MRI Interventions, Inc.

13,807,533 Shares of Common Stock

This prospectus relates 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, or the Warrants, held by some of our securityholders which are named in this prospectus. The securities we are registering are to be offered for the account of the selling securityholders. We will pay the expenses of registering the shares, but we are not selling any shares of common stock in this offering and therefore will not receive any proceeds from this offering. We will, however, receive the exercise price of the Warrants, if and when such warrants are exercised for cash by the selling securityholders.

Our common stock is traded in the over-the-counter market and quoted on the OTCQB Venture Marketplace organized by the OTC Markets Group Inc. and the OTC Bulletin Board under the ticker symbol "MRIC." On June 21, 2017, the last reported sale price of our common stock was $3.90 per share.

The shares included in this prospectus may be offered and sold directly by the securityholders in accordance with one or more of the methods described in the "Plan of Distribution," which begins on page 40 of this prospectus. To the extent the securityholders decide to sell their shares, we will not control or determine the price at which the shares are sold. Brokers or dealers effecting transactions in these shares should confirm that the shares are registered under applicable state law or that an exemption from registration is available.

We are an "emerging growth company" under the federal securities laws and will be subject to reduced public company reporting requirements. Investing in our common stock involves risk. See "Risk Factors" on page 12 to read about factors you should consider before buying shares of our common stock.

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

Prospectus dated July 7, 2017

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

Trademarks, Trade Names and Service Marks

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

Industry and Market Data

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

PROSPECTUS SUMMARY

This summary highlights the information contained elsewhere in this prospectus. Because this is only a summary, it does not contain all of the information that may be important to you. Before investing in our common stock, you should read this entire prospectus, including the information set forth under the heading "Risk Factors" and the financial statements and the notes thereto.

Unless the context otherwise requires, references in this prospectus to "MRI Interventions," "we," "our," "us" and the "Company" refer to MRI Interventions, Inc.

Our Business

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.

- *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 the use of our products, we believe that the result will be a reduction in overall healthcare costs.

Our Business Model and Strategy

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.

Our Market Opportunity

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 electrodes, such as deep brain stimulation, 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. In October 2016, St. Jude Medical (now part of Abbott Laboratories) received FDA clearance for its Infinity® DBS system, the first system with directional lead technology and iOS-based programming features, which we believe will drive demand for DBS therapy. Thus, 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 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, a small structure in the brain that may serve as the foci of certain types of epileptic seizures, is a viable, minimally invasive 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.

Risks Related to Our Business

We are subject to a number of risks of which you should be aware before you decide to buy our common stock. These risks are discussed more fully in the "Risk Factors" section of this prospectus beginning on page 12 and should be read in their entirety. In general, we face risks associated with the following:

- our ability to achieve broader market acceptance of our products;
- our ability to expand, manage and maintain our marketing and sales capabilities;
- our dependence on a relatively small number of customers;
- product quality and patient safety issues, which could lead to product recalls, withdrawals, launch delays, sanctions, seizures, litigation, or declining sales;
- our dependence on existing, and ability to establish future, collaboration relationships and licensing arrangements;
- individual, group or class action alleging products liability claims;
- legislation, regulation and other governmental pressures in the United States or globally, which may affect pricing, reimbursement, taxation and rebate policies of government agencies and private payors or other elements of our business;
- future actions of the United States Food and Drug Administration, or FDA, or any other regulatory body or government authority that could delay, limit or suspend product manufacturing, sale or development, or result in seizures, injunctions, monetary sanctions or criminal or civil liabilities;
- our ability to successfully complete the development of, and to obtain regulatory clearance or approval for, future products, including our ClearTrace system;
- our ability to identify business development and growth opportunities for current or future products;
  the sufficiency of our cash resources to maintain planned commercialization efforts and research and development programs;
- our independent registered public accounting firm's expression of substantial doubt about our ability to continue as a going concern;
  our ability to enforce our patent rights or patents of third parties preventing or restricting the manufacture, sale or use of affected products or technology; and
- any impact of the commercial and credit environment on us and our customers and suppliers.

2016 Reverse Stock Split

On June 30, 2016, our stockholders approved a reverse stock split of our issued and outstanding shares of common stock at a ratio of 1-for-15, 1-for-20, 1-for-25, 1-for-30, 1-for-35 or 1-for-40, with the specific ratio and effective time of the reverse stock split to be determined by our Board of Directors, or our Board. On July 21, 2016, our Board approved a reverse stock split of 1-for-40 reverse stock split, or the Reverse Split, which was effectuated on July 26, 2016.

Corporate Information

We were incorporated in Delaware in 1998 under the name Surgi-Vision, Inc. On November 12, 2008, we changed our name to SurgiVision, Inc. On May 13, 2011, we changed our name to MRI Interventions, Inc. We operate in only one business segment. Our principal executive office and our principal operations are located at 5 Musick, Irvine, CA 92618, and our telephone number is (949) 900-6833. Our website address is www.mriinterventions.com. We do not incorporate the information on our website into this prospectus, and you should not consider it part of this prospectus.

Summary of the Offering

This offering involves 6,693,333 shares of our common stock issued or issuable to the selling securityholders and 7,114,200 shares of our common stock issuable upon exercise of Warrants.

Common stock offered by the selling securityholders	13,807,533 shares (1)
Common stock outstanding prior to this offering	10,335,365 shares (2)
Common stock to be outstanding after the offering, assuming the exercise of all warrants for the shares covered by this prospectus	17,449,565 shares (2)
Trading symbol	MRIC
Risk Factors	An investment in our common stock involves significant risks. See "Risk Factors" beginning on page 12.

(1) Includes 7,114,200 shares of common stock issuable upon exercise of outstanding Warrants, at an exercise price of $2.20 per share.

(2) Based on 10,335,365 shares outstanding as of June 5, 2017, and excluding:

- 226,316 shares of common stock issuable upon exercise of options issued under our stock option plans, at a weighted average exercise price of $42.53 per share;
- 80,000 shares of common stock issuable upon the exercise of options not issued under our stock option plans, at a weighted average exercise price of $43.84 per share;
- 9,034,023 shares of common stock issuable upon exercise of warrants, at a weighted average exercise price of $4.16 per share; and
- 19,506 shares of common stock reserved for future issuance under our Amended and Restated 2013 Incentive Compensation Plan.

Summary Financial Information

The summary financial information below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements, notes thereto and other financial information included elsewhere in this prospectus. The summary information presented for the three-month periods ended March 31, 2017 and March 31, 2016 is derived from unaudited financial statements and includes, in the opinion of management, all adjustments, consisting only of normal recurring accruals, necessary to present fairly the information for such periods. The results for the three-month period ended March 31, 2017 are not necessarily indicative of the results to be expected for the full fiscal year. The summary financial information for the fiscal years ended December 31, 2016 and 2015 has been derived from our audited financial statements and the notes thereto included elsewhere in this prospectus. Our historical results are not necessarily indicative of our results to be expected in any future period.

	Three Months Ended March 31,		Years Ended December 31,	
	2017	2016	2016	2015
Statements of Operations Data:				
Revenues:				
Product revenues	$ 1,922,215	$ 1,366,153	$ 5,612,857	$ 4,416,036
Development service revenues	-	-	-	37,405
Other service revenues	84,857	27,981	136,597	140,751
Total revenues	2,007,072	1,394,134	5,749,454	4,594,192
Cost of product revenues	752,464	696,546	2,642,763	1,987,636
Research and development costs	557,699	657,192	2,628,179	1,957,332
Selling, general, and administrative expenses	2,050,529	1,974,249	7,967,250	8,370,749
Restructuring charges	-	-	-	1,252,584
Operating loss	(1,353,620)	(1,933,853)	(7,488,738)	(8,974,109)
Other income (expense):				
Gain (loss) on change in fair value of derivative liabilities	(93,046)	160,118	1,065,935	1,539,876
Loss on debt restructuring	-	-	(811,909)	-
Other income, net	4,127	75,142	216,075	230,875
Interest expense, net	(213,199)	(345,225)	(1,051,258)	(1,245,888)
Net loss	$ (1,655,738)	$ (2,043,818)	$ (8,069,895)	$ (8,449,246)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.46)	$ (0.89)	$ (2.93)	$ (4.48)
Weighted average shares outstanding:				
Basic and diluted	3,622,032	2,291,147	2,754,803	1,884,849

	March 31, 2017	December 31, 2016
Balance Sheet Data:		
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,969,597	$ 3,315,774
Accounts receivable	1,009,775	865,943
Inventory, net	1,809,020	1,768,382
Prepaid expenses and other current assets	95,625	134,996
Total current assets	4,884,017	6,085,095
Property and equipment, net	383,534	328,249
Software license inventory	906,900	976,900
Other assets	16,300	10,641
Total assets	$ 6,190,751	$ 7,400,885
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,308,056	$ 1,546,926
Accrued compensation	811,951	666,060
Other accrued liabilities	618,839	450,424
Derivative liabilities	224,219	131,173
Deferred product and service revenues	263,097	223,117
Total current liabilities	3,226,162	3,017,700
Accrued interest	577,125	647,500
Senior secured note payable	2,000,000	2,000,000
2014 junior secured notes payable, net of unamortized discount and deferred issuance costs of $160,688 and $180,774 at March 31, 2017 and December 31, 2016, respectively	1,814,312	1,794,226
2010 junior secured notes payable, net of unamortized discount of $2,221,936 and $2,302,472 at March 31, 2017 and December 31, 2016, respectively	778,064	697,528
Total liabilities	8,395,663	8,156,954
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized at March 31, 2017 and December 31, 2016; none issued and outstanding at March 31, 2017 and December 31, 2016	-	-
Common stock, $0.01 par value; 200,000,000 shares authorized at March 31, 2017 and December 31, 2016; 3,622,032 shares issued and outstanding at March 31, 2017 and December 31, 2016	36,220	36,220
Additional paid-in capital	93,283,370	93,076,475
Accumulated deficit	(95,524,502)	(93,868,764)
Total stockholders' deficit	(2,204,912)	(756,069)
Total liabilities and stockholders' deficit	$ 6,190,751	$ 7,400,885

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 prospectus before you decide whether to purchase our common stock. If any of the following risks 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, Emory University Hospital, or Emory, and the University of California, San Francisco Medical Center, or UCSF, account for a disproportionately large portion of our ClearPoint product revenues. Sales to almost all of our customers, including Emory and UCSF, are not based on long-term, committed volume purchase contracts, and we may not continue to generate a similar level of revenues from Emory, UCSF, 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 prospectus 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' deficit and working capital and could result in a decline in our stock price or cause us to cease operations.

Our independent registered public accounting firm has expressed in its report to our 2016 audited financial statements a substantial doubt about our ability to continue as a going concern.

We have not yet generated sufficient revenues from our operations to fund our activities, and are therefore dependent upon external sources for financing our operations. There is a risk that we will be unable to obtain necessary financing to continue our operations on terms acceptable to us or at all. As a result, our independent registered public accounting firm has included in its report on our Consolidated Financial Statements as of and for the year ended December 31, 2016, included elsewhere in this prospectus, an explanatory paragraph in which is expressed a substantial doubt regarding our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of the uncertainty regarding our ability to continue as a going concern. This explanatory paragraph with respect to our ability to continue as a going concern could materially limit our ability to raise additional funds through the issuance of equity or debt securities or otherwise. Future reports on our financial statements may continue to include such an explanatory paragraph. If we cannot continue as a going concern, our stockholders may lose their entire investment in the common stock.

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 of 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 March 31, 2017 was approximately $96 million. Net cash used in operations was $5.8 million for the year ended December 31, 2016 and $1.3 million for the three months ended March 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 September 2016 private placement of equity, which resulted in net proceeds of $4.1 million; (ii) 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 (ii) are also referred to herein as the Note Conversion); (iii) 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; (iv) a December 2015 private placement of equity, which resulted in net proceeds of $4.7 million; (v) a December 2014 private placement of equity, which resulted in net proceeds of $9.4 million; and (vi) 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, resulting primarily from the completed operational restructuring, 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 your ownership interest, 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, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we secure additional funds through arrangements with a strategic or other collaboration partner, we may have to relinquish valuable rights to our technologies, products or product candidates or grant licenses on terms that are not favorable to us. Any of these events could adversely affect our ability to achieve our commercialization and/or product development goals and have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

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

Our commercial success depends, in part, on obtaining patent and other intellectual property protection for the technologies contained in our products and product candidates. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. Our patent position is uncertain and complex, in part, because of our dependence on intellectual property that we license from others. If we, or the third parties from whom we license intellectual property, fail to obtain adequate patent or other intellectual property protection for intellectual property covering our products or product candidates, or if any protection is reduced or eliminated, others could use the intellectual property covering our products or product candidates, resulting in harm to our competitive business position. In addition, patent and other intellectual property protection may not provide us with a competitive advantage against competitors that devise ways of making competitive products without infringing any patents that we own or 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 legislation, regulation and government policy as a result of the 2016 U.S. presidential and congressional elections may have a material adverse effect on our business in the future.

The recent presidential and congressional elections in the United States could result in significant changes in, and uncertainty with respect to, legislation, regulation and government policy directly affecting our business or indirectly affecting us because of impacts on our customers and suppliers. Legislative and regulatory proposals discussed during and after the election that could have a material direct or indirect impact on us include, but are not limited to, a disallowance of the deduction for net interest expense, a tax on existing unrepatriated foreign earnings, restrictions on imports and exports, modifications to international trade policy, including withdrawal from trade agreements, environmental regulation, changes to immigration policy, changes to health insurance legislation and the imposition of tariffs and other taxes on imports. We are currently unable to predict whether such changes will occur and, if so, the ultimate impact on our business. To the extent that such changes have a negative impact on us, our suppliers or our customers, including as a result of related uncertainty, these changes may materially and adversely impact our business, prospects, financial condition, results of operations, or cash flows.

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

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

Our 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 you may not be able to resell your shares at or above the price at which you purchased them.

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.

All of the shares of our common stock covered by this prospectus will be freely transferable, unless held by an affiliate of ours. Excluding the shares of our common stock covered by this prospectus, as of June 1, 2017, 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 your investment will only occur if our stock price appreciates.

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

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.

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

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. 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 prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain.

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

USE OF PROCEEDS

We will not receive any proceeds from the sale of the common stock by the selling securityholders pursuant to this prospectus. All proceeds from the sale of the shares will be for the account of the selling securityholders. We could receive up to approximately $15.65 million in proceeds from the exercise of all of the warrants held by the securityholders covered by this prospectus, when and if such warrants are exercised for cash. However, the warrants are exercisable on a cashless basis under certain circumstances, and, to the extent the warrants are exercised, we expect that most securityholders would utilize the cashless exercise feature. To the extent we receive any cash proceeds from the exercise of the warrants, we intend to use the proceeds for working capital and general corporate purposes. We will pay the expenses of registration of the shares of our common stock covered by this prospectus, including legal and accounting fees.

SELLING SECURITYHOLDERS FOR WHOSE ACCOUNT WE ARE REGISTERING SHARES

The common stock being offered by the selling securityholders are those previously issued to the selling securityholders, and those issuable to the selling securityholders, upon exercise of the warrants. We are registering the shares of common stock in order to permit the selling securityholders to offer the shares for resale from time to time. Except for the ownership of the shares of common stock and the warrants, the selling securityholders have not had any material relationship with us within the past three years.

The table below lists the selling securityholders and other information regarding the beneficial ownership of the shares of common stock by each of the selling securityholders. The second column lists the number of shares of common stock beneficially owned by each selling securityholder, based on its ownership of the shares of common stock and warrants, as of June 5, 2017, assuming exercise of the warrants held by the selling securityholders on that date, without regard to any limitations on exercises.

The third column lists the shares of common stock being offered by this prospectus by the selling securityholders.

In accordance with the terms of a registration rights agreement with the selling securityholders, this prospectus generally covers the resale of the sum of (i) the number of shares of common stock issued to the selling securityholders in this offering and (ii) the maximum number of shares of common stock issuable upon exercise of the related warrants, determined as if the outstanding warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the registration rights agreement, without regard to any limitations on the exercise of the warrants. The fourth column assumes the sale of all of the shares offered by the selling securityholders pursuant to this prospectus.

Under the terms of the warrants, a selling securityholder may not exercise the warrants to the extent such exercise would cause such selling securityholder, together with its affiliates and attribution parties, to beneficially own a number of shares of common stock which would exceed 4.99% or 9.99%, as applicable, of our then outstanding common stock following such exercise, excluding for purposes of such determination shares of common stock issuable upon exercise of the warrants which have not been exercised. The number of shares in the second column does not reflect this limitation. The selling securityholders may sell all, some or none of their shares in this offering. See "Plan of Distribution."

Name of Selling Securityholder	Shares Beneficially Owned Prior to Offering (1)(2)	Shares Offered by this Prospectus (3)	Shares Beneficially Owned After Offering (4)(5)	
			Shares	Percent
Acoustic Medsystems, Inc.	30,000	30,000	0	*
A. G. Family L.P.	500,000(6)	500,000	0	*
AIGH Investment Partners, LP	1,600,000(7)	1,600,000	0	*
Alan Eisenman	573,212(8)	500,000	73,212	*
Alpha Capital Anstalt	350,000(9)	350,000	0	*
Andrew David Daniels	5,000(10)	5,000	0	*
Anthony Sica	21,386(11)	21,386	0	*
Bigger Capital Fund, LP	500,000(12)	500,000	0	*
Brant Investments Limited A/C 185814007(13)	500,000(14)	250,000	250,000	2.4
Brian Eliot Peierls	120,000(15)	120,000	0	*
Brio Capital Master Fund Ltd.	300,000(16)	300,000	0	*
Bruce A. Robson	88,736(17)	85,000	3,736	*
Bruce C. Conway	1,352,442(18)	1,000,000	352,442	3.4
Clayton A. Struve	50,000(19)	50,000	0	*
Craig Skop	17,822(20)	17,822	0	*
David S. Nagelberg 2003 Revocable Trust(21)	250,000(22)	250,000	0	*
DWBI Investments, LLC	56,089(23)	51,250	4,839	*
Dyke Rogers	50,000(24)	50,000	0	*
E. Jeffrey Peierls	170,000(25)	170,000	0	*
E.L.M. Realty LLC(26)	50,000(27)	50,000	0	*
EDJ Limited(28)	50,000(29)	50,000	0	*
Edward L. Scanlon and Barbara A. Scanlon	50,000(30)	50,000	0	*
Empery Asset Master, LTD(31)	228,663(32)	227,100	1,563	*
Empery Tax Efficient II, LP(33)	158,430(34)	158,430	0	*
Empery Tax Efficient, LP(35)	114,470(36)	114,470	0	*
Eric Lord	44,555(37)	44,555	0	*
Graham A. Powis	6,750 (38)	6,750	0	*
Halevi Enterprises	215,000(39)	215,000	0	*
Harris Lydon	50,744(40)	42,750	7,994	*
Highline Innovation Investments, LLC(41)	33,170(42)	25,000	8,170	*
Hill Blalock, Jr.	50,000(43)	50,000	0	*
Hudson Bay Master Fund, Ltd.(44)	250,000(45)	250,000	0	*
Iroquois Capital Investments Group LLC(46)	200,000(47)	200,000	0	*
Iroquois Master Fund Ltd.(48)	303,885(49)	300,000	3,885	*
Jai K. Singhania	31,593(50)	25,000	6,593	*
John Culling Slaughter	3,760(51)	3,760	0	*
Joseph A. Alagna, Jr.	53,466(52)	53,466	0	*
Justin Keener D/B/A JMJ Financial(53)	100,000(54)	100,000	0	*
Kenn S. George	26,930(55)	22,500	4,430	*
Kevin Mangan	39,208(56)	39,208	0	*
Kingsbrook Opportunities Master Fund LP(57)	250,000(58)	250,000	0	*
Lagom LLC	46,552(59)	30,000	16,552	*
Lowry Mays	99,361(60)	85,000	14,361	*
Lurie Family Trust(61)	30,000(62)	30,000	0	*
Mark C. McKinley	197,303(63)	190,000	7,303	*
Mayo Foundation for Medical Education and Research	58,333	58,333	0	*
Mellon Group, LLC	250,000(64)	200,000	50,000	*
Michael Fontaine	4,500(65)	4,000	500	*
Osher Capital Partners LLC(66)	50,000(67)	50,000	0	*
Patrick Alexander Sturgeon	5,500(68)	5,000	500	*
Porter Partners, L.P.(69)	200,000(70)	200,000	0	*
Priyanka Mahajan	35,644(71)	35,644	0	*
Ramnarain Jaigobind	112,279(72)	112,279	0	*

Richard Brock Compton	49,950[73]	49,950	0	*
Richard Brock Compton PSP UA Jan 01 1996, Richard Brock Compton TR[74]	49,276[75]	45,050	4,226	*
Richard W. Baskerville Living Trust[76]	100,000[77]	100,000	0	*
Robert A. Innamorati	20,100[78]	20,000	100	*
S.H.N Financial Investments Ltd.[79]	250,000[80]	250,000	0	*
S2 Partners, L.P.[81]	250,000[82]	250,000	0	*
Scott A. Katzmann	76,594[83]	42,750	33,844	*
Stephan A. Stein	32,080[84]	32,080	0	*
Steven Cohen	100,000[85]	100,000	0	*
Steven L Korby & Mary R Korby JT TEN	228,028[86]	212,500	15,528	*
Steven S. Marco	242,177[87]	230,000	12,177	*
Syam Prasad Kethi Reddy	20,000[88]	20,000	0	*
Tatiana Kotchoubey	25,000[89]	25,000	0	*
The Clement E & Betty S George Trust UA Mar 10 1999, Kenn S George TR[90]	17,285[91]	13,750	3,535	*
The Feldman Family Trust[92]	60,000[93]	60,000	0	*
The Hewlett Fund, L.P. [94]	1,200,000[95]	1,200,000	0	*
The Peierls Bypass Trust[96]	14,000[97]	14,000	0	*
The Peierls Foundation, Inc.[98]	720,000[99]	720,000	0	*
Thomas A. Satterfield, Jr.	100,000[100]	100,000	0	*
Tomsat Investment & Trading Co., Inc.[101]	200,000[102]	200,000	0	*
Trisha Wilson	245,876[103]	225,000	20,876	*
UD E.F. Peierls for Brian E. Peierls[96]	46,000[104]	46,000	0	*
UD E.F. Peierls for E. Jeffrey Peierls[96]	46,000[105]	46,000	0	*
UD E.S. Peierls for E.F. Peierls et al[96]	32,000[106]	32,000	0	*
UD Ethel F. Peierls Charitable Lead Trust[96]	68,000[107]	68,000	0	*
UD J.N. Peierls for Brian Eliot Peierls[96]	60,000[108]	60,000	0	*
UD J.N. Peierls for E. Jeffrey Peierls[96]	60,000[109]	60,000	0	*
UW E.S. Peierls for Brian E. Peierls – Accumulation[96]	42,000[110]	42,000	0	*
UW E.S. Peierls for E. Jeffrey Peierls – Accumulation[96]	26,000[111]	26,000	0	*
UW J.N. Peierls for Brian E. Peierls[96]	48,000[112]	48,000	0	*
UW J.N. Peierls for E. Jeffrey Peierls[96]	48,000[113]	48,000	0	*
V2M Life Sciences LP[114]	250,000[115]	250,000	0	*
William Barclay Buchanan, Jr.	68,825[116]	42,750	26,075	*

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

(1) Includes an aggregate of 7,389,054 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(2) Does not take into account any limitations on exercise contained in any warrants.
(3) Includes an aggregate of 7,114,200 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(4) Assumes the securityholders sell all of the shares of common stock included in this prospectus.
(5) Includes an aggregate of 274,854 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(6) Includes an aggregate of 250,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(7) Includes an aggregate of 800,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(8) Includes an aggregate of 250,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(9) Includes an aggregate of 175,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(10) Constitutes 5,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(11) Constitutes 21,386 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(12) Includes an aggregate of 250,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(13) These shares are held in trust by the custodian of Next Edge Bio-Tech Plus Fund. Eden Rahim, as the portfolio manager of Next Edge Bio-Tech Plus Fund, is the natural person who controls Next Edge Bio-Tech Plus Fund and has voting and investment power with respect to these shares.
(14) Includes an aggregate of 250,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(15) Includes an aggregate of 60,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(16) Includes an aggregate of 150,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(17) Includes an aggregate of 42,500 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(18) Includes 3,600 shares jointly held with Mr. Conway's spouse, 16,500 shares held solely by his spouse, 570,995 shares that Mr. Conway has the right to acquire through the exercise of warrants, and 39,654 shares in the aggregate owned by the Alden M. Conway Trust, the Chase T. Conway Trust, the Merritt Elizabeth Conway Trust, the Edna N. Conway Irrevocable Trust FBO Alden M. Conway, the Edna N. Conway Irrevocable Trust FBO Chase T. Conway, the Edna N. Conway Irrevocable Trust FBO Merritt Elizabeth Conway and the Conway Family GST Trust. Mr. Conway is the trustee of each of the aforementioned trusts and has voting and investment power of each trust's shares, which are held in trust for the benefit of members of his family. Also includes 5,500 shares owned by the BCC Life Insurance Trust, which shares are held in trust for the benefit of Mr. Conway's children. A third party serves as trustee for such trust. All of the foregoing numbers for shares underlying warrants assume a cash exercise of such warrants.

(19) Includes an aggregate of 25,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(20) Constitutes 17,822 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(21) David S. Nagelberg is the natural person who controls the David S. Nagelberg 2003 Revocable Trust and has voting and investment power with respect to the shares owned by it.
(22) Includes an aggregate of 125,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(23) Includes an aggregate of 25,625 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(24) Includes an aggregate of 25,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(25) Includes an aggregate of 85,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(26) Elliot Messing is the natural person who controls E.L.M. Realty LLC and has voting and investment power with respect to the shares owned by it.
(27) Includes an aggregate of 25,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(28) Jeffrey H. Porter is the natural person who controls EDJ Limited and has voting and investment power with respect to the shares owned by it.
(29) Includes an aggregate of 25,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(30) Includes an aggregate of 25,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(31) Empery Asset Management LP, the authorized agent of Empery Asset Master Ltd. ("EAM"), has discretionary authority to vote and dispose of the shares held by EAM and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by EAM. EAM, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.
(32) Includes an aggregate of 115,113 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(33) Empery Asset Management LP, the authorized agent of Empery Tax Efficient II, LP ("ETE II"), has discretionary authority to vote and dispose of the shares held by ETE II and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE II. ETE II, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.
(34) Includes an aggregate of 79,215 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(35) Empery Asset Management LP, the authorized agent of Empery Tax Efficient, LP ("ETE"), has discretionary authority to vote and dispose of the shares held by ETE and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE. ETE, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.
(36) Includes an aggregate of 57,235 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(37) Constitutes 44,555 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(38) Constitutes 6,750 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(39) Includes an aggregate of 107,500 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(40) Constitutes 50,744 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(41) Raymond Scott Livingstone is the natural person who controls Highline Innovation Investments, LLC and has voting and investment power with respect to the shares owned by it.
(42) Includes an aggregate of 15,195 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(43) Includes an aggregate of 25,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.

(44) Hudson Bay Capital Management, LP, the investment manager of Hudson Capital Bay Master Fund Ltd., has voting and investment power over these shares. Sander Gerber is the managing member of Hudson Bay Capital GP, LLC, which is the general partner of Hudson Bay Capital Management LP. Each of Hudson Bay Master Fund Ltd. and Sander Gerber disclaims beneficial ownership over these shares.
(45) Includes an aggregate of 125,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(46) Richard Abbe is the natural person who controls Iroquois Capital Investments Group LLC and has voting and investment power with respect to the shares owned by it.
(47) Includes an aggregate of 100,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(48) Iroquois Capital Management, LLC ("ICM") is the investment manager of Iroquois Master Fund Ltd. ("IMF") and consequently has voting control and investment discretion over the shares held by IMF. Richard Abbe as President of ICM may be considered a beneficial owner of any shares deemed beneficially owned by IMF. Mr. Abbe disclaims beneficial ownership of these shares.
(49) Includes an aggregate of 153,885 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(50) Includes an aggregate of 16,533 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(51) Constitutes 3,760 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(52) Constitutes 53,466 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(53) Justin Keener is the natural person who controls Justin Keener D/B/A JMJ Financial and has voting and investment power with respect to the shares owned by it.
(54) Includes an aggregate of 50,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(55) Includes an aggregate of 11,250 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(56) Constitutes 39,208 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(57) Kingsbrook Partners LP ("Kingsbrook Partners") is the investment manager of Kingsbrook Opportunities Master Fund LP ("Kingsbrook Opportunities") and consequently has voting control and investment discretion over the shares held by Kingsbrook Opportunities. Kingsbrook Opportunities GP LLC ("Opportunities GP") is the general partner of Kingsbrook Opportunities and may be considered the beneficial owner of any shares deemed to be beneficially owned by Kingsbrook Opportunities. KB GP LLC ("GP LLC") is the general partner of Kingsbrook Partners and may be considered the beneficial owner of any shares deemed to be beneficially owned by Kingsbrook Partners. Ari J. Storch, Adam J. Chill and Scott M. Wallace are the sole managing members of Opportunities GP and GP LLC and as a result may be considered beneficial owners of any shares deemed beneficially owned by Opportunities GP and GP LLC. Each of Kingsbrook Partners, Opportunities GP, GP LLC and Messrs. Storch, Chill and Wallace disclaim beneficial ownership of these shares.
(58) Includes an aggregate of 125,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(59) Includes an aggregate of 15,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(60) Includes an aggregate of 46,385 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(61) Philip Lurie is the natural person who controls the Lurie Family Trust and has voting and investment power with respect to the shares owned by it.
(62) Includes an aggregate of 15,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(63) Includes an aggregate of 95,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(64) Includes an aggregate of 100,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(65) Constitutes 4,500 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(66) Ari Kluger is the natural person who controls Osher Capital Partners LLC and has voting and investment power with respect to the shares owned by it.
(67) Includes an aggregate of 25,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(68) Constitutes 5,500 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(69) Jeffrey H. Porter is the natural person who controls Porter Partners, L.P. and has voting and investment power with respect to the shares owned by it.

(70) Includes an aggregate of 100,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(71) Constitutes 35,644 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(72) Constitutes 112,279 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(73) Includes an aggregate of 24,975 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(74) Richard Brock Compton is the natural person who controls Richard Brock Compton PSP UA Jan 01 1996, Richard Brock Compton TR and has voting and investment power with respect to the shares owned by it.
(75) Includes an aggregate of 22,525 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(76) Richard W. Baskerville is the natural person who controls Richard W. Baskerville Living Trust and has voting and investment power with respect to the shares owned by it.
(77) Includes an aggregate of 50,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(78) Includes an aggregate of 10,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(79) Mr. Hadar Shamir and Mr. Nir Shamir are the natural persons who control S.H.N. Financial Investments Ltd. and have voting and investment power with respect to the shares owned by it.
(80) Includes an aggregate of 125,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(81) Scott Allen Billeadeam is the natural person who controls S2 Partners, L.P. and has voting and investment power with respect to the shares owned by it.
(82) Includes an aggregate of 125,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(83) Includes an aggregate of 71,594 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(84) Constitutes 32,080 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(85) Includes an aggregate of 50,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(86) Includes an aggregate of 110,135 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(87) Includes an aggregate of 115,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(88) Includes an aggregate of 10,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(89) Includes an aggregate of 12,500 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(90) Kenn S. George is the natural person who controls The Clement E & Betty S George Trust UA Mar 10 1999, Kenn S George TR and has voting and investment power with respect to the shares owned by it.
(91) Includes an aggregate of 6,875 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(92) Andrew A. Feldman is the natural person who controls The Feldman Family Trust and has voting and investment power with respect to the shares owned by it.
(93) Includes an aggregate of 30,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(94) Martin Chopp is the natural person who controls The Hewlett Fund, LP and has voting and investment power with respect to the shares owned by it.
(95) Includes an aggregate of 600,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(96) Deserae B. Smith, on behalf of the Northern Trust Company of Delaware, as trustee, is the natural person who controls this entity and has voting and investment power with respect to the shares owned by it.
(97) Includes an aggregate of 7,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(98) E. Jeffery Peierls is the natural person who controls The Peierls Foundation, Inc. and has voting and investment power with respect to the shares owned by it.
(99) Includes an aggregate of 360,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.

(100) Includes an aggregate of 50,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(101) Thomas A. Satterfield, Jr. is the natural person who controls Tomsat Investment & Trading Co., Inc. and has voting and investment power with respect to the shares owned by it.
(102) Includes an aggregate of 100,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(103) Includes an aggregate of 112,500 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(104) Includes an aggregate of 23,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(105) Includes an aggregate of 23,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(106) Includes an aggregate of 16,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(107) Includes an aggregate of 34,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(108) Includes an aggregate of 30,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(109) Includes an aggregate of 30,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(110) Includes an aggregate of 21,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(111) Includes an aggregate of 13,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(112) Includes an aggregate of 24,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(113) Includes an aggregate of 24,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(114) John Misha Petkevich is the natural person who controls V2M Life Sciences LP and has voting and investment power with respect to the shares owned by it.
(115) Includes an aggregate of 125,000 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.
(116) Includes an aggregate of 63,825 shares issuable upon exercise of warrants, and assumes a cash exercise of such warrants.

PLAN OF DISTRIBUTION

Each selling securityholder and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby in the over-the-counter market, or any other market, stock exchange or trading facility on which our common stock is listed or quoted for trading at such time, or in private transactions. These sales may be at fixed or negotiated prices. A selling securityholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;

- settlement of short sales;
- in transactions through broker-dealers that agree with the selling securityholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling securityholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling securityholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling securityholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

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

The selling securityholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling securityholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the selling securityholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the selling securityholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling securityholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the selling securityholders or any other person. We will make copies of this prospectus available to the selling securityholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

MARKET PRICE AND DIVIDENDS ON COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information

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 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		
Second Quarter 2017 (through June 21, 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
Fiscal 2015		
Fourth Quarter 2015 (through December 31, 2015)	$26.40	$12.80
Third Quarter 2015 (through September 30, 2015)	$45.20	$22.80
Second Quarter 2015 (through June 30, 2015)	$58.40	$37.60
First Quarter 2015 (through March 31, 2015)	$42.80	$28.40

Holders

As of June 5, 2017, we had 10,335,365 shares of common stock outstanding and no shares of preferred stock outstanding. As of June 5, 2017, we had approximately 600 stockholders of record. In addition, as of June 5, 2017 and including the warrant shares being registered hereby, options and warrants to purchase 9,340,339 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)	187,191	$33.64	6
Equity compensation plans not approved by stockholders (1)(2)(3)(4)(5)(6)(7)	150,250	$54.19	64
Total	337,441	$42.79	70

(1) The information presented in this table is as of December 31, 2016 and gives retroactive 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, 2016, options to purchase 53,625 shares of our common stock were outstanding under the 2010 Non-Qualified Stock Option Plan.

(3) In November 2012 and November 2014, we entered into written compensatory contracts with Robert C. Korn, our Vice President, Sales, pursuant to which we awarded Mr. Korn non-qualified stock options to purchase 3,750 shares and 2,500 shares, respectively, of our common stock.

(4) 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, 2016, awards with respect to 10,375 shares of our common stock were outstanding under the 2013 Non-Employee Director Equity Incentive Plan.

(5) 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.

(6) In December 2014, we entered into a written compensatory contract with Wendelin C. Maners, our Vice President, Sales and Marketing, pursuant to which we awarded Ms. Maners non-qualified stock options to purchase 8,750 shares of our common stock.

(7) 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.

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 prospectus. 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 prospectus 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 still in development, 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 of our product revenues for the three months ended March 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 March 31, 2017, we had accumulated losses of approximately $96 million. We may continue to incur operating losses as we commercialize our ClearPoint system products, continue to develop our ClearTrace system, and expand our business.

Factors Which May Influence Future Results of Operations

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

Revenues

In June 2010, we received 510(k) clearance from the FDA to market our ClearPoint system in the 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 disposable products is an important part of our business model for our ClearPoint system. We anticipate that, over time, recurring revenues will constitute an increasing percentage of our total revenues as we leverage installations of our ClearPoint system to generate recurring sales of our ClearPoint disposable products. Our product revenues were approximately $5.6 million for the year ended December 31, 2016 and approximately $1.9 million for the quarter ended March 31, 2017.

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

Cost of Product Revenues

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

Research and Development Costs

Our research and development costs consist primarily of costs associated with the conceptualization, design, testing, and prototyping of our ClearPoint system products and our ClearTrace system components (prior to the suspension of such development). 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 March 31, 2017, we have incurred approximately $49 million in research and development expenses.

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

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of salaries, incentive-based compensation, travel and benefits, including related share-based compensation; marketing costs; professional fees, including fees for attorneys and outside accountants; occupancy costs; insurance; medical device excise taxes; and other general and administrative expenses, which include, 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 prospectus, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

Revenue Recognition. Our revenues are comprised of: (1) product revenues resulting from the sale of ClearPoint system reusable products and disposable products; (2) development service revenues; and (3) other service revenues. We recognize revenue when persuasive evidence of an arrangement exists, the selling price or fee is fixed or determinable, collection is reasonably assured, and, for product revenues, risk of loss has transferred to the customer. For all sales, we require either a purchase agreement or a purchase order as evidence of an arrangement. We analyze revenue recognition on an 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.

(1) *Product Revenues — Sales of ClearPoint system reusable products*: The predominance of ClearPoint system reusable product sales (consisting primarily of integrated computer hardware and software) 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, reusable product 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 reusable products not having been preceded by an evaluation period are recognized on an individual agreement basis as described in the preceding paragraph.

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

(2) *Development Service Revenues* — Under the terms of an agreement that call for us to provide development services to a third party, we earn revenue equal to costs incurred for outside expenses related to the development services provided, actual direct internal labor costs (including the cost of employee benefits), and an overhead markup of the direct internal labor costs incurred. Revenue is recognized in the period in which we incur the related costs.

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

Inventory. Inventory is carried at the lower of cost (first-in, first-out method) or net realizable value. All items included in inventory relate to our ClearPoint system. Software license inventory that is not expected to be utilized within the next twelve months is classified as a non-current asset. We periodically review our inventory for obsolete items and provide a reserve upon identification of 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 for materials used in research and development activities, sponsored research and costs for outside services. Since most of the expenses associated with our development service revenues relate to existing internal resources, these amounts are included in research and development costs.

Results of Operations

Comparison of Three Months Ended March 31, 2017 to the Three Months Ended March 31, 2016

($ amounts in thousands)	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016	Percentage Change
Product and other service revenues	$ 2,007	$ 1,394	44%
Cost of product revenues	752	697	8%
Research and development costs	558	657	(15)%
Selling, general and administrative expenses	2,051	1,974	4%
Other income (expense):			
Gain (loss) from change in fair value of derivative liabilities	(93)	160	(158)%
Other income, net	4	75	(95)%
Interest expense, net	(213)	(345)	(38)%
Net loss	(1,656)	(2,044)	(19)%

NM = not meaningful

Product and Other Service Revenues. Product and other service revenues were $2.0 million for the three months ended March 31, 2017, and $1.4 million for the same period in 2016, an increase of $613,000, or 44%. This increase was due primarily to an increase in our disposable product sales.

ClearPoint disposable product sales for the three months ended March 31, 2017 were $1.7 million, compared with $1.1 million for the same period in 2016, representing an increase of $559,000, or 51%. This growth in disposable sales reflected a greater number of ClearPoint procedures performed during the three months ended March 31, 2017, compared to the same period in 2016. Disposable product price increases implemented during the three months ended March 31, 2017 did not extend to the entire product line and averaged less than 1% for a typical customer order.

ClearPoint reusable product sales for the three months ended March 31, 2017 were $259,000, which were relatively unchanged from such sales of $262,000 for the same period in 2016. Sales of our reusable products, which consist primarily of computer hardware and software bearing sales prices that are appreciably higher than those for disposable products, may vary, sometimes significantly, from quarter to quarter. Reusable product price increases implemented during the three months ended March 31, 2017 did not extend to the entire disposable product line and averaged approximately 2% for a typical customer order.

Cost of Product Revenues. Cost of product revenues was $752,000 for the three months ended March 31, 2017, representing gross margin on product revenues of 61%, compared to $697,000 for the same period in 2016, representing gross margin of 49%. The increase in gross margin was due primarily to favorable product mix related to reusable product sales and greater production efficiencies achieved during the three months ended March 31, 2017 due to higher sales and production volumes relative to the same period in 2016.

Research and Development Costs. Research and development costs were $558,000 for the three months ended March 31, 2017, compared to $657,000 for the same period in 2016, a decrease of $99,000, or 15%. The decrease was due primarily to decreases in: (a) compensation and related expenses of $44,000 due to headcount reductions and recruiting costs incurred in 2016 that did not recur in 2017; (b) regulatory legal and consulting expenses of $21,000 that are project-based and vary from period to period; and (c) product development costs of $17,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $2.1 million for the three months ended March 31, 2017 as compared with $2.0 million for the same period in 2016, an increase of $76,000, or 4%. The increase was primarily attributable to increases in: (a) compensation and recruiting costs of $63,000 primarily associated with additions to our clinical specialist group; and (b) professional fees of $45,000 primarily related to accounting and legal fees. These increases were partially offset by a $42,000 decrease in stock-based compensation costs.

Other Income (Expense). During the three months ended March 31, 2017, we recorded a loss of $93,000, and during the three months ended March 31, 2016, we recorded a gain of $160,000, in each case resulting from changes in the fair value of our derivative liabilities. For the three months ended March 31, 2017, such derivative liabilities related to: (a) the issuance of warrants in connection with 2012 and 2013 private placement transactions; and (b) an amendment, in June 2016, of the note payable to Brainlab to add contingent conversion terms and potential down round pricing protection of warrants issued in connection with that note as discussed in Note 4 to the Condensed Consolidated Financial Statements included elsewhere in this prospectus. For the three months ended March 31, 2016, derivative liabilities were limited to the issuance of warrants in connection with the 2012 and 2013 private placement transactions.

Net other income was relatively insignificant, amounting to $4,000 and $75,000 for the three months ended March 31, 2017 and 2016, respectively.

Net interest expense for the three months ended March 31, 2017 was $213,000, compared with $345,000 for the same period in 2016, a decrease of $132,000, or 38%. This decrease was due to the reduction of principal balances of: (a) the New Brainlab Note under the terms of the 2016 Purchase Agreement and the New Brainlab Note; and (b) the 2014 Secured Notes resulting from the Note Conversion, both as described in Note 4 to the Condensed Consolidated Financial Statements included elsewhere in this prospectus.

Comparison of the Year Ended December 31, 2016 to the Year Ended December 31, 2015

	Year Ended December 31,		Percentage
($ amounts in thousands)	**2016**	**2015**	**Change**
Product revenues	$ 5,613	$ 4,416	27%
Development service revenues	-	37	(100)%
Other service revenues	136	141	(3)%
Total revenues	5,749	4,594	25%
Cost of product revenues	2,643	1,987	33%
Research and development costs	2,628	1,957	34%
Selling, general and administrative expenses	7,967	8,371	(5)%
Restructuring charges	-	1,253	(100)%
Other income (expense):			
Gain on change in fair value of derivative liabilities	1,066	1,540	(31)%
Loss on debt restructuring	(812)	-	NM
Other income, net	216	231	(6)%
Interest expense, net	(1,051)	(1,246)	16%
Net loss	(8,070)	(8,449)	4%

NM = not meaningful

Product Revenues. Product revenues were $5.6 million for the year ended December 31, 2016, and $4.4 million for the year ended December 31, 2015, an increase of $1.2 million, or 27%.

ClearPoint disposable product sales in 2016 were $4.8 million, compared with $3.5 million in 2015, representing an increase of $1.3 million, or 36%, substantially due to an increased volume of procedures performed using our ClearPoint system within a larger installed base for ClearPoint in 2016, relative to 2015. Disposable product price increases were implemented in early 2016, did not extend to the entire disposable product line and averaged approximately 1% for a typical customer order.

ClearPoint reusable product sales in 2016 were $831,000, compared with $907,000 in 2015, representing a decrease of $76,000, or 8%. Sales of our reusable products, which consist primarily of computer hardware and software bearing sales prices that are appreciably higher than those for disposable products, may vary, sometimes significantly, from period to period. Reusable product price increases were implemented in early 2016, did not extend to our entire reusable product line and averaged approximately 7% for a typical customer order.

Cost of Product Revenues. Cost of product revenues was $2.6 million in 2016, as compared with $2.0 million in 2015, representing gross margin on product revenues of 53% for 2016, compared to 55% for 2015. The decrease in gross margin was due primarily to: (a) differences between 2015 and 2016 in the equipment configuration of ClearPoint systems sold that resulted in: (i) hardware configurations sold in 2016 bearing an aggregate gross margin that was 23 percentage points lower than hardware configurations sold in 2015; and (ii) a decrease from 2015 to 2016 in software revenues, which bear higher gross margins than hardware; (b) an increase of $254,000 from 2015 to 2016 in charges to the provision for obsolete and expired product; and (c) a $296,000 increase in 2016, relative to 2015, in the allocation of indirect labor to production activities, commensurate with our transition from research and development to commercial activities; that were partially offset by increases in 2016, relative to 2015, in average unit selling prices and decreases in 2016, relative to 2015, in average unit costs due to more favorable pricing from vendors resulting from higher order quantities.

Research and Development Costs. Research and development costs were $2.6 million in 2016, compared to $2.0 million in 2015, an increase of $671,000, or 34%. The increase was due primarily to: (a) an increase of $253,000 in connection with our development of the next generation of the ClearPoint operating system; (b) an increase of $325,000 related to intellectual property costs; (c) an increase of $83,000 for other professional fees and consultants; and (d) an increase of $61,000 in personnel costs. Partially offsetting these items was a $168,000 increase in departmental costs allocated to production activities.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $8.0 million in 2016, compared with $8.4 million in 2015, a decrease of $403,000, or 5%. The decrease was primarily attributable to: (a) a decrease of $568,000 in personnel costs, which includes share-based compensation, and travel and entertainment expenses; (b) an increase of $221,000 in the allocation of departmental resources to production activities; (c) a decrease of $81,000 in medical device excise taxes, suspended by federal legislation for a two-year period beginning January 1, 2016; and (d) a decrease of $58,000 in non-personnel related marketing expenses. Partially offsetting these factors were increases of $180,000 in public company costs and $265,000 in professional fees. With respect to professional fees, in August 2016, we elected to suspend efforts then underway to sell equity units through a public offering and instead commenced a private placement of equity units through a September 2016 private placement of equity (the "2016 PIPE"), as discussed in Note 6 to the Consolidated Financial Statements included elsewhere in this prospectus. Upon suspension of those public offering efforts, we 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, we determined that a future public offering we might consider was not likely to be commenced within this six-month time frame, and accordingly, in the fourth quarter of 2016, we recorded a charge of $459,000 to general and administrative expense.

Restructuring Charges. In March 2015, we announced the consolidation of all major business functions into our Irvine, California headquarters. In connection with this consolidation, we closed our Memphis, Tennessee office in May 2015. We did not retain any of our Memphis-based employees. A total of seven employees were impacted by the consolidation, including three of our executives. As a result, we incurred expense of $1.3 million primarily related to termination costs, including the modifications of option terms, in 2015.

Other Income (Expense). In 2016 and 2015, we recorded gains of $1.1 million and $1.5 million, respectively, resulting from changes in the fair value of our derivative liabilities. In 2016, such derivative liabilities related to: (a) the issuance of warrants in connection with 2012 and 2013 private placement transactions; and (b) the amendments, in June and August 2016, of certain notes to add contingent conversion terms and potential down round pricing protection of warrants issued in connection with such notes, as discussed below and in Note 8 to the Consolidated Financial Statements included elsewhere in this prospectus. In 2015, derivative liabilities were limited to the issuance of warrants in connection with the 2012 and 2013 private placement transactions.

In April 2016, we entered into a securities purchase agreement with Brainlab (the "2016 Purchase Agreement") under which the Brainlab Note was restructured and, among other items, we: (i) entered into a patent and technology license agreement with Brainlab (the "License Agreement") for software relating to our SmartFrame device, in consideration for the cancellation of $1.0 million of the principal amount of the Brainlab Note; and (ii) issued to Brainlab, in consideration for the cancellation of approximately $1.3 million of the principal amount of the Brainlab Note, 99,310 units, each consisting of one share of our common stock, a Series A Warrant to purchase 0.4 shares of our common stock and a Series B Warrant to purchase 0.3 shares of our common stock. Execution of the 2016 Purchase Agreement constituted a debt extinguishment under GAAP, necessitating us to record a restructuring gain of $941,000 representing the difference between (a) the aggregate fair value of the License Agreement, which had no cost basis on our consolidated balance sheets, and the equity units, and (b) the aggregate principal amount of the Brainlab Note cancelled as consideration.

In June 2016, we entered into amendments with Brainlab, with respect to the New Brainlab Note, and with two holders of the 2014 Secured Notes, one of whom is a trust for which one of our non-employee directors serves as a trustee. Pursuant to the amendments, the parties agreed that, in the event we close a qualified public offering: (i) $2,000,000 of the principal balance of those notes, plus all unpaid accrued interest on that amount, will 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 46,207 shares of common stock underlying warrants issued in connection with those notes will 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 our common stock is issuable upon conversion of such convertible stock or upon exercise of such common stock warrants. Execution of the amendments constituted debt extinguishments under GAAP, necessitating us to record, on June 30, 2016, a debt restructuring loss of $820,000, representing the aggregate difference in fair value between: (a) the sum of the fair value of amended notes plus the fair value of the derivative liabilities created by the amendments; and (b) the carrying value of the notes immediately prior to the execution of the amendments.

On August 31, 2016, we entered into second amendments with the two holders of 2014 Secured Notes described in the preceding paragraph pursuant to which the parties agreed that, in the event we close a PIPE Transaction (as that term is defined therein): (i) an aggregate $1.75 million of aggregate principal balance of notes would automatically convert into the security offered by us in the 2016 PIPE, based on the offering price of that security in the 2016 PIPE; and (ii) the exercise price for shares of common stock that may be purchased upon exercise of warrants issued in connection with the issuance of such notes 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 our common stock is issuable upon conversion of such convertible stock or upon exercise of such common stock warrants. Execution of the second amendments constituted a debt extinguishment under GAAP, necessitating us to record a debt restructuring loss of $933,000, representing the aggregate difference in the fair value of the derivative liabilities created by the June 2016 amendments described in the preceding paragraph between the points in time (i) immediately preceding, and (ii) immediately subsequent to, the execution of the second amendments.

Net other income did not significantly fluctuate, amounting to $216,000 and $231,000 in 2016 and 2015, respectively.

Net interest expense was $1.1 million and $1.2 million in 2016 and 2015, respectively. The decrease was due primarily to the reduced principal balance of the New Brainlab Note and the two 2014 Secured Notes resulting from the restructuring of those notes as described above.

Liquidity and Capital Resources

The cumulative net loss from our inception through March 31, 2017 was approximately $96 million. Net cash used in operating activities was $1.3 million for the three months ended March 31, 2017. Since inception, we have financed our operations principally from the sale of equity securities, the issuance of notes payable and license arrangements. Recent financing activities consist of: (i) the 2016 PIPE, which resulted in net cash proceeds of $3.8 million and the conversion of $1.75 million in debt; (ii) a December 2015 private placement of equity (the "2015 PIPE"), which resulted in net cash proceeds of $4.7 million; (iii) a December 2014 private placement of equity, which resulted in net cash proceeds of $9.4 million; and (iv) the private placement of the 2014 Secured Notes and related warrants, which resulted in net cash proceeds of $3.5 million.

In addition, as discussed in Note 6 to the Consolidated Financial Statements included elsewhere in this prospectus:

- On April 4, 2016, we entered into the 2016 Purchase Agreement with Brainlab, which resulted in a reduction of the principal amount outstanding under the Brainlab Note, and which is reflected in the New Brainlab Note that matures on December 31, 2018.

- Pursuant to amendments we executed on August 31, 2016 with certain note holders, upon completion of the 2016 PIPE an aggregate $1.75 million of principal balance of such holders' 2014 Secured Notes automatically converted into units, each unit consisting of one share of the Company's common stock and one warrant to purchase 0.90 share of our common stock, based on the offering price per unit in the 2016 PIPE.

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 as a result of greater utilization at existing installed sites and the installation of the ClearPoint system at new sites. Management also anticipates 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 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 it will be necessary to seek additional financing from the sale of equity or debt securities, which would result in dilution to our current stockholders, the establishment of a credit facility, or the entry into an agreement with a strategic partner or some other form of collaborative relationship. 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 that 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 our anticipated results, and we may not be able to meet our other obligations as they become due. As such, there is substantial doubt as to our ability to continue as a going concern.

Cash Flows

Cash activity for the three months ended March 31, 2017 and 2016 is summarized as follows:

	Three Months Ended March 31,	
	2017	**2016**
Cash used in operating activities	$ (1,346,177)	$ (1,608,561)
Cash used in investing activities	-	(77,649)
Cash used in financing activities	-	(140,086)
Net decrease in cash and cash equivalents	$ (1,346,177)	$ (1,826,296)

Net Cash Flows from Operating Activities. We used $1.3 million and $1.6 million of cash for operating activities during the three months ended March 31, 2017 and 2016, respectively.

During the three months ended March 31, 2017, uses of cash in operating activities primarily consisted of: (i) our $1.7 million net loss; and (ii) increases in accounts receivable of $144,000, inventory of $62,000 and other assets of $6,000. These uses were partially offset by: (a) a decrease in prepaid expenses and other current assets of $39,000; (b) increases in accounts payable and accrued expenses of $5,000 and in deferred revenue of $40,000; and (c) non-cash expenses included in our loss from operations aggregating $437,000 and consisting of depreciation and amortization, share-based compensation, loss on change in fair value of derivative liabilities, and amortization of debt issuance costs and original issue discounts.

During the three months ended March 31, 2016, uses of cash in operating activities primarily consisted of: (i) our $2.0 million net loss; and (ii) increases in accounts receivable of $279,000, prepaid expenses and other current assets of $18,000, and other assets of $58,000. These uses were partially offset by: (a) a decrease in inventory of $218,000; (b) increases in accounts payable and accrued expenses of $53,000, and in deferred revenue of $36,000; and (c) non-cash expenses included in our loss from operations aggregating $645,000 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 $160,000 decrease in the fair value of our derivative liabilities.

Net Cash Flows from Investing Activities. Net cash flows used in investing activities for the three months ended March 31, 2016 were $78,000, and consisted of equipment acquisitions. There were no investing activities affecting cash during the three months ended March 31, 2017.

Net Cash Flows from Financing Activities. Net cash used in financing activities for the three months ended March 31, 2016 of $140,000 consisted of costs paid in connection with the 2015 PIPE. There were no financing activities affecting cash during the three months ended March 31, 2017.

Cash activity for the years ended December 31, 2016 and 2015 is summarized as follows:

	Year Ended December 31,	
	2016	**2015**
Cash used in operating activities	$ (5,820,043)	$ (8,637,734)
Cash used in investing activities	(101,002)	(76,883)
Cash provided by financing activities	3,828,296	4,879,134
Net decrease in cash and cash equivalents	$ (2,092,749)	$ (3,835,483)

Net Cash Flows from Operating Activities. We used $5.8 million and $8.6 million of cash for operating activities in 2016 and 2015, respectively.

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.

In 2015, uses of cash in operating activities primarily consisted of: (i) our $8.4 million net loss; (ii) a reduction of accounts payable and accrued expenses of $436,000; and (iii) increases in accounts receivable of $749,000 and in prepaid expenses and other current assets of $68,000. These uses were partially offset by: (a) decreases in inventory of $68,000, and in other assets of $10,000; (b) an increase in deferred revenue of $13,000; and (c) non-cash expenses included in our net loss aggregating $2.5 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 $1.5 million decrease in the fair value of our derivative liabilities.

Net Cash Flows from Investing Activities. Net cash flows used in investing activities in 2016 and 2015 were $101,000 and $77,000, respectively, and consisted primarily of equipment purchases.

Net Cash Flows from Financing Activities. Net cash provided by financing activities in 2016 of $3.8 million reflected primarily net proceeds received from the 2016 PIPE. Net cash provided by financing activities in 2015 of $4.9 million reflected primarily net proceeds received in connection with the 2015 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 interest bearing instruments, including interest bearing demand accounts and certificates of deposit. Cash in excess of immediate requirements is invested primarily with a view to liquidity and capital preservation.

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

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

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.

- *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 the 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 electrodes, such as deep brain stimulation, 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. In October 2016, St. Jude Medical (now part of Abbott Laboratories) received FDA clearance for its Infinity® DBS system, the first system with directional lead technology and iOS-based programming features, which we believe will drive demand for DBS therapy. Thus, 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 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, 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 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 four years following the European product release date of the host features for the applicable Siemens MAGNETOM MRI systems, which occurred in October 2014.

Boston Scientific

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

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

In March 2008, we entered into a development agreement and license agreement with Boston Scientific in the field of implantable medical leads for cardiac applications. The development agreement related to feasibility assessment, design and development of certain MRI-compatible, MRI-safe implantable cardiac rhythm management leads. Under the license agreement, we granted Boston Scientific an exclusive, worldwide license with respect to certain of our intellectual property in the field of implantable medical leads for cardiac applications to make, have made, use, promote, market, import, distribute, lease, sell, offer for sale and commercialize products in that particular field of use. Boston Scientific is responsible for patent prosecution of the intellectual property it licensed and the payment of costs associated with patent prosecution.

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

The Johns Hopkins University

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

Sales and Marketing

Commercializing our ClearPoint system involves marketing primarily to:

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

Presently, our commercialization efforts for our ClearPoint system are being coordinated primarily through our Vice President, Sales and Marketing, Wendelin C. Maners. As of June 1, 2017, our sales, clinical support and marketing team consisted of 12 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 June 1, 2017, our research and development team consisted of eight employees. We have assembled an experienced team with recognized expertise in both the development of medical devices and advanced MRI technologies, including interventional MRI microcoils and catheters. We believe that our current research and development team is sufficient for our current needs; however, we may increase the size of our team depending on the progress of our ongoing research and development efforts. 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, Emory University Hospital, or Emory, and the University of California, San Francisco Medical Center, or UCSF, 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 June 1, 2017, we wholly-owned, co-owned or licensed a total of 77 United States patents and 31 United States patent applications, as well as various foreign patents and foreign patent applications corresponding with many of our United States patents and applications. Our owned, issued patents expire at various dates beginning in 2020. Our licensed, issued patents began to expire at various dates beginning in 2016. 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 June 1, 2017, we had 32 full time employees, of whom eight were engaged primarily in research and development, eight in manufacturing and quality assurance, 12 in sales, clinical support and marketing, and four 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.

Facilities

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.

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.

MANAGEMENT

Directors and Executive Officers

The following table sets forth information about our directors and executive officers as of June 5, 2017.

Name	Age	Position(s)
Kimble L. Jenkins	55	Director; Chairman
R. John Fletcher	71	Director
Pascal E.R. Girin[1]	57	Director
Charles E. Koob[1][3]	72	Director
Philip A. Pizzo[2][3]	72	Director
Timothy T. Richards[2]	59	Director
Maria Sainz[3]	51	Director
John N. Spencer, Jr.[1][2]	76	Director
Francis P. Grillo	55	Director; Chief Executive Officer and President
Harold A. Hurwitz	65	Chief Financial Officer and Corporate Secretary
Peter G. Piferi	57	Chief Operating Officer
Wendelin C. Maners	54	Vice President, Sales and Marketing

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

Kimble L. Jenkins joined our Board in September 2002. Mr. Jenkins, who currently serves as the Chairman of our Board, previously served as our President from January 2003 to October 2014, and as our Chief Executive Officer from September 2004 through December 2014. Mr. Jenkins served in those two positions on a part-time basis until May 2008, at which time he began serving as President and Chief Executive Officer on a full-time basis. Since December 2016, Mr. Jenkins has served as a director of Cardiac Designs, Inc., a privately held cardiac arrhythmia monitoring company. Since October 2014, Mr. Jenkins has also served as the President of Theraplex Company LLC, a privately held skin care products company. Prior to May 2008, Mr. Jenkins was a Managing Director with the investment bank Morgan Keegan & Company, Inc., where he founded that firm's Private Equity Group in 1998. Mr. Jenkins has over 20 years of experience building and working with growth stage companies. As our former Chief Executive Officer, we believe Mr. Jenkins' perspective into our business is an invaluable resource for our Board.

R. John Fletcher joined our Board in May 2017. Mr. Fletcher founded Fletcher Spaght in 1983 where he leads both the consulting practice and venture capital activities, with analytical insights and creative solutions derived from his years of experience with clients, portfolio companies and the investment community. Mr. Fletcher works across Fletcher Spaght's practice groups, with a focus on healthcare. He has particular interests in devices, specifically in cardiology, cardiac surgery, and orthopedics, as well as in biopharma and healthcare IT. Prior to founding Fletcher Spaght, Mr. Fletcher was a Senior Manager at The Boston Consulting Group, advising a broad range of companies in healthcare and high technology industries. Mr. Fletcher serves on the Board of Directors of Spectranetics, Axcelis and Metabolon. He is Chairman of the Corporate Collaboration Council at the Thayer School of Engineering/Tuck School of Business at Dartmouth College and serves on the Board of Advisors of Beth Israel Deaconess Medical Center and the Whitehead Institute at MIT. Mr. Fletcher received his MBA from Southern Illinois University, and a BBA in Marketing from George Washington University. He was an Instructor for courses in international business and a PhD Candidate at the Wharton School of the University of Pennsylvania. He served as a Captain and jet pilot in the U.S. Air Force, and continues to be active in aviation. We believe Mr. Fletcher brings strategic insight, leadership and a wealth of experience in healthcare to our Board. Additionally, he has experience as a director on other publicly traded company boards.

Pascal E.R. Girin joined our Board in September 2014. Mr. Girin possesses over two decades of management and executive experience in the field of medical technology. Since September 2016, Mr. Girin has served as Chairman and CEO of Balt Inc., a private company specialized in the treatment of neurovascular diseases, where he was recruited to lead the company's global expansion. Mr. Girin served as Executive Vice President and Chief Operating Officer of Wright Medical Technology, Inc. from November 2012 until October 2015, at which time the company successfully merged with Tornier N.V. and formed Wright Medical Group N.V. Prior to joining Wright Medical, Mr. Girin served as President and Chief Executive Officer of Keystone Dental Inc. from February 2011 to June 2012, at which time the company successfully merged with Southern Implants Inc. From October 2010 to February 2011, Mr. Girin served as Executive Vice President and Chief Operating Officer of Keystone Dental Inc. From July 2010 to September 2010, Mr. Girin served as Chief Operating Officer of ev3 Inc. following its acquisition by a wholly owned subsidiary of Covidien Group S.a.r.l. Prior to that time, Mr. Girin served as Executive Vice President and Chief Operating Officer of ev3 Inc. from January 2010 to July 2010, as Executive Vice President and President, Worldwide Neurovascular and International of ev3 Neurovascular Inc. from July 2008 to January 2010, as Senior Vice President and President, International of ev3 International from July 2005 to July 2008, and as General Manager, Europe of ev3 Inc. from September 2003 to July 2005. From September 1998 to August 2003, Mr. Girin served in various capacities at BioScience Europe Baxter Healthcare Corporation, most recently as Vice President. Mr. Girin received an engineering education at the French Ecole des Mines. From November 2010 until November 2, 2012, Mr. Girin had served as a director of Tornier N.V., a publicly traded global medical device company, as well as a member of its Nominating, Corporate Governance and Compliance Committee. With nearly three decades of experience as an executive and director in the medical device industry, both in the U.S. and in Europe, we believe Mr. Girin brings invaluable industry experience and leadership qualities to our Board, as well as insight into international markets.

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

Philip A. Pizzo joined our Board in April 2013. Dr. Pizzo served as Dean of the Stanford School of Medicine from April 2001 to December 1, 2012, where he was also the Carl and Elizabeth Naumann Professor of Pediatrics and of Microbiology and Immunology. Dr. Pizzo has devoted much of his distinguished medical career to the diagnosis, management, prevention and treatment of childhood cancers and the infectious complications that occur in children whose immune systems are compromised by cancer and AIDS. He has also been a leader in academic medicine, championing programs and policies to improve the future of science, education and healthcare in the United States and beyond. Before joining Stanford, Dr. Pizzo was the physician-in-chief of Children's Hospital in Boston and chair of the Department of Pediatrics at Harvard Medical School from 1996 to 2001. He is the author of more than 500 scientific articles and 16 books and monographs. Dr. Pizzo presently serves on the board of directors, or the equivalent governing body, of Global Blood Therapeutics, Inc., a publicly-traded, clinical-stage biopharmaceutical company, the University of Rochester, a private university, and Koc University, a private university located in Istanbul, Turkey. We believe Dr. Pizzo offers a deep understanding of medical sciences and innovation, as well as physicians and other healthcare providers who are central to the use of our products.

Timothy T. Richards joined our Board in March 2014. Since October 2012, Mr. Richards has worked for Seventh Sense BioSystems, Inc., a venture capital-backed start-up with a focus on point-of-care diagnostic testing, where he was recruited to build and develop the company's business development and commercial organization. Currently, Mr. Richards serves as Seventh Sense BioSystems' Chief Operating Officer. Prior to joining Seventh Sense BioSystems, from October 2011 through August 2012, Mr. Richards served as President of Facet Technologies, LLC, a privately-held supplier to major diagnostic companies, where he led the company's manufacturing and supply chain platform. From November 2008 until May 2010, Mr. Richards held executive-level positions within the Covidien organization, first as U.S. President of the Patient Care & Safety Products business unit, and subsequently as President of VNUS Medical Technologies following its acquisition by Covidien in 2009. From October 2003 through October 2008, Mr. Richards served as Senior Vice President, Chief Marketing Officer and a member of the Executive Board of B. Braun Medical Inc., a leader in infusion therapy and pain management. Before joining B. Braun Medical, he held a number of progressive leadership positions throughout the U.S. and Asia with Becton Dickinson and Company. We believe Mr. Richards brings to our Board extensive leadership experience and expertise in general management, operations, commercial management and strategy in the medical device field.

Maria Sainz joined our Board in January 2014. Since April 2012, Ms. Sainz has served as President and Chief Executive Officer of CardioKinetix, Inc., a privately-held medical device company based in Menlo Park, California that is pioneering a catheter-based treatment for heart failure. Beginning in April 2008, she served as President and Chief Executive Officer of Concentric Medical, Inc., a privately-held medical device company focused on developing endovascular devices for revascularizing stroke patients. Ms. Sainz held that position until October 2011, when Concentric Medical was acquired by Stryker Corporation, at which time she was named General Manager of the Stryker Neurovascular business unit, a position she held until April 2012. Prior to Concentric Medical, as an advisor to Boston Scientific Corporation's Chief Operating Officer, Ms. Sainz led integration activities following Boston Scientific's acquisition of Guidant Corporation. From February 2003 through June 2006, she served as President of Guidant Corporation's Cardiac Surgery Division, during which time she successfully grew the multi-therapy division's revenue from $90 million to $176 million. Prior to that, from January 2001 through February 2003, Ms. Sainz served as Vice President, Global Marketing for the Vascular Intervention Division of Guidant Corporation, where she was responsible for worldwide new product and market development activities. Ms. Sainz currently serves as a director of The Spectranetics Corporation, Orthofix International N.V. and Halyard Health Corporation, each a publicly-traded medical device company, as well as a director of CardioKinetix, Inc. Ms. Sainz brings to our Board over 20 years of experience in the medical device industry having held commercial and general management positions both in the United States and Europe.

John N. Spencer, Jr. joined our Board in March 2010. Mr. Spencer is a certified public accountant and was a partner of Ernst & Young LLP where he spent more than 38 years until his retirement in 2000. Mr. Spencer serves on the board of directors of GeoVax Labs, Inc., a publicly traded biotechnology company. In addition, he serves on the boards of directors of, and as a consultant for various accounting and financial reporting matters to, various privately owned companies. From November 2013 until February 2014, Mr. Spencer served as interim Chief Financial Officer of Applied Genetic Technologies Corporation, which is now a publicly traded biotechnology company, while such company was in registration with the SEC. By virtue of his experience at Ernst & Young, where he was the partner in charge of its life sciences practice for the southeastern United States, together with his continuing expertise as a director of, and a consultant to, other publicly traded and privately held companies, we believe Mr. Spencer offers expertise in accounting, finance and the medical device industry.

Francis (Frank) P. Grillo joined us in October 2014 as President. Mr. Grillo also became our Chief Executive Officer effective January 1, 2015 and became a member of our Board in April 2015. Prior to joining our company, Mr. Grillo served as Vice President, Marketing and New Business Development of Intuitive Surgical, Inc., a publicly-traded medical technology company, since August 2008. Before joining Intuitive Surgical, Mr. Grillo worked for Kyphon Inc. from February 2006 to June 2008, most recently as Vice President, Marketing and Business Development. Kyphon was a publicly-traded medical technology company prior to its acquisition by Medtronic, Inc. in November 2007. Prior to Kyphon, from September 1996 to January 2006, Mr. Grillo held various positions at Boston Scientific Corporation, most recently as Vice President, Marketing, Women's Health, Urology/Gynecology Division. Mr. Grillo presently serves on the board of directors of Embolx, Inc., a privately held medical device company. As our Chief Executive Officer, and as a result of his substantial experience as an executive of medical device companies, we believe Mr. Grillo offers a unique understanding of our business and industry with a particular focus on driving adoption of new medical technologies.

Harold A. Hurwitz joined us in March 2015 as Vice President, Finance, and, in May 2015, became our Chief Financial Officer. From February 2013 to January 2015, Mr. Hurwitz served as Chief Executive Officer and President of Pro-Dex, Inc., a publicly-traded contract engineering and manufacturing company serving the medical device, factory automation and scientific research markets. Mr. Hurwitz also held the positions of Chief Financial Officer, Treasurer and Secretary of Pro-Dex from October 2010, when he joined that company, to January 2015. Between March 2010 and September 2010, Mr. Hurwitz served as an independent consultant, providing service primarily to a molecular diagnostics company. From April 2008 to February 2010, Mr. Hurwitz served as Chief Financial Officer and Vice President of Interventional Spine, Inc., a venture-backed medical device company. Prior to joining Interventional Spine, Mr. Hurwitz served as Principal Consultant with McDermott & Bull, a retained executive search firm, from December 2005 to March 2008, where he led the life science and medical technology practice. Mr. Hurwitz served as an independent consultant from December 2004 to December 2005, with his primary client during that time being Micro Therapeutics, Inc., then a publicly-traded medical device company (subsequently acquired by ev3, Inc., and now part of Medtronic plc). He was Chief Financial Officer of Micro Therapeutics, Inc. from December 1997 to December 2004. Earlier in his career, Mr. Hurwitz was a Partner with Coopers & Lybrand L.L.P. (now part of PricewaterhouseCoopers LLP), where he was a Business Assurance Partner, Team Leader of its Orange County Medical Device Practice and an SEC Review Partner. Mr. Hurwitz served as a director of Pro-Dex, Inc. from May 2013 to January 2015.

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

Wendelin C. Maners joined us in December 2014 as Vice President, Marketing, and, in April 2017, became our Vice President, Sales and Marketing. Ms. Maners has more than two decades of global medical device experience focused on the marketing, acquisition, and licensing of medical device technologies. Prior to joining MRI Interventions, Ms. Maners served as Vice President, Emerging Technologies with CSA Medical Inc., where she managed commercial marketing for the company's products, led market development efforts for the company's emerging applications in new market and disease segments and developed internal and external product training programs. Prior to her time with CSA Medical, Ms. Maners served for over 14 years in various roles at Boston Scientific Corporation, most recently as Vice President, Strategy and Business Development. During that time, she developed and executed acquisition strategies in the Neuromodulation and Electrophysiology markets, managed and built technology and venture capital business relationships to assemble a portfolio of investment options for supported divisions and served as a delegate Board member/observer for Boston Scientific investments, including Cyberonics, Inc., Northstar Neuroscience, Inc., Neuropace, Inc., Intelect Medical, Inc., IntraPace, Inc., Quallion LLC and the Company.

Board Composition

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

Board Independence

Even though we are not currently listed on a national securities exchange, for purposes of determining independence, we have adopted the provisions of Nasdaq Marketplace Rule 5605. Our Board of Directors undertook a review of the composition of our Board of Directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board of Directors has determined that none of Dr. Pizzo, Ms. Sainz, or Messrs. Fletcher, Girin, Koob, Richards or Spencer, representing seven of our nine directors, has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under Rule 5605(a)(2) of the Nasdaq Marketplace Rules. In making such determination, our Board of Directors considered the relationships that each such director has with us and all other facts and circumstances the Board of Directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each director.

Board Committees

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

Audit Committee

Our audit committee consists of Messrs. Girin, Koob and Spencer. Mr. Spencer serves as the Chairperson of the audit committee. The functions of the audit committee include:

- overseeing the audit and other services of our independent registered public accounting firm and being directly responsible for the appointment, compensation, retention and oversight of the independent registered public accounting firm, who will report directly to the audit committee;
- reviewing and pre-approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services;
- overseeing compliance with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as required;
- reviewing our annual and quarterly financial statements and reports and discussing the financial statements and reports with our independent registered public accounting firm and management;
- reviewing and approving all related person transactions pursuant to our Related Party Transaction Policy;
- reviewing with our independent registered public accounting firm and management significant issues that may arise regarding accounting principles and financial statement presentation, as well as matters concerning the scope, adequacy and effectiveness of our internal controls over financial reporting;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding internal controls over financial reporting, accounting or auditing matters; and
- preparing the audit committee report for inclusion in our proxy statement for our annual meeting.

Our Board of Directors has determined that, at this time, Mr. Spencer is an audit committee financial expert within the meaning of SEC rules. Furthermore, our Board of Directors has determined that all the members of the Audit Committee satisfy the independence, experience and other requirements established by the Nasdaq Marketplace Rules, which were adopted by us, and the applicable rules of the SEC related to audit committee member independence. Our Audit Committee met five times during 2016. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

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

Compensation Committee

Our compensation committee consists of Dr. Pizzo and Messrs. Richards and Spencer. Mr. Richards serves as the Chairperson of the compensation committee. The functions of the compensation committee include:

- determining the compensation and other terms of employment of our Chief Executive Officer and other executive officers and reviewing and approving our performance goals and objectives relevant to such compensation;
- administering and implementing our incentive compensations plans and equity-based plans, including approving option grants, restricted stock and other awards;
- evaluating and recommending to our Board of Directors the equity incentive-compensation plans, equity-based plans and similar programs advisable for us, as well as modifications or terminations of our existing plans and programs;
- reviewing and approving the terms of any employment-related agreements, severance arrangements, change-in-control and similar agreements/provisions and any amendments, supplements or waivers to the foregoing agreements with our Chief Executive Officer and other executive officers;
- to the extent required, reviewing and discussing the Compensation Discussion & Analysis for our annual report and proxy statement with management and determining whether to recommend to our Board of Directors the inclusion of the Compensation Discussion & Analysis in the annual report and proxy statement; and
- to the extent required, preparing a report on executive compensation for inclusion in our proxy statement for our annual meeting.

Each member of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986. Furthermore, our Board of Directors has determined that Dr. Pizzo and Messrs. Richards and Spencer each satisfy the independence standards for compensation committees established by the Nasdaq Marketplace Rules. Our Compensation Committee met one time during 2016.

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

Corporate Governance and Nominating Committee

Our corporate governance and nominating committee consists of Mr. Koob, Dr. Pizzo and Ms. Sainz. Mr. Koob serves as Chairperson of the corporate governance and nominating committee. The functions of the corporate governance and nominating committee include:

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

Our Board of Directors has determined that Mr. Koob, Dr. Pizzo and Ms. Sainz each satisfy the independence standards for the corporate governance and nominating committees established by the Nasdaq Marketplace Rules. Our corporate governance and nominating committee met one time during 2016.

A copy of the charter for our corporate governance and nominating committee is posted on our website at www.mriinterventions.com. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

Code of Business Conduct and Ethics

Our Board of Directors has adopted a Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics applies to all of our employees, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions), and directors. The Code of Business Conduct and Ethics is posted on our website at www.mriinterventions.com. We will provide a copy of this document to any person, without charge, upon request, by writing to our Investor Relations Department, 5 Musick, Irvine, CA 92618. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics, or waivers of such provisions, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors on our website identified above. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

Compensation Committee Interlocks and Insider Participation

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

Compensation Risks

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

Summary Compensation Table

The following table shows the compensation awarded or paid to, or earned by, our Chief Executive Officer, Chief Financial Officer and Vice President, Sales for the years ended December 31, 2016 and 2015. We refer to these executive officers as our "named executive officers."

Named Executive Officer	Year	Salary ($)	Bonus ($)	Option Awards ($)[1]	All Other Compensation ($)[2]	Total ($)
Francis P. Grillo	2016	350,000	61,600[3]	-	9,131	420,731[4]
Chief Executive Officer	2015	350,000	100,000[5]	87,500[6]	9,380	546,880[7]
Harold A. Hurwitz[8]	2016	230,000	49,680[9]	22,365[10]	5,657	307,702[11]
Chief Financial Officer	2015	174,269	48,300[12]	271,551[13]	3,797	497,917[14]
Robert C. Korn[15]	2016	220,000	75,751[16]	-	9,372	305,123[17]
Vice President, Sales	2015	220,000	77,994[16]	70,000[18]	11,283	379,277[19]

(1) These amounts do not represent cash compensation paid to the named individual. These non-cash amounts represent only the aggregate grant date fair value of the option awards as computed in accordance with the Financial Accounting Standards Board Accounting Standards Codification, or ASC, Topic 718. For a discussion of the assumptions made in the valuation of the awards, see the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates—Share-based Compensation" and Note 7 to the Consolidated Financial Statements included elsewhere in this prospectus.

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

(3) Of this amount, $20,944 is payable to Mr. Grillo in cash, and $40,656 is to be granted in shares of our common stock, such grant contingent upon the approval by stockholders of a proposal in our 2017 proxy statement to increase the number of shares available for issuance under our Amended and Restated 2013 Incentive Compensation Plan, with the number of shares of such stock-based compensation to be calculated on the basis of the per share market value of our common stock at the close of trading on the date of grant.

(4) Of this amount, the cash compensation paid, or to be paid, to Mr. Grillo totals $370,944.

(5) Of this amount, Mr. Grillo was paid $33,333 in cash and $66,667 in shares of our common stock on February 1, 2016, and the number of shares of such stock-based compensation was calculated on the basis of the per share market value of our common stock at the close of trading on that date.

(6) Does not represent cash compensation. Represents only the aggregate grant date fair value in accordance with ASC Topic 718 of options to purchase an aggregate of 6,250 shares of our common stock issued to Mr. Grillo with an exercise price of $29.60 per share.

(7) Of this amount, the cash compensation paid to Mr. Grillo totaled $383,333.

(8) Mr. Hurwitz joined us in March 2015 as our Vice President, Finance, and became our Chief Financial Officer in May 2015.

(9) Of this amount, $24,840 is payable to Mr. Hurwitz in cash, and $24,840 is to be granted in shares of our common stock, such grant contingent upon the approval by stockholders of a proposal in our 2017 proxy statement to increase the number of shares available for issuance under our Amended and Restated 2013 Incentive Compensation Plan, with the number of shares of such stock-based compensation to be calculated on the basis of the per share market value of our common stock at the close of trading on the date of grant.

(10) Does not represent cash compensation. Represents only the aggregate grant date fair value in accordance with ASC Topic 718 of options to purchase an aggregate of 3,750 shares of our common stock issued to Mr. Hurwitz with an exercise price of $12.40 per share pursuant to the terms of a written compensatory contract we entered into with Mr. Hurwitz in March 2015.

(11) Of this amount, the cash compensation paid, or to be paid, to Mr. Hurwitz totals $254,840.

(12) Of this amount, Mr. Hurwitz was paid $36,225 in cash and $12,075 in shares of our common stock on February 1, 2016, and the number of shares of such stock-based compensation was calculated on the basis of the per share market value of our common stock at the close of trading on that date.

(13) Does not represent cash compensation. Represents only the aggregate grant date fair value in accordance with ASC Topic 718 of options to purchase an aggregate of 15,000 shares of our common stock issued to Mr. Hurwitz with a weighted average exercise price of $39.20 per share.

(14) Of this amount, the cash compensation paid to Mr. Hurwitz totals $210,494.

(15) As reported in Item 9B of our Annual Report on Form 10-K for the year ended December 31, 2016, on March 3, 2017, Mr. Korn tendered his voluntary resignation to the Company, which was effective March 31, 2017.

(16) Represents amounts paid pursuant to Mr. Korn's sales incentive plan.

(17) Of this amount, the cash compensation paid, or to be paid, to Mr. Korn totals $295,751.
(18) Does not represent cash compensation. Represents only the grant date fair value in accordance with ASC Topic 718 of an option to purchase 5,000 shares of our common stock issued to Mr. Korn with an exercise price of $29.60 per share.
(19) Of this amount, the cash compensation paid to Mr. Korn totaled $297,994.

Outstanding Equity Awards at December 31, 2016

The table below sets forth information regarding the outstanding equity awards held by our named executive officers at December 31, 2016 and after giving effect to the Reverse Split.

	Option Awards			
Name	**Number of Securities Underlying Unexercised Options (#) Exercisable**	**Number of Securities Underlying Unexercised Options (#) Unexercisable**	**Option Exercise Price ($)**	**Option Expiration Date**
Francis P. Grillo	40,000(1)	20,000(1)	45.20	October 6, 2024
	2,777(2)	3,473(2)	29.60	August 13, 2025
Harold A. Hurwitz	3,750(3)	7,500(3)	42.40	March 30, 2025
	1,667(4)	2,083(4)	29.60	August 13, 2025
	-(5)	3,750(5)	12.40	March 30, 2026
Robert C. Korn	7,500(6)	-	65.20	November 10, 2022
	2,500(6)(7)	-(7)	60.40	November 5, 2023
	1,667(6)(8)	833(6)(8)	39.20	November 10, 2024
	2,223(6)(8)	2,777(6)(9)	29.60	August 13, 2025

(1) One-third of the shares subject to this option vested on the first anniversary of the grant date, October 6, 2015. An additional one-third of the shares vested on the second anniversary of the grant date, October 6, 2016. The remaining shares vest on the third anniversary of the grant date, October 6, 2017.

(2) One-third of the shares subject to this option vested on the first anniversary of the grant date, August 13, 2016. The remaining two-thirds of the shares were scheduled to vest ratably in 24 equal monthly installments beginning in the first month following the first anniversary of the grant date. Of these 24 equal monthly installments, four had vested as of December 31, 2016.

(3) One-third of the shares subject to this option vested on the first anniversary of the grant date, March 30, 2016. An additional one-third of the shares will vest on the second anniversary of the grant date, March 30, 2017. The remaining shares will vest on the third anniversary of the grant date, March 30, 2018.

(4) One-third of the shares subject to this option vested on the first anniversary of the grant date, August 13, 2016. The remaining two-thirds of the shares were scheduled to vest ratably in 24 equal monthly installments beginning in the first month following the first anniversary of the grant date. Of these 24 equal monthly installments, four had vested as of December 31, 2016.

(5) One-third of the shares subject to this option will vest on the first anniversary of the grant date, March 30, 2017. An additional one-third of the shares will vest on the second anniversary of the grant date, March 30, 2018. The remaining shares will vest on the third anniversary of the grant date, March 30, 2019.

(6) As previously disclosed, Mr. Korn voluntarily resigned from the Company effective March 31, 2017. Per the terms of his option award agreements, as a result, all options outstanding as of that date were terminated immediately and of no further force or effect.

(7) One-third of the shares subject to this option vested on the first anniversary of the grant date, November 5, 2014. An additional one-third of the shares vested on the second anniversary of the grant date, November 5, 2015. The remaining shares vested on the third anniversary of the grant date, November 5, 2016.

(8) One-third of the shares subject to this option vested on the first anniversary of the grant date, November 10, 2015. An additional one-third of the shares vested on the second anniversary of the grant date, November 10, 2016. The remaining shares were scheduled to vest on the third anniversary of the grant date, November 10, 2017.

(9) One-third of the shares subject to this option vested on the first anniversary of the grant date, August 13, 2016. The remaining two-thirds of the shares were scheduled to vest ratably in 24 equal monthly installments beginning in the first month following the first anniversary of the grant date. Of these 24 equal monthly installments, four had vested as of December 31, 2016.

Option Exercises

None of our named executive officers exercised stock options in 2016.

Employment Agreements

Each of our named executive officers had a written compensatory contract with the Company during 2016. In September 2014, we entered into an employment agreement with Mr. Grillo. In March 2015, we entered into a written compensatory contract with Mr. Hurwitz. In November 2012, we entered into an employment agreement with Mr. Korn.

Term

Under each of the compensatory contracts, the employment of the named executive officer may be terminated by either party upon written notice to the other party.

Compensation

The base salaries of our named executive officers, as of December 31, 2016, were as follows:

Named Executive Officer	Title	Base Salary[1]
Francis P. Grillo	Chief Executive Officer and President	$350,000
Harold A. Hurwitz	Chief Financial Officer and Corporate Secretary	$230,000
Robert C. Korn[2]	Vice President, Sales	$220,000

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

(2) As previously disclosed, Mr. Korn voluntarily resigned from the Company effective March 31, 2017.

Bonus. Mr. Grillo is 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. The amount of the incentive bonus payable to Mr. Grillo may be more or less than the target amount, depending on whether, and to what extent, applicable performance goals for such year have been achieved. Mr. Hurwitz is eligible to receive an annual target incentive bonus of 30% of his annual base salary, subject to certain performance goals to be established by the Compensation Committee. The amount of the incentive bonus payable to Mr. Hurwitz may be more or less than the target amount, depending on whether, and to what extent, applicable performance goals for such year have been achieved. Mr. Korn is eligible for additional cash compensation under a sales incentive plan, which is targeted to yield an annual payout of at least $100,000 for reaching targeted sales levels. The actual payout under Mr. Korn's sales incentive plan may be more or less than the targeted payout based on actual sales achieved.

Option Awards. Pursuant to our employment agreement with Mr. Grillo, Mr. Grillo received, on the start date of his employment, an option to purchase 60,000 shares of our common stock. That option, which was granted October 6, 2014, has an exercise price of $45.20 per share, has a term of 10 years from the date of grant and vests in three equal annual installments, which began on October 6, 2015, subject to vesting acceleration under certain circumstances. Pursuant to our written compensatory contract with Mr. Hurwitz, Mr. Hurwitz received, on the start date of his employment, an option to purchase 11,250 shares of our common stock. That option, which was granted March 30, 2015, has an exercise price of $42.40 per share, has a term of 10 years from the date of grant and vests in three equal annual installments beginning March 30, 2016, subject to vesting acceleration under certain circumstances. In addition, on March 30, 2016, Mr. Hurwitz was granted an additional stock option entitling him to purchase 3,750 shares. That option has an exercise price of $12.40 per share, has a term of 10 years from the date of grant and vests in three equal annual installments beginning March 30, 2017, subject to vesting acceleration under certain circumstances. Further, the terms of Mr. Hurwitz' compensatory contract provide that, on March 30, 2017, he would be entitled to receive an additional stock option entitling him to purchase 3,750 shares, which option grant would have an exercise price equal to the then fair market value of our common stock, have a term of 10 years from the date of grant and vest over three years in equal installments, on the first, second and third year anniversaries of the grant date. We intend to grant an option to Mr. Hurwitz on these terms subject to the approval by stockholders of a proposal in our 2017 proxy statement to increase the number of shares available for issuance under our Amended and Restated 2013 Incentive Compensation Plan. Pursuant to our employment agreement with Mr. Korn, Mr. Korn received options to purchase 7,500 shares of our common stock on the start date of his employment and additional options to purchase 2,500 shares of our common stock on or about the first and second year anniversaries of the start date of his employment. The first of those anniversary date option awards was granted on November 5, 2013, with an exercise price of $60.40 per share. The second anniversary date option award was granted on November 10, 2014, with an exercise price of $39.20 per share. Both options granted to Mr. Korn had 10-year terms and provided for vesting in three equal annual installments measured from the applicable option grant date, subject to vesting acceleration under certain circumstances. On March 3, 2017, Mr. Korn resigned his position as Vice President, Sales, effective March 31, 2017, and all of Mr. Korn's options, none of which were exercised, were terminated as of that effective date. Our named executive officers may receive additional grants under our compensation plans at the discretion of the Compensation Committee. All information presented in this paragraph gives retroactive effect to the Reverse Split.

All Other Compensation. Each named executive officer was entitled to participate in any benefit plan from time to time in effect for our executives and/or employees generally, subject to the eligibility provisions of that plan.

Payments Upon Termination or Change of Control

Termination Payments. In the event we terminate the employment of Mr. Grillo without cause or if Mr. Grillo terminates his employment for good reason, as those terms are defined in his employment agreement, then he will be entitled to receive: (1) an amount equal to his annual base salary in effect on the termination date; (2) an amount equal to his average bonus for the previous two years; and (3) $18,000. In addition, if we terminate Mr. Grillo's employment without cause or Mr. Grillo terminates his employment for good reason, any unvested stock options and restricted stock previously granted to him will become fully vested on the termination date and, in the case of stock options, will be exercisable until the earlier of three years after the termination date or the final expiration date provided for in the applicable award agreement.

In the event we terminate the employment of Mr. Hurwitz without cause, as that term is defined in his written compensatory contract, then Mr. Hurwitz will receive: (1) any portion of base salary and bonus compensation earned but unpaid as of the termination date, plus any unreimbursed business expenses he incurred as of the termination date; (2) any amounts due pursuant to the terms of any award or benefit plans in which he was a participant, in accordance with the terms of such plans; and (3) an amount equal to 25% of his base salary in effect on the termination date, which will be paid in six semi-monthly installments.

As previously reported, Mr. Korn resigned effective March 31, 2017. Mr. Korn's employment agreement provided that if we had terminated his employment without cause, then he would have been entitled to receive an amount equal to 25% of his base salary in effect on the termination date, which amount would be paid in six semi-monthly installments. Following Mr. Korn's voluntary resignation, no termination payments were owed to him under his employment agreement, nor do any such payments remain outstanding.

Change of Control Payments. Upon a change of control, as such term is defined in Mr. Grillo's employment agreement, any unvested stock options and restricted stock previously granted to Mr. Grillo will become fully vested. In addition, if we terminate Mr. Grillo's employment without cause, or if he terminates his employment for good reason, in either case within two months prior to or within 12 months following the change of control, then Mr. Grillo will be entitled to receive a lump sum payment equal to the sum of: (1) two times his annual base salary in effect on the termination date; (2) two times the average of his two highest bonuses paid in the previous three years; and (3) $18,000.

Upon a change of control, as such term is defined in Mr. Hurwitz's written compensatory contract, any unvested stock options previously granted to Mr. Hurwitz will become fully vested. In addition, if we terminate Mr. Hurwitz's employment without cause within two months prior to or within six months following the change of control, then Mr. Hurwitz will be entitled to receive: (1) any portion of base salary and bonus compensation earned but unpaid as of the termination date, plus unreimbursed business expenses he incurred as of the termination date; (2) any amounts due pursuant to the terms of any award or benefit plans in which he was a participant, in accordance with the terms of such plans; and (3) a lump sum amount equal to 50% of his base salary in effect on the termination date.

Upon a change of control involving a sale transaction, as those terms are defined in Mr. Korn's employment agreement, any unvested stock options and restricted stock previously granted to Mr. Korn will become fully vested.

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

2016 Director Compensation

The following table sets forth information with respect to the compensation of our non-employee directors in 2016.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1]	All Other Compensation ($)	Total ($)
Kimble L. Jenkins	17,500[2]	2,426[3]	8,189[4]	28,115
R. John Fletcher[5]	–	–	–	–
Pascal E.R. Girin	21,000[6]	2,426[3]	–	23,426
Charles E. Koob	27,500[7]	2,426[3]	–	29,926
Philip A. Pizzo	23,000[8]	2,426[3]	–	25,426
Timothy T. Richards	23,000[9]	2,426[3]	–	25,426
Andrew K. Rooke[10]	17,500[11]	2,426[3]	–	19,926
Maria Sainz	20,500	2,426[3]	–	22,926
John N. Spencer, Jr.	28,500[12]	2,426[3]	–	30,926

(1) These amounts do not represent cash compensation paid to the named individuals. These non-cash amounts represent either: (a) the aggregate grant date fair value of option awards; or (b) the date on which original option terms were modified, as applicable and as described below, computed in accordance with ASC Topic 718. For a discussion of the assumptions made in the valuation of the awards, see the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations–Critical Accounting Policies and Significant Judgments and Estimates–Share-based Compensation" and Note 7 to the audited financial statements included elsewhere in this prospectus.

(2) Under our Non-Employee Director Compensation Plan, Mr. Jenkins elected to receive 2,196 shares of our common stock in lieu of cash fees totaling $11,660.

(3) Represents the grant date fair value of a stock option grant following our 2016 annual meeting of stockholders, which entitles the director to purchase 500 shares of our common stock at an exercise price of $10.00 per share.
(4) Represents compensation under Mr. Jenkins' consulting agreement dated April 1, 2015 and amended as of December 15, 2016.
(5) Mr. Fletcher joined the Board in May 2017.
(6) Under our Non-Employee Director Compensation Plan, Mr. Girin elected to receive 3,837 shares of our common stock in lieu of cash fees totaling $21,000.
(7) Under our Non-Employee Director Compensation Plan, Mr. Koob elected to receive 5,123 shares of our common stock in lieu cash fees totaling $27,500.
(8) Under our Non-Employee Director Compensation Plan, Dr. Pizzo elected to receive 4,351 shares of our common stock in lieu cash fees totaling $23,000.
(9) Under our Non-Employee Director Compensation Plan, Mr. Richards elected to receive 467 shares of our common stock in lieu cash fees totaling $5,750.
(10) Mr. Rooke resigned as a director of the Company as of May 9, 2017. Mr. Rooke voluntarily elected to step down from our Board to give another qualified director candidate, Mr. R. John Fletcher, the opportunity to serve on the Board. Mr. Rooke's resignation was not the result of any disagreement with the Company, its management or its operations, policies or practices.
(11) Under our Non-Employee Director Compensation Plan, Mr. Rooke elected to receive 3,295 shares of our common stock in lieu of cash fees totaling $17,500.
(12) Under our Non-Employee Director Compensation Plan, Mr. Spencer elected to receive 3,537 shares of our common stock in lieu cash fees totaling $19,000.

Benefit Plans

The information presented below gives retroactive effect to the Reverse Split.

2007 Stock Incentive Plan

We adopted the 2007 Stock Incentive Plan in March 2007 to enable us to attract, retain and motivate our officers, directors, employees and consultants. Of the 15,625 shares of common stock that were eligible for issuance pursuant to awards made under this plan, 1,080 shares of common stock were subject to options outstanding as of December 31, 2016. As of such date, the outstanding options had a weighted average exercise price of $322.73 per share and had expiration dates ranging from March 2017 to December 2019. Although this plan remains in effect and options under the plan remain outstanding, we ceased making awards under the plan upon the adoption of our 2010 Incentive Compensation Plan.

2010 Equity Plans

We adopted our 2010 Incentive Compensation Plan in April 2010, and we adopted our 2010 Non-Qualified Stock Option Plan in December 2010. The principal purpose of both plans was to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards. Of the 31,250 shares of common stock that were eligible for issuance pursuant to awards made under the 2010 Incentive Compensation Plan, 8,021 shares of common stock were subject to options outstanding as of December 31, 2016. As of such date, the outstanding options had exercise prices of $72.00 per share and had expiration dates in December 2020. Of the 64,141 shares of common stock that were eligible for issuance pursuant to awards made under the 2010 Non-Qualified Stock Option Plan, 53,625 shares of common stock were subject to options outstanding December 31, 2016. As of such date, the outstanding options had exercise prices of $72.00 per share and had expiration dates in December 2020. Although these plans remain in effect and options under the plans remain outstanding, we ceased making awards under these plans upon the adoption of our 2012 Incentive Compensation Plan.

2012 Incentive Compensation Plan

We adopted our 2012 Incentive Compensation Plan in February 2012. The principal purpose of the plan was to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards. Of the 75,000 shares of common stock that were eligible for issuance pursuant to awards made under this plan, 63,646 shares of common stock were subject to options outstanding as of December 31, 2016. As of such date, the outstanding options had a weighted average exercise price of $41.68 per share and had expiration dates ranging from April 2022 to May 2023. Although this plan remains in effect and options under the plan remain outstanding, we ceased making awards under the plan upon stockholder approval of our 2013 Incentive Compensation Plan.

Amended and Restated 2013 Incentive Compensation Plan

We adopted our 2013 Incentive Compensation Plan in March 2013. The principal purpose of the 2013 Incentive Compensation Plan is to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards, and at our 2015 annual meeting, our stockholders approved the adoption of the MRI Interventions, Inc. Amended and Restated 2013 Incentive Compensation Plan, or the 2013 Plan. The material change effected by the amendment was to increase the number of shares of our common stock available for awards thereunder by 125,000 shares, resulting in a total of 156,250 shares of our common stock being reserved for issuance under the 2013 Plan. The 2013 Plan is also designed to permit us to make cash-based awards and equity-based awards intended to qualify as "performance-based compensation" under Section 162(m) of the Code.

Eligibility. Awards may be granted under the 2013 Plan to officers, directors (including non-employee directors) and our other employees or any of our subsidiaries or other affiliates, and to any individual who is an advisor, consultant or other provider of services to us or any of our subsidiaries or other affiliates. Only our employees or those of any of our subsidiaries are eligible to receive incentive stock options.

Administration, Amendment and Termination. Our Compensation Committee has the power and authority to administer the 2013 Plan. The Compensation Committee has the authority to interpret the terms and intent of the 2013 Plan, determine eligibility for and terms of awards for participants and make all other determinations necessary or advisable for the administration of the 2013 Plan.

The Compensation Committee may amend, suspend or terminate the 2013 Plan at any time with respect to any shares of common stock as to which awards have not been made. However, no amendment may be made without the approval of our stockholders if the amendment would increase the total number of shares reserved for the purposes of the 2013 Plan or change the maximum number of shares for which awards may be granted to any participant (which does not include adjustments made by the Compensation Committee in the event of certain changes in our capitalization, as described below).

Awards. Awards under the 2013 Plan may be made in the form of: options; stock appreciation rights; stock awards; restricted share units; cash bonuses; or other incentive awards granted under the 2013 Plan; whether singly, in combination, or in tandem. Any of the foregoing awards may be made subject to attainment of performance goals over any applicable performance period.

Shares Subject to the Plan. The aggregate number of shares of our common stock that may be issued pursuant to awards under the 2013 Plan and the maximum number of shares that may be issued pursuant to the exercise of incentive stock options under the 2013 Plan is 156,250 shares. Shares issued under the 2013 Plan may be authorized but unissued shares or treasury shares. Any shares covered by an award, or portion of an award, granted under the 2013 Plan that is forfeited or canceled or expires will be deemed not to have been issued for purposes of determining the maximum number of shares available for issuance under the plan. Of the 156,250 shares of common stock that are eligible for issuance pursuant to awards made under the 2013 Plan, 94,319 shares of common stock were subject to options outstanding as of June 5, 2017. As of such date, the outstanding options had a weighted average exercise price of $21.79 per share and had expiration dates ranging from 2023 to 2027. No awards other than options were outstanding under the 2013 Plan as of June 5, 2017.

Change of Control. Upon the occurrence of a change of control, the Compensation Committee may:

- accelerate, vest or cause the restrictions to lapse with respect to all or any portion of an award under the 2013 Plan;
- cancel such awards for fair value (as determined by the Compensation Committee);
- provide for the issuance of substitute awards that will substantially preserve the otherwise applicable terms of any affected awards previously granted under the 2013 Plan, as determined by the Compensation Committee; or
- provide that for a period of at least 10 days prior to the change of control, option awards will be exercisable as to all shares of common stock subject thereto and that upon the occurrence of the change of control, such awards will terminate and be of no further force or effect.

Corporate Performance Objectives. Section 162(m) of the Code limits a publicly held corporation to an annual deduction for federal income tax purposes of $1,000,000 for compensation paid to its Chief Executive Officer and its four other most highly compensated officers determined at the end of each year. Performance-based compensation is excluded from this limitation. The Plan is designed to permit the Compensation Committee to grant awards that qualify as performance-based compensation for purposes of satisfying the conditions of Section 162(m).

As noted above, we intend to submit for stockholder vote at our 2017 annual meeting of stockholders a proposal to increase the number of shares available for issuance under the Amended and Restated 2013 Incentive Compensation Plan.

2013 Non-Employee Director Equity Incentive Plan

We adopted the 2013 Non-Employee Director Equity Incentive Plan in December 2013 to enable us to attract, retain and motivate non-employee directors of outstanding ability through the granting of stock-based awards. Of the 14,375 shares of common stock that were eligible for issuance pursuant to awards made under this plan, 10,375 shares of common stock were subject to options outstanding with a weighted average exercise price of $41.60 per share and expiration dates ranging from January 2024 to June 2025. Although this plan remains in effect and options under the plan remain outstanding, upon exhaustion of awards of shares eligible for issuance under this plan, stock-based awards to our non-employee directors are now made under the provisions of the 2013 Amended and Restated Incentive Compensation Plan which is discussed above.

Key Personnel Incentive Program

We adopted, with an effective date in September 2006 and as amended in June 2010 and June 2013, the Key Personnel Incentive Program, or the KPIP, to provide a consultant and a then-employee who, at the time of adoption of the KPIP, were key to our development and licensing activities, with the opportunity to receive incentive bonus payments upon a consummation of a sale transaction, as defined in the KPIP. The Compensation Committee is responsible for administering the program, and the only participants in the program are Paul A. Bottomley and Parag Karmarkar. The program will terminate on the earlier of December 31, 2025 or the occurrence of a sale transaction.

In the event of a sale transaction, each of the participants will be entitled to receive a bonus payment under the program as of the date of the transaction. Mr. Karmarkar would receive a bonus equal to $1,000,000. Dr. Bottomley would receive a bonus equal to: (1) $1,000,000, plus (2) 1.4% of the amount by which the “net proceeds” from the sale transaction exceed $50,000,000, but not to exceed $700,000. For purposes of the KPIP, the “net proceeds” from a sale transaction will be the portion of the aggregate cash and non-cash consideration paid or payable in connection with the consummation of the sale transaction that is distributed, or otherwise available for distribution, to holders of our common stock.

401(k) Plan

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

Limitations on Directors' Liability and Indemnification Agreements

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

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

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

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

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

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

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

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Policies and Procedures for Related Person Transactions

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

Related Person Transactions

The following is a description of transactions since January 1, 2015 to which we have been a party, in which the amount involved in the transaction exceeds $87,518, which is 1% of the average of our total assets at year-end for our 2015 and 2016 fiscal years, and in which any of our executive officers, directors and principal stockholders, including their immediate family members, had or will have a direct or indirect material interest. All information presented below gives retroactive effect to the Reverse Split.

In December 2015, we entered into a securities purchase agreement with certain investors for the sale of shares of our common stock, Series A Warrants to purchase shares of our common stock and Series B Warrants to purchase shares of our common stock in a private placement offering. In the offering, we sold to the investors 407,731 shares of common stock, together with Series A Warrants to purchase 163,092 shares of common stock and Series B Warrants to purchase 122,319 shares of common stock, for aggregate gross proceeds of $5,294,000. The Series A Warrants were fully vested and exercisable upon issuance, have a term of five years from the date of issuance and have an exercise price of $16.23 per share. The Series B Warrants were fully vested and exercisable upon issuance, have a term of five years from the date of issuance and have an exercise price of $21.10 per share. Our placement agents for the financing, together with the sub-agents it engaged, collectively received Placement Agent Warrants to purchase up to 40,773 shares of our common stock. The Placement Agent Warrants have the same exercise price and substantially the same terms and conditions as the Series A Warrants, except that the Placement Agent Warrants have a terms of seven and one-half years. The placement agents also earned aggregate commissions of $380,120.83 from the 2015 PIPE. Our Chief Executive Officer and director, Francis P. Grillo, one of our non-employee directors, Timothy T. Richards, a foundation for which another of our then-serving non-employee directors, Andrew K. Rooke, serves as president, and a trust for which another of our non-employee directors, Charles E. Koob, serves as trustee invested, in the aggregate, $475,000 in the offering and acquired, in the aggregate, 36,583 shares of our common stock, Series A Warrants to purchase 14,633 shares of our common stock and Series B Warrants to purchase 10,975 shares of our common stock.

In September 2016, we entered into a securities purchase agreement with certain investors for the sale of shares of our common stock and warrants to purchase shares of our common stock in a private placement offering. In the offering, we sold to the investors 851,000 shares of common stock, together with warrants to purchase 765,900 shares of common stock, for aggregate gross proceeds of approximately $4.25 million. The warrants were fully vested and exercisable upon issuance, have a term of five years from the date of issuance and have an exercise price of $5.50 per share. Our Chief Executive Officer and director, Francis P. Grillo, a trust for which another of our then-serving non-employee directors, Andrew K. Rooke, serves as trustee, and Voyager Therapeutics, Inc. and Bruce C. Conway, each a beneficial owner of more than five percent of our common stock, invested $2,350,000 in the offering and acquired, in the aggregate, 470,000 shares of our common stock and warrants to purchase 423,000 shares of our common stock. In addition, under the terms of an amendment we entered into on August 31, 2016 with two holders of our 12% Second-Priority Secured Non-Convertible Promissory Notes Due 2019 and two common stock warrants issued by us in connection therewith (the “2014 Note Holders”), we sold an aggregate of 350,000 units (consisting of shares of our common stock and warrants to purchase shares of our common stock) to the 2014 Note Holders simultaneously with the September 2016 sale of the common stock and warrants described herein. As a result, $1.75 million of the aggregate principal balance of these holders’ notes automatically converted into 350,000 units on the same terms and conditions as in the transactions contemplated by the securities purchase agreement, and the exercise price for 13,125 shares of common stock that may be purchased upon exercise of the holders’ warrants was reduced to $5.50 per share.

In May 2017, we entered into a securities purchase agreement with certain investors for the sale of shares of our common stock and warrants to purchase shares of our common stock in a private placement offering. In the offering, we sold to the investors 6,625,000 shares of common stock, together with warrants to purchase 6,625,000 shares of common stock, for aggregate gross proceeds of approximately $13.25 million. The warrants were fully vested and exercisable upon issuance, have a term of five years from the date of issuance and have an exercise price of $2.20 per share. Francis P. Grillo, our Chief Executive Officer and director, Kimble L. Jenkins, the Chairman of our Board of Directors, and Bruce C. Conway, a beneficial owner of more than five percent of our common stock, invested $1,040,000 in the offering and acquired, in the aggregate, 520,000 shares of our common stock and warrants to purchase 520,000 shares of our common stock.

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

Indemnification Agreements

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

PRINCIPAL STOCKHOLDERS

The following table sets forth information as of June 5, 2017 regarding the beneficial ownership of our common stock by:

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

Percentage ownership calculations for beneficial ownership are based on 10,335,365 shares outstanding as of June 5, 2017. Except as otherwise indicated below, the address of each beneficial owner of our common stock is c/o MRI Interventions, Inc., 5 Musick, Irvine, California 92618.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options and warrants that are either immediately exercisable or exercisable within 60 days of June 5, 2017. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them.

Beneficial Owner	Number of Shares Owned	% of Shares Outstanding
5% Stockholders		
Bruce C. Conway 5403 Drane Dr. Dallas, TX 75209	1,352,442(1)	12.4%
AIGH Investment Partners, L.P. 6006 Berkeley Avenue Baltimore, MD 21209	800,000(2)	7.7%
Voyager Therapeutics, Inc. 75 Sidney Street Cambridge, MA 02139	760,000(3)	7.1%
The Hewlett Fund, L.P. 100 Merrick Road, Suite 400W Rockville Centre, NY 11570	600,000(4)	5.8%
Alan Eisenman 5213 Braeburn Drive Bellaire, TX 77401	573,212(5)	5.4%
Andrew K. Rooke 600 W. Germantown Ave., Suite 400 Plymouth Meeting, PA 19462	556,055(6)	5.3%
Directors and Named Executive Officers		
Kimble L. Jenkins	77,274(7)	*
R. John Fletcher	–	*
Pascal E.R. Girin	6,585(8)	*
Charles E. Koob	31,310(9)	*
Philip A. Pizzo	8,989(10)	*
Timothy T. Richards	7,601(11)	*
Maria Sainz	3,777(12)	*
John N. Spencer, Jr.	11,939(13)	*
Francis P. Grillo	120,478(14)	1.2%
Harold A. Hurwitz	11,940(15)	*
Robert C. Korn	–(16)	*
All directors and executive officers as a group (12 persons)	322,163(17)	3.1%

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

(1) Based in part on a Schedule 13D filed by Mr. Conway with the SEC on June 5, 2017. Includes 3,600 shares jointly held with his spouse, 16,500 shares held solely by his spouse, 570,995 shares that Mr. Conway has the right to acquire through the exercise of warrants and 39,654 shares in the aggregate owned by the Alden M. Conway Trust, the Chase T. Conway Trust, the Merritt Elizabeth Conway Trust, the Edna N. Conway Irrevocable Trust FBO Alden M. Conway, the Edna N. Conway Irrevocable Trust FBO Chase T. Conway, the Edna N. Conway Irrevocable Trust FBO Merritt Elizabeth Conway and the Conway Family GST Trust. Mr. Conway is the trustee of each of the aforementioned trusts and has voting and investment power of each trust's shares, which are held in trust for the benefit of members of his family. Also includes 5,500 shares owned by the BCC Life Insurance Trust, which shares are held in trust for the benefit of Mr. Conway's children. A third party serves as trustee for such trust.

(2) Based in part on a Schedule 13G filed jointly by AIGH Investment Partners, L.P. ("AIGH LP"), AIGH Investment Partners, L.L.C. ("AIGH LLC") and Mr. Orin Hirschman, who is the Managing Member of AIGH LP's General Partner and president of AIGH LLC, with the SEC on June 8, 2017. Excludes 800,000 shares underlying warrants that are not exercisable within 60 days of June 5, 2017.

(3) Based in part on a Schedule 13D filed by Voyager Therapeutics, Inc. with the SEC on September 12, 2016. Includes 360,000 shares that Voyager Therapeutics, Inc. has the right to acquire through the exercise of warrants.

(4) Excludes 600,000 shares underlying warrants that are not exercisable within 60 days of June 5, 2017.

(5) Includes 250,000 shares that Mr. Eisenman has the right to acquire through the exercise of warrants.

(6) Includes 12,500 shares owned by Payne Partners LLC, 12,353 shares owned by the Withington Foundation, 51,455 shares owned by Rooke Fiduciary Management, 2,695 shares that the Withington Foundation has the right to acquire through the exercise of warrants, 3,125 shares that Mr. Rooke has the right to acquire through the exercise of options and 196,500 shares that the Robert L. and Alice W. Rooke Trust, for which Mr. Rooke serves as trustee, has the right to acquire through the exercise of warrants. Mr.

Rooke has voting and investment power over the shares owned by Payne Partners LLC, the Withington Foundation and Rooke Fiduciary Management. Also includes 249,445 shares owned by 13 trusts established for the benefit of Mr. Rooke and his family members. Mr. Rooke is the trustee of each of those trusts and has voting and investment power over each trust's shares.

(7) Includes 35,136 shares that Mr. Jenkins has the right to acquire through the exercise of options and 7,500 shares Mr. Jenkins has the right to acquire through the exercise of warrants.

(8) Includes 1,750 shares that Mr. Girin has the right to acquire through the exercise of options.

(9) Includes 500 shares held jointly with his spouse, 4,592 shares that Mr. Koob has the right to acquire through the exercise of options, 3,850 shares owned by the Koob Family Trust and 2,695 shares the Koob Family Trust has the right to acquire through the exercise of warrants. Mr. Koob is trustee of the Koob Family Trust and has voting and investment power over the securities held by the Koob Family Trust.

(10) Includes 3,125 shares that Dr. Pizzo has the right to acquire through the exercise of options and 5,625 shares held by the Philip and Margaret Living Trust. Dr. Pizzo is trustee of the Philip and Margaret Living Trust and has voting and investment power over the securities held by the Philip and Margaret Living Trust.

(11) Includes 2,625 shares that Mr. Richards has the right to acquire through the exercise of options and 1,347 shares Mr. Richards has the right to acquire through the exercise of warrants.

(12) Includes 919 shares owned by the Maria Sainz Trust, 233 shares that the Maria Sainz Trust has the right to acquire through the exercise of warrants, and 2,625 shares that Ms. Sainz has the right to acquire through the exercise of options. Ms. Sainz is the trustee of the Maria Sainz Trust and has voting and investment power over the securities held by the Maria Sainz Trust.

(13) Includes 5,986 shares jointly held with Mr. Spencer's spouse, 510 shares held in an IRA, 187 shares held in Mr. Spencer's daughter's IRA, 249 shares that Mr. Spencer and his spouse jointly have the right to acquire through the exercise of warrants, and 4,375 shares that Mr. Spencer has the right to acquire through the exercise of options.

(14) Includes 35,890 shares that Mr. Grillo has the right to acquire through the exercise of warrants and 40,000 shares that Mr. Grillo has the right to acquire through the exercise of options.

(15) Includes 11,146 shares that Mr. Hurwitz has the right to acquire through the exercise of options.

(16) On March 3, 2017, Mr. Korn resigned his position as Vice President, Sales, effective March 31, 2017, and all of Mr. Korn's options, none of which were exercised, were terminated as of that effective date.

(17) Includes 193,936 shares issuable upon the exercise of options and warrants held by directors, executive officers or entities/trusts controlled by a director.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital, certificate of incorporation, and bylaws are only summaries, and we encourage you to review complete copies of these documents. You can obtain copies of these documents by following the directions outlined in "Where You Can Find More Information" elsewhere in this prospectus.

Common Stock

Under our Amended and Restated Certificate of Incorporation, as amended, or our certificate of incorporation, we have 200,000,000 authorized shares of common stock, $0.01 par value per share. As of June 5, 2017, we had 10,335,365 shares of common stock outstanding.

Voting Rights

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

Dividends

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

Liquidation

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

Rights and Preferences

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

Fully Paid and Nonassessable

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

Preferred Stock

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

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

Delaware Law

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

Certificate of Incorporation and Bylaw Provisions

Our certificate of incorporation:

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

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

Transfer Agent and Registrar

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

SHARES ELIGIBLE FOR FUTURE SALE

As of June 5, 2017, we had 10,335,365 shares of common stock outstanding. Of this amount, the registration statement of which this prospectus is a part registers 6,693,333 shares of our common stock and 7,114,200 shares of common stock issuable upon the exercise of the Warrants. Excluding the shares of our common stock covered by this registration statement, as of June 5, 2017, nearly all of our outstanding shares were freely transferable or could be publicly resold pursuant to Rule 144 under the Securities Act. The sale, or availability for sale, of substantial amounts of common stock could, in the future, adversely affect the market price of our common stock and could impair our ability to raise additional capital through the sale of our equity securities or debt financing.

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 persons who may be deemed our affiliates, would be entitled to sell such securities, provided that sales under Rule 144 are subject to the availability of current public information about us. 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 also subject to volume limitations, manner of sale provisions and notice requirements.

In addition, we have filed with the SEC two registration statements under the Securities Act covering the shares of common stock issuable under most of our stock option plans, as well as certain written compensatory contracts. Accordingly, shares registered under those registration statements are available for sale in the open market, subject to Rule 144 volume limitations applicable to affiliates and subject to the terms of the derivative restriction agreements entered into by our directors and executive officers.

VALIDITY OF THE COMMON STOCK

The validity of the shares of common stock offered hereby and certain other legal matters will be passed upon for us by Bass, Berry & Sims PLC, Memphis, Tennessee.

EXPERTS

The financial statements of MRI Interventions, Inc. as of December 31, 2016 and 2015 appearing in this prospectus and registration statement, have been audited by Cherry Bekaert LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report, given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

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

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at http://www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street NE, Washington, D.C. 20549, on official business days during the hours of 10 a.m. to 3 p.m. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

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

INDEX TO FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of MRI Interventions, Inc. and subsidiary (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations, stockholders' deficit and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the accompanying consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of MRI Interventions, Inc. and subsidiary as of December 31, 2016 and 2015 and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company incurred net losses during the years ended December 31, 2016 and 2015 of approximately $8.1 million and $8.4 million, respectively. Additionally, the stockholders' deficit at December 31, 2016 was approximately $756,000. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 1. The consolidated financial statements do not include any adjustments with respect to the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

/s/ Cherry Bekaert LLP
Charlotte, North Carolina
March 9, 2017

MRI INTERVENTIONS, INC.

Consolidated Balance Sheets

	December 31,	
	2016	**2015**
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 3,315,774	$ 5,408,523
Accounts receivable	865,943	1,218,043
Inventory, net	1,768,382	1,807,895
Prepaid expenses and other current assets	134,996	97,249
Total current assets	6,085,095	8,531,710
Property and equipment, net	328,249	440,606
Software license inventory	976,900	937,100
Other assets	10,641	27,306
Total assets	$ 7,400,885	$ 9,936,722
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,546,926	$ 697,807
Accrued compensation	666,060	557,784
Other accrued liabilities	450,424	1,398,707
Derivative liabilities	131,173	658,286
Deferred product and service revenues	223,117	116,009
Senior secured note payable, net of unamortized discount of $64,835 at December 31, 2015	-	4,224,609
Total current liabilities	3,017,700	7,653,202
Accrued interest	647,500	542,500
Senior note payable	2,000,000	-
2010 junior secured notes payable, net of unamortized discount of $2,302,472 and $2,535,230 at December 31, 2016 and 2015, respectively	697,528	464,770
2014 junior secured 12% notes payable, net of unamortized discount and deferred issuance costs aggregating $180,774 and $467,611 at December 31, 2016 and 2015, respectively	1,794,226	3,257,389
Total liabilities	8,156,954	11,917,861
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized at December 31, 2016 and 2015; none issued and outstanding at December 31, 2016 and 2015	-	-
Common stock, $0.01 par value; 200,000,000 shares authorized at December 31, 2016 and 2015; 3,622,032 and 2,284,537 shares issued and outstanding at December 31, 2016 and 2015, respectively	36,220	22,845
Additional paid-in capital	93,076,475	83,722,596
Accumulated deficit	(93,868,764)	(85,726,580)
Total stockholders' deficit	(756,069)	(1,981,139)
Total liabilities and stockholders' deficit	$ 7,400,885	$ 9,936,722

See notes to consolidated financial statements.

MRI INTERVENTIONS, INC.

Consolidated Statements of Operations

	Years Ended December 31,	
	2016	**2015**
Revenues:		
Product revenues	$ 5,612,857	$ 4,416,036
Development service revenues	-	37,405
Other service revenues	136,597	140,751
Total revenues	5,749,454	4,594,192
Cost of product revenues	2,642,763	1,987,636
Research and development costs	2,628,179	1,957,332
Selling, general, and administrative expenses	7,967,250	8,370,749
Restructuring charges	-	1,252,584
Operating loss	(7,488,738)	(8,974,109)
Other income (expense):		
Gain on change in fair value of derivative liabilities	1,065,935	1,539,876
Loss on debt restructuring	(811,909)	-
Other income, net	216,075	230,875
Interest income	8,807	16,455
Interest expense	(1,060,065)	(1,262,343)
Net loss	$ (8,069,895)	$ (8,449,246)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (2.93)	$ (4.48)
Weighted average shares outstanding:		
Basic and diluted	2,754,803	1,884,849

See notes to consolidated financial statements.

MRI INTERVENTIONS, INC.

Consolidated Statements of Stockholders' Deficit
Years Ended December 31, 2016 and 2015

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balances, January 1, 2015	1,871,061	$ 18,711	$ 77,158,293	$ (77,277,334)	$ (100,330)
Share-based compensation			1,682,063		1,682,063
Issuance of common stock in payment of director fees	5,744	57	145,930		145,987
December 2015 private placement, net of offering costs of $552,283	407,732	4,077	4,736,310		4,740,387
Net loss for the year				(8,449,246)	(8,449,246)
Balances, December 31, 2015	2,284,537	22,845	83,722,596	(85,726,580)	(1,981,139)
Share-based compensation			959,585		959,585
Issuances of common stock:					
In payment of employee bonuses	6,804	68	103,349		103,417
In payment of director fees	22,313	223	123,875		124,098
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)

See notes to consolidated financial statements.

MRI INTERVENTIONS, INC.

Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$ (8,069,895)	$ (8,449,246)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	155,707	211,946
Share-based compensation	959,585	1,682,063
Expenses paid through the issuance of common stock	290,245	145,987
Gain on change in fair value of derivative liabilities	(1,065,935)	(1,539,876)
Loss on debt restructuring	811,909	-
Loss on retirement of equipment	1,689	2,053
Amortization of debt issuance costs and original issue discounts	424,431	471,146
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	352,100	(749,094)
Inventory	72,342	68,626
Prepaid expenses and other current assets	(37,748)	(68,029)
Other assets	-	9,811
Accounts payable and accrued expenses	178,419	(436,420)
Deferred revenue	107,108	13,299
Net cash flows from operating activities	(5,820,043)	(8,637,734)
Cash flows from investing activities:		
Purchases of property and equipment	(101,002)	(76,883)
Net cash flows from investing activities	(101,002)	(76,883)
Cash flows from financing activities:		
Net proceeds from equity private placements	3,833,052	4,879,134
Cash paid in lieu of issuing fractional shares in reverse split of common stock	(4,756)	-
Net cash flows from financing activities	3,828,296	4,879,134
Net change in cash and cash equivalents	(2,092,749)	(3,835,483)
Cash and cash equivalents, beginning of year	5,408,523	9,244,006
Cash and cash equivalents, end of year	$ 3,315,774	$ 5,408,523
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ -	$ -
Interest	$ 976,295	$ 223,500

See notes to consolidated financial statements.

MRI INTERVENTIONS, INC.

Consolidated Statements of Cash Flows

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

- During the years ended December 31, 2016 and 2015, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of $55,963 and $94,751, respectively, from loaned systems, which are included in property and equipment in the accompanying consolidated balance sheets, to inventory.

- Costs, amounting to $74,000 and $138,747, were incurred and unpaid at December 31, 2016 and 2015, respectively, in connection with the Company's 2016 and 2015 private placements (see Note 7), are included in accounts payable and were charged to stockholders' deficit in the accompanying December 31, 2016 and 2015 consolidated balance sheets.

- As discussed in Note 6:

    - On June 30, 2016, the fair value of derivatives, amounting to $72,289 and arising from the First Amendments (as defined in Note 6) 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.

- Exercise of a warrant accounted for as a derivative resulted in a $37,672 reduction in the balance of derivative liabilities and a corresponding increase to stockholders' equity.

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

Liquidity and Management's Plans

The cumulative net loss from the Company's inception through December 31, 2016 was approximately $94 million. Net cash used in operations was $5.8 million and $8.6 million for the years ended December 31, 2016 and 2015, respectively. Since inception, the Company has financed its operations principally from the sale of equity securities, the issuance of notes payable and license arrangements. Recent financing activities consist of: (i) a September 2016 private placement of equity, which resulted in net cash proceeds of $3.8 million and the conversion of $1.75 million in debt (the "2016 PIPE"); (ii) a December 2015 private placement of equity, which resulted in net cash proceeds of $4.7 million (the "2015 PIPE"); (iii) a December 2014 private placement of equity, which resulted in net cash proceeds of $9.4 million; and (iv) a March 2014 private placement of debt and warrants, which resulted in net cash proceeds of $3.5 million.

In addition, as discussed in Note 6:

- On April 4, 2016, the Company and Brainlab AG ("Brainlab") finalized a securities purchase agreement (the "2016 Purchase Agreement") that provided, among other items, for the restructuring of a senior secured note payable to Brainlab, which was originally issued to Brainlab on April 5, 2011, and subsequently amended and restated on March 6, 2013 (the "Brainlab Note"). The restructuring of the Brainlab Note resulted in a reduction of the principal amount outstanding under the Brainlab Note, which is reflected in a new, amended and restated note payable to Brainlab that matures on December 31, 2018.

- Pursuant to amendments executed on August 31, 2016, by the Company and certain holders (the "2014 Convertible Note Holders") upon completion of the 2016 PIPE, an aggregate $1.75 million of principal balance of such holders' 2014 junior secured notes automatically converted into units, each unit consisting of one share of the Company's common stock and one warrant to purchase 0.90 share of the Company's common stock, based on the offering price per unit in the 2016 PIPE.

The Company's plans for the next twelve months reflect management's 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. Management also anticipates 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 the Company will be able to achieve its anticipated results, and even in the event such results are achieved, the Company expects to continue to consume cash in its operations over at least the next twelve months.

As a result of the foregoing, the Company believes it will be necessary to seek additional financing from the sale of equity or debt securities, which would result in dilution to the Company's current stockholders, the establishment of a credit facility, or the entry into an agreement with a strategic partner of some other form of collaborative relationship. There is no assurance, however, that the Company will be able to obtain such additional financing on commercially reasonable terms, if at all, and there is no assurance that any additional financing that the Company does obtain will be sufficient to meet its needs. If the Company is not able to obtain the additional financing on a timely basis, the Company may be unable to achieve its anticipated results, and the Company may not be able to meet its other obligations as they become due. As such, there is substantial doubt as to the Company's ability to continue as a going concern within one year after the issuance date of these financial statements.

The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable 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 7, 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 8). 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. 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, 2016				
Derivative liabilities – warrants	$ -	$ -	$ 91,173	$ 91,173
Derivative liabilities – debt conversion feature	$ -	$ -	$ 40,000	$ 40,000
December 31, 2015				
Derivative liabilities – warrants	$ -	$ -	$ 658,286	$ 658,286

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 and stock price volatility, all of which are further discussed in Note 8.

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, 2016:

	Carrying Value	Estimated Fair Value
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 systems 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, 2016 or 2015.

Revenue Recognition

The Company's revenues are comprised of: (1) product revenues resulting from the sale of ClearPoint system reusable products and disposable products; and (2) other service revenues. The Company recognizes revenue when persuasive evidence of an arrangement exists, the selling price or fee is fixed or determinable, collection is reasonably assured, and, for product revenues, risk of loss has transferred to the customer. For all sales, the Company requires either a purchase agreement or a purchase order as evidence of an arrangement. The Company analyzes revenue recognition on a case-by-case basis, and 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.

(1) *Product Revenues*

Sales of ClearPoint system reusable products: The predominance of ClearPoint system reusable product sales (consisting primarily of integrated computer hardware and software) are preceded by customer evaluation periods, generally with 90-day terms. 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, reusable product sales following such evaluation periods are recognized on the basis of an executed purchase agreement or purchase order that provide for risk of loss to pass to the customer. Sales of reusable products not having been preceded by an evaluation period are recognized on an individual agreement basis as described in the preceding paragraph.

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

(2) *Other Service Revenues*

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

Product Warranties

The Company's standard policy is to warrant ClearPoint system reusable products against defects in material or workmanship for one year following installation. The Company 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, 2016 and 2015, 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 7, would be anti-dilutive.

Share-Based Compensation

The Company accounts for compensation for all arrangements under which employees and others receive shares of stock or other equity instruments (including options and warrants) based on fair value. The fair value of each award is estimated as of the grant date and amortized as compensation expense over the requisite vesting period. The fair values of the Company's share-based awards are estimated on the grant dates using the Black-Scholes valuation model. This valuation model requires the input of highly subjective assumptions, including the expected stock volatility, estimated award terms and risk-free interest rates for the expected terms. To estimate the expected terms, the Company utilizes the "simplified" method for "plain vanilla" options discussed in the Staff Accounting Bulletin 107 ("SAB 107") issued by the Securities and Exchange Commission (the "SEC"). The Company believes that all factors listed within SAB 107 as pre-requisites for utilizing the simplified method apply to the Company and 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

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

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, 2016, the Company had approximately $161,000 in bank balances that were in excess of the insured limits.

At December 31, 2016, three customers represented 20%, 13% and 10% of the Company's accounts receivable balance. At December 31, 2015, three customers represented 14%, 14% and 12% of the Company's accounts receivable balance. No other customer represented more than 9% of total accounts receivable at each of December 31, 2016 and 2015.

For the year ended December 31, 2016, sales to one customer represented 10% of product revenues, and for the year ended December 31, 2015, sales to one customer represented 12% of product revenues. In each of the years ended December 31, 2016 and 2015, no other single customer accounted for more than 9% of product revenues. 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, 2016 and 2015 was $25,000 and $28,000, 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 July 2015, the FASB issued ASU 2015-11, "Simplifying the Measurement of Inventory," which requires an entity to measure inventory at the lower of cost or net realizable value, as opposed to the current requirement to measure inventory at the lower of cost or market, where market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016 and interim periods within fiscal years beginning after December 15, 2017. ASU 2015-11 is to be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company believes that its current methods of inventory valuation are in substantial compliance with the requirement of ASU 2015-11. Adoption of ASU 2015-11 did not have a material effect on the Company's consolidated financial statements.

In August 2015, the FASB issued 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 and 2016-12 discussed below, are effective for the Company beginning in 2018. Earlier application is permitted only as of 2017.

- 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 that are not expected to have a significant effect on the Company's current accounting practice.

The Company believes, based on a preliminary assessment in which the Company considered such factors as the short duration of its contract terms with customers, that the adoption of ASU 2015-14, and the subsequently issued related ASUs discussed above, will not have a material effect on its consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, "Balance Sheet Classification of Deferred Taxes," which simplifies the presentation of deferred income taxes by requiring that deferred income tax liabilities and assets be classified as noncurrent in a classified balance sheet. Until implementation of this standard, deferred income tax liabilities and assets are required to be classified as current or noncurrent based on the classification of the related asset or liability for financial reporting purposes. Deferred tax liabilities and assets that are not related to an asset or liability for financial reporting are classified according to the expected reversal date of the temporary difference. This standard is effective for the Company beginning in 2017. Adoption will have no effect on the Company's consolidated financial statements.

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 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 March 2016, the FASB issued ASU 2016-09, "Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting," which is intended to reduce the complexity in accounting for aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The standard is effective for the Company beginning in 2017, and early adoption is permitted. The Company believes that adoption of ASU 2016-09 will not have a material effect on its 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.

Adoption of New Accounting Standards

In April 2015, the FASB issued ASU 2015-03, "Simplifying the Presentation of Debt Issuance Costs," which requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 required retrospective adoption and became effective with respect to the Company's financial statements on January 1, 2016. Prior to the effective date, such issuance costs were classified as assets and included as other assets in the Company's balance sheet. Under the provisions of ASU 2015-03, such issuance costs are presented as a direct deduction from the carrying amount of the related debt (see Note 6) in the accompanying December 31, 2016 consolidated balance sheet, and such issuance costs, amounting to $166,080, have been reclassified in the December 31, 2015 condensed consolidated balance sheet to conform to the 2016 presentation.

In August 2014, the FASB issued ASU 2014-15, "Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern," which provides guidance on determining when and how to disclose going-concern uncertainties in financial statements. The new standard required management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued and became effective for annual periods ending after December 15, 2016. Under the provisions of ASU 2014-15, an entity must provide certain disclosures if conditions or events raise substantial doubt about the entity's ability to continue as a going concern. These disclosures are included in Note 1, under the heading "Liquidity and Management's Plans," and are substantially unchanged from the Company's historical disclosures.

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 7). 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:

	2016	2015
Raw materials and work in process	$ 1,025,368	$ 853,034
Software licenses	70,000	179,400
Finished goods	673,014	775,461
Inventory included in current assets	1,768,382	1,807,895
Software licenses – non-current	976,900	937,100
	$ 2,745,282	$ 2,744,995

4. Property and Equipment

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

	2016	2015
Equipment	$ 1,165,076	$ 1,119,295
Furniture and fixtures	112,143	112,143
Leasehold improvements	179,999	179,999
Computer equipment and software	150,304	135,129
Loaned systems	431,608	627,060
	2,039,130	2,173,626
Less accumulated depreciation and amortization	(1,710,881)	(1,733,020)
Total property and equipment, net	$ 328,249	$ 440,606

Depreciation and amortization expense related to property and equipment for the years ended December 31, 2016 and 2015 was $155,707 and $211,946, respectively. Loaned systems are ClearPoint systems that are in operation at customer sites on an evaluation basis.

5. Restructuring Charges

In March 2015, the Company announced its plan to consolidate all major business functions into its Irvine, California headquarters and close its Memphis, Tennessee office. The Company completed this consolidation and closure in May 2015. The Company did not retain any of its Memphis-based employees. A total of seven employees were impacted by the consolidation, including three executives of the Company. In connection with this consolidation and closure, the Company recorded restructuring charges of $1,252,584 during the year ended December 31, 2015, that related primarily to costs associated with severance and other compensation for the impacted employees.

6. Notes Payable

Senior Secured Note Payable

The indebtedness outstanding under the Brainlab Note at December 31, 2015 was approximately $5.0 million and was to mature in April 2016. The indebtedness included approximately $740,000 of accrued interest, which had accrued at a rate of 5.5% and was payable in a single aggregate installment upon maturity.

On April 4, 2016 (the “Closing Date”), the Company and Brainlab consummated the transactions under 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, with each unit consisting of: (a) one share of the Company's common stock; (b) a warrant to purchase 0.4 share of common stock (the "2016 Series A Warrants"); and (c) a warrant 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 (the "2016 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 (together, the "2016 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 Registration Rights Agreement

The 2016 Registration Rights Agreement imposed deadlines by which the Company was required to file the 2016 Registration Statement and use its best efforts to have the 2016 Registration Statement declared effective. The 2016 Registration Statement was filed, and declared effective on June 20, 2016, within the deadlines imposed by the 2016 Registration Rights Agreement. Pursuant to the 2016 Registration Rights Agreement, if the Company fails to continuously maintain the effectiveness of the 2016 Registration Statement (with certain permitted exceptions), the Company will incur certain liquidated damages in a range of 2%-10%, depending on the duration of such failure, of the approximately $1.3 million principal reduction of the Brainlab Note as described above. The 2016 Registration Rights Agreement also contains mutual indemnifications by the Company and Brainlab, which the Company believes are customary for transactions of this type.

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. The 2016 Warrants provide for certain adjustments that may be made to the exercise price and the number of shares issuable upon exercise due to future corporate events or otherwise. In the case of certain fundamental transactions affecting the Company, the holder of such 2016 Warrants, upon exercise of such warrants after such fundamental transaction, will have the right to receive, in lieu of shares of the Company's common stock, the same amount and kind of securities, cash or property that such holder would have been entitled to receive upon the occurrence of the fundamental transaction, had the 2016 Warrants been exercised immediately prior to such fundamental transaction. The 2016 Warrants contain a "cashless exercise" feature that allows the holders to exercise the warrants without a cash payment to the Company upon the terms set forth in the respective 2016 Warrant agreements.

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 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. 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. Prior to the third anniversary of the issuance date, the Company may prepay all, but not less than all, of the principal and unpaid accrued interest under the 2014 Secured Notes at any time, subject to the Company's payment of the additional prepayment premium stated in the notes. The 2014 Secured Notes are collateralized by a security interest in the Company's property and assets, which security interest is junior and subordinate to the security interest that collateralizes the New Brainlab Note.

The warrants issued to the investors (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 adjustment from time-to-time for stock splits or combinations, stock dividends, stock distributions, recapitalizations and other similar transactions. Assumptions used in calculating the fair value of the investor warrants using the Black-Scholes valuation model were:

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

Under GAAP, the Company allocated the $3,725,000 in proceeds proportionately between the 2014 Secured Notes and the investor warrants based on their relative fair values, with $413,057 being allocated to the fair value of the investor warrants, recorded as equity. The 2014 Secured Notes were recorded at the principal amount, less a discount equal to $413,057. After giving effect to the conversions discussed below under the heading *"August 31, 2016 Amendments,"* the unamortized discount at December 31, 2016 and 2015 was $121,985 and $301,531, 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 consolidated balance sheets. These deferred financing costs, having an unamortized balance of $58,789 and $166,080 at December 31, 2016 and 2015, 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 the assets of the Company, which security interest is junior and subordinate to the security interests that collateralize the 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, with the fair value of the notes being estimated based on an assumed market interest rate for notes of similar terms and risk, and the fair value of the Company's common stock being estimated by management using a market approach, with input from a third-party valuation specialist. The allocation of such relative fair values resulted in $2,775,300 being allocated to the value of the shares of common stock, which was recorded as equity. The 2010 Secured Notes were recorded at the principal amount of $3,000,000, less a discount equal to $2,775,300. The unamortized discount at December 31, 2016 and 2015 was $2,302,472 and $2,535,230, 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 "First Amendments") with: (a) Brainlab, with respect to the New Brainlab Note; and (b) the 2014 Convertible Note Holders, one of whom is a trust for which one of the Company's non-employee directors serves as a trustee, having an aggregate principal balance of $3 million. Pursuant to the First 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. These provisions 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 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, under GAAP, are required to be accounted for as derivatives, the calculation and accounting for which is described in Note 8.

Execution of the First Amendments constituted a debt extinguishment under GAAP, necessitating the Company to record a debt restructuring loss of approximately $820,000, representing the aggregate difference in the fair values of the New Brainlab Note and the affected 2014 Secured Notes between (i) their respective original dates of issuance, and (ii) June 30, 2016, the execution date of the First Amendments.

August 31, 2016 Amendments

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

Pursuant to the Second Amendments, the parties agreed that, in the event the Company closes a PIPE Transaction (as that term is defined in the Second 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, under GAAP, are required to be accounted for as derivatives, the calculation and accounting for which is described in Note 8.

Execution of the Second 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 Second Amendments.

As more fully described in Note 7, 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 Second 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, 2016 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	(2,424,457)
Less unamortized deferred financing costs	(58,789)
	$ 4,491,754

7. Stockholders' Deficit

Reverse Stock Split

On June 30, 2016, the Company's stockholders approved a reverse stock split of the Company's issued and outstanding shares of common stock at a ratio of 1-for-15, 1-for-20, 1-for-25, 1-for-30, 1-for-35 or 1-for-40, with the specific ratio and effective time of the reverse stock split to be determined by the Company's Board of Directors. 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. The reverse stock split did not cause an adjustment to the par value of the authorized shares of common stock. As a result of the reverse stock split, the share and per-share amounts under the Company's various share-based compensation plans, share-based compensatory contracts and warrants with third parties were adjusted. No fractional shares were issued in connection with the reverse stock split. In lieu of issuing fractional shares, the Company remitted approximately $4,800 to affected stockholders. All disclosure 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.

September 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 "Purchase Agreement"), by and among the Company and certain investors (collectively, the "Investors"). At the closing, in accordance with the terms and conditions of the Purchase Agreement, the Company sold to the Investors an aggregate of 851,000 units (the "Units"), with each 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 "Warrant" and collectively, the "Warrants").

In connection with the sale of the 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 ("Placement Agent Warrants") to purchase up to 29,680 shares of common stock.

Purchase Agreement

The Purchase Agreement contains representations and warranties by the Company and the Investors and covenants of the Company and the 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

The Registration Rights Agreement required the Company to prepare and file a registration statement (the "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 Investors under the Purchase Agreement, as well as the shares of common stock underlying the Warrants and the Placement Agent Warrants. The Company was required to file such Registration Statement on or before October 2, 2016, and was required to use its best efforts to have the Registration Statement declared effective as soon as practicable. The Company filed the Registration Statement on September 30, 2016, and the Registration Statement was declared effective by the SEC on October 11, 2016, both dates being in conformity with the foregoing requirements. Pursuant to the Registration Rights Agreement, if the Company fails to continuously maintain the effectiveness of the Registration Statement (with certain permitted exceptions), the Company will incur certain liquidated damages to the Investors. The Registration Rights Agreement also contains mutual indemnifications by the Company and each Investor, which the Company believes are customary for transactions of this type.

Warrants

The 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. The Warrants provide for certain adjustments that may be made to the exercise price and the number of shares issuable upon exercise due to future corporate events. In the case of certain fundamental transactions affecting the Company, the holders of the Warrants, upon exercise of such warrants after such fundamental transaction, have the right to receive, in lieu of shares of the Company's common stock, the same amount and kind of securities, cash or property that such holder would have been entitled to receive upon the occurrence of the fundamental transaction, had the Warrants been exercised immediately prior to such fundamental transaction. The Warrants contain a "cashless exercise" feature that allows the holders to exercise the warrants without a cash payment to the Company upon the terms set forth in the Warrants. The Placement Agent Warrants have the same terms and conditions as the Warrants.

Related Debt Conversion

As discussed in Note 6, pursuant to the Second Amendments, in addition to and simultaneously with the sale of the Units, on September 2, 2016: (i) the 2014 Principal automatically converted into 350,000 Units on the same terms and conditions as applied to purchasers of Units in the 2016 PIPE; 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, which is equal to the exercise price of the 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, 2016 and 2015, 22,313 shares and 5,742 shares, respectively, were issued to directors as payment for director fees, amounting to $124,069 and $145,993, in 2016 and 2015, respectively, in lieu of cash.

December 2015 Private Placement

In December 2015, the Company entered into a securities purchase agreement (the "2015 Purchase Agreement") for the private placement of 407,731 units at a purchase price of $12.984 per unit, with each unit consisting of: (i) one share of the Company's common stock; (ii) series A warrants, which permit each investor to purchase 0.40 share of common stock (the "2015 Series A Warrants"), resulting in the issuance of 2015 Series A Warrants to purchase an aggregate of approximately 162,500 shares of common stock; and (iii) series B warrants, which permit each investor to purchase 0.30 share of common stock (the "2015 Series B Warrants"), resulting in the issuance of 2015 Series B Warrants to purchase an aggregate of approximately 122,500 shares of common stock.

The Company received gross proceeds of $5,292,670, before commissions and offering expenses. The Company's President and Chief Executive Officer invested $100,000, a trust for which one of the Company's non-employee directors serves as president invested $50,000, and another of the Company's non-employee directors invested $25,000 in the transaction.

For their services, the Company's placement agents earned cash commissions of $380,155 and warrants to purchase up to approximately 40,000 shares of common stock (the "2015 Placement Agent Warrants"). The Company incurred other transaction costs related to the financing amounting to $172,128.

At the closing of the December 2015 Private Placement, the Company also entered into a registration rights agreement (the "2015 Registration Rights Agreement") with the investors. Pursuant to the 2015 Registration Rights Agreement, the Company was required to prepare and file a registration statement (the "2015 Registration Statement") with the SEC under the Securities Act covering the resale of the shares of common stock issued to the investors under the 2015 Purchase Agreement and the shares of common stock underlying the 2015 Series A and 2015 Series B Warrants and the 2015 Placement Agent Warrants. The Company filed the 2015 Registration Statement on January 15, 2016, that was declared effective on January 29, 2016, both dates being within the deadlines set forth in the 2015 Registration Statement. The Company continuously maintained the effectiveness of the 2015 Registration Statement for the time period required by the 2015 Registration Statement, and on January 27, 2017 terminated the effectiveness of the 2015 Registration Statement. The 2015 Registration Rights Agreement also contains mutual indemnifications by the Company and each investor, which the Company believes are customary for transactions of this type.

The 2015 Series A and 2015 Series B Warrants are exercisable, in whole or in part, at any time prior to December 18, 2020, at exercise prices of $16.232 and $21.10 per share, respectively. In the case of certain fundamental transactions affecting the Company, the holders of the 2015 Series A and 2015 Series B Warrants, upon exercise of such warrants after such fundamental transaction, have the right to receive, in lieu of shares of the Company's common stock, the same amount and kind of securities, cash or property that such holder would have been entitled to receive upon the occurrence of the fundamental transaction, had the 2015 Series A or 2015 Series B Warrants been exercised immediately prior to such fundamental transaction. The 2015 Series A and 2015 Series B Warrants contain a "cashless exercise" feature that allows the holders to exercise the warrants without a cash payment to the Company under the terms set forth in the respective warrants. The 2015 Placement Agent Warrants have the same terms and conditions as the 2015 Series A Warrants, except that the 2015 Placement Agent Warrants are exercisable, in full or in part, at any time prior to May 18, 2023.

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.

In June 2013, the Company's stockholders approved the 2013 Incentive Compensation Plan. Upon its approval, the Company ceased making awards under other previous Plans, although then-outstanding awards made under such other previous Plans remain outstanding in conformity with their original terms. At the 2015 Annual Meeting, the Company's stockholders approved the adoption of the MRI Interventions, Inc. 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 125,000 shares, resulting in a total of 156,250 shares of the Company's common stock being reserved for issuance under the Amended 2013 Plan. Of this amount, stock grants of 38,294 shares have been awarded and option grants of 117,950 shares were outstanding as of December 31, 2016. Accordingly, 6 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, 2015	258,583		$ 32.00	-	$385.60	$ 54.38	$4,800
Exercisable at January 1, 2015		140,687	$ 40.00		$385.60	$ 62.27	600
Activity during the year ended December 31, 2015							
Granted	61,912		$ 29.60	-	$ 42.40	$ 32.80	
Exercised	-		-	-	-	-	
Cancelled or forfeited	(22,212)		$ 32.00	-	128.00	$ 59.20	
Outstanding at December 31, 2015	298,283		$ 29.60		$385.60	$ 48.73	-
Exercisable at December 31, 2015		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	-

(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, 2016 (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
$5.00 - $45.20	247,469	7.67	$ 32.48	156,351	6.91	$ 38.71
$46.40 - $83.60	88,892	5.16	$ 68.09	88,558	5.15	$ 68.16
$128.00 - $385.60	1,080	1.61	$ 322.73	1,080	1.61	$ 322.73
	337,441	7.67	$ 42.07	245,989	6.26	38.71

The weighted average grant date fair value of options granted during the years ended December 31, 2016 and 2015 was $3.01 and $15.60, respectively. A summary of the status of the Company's nonvested stock options during the years ended December 31, 2016 and 2015 is presented below:

Nonvested Stock Options	Shares	Weighted - Average Grant Date Fair Value
Nonvested January 1, 2015	117,895	$ 20.80
Activity during the year ended December 31, 2015		
Granted	61,912	$ 18.77
Forfeited	(2,562)	$ 23.76
Vested	(58,178)	$ 21.13
Nonvested December 31, 2015	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

The Company records share-based compensation expense on a straight-line basis over the related vesting period. For the years ended December 31, 2016 and 2015, share-based compensation expense related to options was:

Year Ended December 31,	
2016	2015
$ 959,585	$ 1,682,063

As further discussed in Note 5, the Company, in April and May 2015, recorded $492,926 of non-cash, share-based compensation expense, classified as restructuring costs in the accompanying 2015 consolidated statements of operations, related to the modification of the terms of options held by certain former officers. In addition, effective April 1, 2015, a member of the Company's Board of Directors resigned. In recognition of the director's contributions to the Company, the Company's Board of Directors accelerated the vesting of two stock options previously awarded to the director and extended the exercise period through April 1, 2017 for all vested options held by the director. Prior to such extension, the exercise period under the options' original terms was three months subsequent to the date the individual ceased to be a director of the Company. The Company revalued the director's stock option based on the modified terms described above and recorded non-cash, share-based compensation expense of $12,005.

As of December 31, 2016, approximately $964,000 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 1.35 years.

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

	Years Ended December 31,	
	2016	2015
Dividend yield	0%	0%
Expected Volatility	47.47% to 50.69%	46.67% to 47.93%
Risk free Interest rates	1.23% to 1.39%	1.48% to 1.80%
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, 2016 and 2015 is as follows:

	Shares	Weighted - Average Exercise Price
Outstanding at January 1, 2015	518,978	$ 32.13
Activity during the year ended December 31, 2015		
Issued	327,060	$ 18.12
Terminated	(781)	$ 320.00
Outstanding at December 31, 2015	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)

(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.

Information regarding outstanding warrants at December 31, 2016 is as follows (contractual life expressed in years):

Exercise Price	Number Outstanding	Weighted - Average Remaining Contractual Life	Intrinsic Value (1)
$ 1.83	1,540	3.96	$ 1,648
5.00	28,750	1.07	-
5.50	1,129,330	4.67	-
12.80	70,627	1.07	-
16.23	242,021	3.96	-
21.10	152,084	3.96	-
24.00	11,471	0.15	-
30.00	45,999	0.13	-
34.32	185,779	2.98	-
36.00	68,155	0.50	-
38.80	8,583	0.50	-
40.00	34,875	0.35	-
70.00	12,079	2.23	-
	1,991,293	3.81	$ 1,648

(1) Intrinsic value is calculated as the estimated fair value of the Company's stock at December 31, 2016 less the warrant exercise price of in-the-money warrants.

8. Derivative Liabilities

As discussed in Note 6, on June 30, 2016, the Company entered into the First Amendment with Brainlab, with respect to the New Brainlab Note, the provisions of which created: (a) a conversion feature allowing for $500,000 of the principal balance of the New Brainlab Note to be converted into the security offered in a qualified public offering, and at a price that may be less than market value per share of the Company's common stock; and (b) down round protection with respect to the exercise price for 34,957 shares of common stock underlying warrants issued in connection with the New Brainlab Note.

In addition, warrants issued in 2012 and 2013 financing transactions contain either or both net-cash settlement and down round exercise price protection provisions.

Under GAAP, the conversion feature and the down round price protection described in the two preceding paragraphs are required to be accounted for as derivatives, thus necessitating 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 these derivatives were calculated using the Monte Carlo simulation valuation method.

Assumptions used in calculating the fair value of the conversion feature at December 31, 2016 include the following:

Risk free interest rates	1.20%
Volatility	60%

Assumptions used in calculating the fair value of the warrants described in this Note 8 at December 31, 2016 include the following:

Dividend yield	0%
Expected volatility	55% - 60%
Risk free interest rates	0.62% - 1.76%
Expected remaining term (in years)	0.50 - 4.26

In addition to the assumptions above, the Company also estimates the likelihood of whether it will participate in a future round of qualifying equity financing, 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 as of, and during the years ended, December 31, 2016 and 2015 are as follows:

	Year Ended December 31,	
	2016	2015
Balance, beginning of period	$ 658,286	$ 2,198,162
Conversion of equity warrants to liabilities	192,173	-
Addition from debt restructurings	1,592,134	-
Reduction from debt conversions	(1,207,813)	-
Reduction from warrant exercise	(37,672)	-
Gain on change in fair value for the period	(1,065,935)	(1,539,876)
Balance, end of period	$ 131,173	$ 658,286

9. Income Taxes

The Company had no income tax expense for the years ended December 31, 2016 and 2015. Due to uncertainties surrounding the realization of its deferred income tax assets in future periods, the Company has recorded a 100% valuation allowance against its net deferred income tax assets. If it is determined in the future that it is more likely than not that any deferred income tax assets are realizable, the valuation allowance will be reduced by the estimated net realizable amounts. For the years ended December 31, 2016 and 2015, the valuation allowance increased by approximately $3.5 million and $5.0 million, respectively.

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

	As of December 31,	
	2016	2015
Deferred income tax assets (liabilities):		
Property and equipment	$ 107,308	$ (35,232)
Deferred revenue	88,877	46,211
Accrued expenses	53,112	53,112
Share based compensation	3,186,133	2,110,364
Derivative liability	164,258	-
Other	248,561	216,544
Net operating loss carryforwards	30,800,732	28,798,998
	34,648,981	31,189,997
Less valuation allowance	(34,648,981)	(31,189,997)
	$ -	$ -

The Company had a cumulative federal net operating loss of approximately $77 million as of December 31, 2016, which will begin expiring in 2020. Under Sections 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation," as defined, there are annual limitations on the amount of the net operating loss and other deductions which are available to the Company. The Company has not determined whether such an ownership change has occurred. However, given the equity transactions in which the Company has engaged, the Company believes that the use of the net operating losses shown as deferred tax assets will be significantly limited.

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

10. 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 2018. At December 31, 2016, future minimum lease payments under non-cancellable operating leases were $164,591.

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,	
2017	92,624
2018	71,967
Total minimum payments	$ 164,591

Rent expense under all operating leases, which includes a non-cancellable lease for the Company's former headquarters in Memphis, Tennessee that was in effect for the first ten months of 2015, was approximately $92,000 and $125,000 for the years ended December 31, 2016 and 2015, respectively

Licenses

Certain license arrangements require minimum royalty payments. As of December 31, 2016, future minimum payments under these arrangements are as follows:

Years ending December 31,	
2017	60,000
2018	50,000
2019	50,000
2020	50,000
2021	50,000
Thereafter	270,000
Total minimum payments	$ 530,000

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 2016, under which the Company may receive technical and training services. Pursuant to the terms of the amended agreements, the Company paid the university approximately $45,000 for technical research services in 2016 and did not incur any costs for training services (as such services may be rendered by the university upon the Company's request) in 2016. The January 2016 amendments expired in January 2017 and new amendments to the agreements are under negotiation.

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, 2016, the participation interest was 1.38%. The plan will terminate in June 2025.

Employment Agreements

The Company has employment agreements with its 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.

MRI INTERVENTIONS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)

	March 31, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,969,597	$ 3,315,774
Accounts receivable	1,009,775	865,943
Inventory, net	1,809,020	1,768,382
Prepaid expenses and other current assets	95,625	134,996
Total current assets	4,884,017	6,085,095
Property and equipment, net	383,534	328,249
Software license inventory	906,900	976,900
Other assets	16,300	10,641
Total assets	$ 6,190,751	$ 7,400,885
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,308,056	$ 1,546,926
Accrued compensation	811,951	666,060
Other accrued liabilities	618,839	450,424
Derivative liabilities	224,219	131,173
Deferred product and service revenues	263,097	223,117
Total current liabilities	3,226,162	3,017,700
Accrued interest	577,125	647,500
Senior secured note payable	2,000,000	2,000,000
2014 junior secured notes payable, net of unamortized discount and deferred issuance costs of $160,688 and $180,774 at March 31, 2017 and December 31, 2016, respectively	1,814,312	1,794,226
2010 junior secured notes payable, net of unamortized discount of $2,221,936 and $2,302,472 at March 31, 2017 and December 31, 2016, respectively	778,064	697,528
Total liabilities	8,395,663	8,156,954
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized at March 31, 2017 and December 31, 2016; none issued and outstanding at March 31, 2017 and December 31, 2016	-	-
Common stock, $0.01 par value; 200,000,000 shares authorized at March 31, 2017 and December 31, 2016; 3,622,032 shares issued and outstanding at March 31, 2017 and December 31, 2016	36,220	36,220
Additional paid-in capital	93,283,370	93,076,475
Accumulated deficit	(95,524,502)	(93,868,764)
Total stockholders' deficit	(2,204,912)	(756,069)
Total liabilities and stockholders' deficit	$ 6,190,751	$ 7,400,885

See accompanying notes.

MRI INTERVENTIONS, INC.
Condensed Consolidated Statements of Operations
(Unaudited)

	For The Three Months Ended March 31,	
	2017	**2016**
Revenues:		
Product revenues	$ 1,922,215	$ 1,366,153
Other service revenues	84,857	27,981
Total revenues	2,007,072	1,394,134
Cost of product revenues	752,464	696,546
Research and development costs	557,699	657,192
Selling, general, and administrative expenses	2,050,529	1,974,249
Operating loss	(1,353,620)	(1,933,853)
Other income (expense):		
Gain (loss) on change in fair value of derivative liabilities	(93,046)	160,118
Other income, net	4,127	75,142
Interest expense, net	(213,199)	(345,225)
Net loss	$ (1,655,738)	$ (2,043,818)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.46)	$ (0.89)
Weighted average shares outstanding:		
Basic and diluted	3,622,032	2,291,147

See accompanying notes.

MRI INTERVENTIONS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	For The Three Months Ended March 31,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$ (1,655,738)	$ (2,043,818)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	36,121	41,022
Share-based compensation	206,896	260,149
Expenses paid through the issuance of common stock	-	192,166
(Gain) loss on change in fair value of derivative liabilities	93,046	(160,118)
Amortization of debt issuance costs and original issue discounts	100,622	151,759
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(143,832)	(279,494)
Inventory	(62,043)	217,873
Prepaid expenses and other current assets	39,371	(18,114)
Other assets	(5,659)	(58,473)
Accounts payable and accrued expenses	5,059	52,790
Deferred revenue	39,980	35,697
Net cash flows from operating activities	(1,346,177)	(1,608,561)
Cash flows from investing activities:		
Purchases of property and equipment	-	(77,649)
Net cash flows from investing activities	-	(77,649)
Cash flows from financing activities:		
Payment of 2015 private placement financing costs	-	(140,086)
Net cash flows from financing activities	-	(140,086)
Net change in cash and cash equivalents	(1,346,177)	(1,826,296)
Cash and cash equivalents, beginning of period	3,315,774	5,408,523
Cash and cash equivalents, end of period	$ 1,969,597	$ 3,582,227
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ -	$ -
Interest	$ 146,611	$ 223,500

See accompanying notes.

MRI INTERVENTIONS, INC.
Condensed Consolidated Statements of Cash Flows (continued)
(Unaudited)

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

- During the three months ended March 31, 2017, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of $91,405 from inventory to loaned systems, which are included in property and equipment in the accompanying condensed consolidated balance sheet. During the three months ended March 31, 2016, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of $24,223 from loaned systems to inventory.

MRI INTERVENTIONS, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of the Business and Liquidity

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

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

Liquidity and Management's Plans

The cumulative net loss from the Company's inception through March 31, 2017 was approximately $96 million. Net cash used in operations was $1.3 million for the three months ended March 31, 2017. Since inception, the Company has financed its operations principally from the sale of equity securities, the issuance of notes payable and license arrangements. Recent financing activities consist of: (i) a September 2016 private placement of equity, which resulted in net cash proceeds of $3.8 million and the conversion of $1.75 million in debt (the "2016 PIPE"); (ii) a December 2015 private placement of equity, which resulted in net cash proceeds of $4.7 million (the "2015 PIPE"); (iii) a December 2014 private placement of equity, which resulted in net cash proceeds of $9.4 million; and (iv) a March 2014 private placement of debt and warrants, which resulted in net cash proceeds of $3.5 million (the "2014 Secured Notes").

In addition, as discussed in Note 4:

- On April 4, 2016 (the "Closing Date"), the Company and Brainlab AG ("Brainlab") finalized a securities purchase agreement (the "2016 Purchase Agreement") that provided, among other items, for the restructuring of a senior secured note payable to Brainlab, which was originally issued to Brainlab on April 5, 2011, and subsequently amended and restated on March 6, 2013 (the "Brainlab Note"). The restructuring of the Brainlab Note resulted in a reduction of the principal amount outstanding under the Brainlab Note, which is reflected in a new, amended and restated note payable to Brainlab that matures on December 31, 2018 (the "New Brainlab Note").

- Pursuant to amendments executed on August 31, 2016 by the Company and certain noteholders (the "2014 Convertible Note Holders") upon completion of the 2016 PIPE, an aggregate $1.75 million of principal balance of such holders' 2014 junior secured notes automatically converted into units, each unit consisting of one share of the Company's common stock and one warrant to purchase 0.90 share of the Company's common stock, based on the offering price per unit in the 2016 PIPE.

The Company's plans for the next twelve months reflect management's 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. Management also anticipates 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 the Company will be able to achieve its anticipated results, and even in the event such results are achieved, the Company expects to continue to consume cash in its operations over at least the next twelve months.

As a result of the foregoing, the Company believes it will be necessary to seek additional financing from the sale of equity or debt securities, which would result in dilution to the Company's current stockholders, the establishment of a credit facility, or the entry into an agreement with a strategic partner or some other form of collaborative arrangement. There is no assurance, however, that the Company will be able to obtain such additional financing on commercially reasonable terms, if at all, and there is no assurance that any additional financing that the Company does obtain will be sufficient to meet its needs. If the Company is not able to obtain the additional financing on a timely basis, the Company may be unable to achieve its anticipated results, and the Company may not be able to meet its other obligations as they become due. As such, there is substantial doubt as to the Company's ability to continue as a going concern within one year after the issuance date of these financial statements.

The accompanying condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

In the opinion of management, the accompanying unaudited condensed consolidated financial statements have been prepared on a basis consistent with the Company's December 31, 2016 audited consolidated financial statements, and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly state the information set forth therein. These condensed consolidated financial statements have been prepared in accordance with United States Securities and Exchange Commission ("SEC") rules for interim financial information, and, therefore, omit certain information and footnote disclosures necessary to present such statements in accordance with generally accepted accounting principles in the U.S. ("GAAP"). The preparation of these condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and the related disclosures at the date of the financial statements and during the reporting period. Actual results could materially differ from these estimates. These condensed financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016, which was filed with the SEC on March 9, 2017 (our "2016 Form 10-K"). The accompanying unaudited condensed consolidated balance sheet as of December 31, 2016 has been derived from the audited consolidated financial statements at that date, but does not include all information and footnotes required by GAAP for a complete set of financial statements. The results of operations for the three months ended March 31, 2017 may not be indicative of the results to be expected for the entire year or any future periods.

Reverse Stock Split

As discussed in Note 5, the Company effectuated a 1-for-40 reverse stock split of its issued common stock on July 26, 2016. All disclosure of common shares and per share data in the accompanying condensed consolidated financial statements and related notes have been adjusted retroactively to reflect the reverse stock split for all periods presented.

Derivative Liabilities

Derivative liabilities represent the fair value of conversion features of certain notes and of certain warrants to purchase common stock (see Note 6). 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 condensed 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. 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
March 31, 2017				
Derivative liabilities – warrants	$ -	$ -	$ 176,719	$ 176,719
Derivative liabilities – debt conversion feature			47,500	47,500
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 and stock price volatility, all of which are further discussed in Note 6.

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 March 31, 2017:

	Carrying Values	Estimated Fair Values
Senior secured note payable, including accrued interest	$ 2,027,500	$ 2,027,500
2014 junior secured notes payable, including accrued interest	1,822,687	1,983,375
2010 junior secured notes payable, including accrued interest	1,451,814	2,858,412

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.

Revenue Recognition

The Company's revenues are comprised of: (1) product revenues resulting from the sale of ClearPoint system reusable products and disposable products; and (2) other service revenues. The Company recognizes revenue when persuasive evidence of an arrangement exists, the selling price or fee is fixed or determinable, collection is reasonably assured, and, for product revenues, risk of loss has transferred to the customer. For all sales, the Company requires either a purchase agreement or a purchase order as evidence of an arrangement. The Company analyzes revenue recognition on a case-by-case basis, and 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.

(1) *Product Revenues*

Sales of ClearPoint system reusable products: The predominance of ClearPoint system reusable product sales (consisting primarily of integrated computer hardware and software) are preceded by customer evaluation periods, generally with 90-day terms. 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, reusable product sales following such evaluation periods are recognized on the basis of an executed purchase agreement or purchase order that provide for risk of loss to pass to the customer. Sales of reusable products not having been preceded by an evaluation period are recognized on an individual agreement basis as described in the preceding paragraph.

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

(2) *Other Service Revenues*

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

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 5, would be anti-dilutive.

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 March 31, 2017, the Company had no bank balances that were in excess of the insured limits.

At March 31, 2017, two customers represented 20% and 13% of the Company's accounts receivable balance. At December 31, 2016, three customers represented 20%, 13% and 10% of the Company's accounts receivable balance. No other customer represented more than 9% of total accounts receivable at each of March 31, 2017 and December 31, 2016.

For the three months ended March 31, 2017, sales to one customer represented 12% of product revenues, and for the three months ended March 31, 2016, sales to one customer represented 11% of product revenues. In each of the three-month periods ended March 31, 2017 and 2016, no other single customer accounted for more than 9% of product revenues. 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 March 31, 2017 and December 31, 2016 was $31,000 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 and 2016-20 discussed below, are effective for the Company beginning in 2018. Earlier application is permitted only as of 2017.

- 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 that are not expected to have a significant effect on the Company's current accounting practice.

The Company believes, based on a preliminary assessment in which the Company considered such factors as the short duration of its contract terms with customers, that the adoption of ASU 2015-14, and the subsequently issued related ASUs discussed above, will not have a material effect on its consolidated financial statements.

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 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.

3. Inventory

Inventory consists of the following as of:

	March 31, 2017	December 31, 2016
Raw materials and work in process	$ 1,214,884	$ 1,025,368
Software licenses	105,000	70,000
Finished goods	489,136	673,014
Inventory included in current assets	1,809,020	1,768,382
Software licenses – non-current	906,900	976,900
	$ 2,715,920	$ 2,745,282

4. Notes Payable

Senior Secured Note Payable

Indebtedness outstanding under the New Brainlab Note at March 31, 2017 and December 31, 2016 was $2.0 million and matures on December 31, 2018. The New Brainlab Note bears interest at 5.5% per annum payable quarterly in arrears, and is collateralized by a senior security interest in the assets of the Company.

2016 Purchase Agreement

Under the 2016 Purchase Agreement, the Company, among other items: (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, with each unit consisting of: (a) one share of the Company's common stock; (b) a warrant to purchase 0.4 share of common stock (the "2016 Series A Warrants"); and (c) a warrant to purchase 0.3 shares of common stock (the "2016 Series B Warrants"); and (v) entered into a Registration Rights Agreement (the "2016 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 (together, the "2016 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.

2016 Registration Rights Agreement

The 2016 Registration Rights Agreement imposed deadlines by which the Company was required to file the 2016 Registration Statement and use its best efforts to have the 2016 Registration Statement declared effective. The 2016 Registration Statement was filed, and declared effective on June 20, 2016, within the deadlines imposed by the 2016 Registration Rights Agreement. The 2016 Registration Rights Agreement also required the Company to continuously maintain the effectiveness of the 2016 Registration Statement for a period that ended on the first anniversary of the Closing Date, with which the Company was in compliance for the required period. The 2016 Registration Rights Agreement also contains mutual indemnifications by the Company and Brainlab, which the Company believes are customary for transactions of this type.

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. The 2016 Warrants provide for certain adjustments that may be made to the exercise price and the number of shares issuable upon exercise due to future corporate events or otherwise. In the case of certain fundamental transactions affecting the Company, the holder of such 2016 Warrants, upon exercise of such warrants after such fundamental transaction, will have the right to receive, in lieu of shares of the Company's common stock, the same amount and kind of securities, cash or property that such holder would have been entitled to receive upon the occurrence of the fundamental transaction, had the 2016 Warrants been exercised immediately prior to such fundamental transaction. The 2016 Warrants contain a "cashless exercise" feature that allows the holders to exercise the warrants without a cash payment to the Company upon the terms set forth in the respective 2016 Warrant agreements.

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.

2014 Junior Secured Notes Payable

In March 2014, the Company entered into securities purchase agreements for the private placement of: (i) the 2014 Secured Notes, which were second-priority secured non-convertible promissory 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. 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. Prior to the third anniversary of the issuance date, the Company may prepay all, but not less than all, of the principal and unpaid accrued interest under the 2014 Secured Notes at any time, subject to the Company's payment of the additional prepayment premium stated in the notes. The 2014 Secured Notes are collateralized by a security interest in the Company's property and assets, which security interest is junior and subordinate to the security interest that collateralizes the New Brainlab Note.

The warrants issued to the investors (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 adjustment from time-to-time for stock splits or combinations, stock dividends, stock distributions, recapitalizations and other similar transactions. Assumptions used in calculating the fair value of the investor warrants using the Black-Scholes valuation model were:

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

Under GAAP, the Company allocated the $3,725,000 in proceeds proportionately between the 2014 Secured Notes and the investor warrants based on their relative fair values, with $413,057 being allocated to the fair value of the investor warrants, recorded as equity. The 2014 Secured Notes were recorded at the principal amount, less a discount equal to $413,057. After giving effect to the conversions discussed below under the heading *"August 31, 2016 Amendments,"* the unamortized discount at March 31, 2017 and December 31, 2016 was $108,431 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 $52,257 and $58,789 at March 31, 2017 and December 31, 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 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, with the fair value of the notes being estimated based on an assumed market interest rate for notes of similar terms and risk, and the fair value of the Company's common stock being estimated by management using a market approach, with input from a third-party valuation specialist. The allocation of such relative fair values resulted in $2,775,300 being allocated to the value of the shares of common stock, which was recorded as equity. The 2010 Secured Notes were recorded at the principal amount of $3,000,000, less a discount equal to $2,775,300. The unamortized discount at March 31, 2017 and December 31, 2016 was $2,221,936 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 "First Amendments") with: (a) Brainlab, with respect to the New Brainlab Note; and (b) the 2014 Convertible Note Holders, one of which is a trust for which one of the Company's non-employee directors serves as a trustee, having an aggregate principal balance of $3 million. Pursuant to the First 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 Second Amendments (defined below), which superseded the First Amendments, and converted the 2014 Principal (defined below), under the terms of the Second Amendments.

The provisions of the First 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 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, under GAAP, are required to be accounted for as derivatives, the calculation and accounting for which is described in Note 6.

August 31, 2016 Amendments

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

Pursuant to the Second Amendments, the parties agreed that, in the event the Company closes a PIPE Transaction (as that term is defined in the Second 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, under GAAP, are required to be accounted for as derivatives, the calculation and accounting for which is described in Note 6.

As described in Note 5, the 2016 PIPE (which constituted a "PIPE Transaction" as defined in the Second Amendments) 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 Second 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 March 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	(2,330,367)
Unamortized deferred financing costs	(52,257)
	$ 4,592,376

5. Stockholders' Equity

Reverse Stock Split

On July 26, 2016, the Company effectuated a 1-for-40 reverse stock split of its issued common stock. The reverse stock split did not cause an adjustment to the par value of the authorized shares of common stock. As a result of the reverse stock split, the share and per-share amounts under the Company's various share-based compensation plans, share-based compensatory contracts and warrants with third parties were adjusted. No fractional shares were issued in connection with the reverse stock split. All disclosure of common shares and per share data in the accompanying condensed consolidated financial statements and related notes have been adjusted retroactively to reflect the reverse stock split for all periods presented.

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 the product of: (i) the fees otherwise payable to each director in cash, times (ii) the percentage of fees the director elected to receive in shares of common stock, by (iii) the volume weighted average price per share of common stock over the last five trading days of the quarter. During the three months ended March 31, 2016, 2,824 shares were issued to directors as payment for director fees in lieu of cash. No shares were issued to directors as payment for director fees during the three months ended March 31, 2017.

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.

Since June 2015, the Company has granted share-based awards under the MRI Interventions, Inc. Amended and Restated 2013 Incentive Compensation Plan (the "Amended 2013 Plan"). Under the Amended 2013 Plan, a total of 156,250 shares of the Company's common stock are reserved for issuance. Of this amount, stock grants of 41,794 shares have been awarded and option grants, net of options terminated, expired or forfeited, of 102,700 shares were outstanding as of March 31, 2017. Accordingly, 11,756 shares remained available for grants under the Amended 2013 Plan as of that date.

Stock option activity under all of the Company's equity compensation plans during the three months ended March 31, 2017 is summarized below:

	Shares	Weighted - Average Exercise Price
Outstanding at December 31, 2016	337,441	$ 42.07
Granted	2,000	2.55
Forfeited	(23,875)	45.53
Outstanding at March 31, 2017	315,566	$ 42.33

The estimated grant date fair values of options granted during the three months ended March 31, 2017 were calculated using the Black-Scholes valuation model, based on the following assumptions:

Dividend yield	0%
Expected volatility	51.79%
Risk free interest rates	2.11%
Expected lives (in years)	6.0

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

Three Months Ended March 31,	
2017	2016
$ 206,896	$ 260,149

As of March 31, 2017, there was unrecognized compensation expense of $670,911 related to outstanding stock options, which is expected to be recognized over a weighted average period of 1.23 years.

Warrants

Warrants have generally been issued for terms of up to five years. Common stock warrant activity for the three months ended March 31, 2017 was as follows:

	Shares	Weighted - Average Exercise Price
Outstanding at December 31, 2016	1,991,293	$ 13.00
Issued	-	-
Exercised	-	-
Terminated	(57,720)	38.43
Outstanding at March 31, 2017	1,933,573	$ 12.71

6. Derivative Liabilities

As discussed in Note 4, on June 30, 2016, the Company entered into the First Amendment with respect to the New Brainlab Note, the provisions of which created: (a) a conversion feature allowing for $500,000 of the principal balance of the New Brainlab Note to be converted into the security offered in a qualified public offering, and at a price that may be less than market value per share of the Company's common stock; and (b) down round protection with respect to the exercise price for 34,957 shares of common stock underlying warrants issued in connection with the New Brainlab Note.

In addition, warrants issued in 2012 and 2013 financing transactions contain either or both net-cash settlement and down round exercise price protection provisions.

Under GAAP, the conversion feature and the down round price protection described in the two preceding paragraphs are required to be accounted for as derivatives, thus necessitating 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 these derivatives were calculated using the Monte Carlo simulation valuation method.

Assumptions used in calculating the fair value of the conversion feature at March 31, 2017 include the following:

Risk free interest rates	1.21%
Volatility	60%

Assumptions used in calculating the fair value of the warrants described in this Note 6 at March 31, 2017 include the following:

Dividend yield	0%
Expected volatility	50% - 60%
Risk free interest rates	0.76% - 1.72%
Expected remaining term (in years)	0.25 – 4.00

In addition to the assumptions above, the Company also estimates the likelihood of whether it will participate in a future round of qualifying equity financing, 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 as of, and during the three months ended March 31, 2017 and 2016 are as follows:

	Three Months Ended March 31,	
	2017	**2016**
Balance, beginning of period	$ 131,173	$ 658,286
(Gain) loss on change in fair value for the period	93,046	(160,118)
Balance, end of period	$ 224,219	$ 498,168

MRI Interventions, Inc.

13,087,533 Shares

Common Stock

PROSPECTUS

July 7, 2017