) establishment of a fixed exercise price and elimination of the down round price protection with respect to the 2014 Warrants, in conformity with the terms set forth in the August 2016 Amendments. Accordingly, concurrent with completion of the 2016 PIPE, derivative liabilities associated with the conversion feature of the 2014 Principal and the down round price protection for the 2014 Warrants were reduced by $1,207,813, with a corresponding amount being recorded as an increase to stockholders' equity.

Scheduled Notes Payable Maturities

Scheduled principal payments as of December 31, 2017 with respect to notes payable are summarized as follows:

Years ending December 31,	
2018	$ 2,000,000
2019	1,975,000
2020	3,000,000
Total scheduled principal payments	6,975,000
Less unamortized discounts	(2,024,228)
Less unamortized deferred financing costs	(32,660)
	$ 4,918,112

6. Stockholders' Equity

2016 Private Placement

On September 2, 2016, the Company completed the 2016 PIPE, pursuant to the terms of a Securities Purchase Agreement dated August 31, 2016 (the "2016 PIPE Purchase Agreement"), by and among the Company and certain investors (collectively, the "2016 PIPE Investors"). At the closing, in accordance with the terms and conditions of the 2016 PIPE Purchase Agreement, the Company sold to the 2016 PIPE Investors an aggregate of 851,000 units (the "2016 PIPE Units"), with each 2016 PIPE Unit consisting of: (i) one share of the Company's common stock; and (ii) a warrant to purchase 0.90 shares of the Company's common stock (each, a "2016 PIPE Warrant" and collectively, the "2016 PIPE Warrants").

In connection with the sale of the 2016 PIPE Units, the Company received aggregate gross proceeds of approximately $4.25 million, before deducting placement agents' fees and offering expenses aggregating approximately $418,000. In addition, the placement agents for the 2016 PIPE received, in the aggregate, warrants ("2016 PIPE Placement Agent Warrants") to purchase up to 29,680 shares of common stock.

Purchase Agreement

The 2016 PIPE Purchase Agreement contains representations and warranties by the Company and the 2016 PIPE Investors and covenants of the Company and the 2016 PIPE Investors (including indemnification from the Company in the event of breaches of its representations and warranties), which the Company believes are customary for transactions of this type.

Warrants

The 2016 PIPE Warrants are exercisable, in full or in part, at any time prior to September 2, 2021, at an exercise price of $5.50 per share, subject to provisions for: (a) adjustments in the case of certain corporate transactions; (b) consideration to be received in lieu of shares of the Company's common stock in the case of certain fundamental transactions; and (c) a "cashless exercise" feature. The 2016 PIPE Placement Agent Warrants have the same terms and conditions as the 2016 PIPE Warrants.

Related Debt Conversion

As discussed in Note 5, pursuant to the August 2016 Amendments, in addition to and simultaneously with the sale of the 2016 PIPE Units, on September 2, 2016: (i) the 2014 Principal automatically converted into 350,000 2016 PIPE Units on the same terms and conditions as applied to purchasers of 2016 PIPE Units; and (ii) the exercise price for 13,125 shares of common stock that may be purchased upon exercise of the holders' 2014 Warrants was reduced to $5.50 per share, which is equal to the per share exercise price of the 2016 PIPE Warrants.

2017 Private Placement

On May 26, 2017, the Company completed the 2017 PIPE pursuant to a Securities Purchase Agreement dated May 25, 2017 (the "2017 PIPE Purchase Agreement") with certain accredited investors (collectively, the "2017 PIPE Investors") for the private placement of 6,625,000 units (the "2017 PIPE Units") at a purchase price of $2.00 per unit, with each unit consisting of: (i) one share of the Company's common stock; and (ii) a warrant to purchase one share of the Company's common stock (each, a "2017 PIPE Warrant" and collectively, the "2017 PIPE Warrants").

In connection with the sale of the 2017 PIPE Units, the Company received aggregate gross proceeds of approximately $13.25 million, before deducting placement agents' fees and offering expenses aggregating approximately $1.3 million. In addition, the placement agents for the 2017 PIPE received, in the aggregate, warrants ("2017 PIPE Placement Agent Warrants") to purchase up to 509,200 shares of common stock.

Purchase Agreement

The 2017 PIPE Purchase Agreement contains representations and warranties by the Company and the 2017 PIPE Investors and covenants of the Company and the 2017 PIPE Investors (including indemnification from the Company in the event of breaches of its representations and warranties), which the Company believes are customary for transactions of this type.

Registration Rights Agreement

Concurrent with completion of the 2017 PIPE, the Company and the 2017 PIPE Investors entered into a Registration Rights Agreement (the "2017 PIPE Registration Rights Agreement") pursuant to which the Company was required to prepare and file a registration statement (the "2017 PIPE Registration Statement") with the SEC under the Securities Act of 1933, as amended, covering the resale of the shares of common stock to be issued to the 2017 PIPE Investors under the 2017 PIPE Purchase Agreement as well as the shares of common stock underlying the 2017 PIPE Warrants and the 2017 PIPE Placement Agent Warrants. The Company was required to file such 2017 PIPE Registration Statement on or before June 26, 2017, and was required to use its best efforts to have the 2017 PIPE Registration Statement declared effective as soon as practicable. The Company filed the 2017 PIPE Registration Statement on June 26, 2017, and the 2017 PIPE Registration Statement was declared effective by the SEC on July 7, 2016, both dates being in conformity with the foregoing requirements. Pursuant to the 2017 PIPE Registration Rights Agreement, if the Company fails to continuously maintain the effectiveness of the 2017 PIPE Registration Statement (with certain permitted exceptions), the Company will incur certain liquidated damages to the 2017 PIPE Investors. The 2017 PIPE Registration Rights Agreement also contains mutual indemnifications by the Company and each 2017 PIPE Investor, which the Company believes are customary for transactions of this type.

Warrants

The 2017 PIPE Warrants are exercisable, in full or in part, at any time prior to the fifth anniversary of their issuance, at an exercise price of $2.20 per share, subject to provisions for: (a) adjustments in the case of certain corporate transactions; (b) consideration to be received in lieu of shares of the Company's common stock in the case of certain fundamental transactions; and (c) a "cashless exercise" feature. The 2017 PIPE Placement Agent Warrants have the same terms and conditions as the 2017 PIPE Warrants.

Issuance of Common Stock in Lieu of Cash Payments

Under the terms of the Amended and Restated Non-Employee Director Compensation Plan, each non-employee member of the Company's Board of Directors may elect to receive all or part of his or her director fees in shares of the Company's common stock. Director fees, whether paid in cash or in shares of common stock, are payable quarterly on the last day of each fiscal quarter. The number of shares of common stock issued to directors is determined by dividing (i) the product of: (x) the fees otherwise payable to each director in cash, times (y) the percentage of fees the director elected to receive in shares of common stock, by (ii) the volume weighted average price per share of common stock over the last five trading days of the quarter. During the years ended December 31, 2017 and 2016, 14,650 shares and 22,313 shares, respectively, were issued to directors as payment for director fees, amounting to $37,740 and $124,069, in 2017 and 2016, respectively, in lieu of cash.

Stock Incentive Plans

The Company has various share-based compensation plans and share-based compensatory contracts (collectively, the "Plans") under which it has granted share-based awards, such as stock grants, and incentive and non-qualified stock options, to employees, directors, consultants and advisors. Awards may be subject to a vesting schedule as set forth in individual award agreements. Certain of the Plans also have provided for cash-based performance bonus awards.

From June 2015 until October 2017, the Company granted share-based awards under the MRI Interventions, Inc. Amended and Restated 2013 Incentive Compensation Plan. At the Annual Meeting of the Company's stockholders on October 3, 2017, the Company's stockholders approved the adoption of the MRI Interventions, Inc. Second Amended and Restated 2013 Incentive Compensation Plan (the "Amended 2013 Plan"). The material change effected in the Amended 2013 Plan was to increase the number of shares of the Company's common stock available for awards thereunder by 1,800,000 shares.

Under the Amended 2013 Plan, a total of 1,956,250 shares of the Company's common stock are reserved for issuance. Of this amount, stock grants of 105,185 shares have been awarded and option grants, net of options terminated, expired or forfeited, of 754,569 shares were outstanding as of December 31, 2017. Accordingly, 1,096,496 shares remained available for grants under the Amended 2013 Plan as of that date.

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

	Options Outstanding	Options Exercisable	Range of Exercise Prices		Weighted-average Exercise price per share	Intrinsic Value (1)
Outstanding at January 1, 2016	298,283		$ 29.60	$ 385.60	$ 48.73	-
Exercisable at January 1, 2016		179,216	$ 29.60	$ 385.60	$ 56.40	-
Activity during the year ended December 31, 2016						
Granted	53,750		$ 5.00	$ 12.40	$ 6.40	
Exercised	-					
Cancelled or forfeited	(14,592)		$ 5.00	$ 385.60	$ 12.67	
Outstanding at December 31, 2016	337,441		$ 5.00	$ 385.60	$ 42.07	-
Exercisable at December 31, 2016		245,989	$ 5.00	$ 385.60	$ 38.71	-
Activity during the year ended December 31, 2017						
Granted	940,875		$ 1.95	$ 6.40	$ 2.58	$ 78,486
Exercised	-		-	-	-	-
Cancelled or forfeited	(40,117)		$ 5.00	$ 385.60	$ 35.74	-
Outstanding at December 31, 2017	1,238,199		$ 1.95	$ 385.60	$ 12.47	$ 78,486
Exercisable at December 31, 2017		567,210				-

(1) Intrinsic value is calculated as the estimated fair value of the Company's stock at the end of the related period less the option exercise price of in-the-money options.

The following table summarizes information about stock options at December 31, 2017 (contractual life expressed in years):

	Options Outstanding			Options Exercisable		
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
$1.95 - $45.20	1,161,323	9.18	$ 8.49	490,428	8.40	$ 16.08
$46.40 - $83.60	75,995	3.89	$ 69.09	75,901	3.88	$ 69.11
$128.00 - $385.60	881	0.88	$ 363.21	881	0.88	$ 363.21
	1,238,199	9.18	$ 12.47	567,210	7.78	$ 16.08

The weighted average grant date fair value of options granted during the years ended December 31, 2017 and 2016 was $0.85 and $3.01, respectively. A summary of the status of the Company's nonvested stock options during the years ended December 31, 2017 and 2016 is presented below:

Nonvested Stock Options	Shares	Weighted - Average Grant Date Fair Value
Nonvested, January 1, 2016	119,067	$ 18.77
Activity during the year ended December 31, 2016		
Granted	53,750	$ 3.01
Forfeited	(6,918)	$ 28.66
Vested	(74,447)	$ 18.16
Nonvested, December 31, 2016	91,452	$ 10.53
Activity during the year ended December 31, 2017		
Granted	940,875	$ 0.85
Forfeited	(17,619)	$ 16.50
Vested	(343,719)	$ 3.09
Nonvested, December 31, 2017	670,989	$ 1.45

The Company records share-based compensation expense on a straight-line basis over the related vesting period. For the years ended December 31, 2017 and 2016, share-based compensation expense related to options was:

Year Ended December 31,	
2017	2016
$ 960,882	$ 959,585

As of December 31, 2017, approximately $813,000 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 1.4 years.

The assumptions used in calculating the fair value under the Black-Scholes option-pricing model are as follows:

	Years Ended December 31,	
	2017	2016
Dividend yield	0%	0%
Expected Volatility	51.77% to 52.98%	47.47% to 50.69%
Risk free Interest rates	2.04% to 2.25%	1.23% to 1.39%
Expected lives (in years)	6.0	6.0

Warrants

Warrants have generally been issued in connection with financing transactions and for terms of up to five years. Common stock warrant activity for the years ended December 31, 2017 and 2016 is as follows:

	Shares	Weighted - Average Exercise Price
Outstanding at January 1, 2016	845,257	$ 25.67(1)
Activity during the year ended December 31, 2016		
Issued	1,208,845	$ 6.23
Exercised	(15,625)	$ 5.00
Terminated	(47,184)	$ 14.77
Outstanding at December 31, 2016	1,991,293	$ 13.00(2)
Activity during the year ended December 31, 2017		
Issued	7,134,200	$ 2.20
Exercised	(8,207)	$ 2.00
Terminated	(168,208)	$ 17.64
Outstanding at December 31, 2017	8,949,078	$ 4.12(3)

(1) The weighted-average exercise price reflects exercise price adjustments triggered by the 2015 PIPE.

(2) The weighted-average exercise price reflects exercise price adjustments triggered by the 2016 Purchase Agreement and the 2016 PIPE.

(3) The weighted-average exercise price reflects exercise price adjustments triggered by the 2017 PIPE.

Information regarding outstanding warrants at December 31, 2017 is as follows (contractual life expressed in years):

Exercise Price	Number Outstanding	Weighted - Average Remaining Contractual Life	Intrinsic Value (1)
$ 1.83	1,540	3.0	$ 1,417
2.00	91,670	0.1	68,753
2.20	7,133,700	4.4	3,923,535
5.50	1,123,705	3.8	-
16.23	242,021	3.0	-
21.10	152,084	3.0	-
34.32	185,779	2.0	-
40.00	875	2.1	-
70.00	17,704	1.3	-
	8,949,078	4.2	$ 3,993,704

(1) Intrinsic value is calculated as the estimated fair value of the Company's stock at December 31, 2017 less the warrant exercise price of in-the-money warrants.

7. Derivative Liabilities

As discussed in Note 5, on June 30, 2016, the Company entered into amendments with Brainlab, with respect to the New Brainlab Note, and with the 2014 Convertible Note Holders, the provisions of which created: (a) a conversion feature allowing for the principal balance described above to be converted at a public offering price that may be less than market value per share of the Company's common stock; and (b) down round strike price protection with respect to the warrants. In addition, warrants issued in 2013 contain net-cash settlement and down round provisions.

Under GAAP, the provisions described above require that the conversion feature and the warrants be accounted for as derivatives, thus requiring that they each be adjusted to estimated fair value at each balance sheet date and shown as liabilities in the accompanying condensed consolidated balance sheets. The fair values of the conversion feature and the warrants were calculated using the Monte Carlo simulation valuation method. Assumptions used in calculating the fair value of the conversion feature at December 31, 2017 are as follows:

Risk free interest rates	1.76%
Volatility	55%

Assumptions used in calculating the fair value of the warrants at December 31, 2017 are as follows:

Dividend yield	0%
Expected volatility	45%
Risk free interest rates	1.28 – 2.01%
Expected remaining term (in years)	0.1 – 3.25

In addition to the assumptions above, the Company also estimates the likelihood of whether it will participate in a future qualified public offering, as defined in either the amended note or warrant agreements, as applicable, that would trigger the conversion feature or the repricing of warrants, and, if so, the estimated timing and pricing of its offering of common stock.

The fair values and the changes in fair values of derivative liabilities during the years ended December 31, 2017 and 2016 are as follows:

	Year Ended December 31,	
	2017	2016
Balance, beginning of period	$ 131,173	$ 658,286
Conversion of equity warrants to liabilities	-	192,173
Additions from debt restructuring	-	1,592,134
Reduction from debt conversions	-	(1,207,813)
Reduction from warrant exercise	(10,659)	(37,672)
Gain on change in fair value for the period	(24,728)	(1,065,935)
Balance, end of period	$ 95,786	$ 131,173

8. Income Taxes

The Company had no income tax expense for the years ended December 31, 2017 and 2016. 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 year ended December 31, 2017, the valuation allowance decreased by approximately $14.9, due primarily to the effects of reduced corporate income tax rates effected under the Tax Act, which were partially offset by changes in deferred tax assets and liabilities. For the year ended December 31, 2016, the valuation allowance increased by approximately $3.5 million, based on changes in deferred tax assets and liabilities.

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,	
	2017	2016
Deferred income tax assets (liabilities):		
Property and equipment	$ 58,036	$ 107,308
Deferred revenue		88,877
Accrued expenses	224,546	53,112
Share based compensation	1,803,943	3,186,133
Derivative liability		164,258
Other	(912,575)	248,561
Net operating loss carryforwards	18,535,794	30,800,732
	19,709,744	34,648,981
Less valuation allowance	(19,709,744)	(34,648,981)
	$ -	$ -

The Company had a cumulative federal net operating loss of approximately $81.5 million as of December 31, 2017, which will begin expiring in 2018. 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 2012 remain open for examination.

9. Commitments

Leases

The Company leases space in Irvine, California that houses its headquarters and manufacturing facility under a non-cancellable operating lease. The lease expires in September 2018. At December 31, 2017, future minimum lease payments under non-cancellable operating leases were $71,967.

Future minimum lease payments for operating leases having an initial or remaining non-cancellable lease term in excess of one year are as follows:

Years ending December 31,	
2018	$ 71,967
Total minimum payments	$ 71,967

Rent expense under all operating leases was approximately $92,000 for each of the years ended December 31, 2017 and 2016.

Licenses

Certain license arrangements require minimum royalty payments. As of December 31, 2017, future minimum payments under these arrangements are as follows:

Years ending December 31,		
2018	$	50,000
2019		50,000
2020		50,000
2021		50,000
2022		50,000
Thereafter		220,000
Total minimum payments	$	470,000

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.

Technical Service and Training Agreements

The Company is a party to agreements with a university, which agreements were amended in January 2017, under which the Company may receive technical and training services. Pursuant to the terms of the amended agreements, the Company incurred approximately $17,000 and $45,000 for technical research services during the years ended December 31, 2017 and 2016, respectively.

Master Services and Software License Agreement

The Company is a party to a Master Services and Licensing Agreement (as amended, the "Master Software Agreement") with Merge Healthcare Canada Corp. f/k/a Cedara Software Corp. ("Merge") under which the Company may internally perform development, maintenance and support of its ClearPoint system software that was originally developed for the Company by Merge, utilizing certain of its own pre-existing software code. Under the Master Software Agreement, the Company received a non-exclusive, worldwide license to Merge's software code, in exchange for which the Company agreed to pay Merge a license fee for each copy of the ClearPoint system software that the Company distributes, subject to a minimum license purchase commitment (the "Minimum License Purchase") that the Company satisfied in 2013. The Company will have an obligation to pay Merge a license fee for each copy of the ClearPoint system software that the Company distributes in excess of the licenses it purchased under the Minimum License Purchase.

Of the licenses purchased under the Minimum License Purchase: (i) those licenses that the Company expects to sell in the next 12 months are included in inventory in the accompanying consolidated balance sheets; (ii) those licenses that the Company has loaned to prospective ClearPoint system customers for evaluation are included in property and equipment in the accompany consolidated balance sheets and depreciated during the evaluation period; and (iii) those licenses not included in (i) or (ii) above are classified as non-current assets and comprise software license inventory on the accompanying consolidated balance sheets.

Cardiac EP Business Participation Plan

The Company is party to agreements under which it may 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 ("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, 2017, the participation interest was 0.48%. The plan will terminate in June 2025.

Management Change

On October 6, 2017, Francis P. Grillo entered into a Separation, Transition and Consulting Agreement (the "Separation Agreement") with the Company, under which Mr. Grillo voluntarily resigned from his position as the Chief Executive Officer and President of the Company, and as a member of the Company's Board of Directors, and separating from the Company, effective as of November 7, 2017 (the "Transition Date").

Under the terms of the Separation Agreement, Mr. Grillo received the following payments and other benefits, subject to certain conditions, pursuant to the Separation Agreement: (i) 87,500 unregistered shares of the Company's common stock; (ii) a lump sum payment of $15,000; (iii) $30,000 per month for the first two months following his separation from the Company in exchange for transition and consulting services provided to the Company by Mr. Grillo, after which Mr. Grillo is being compensated on an hourly basis to the extent he renders any such consulting services; and (iv) the option exercise period of all stock options previously granted to Mr. Grillo was extended to be coterminous with the term of the option award. In addition, Mr. Grillo will receive his annual bonus, amounting to approximately $109,000 and based on his and the Company's performance for the fiscal year ended December 31, 2017, determined in accordance with the applicable policies and procedures set forth in his employment agreement.

In conjunction with Mr. Grillo's resignation from the positions described above, on October 6, 2017, the Company entered into an Employment Agreement (the "Employment Agreement") with Joseph M. Burnett, whereby Mr. Burnett commenced service as the Company's Chief Executive Officer and President, effective as of the Transition Date. In addition, the Mr. Burnett was elected to serve as a director of the Company, effective as of the Transition Date.

Under the terms of the Employment Agreement, Mr. Burnett's base salary, effective as of the Transition Date, is $360,000. Starting with the fiscal year commencing on January 1, 2018 and for each year thereafter, Mr. Burnett will be eligible to receive an annual target incentive bonus of 40% of his annual base salary, subject to certain performance goals to be established by the Compensation Committee of the Board of Directors. In addition, the Company will pay Mr. Burnett up to $50,000 in reasonable relocation expenses during the first two years of his employment, subject to Mr. Burnett's continued employment through such two-year period. The Employment Agreement also provides for certain payments to be made to Mr. Burnett: (a) in the event the Company terminates his employment without cause or if Mr. Burnett voluntarily terminates his employment with the Company for good reason, as those terms are defined in the Employment Agreement; or (b) if the Company terminates his employment without cause or if Mr. Burnett voluntarily terminates his employment with the Company for good reason within two months of a change of control, as such term is defined in the Employment Agreement. Also, in the event of a change of control, any unvested stock options and restricted stock previously granted to Mr. Burnett will become fully vested.

As an inducement to his employment with the Company, Mr. Burnett is entitled to receive an initial signing bonus in the aggregate amount of $100,000 under the Employment Agreement, to be paid in two equal installments: the first installment was paid on the Transition Date, and the second installment is to be paid on the 6-month anniversary of the Transition Date, conditioned upon Mr. Burnett's continued employment. In addition, on the Transition Date Mr. Burnett was granted: (i) a non-qualified stock option to purchase up to 350,000 shares of the Company's common stock at a per share exercise price of $2.50, which was the per share closing price of the Company's common stock on the Transition Date; and (ii) 200,000 restricted shares of the Company's common stock. The stock option and restricted shares will vest as follows: (i) one-third on the first anniversary of the date of grant; and (ii) the remainder in equal quarterly installments during each of the second and third years following the date of grant. In connection with the foregoing, the Company recorded compensation expense in 2017 of approximately $44,000.

Mr. Burnett is entitled to participate in any benefit plan from time to time in effect for the Company's executives and/or employees generally, subject to the eligibility provisions of that plan.

Employment Agreements

In addition to Mr. Burnett's Employment Agreement, the Company has employment agreements with its other executive officers that, among other provisions customary for agreements of this nature, provide for severance payments in the event the Company terminates the officer's employment without cause. The agreements also provide for certain payments in connection with a change of control transaction and a termination of employment following a change of control transaction.

Key Personnel Incentive Program

Under the terms of the Company's Key Personnel Incentive Program (as amended, the "KPIP"), two participants, one a consultant to the Company and a former non-employee director of the Company, and the other a former employee of the Company, will each be entitled to receive a $1 million payment in the event of a sale of the Company. In addition, one of the participants will be entitled to receive a payment equal to $700,000 in the event the net proceeds from a sale of the Company exceeds $50,000,000. If a sale of the Company has not occurred by December 31, 2025, the KPIP will terminate.