IRADIMED CORP
Form 10-K
March 08, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2017

OR

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

FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NO. 001-36534

IRADIMED CORPORATION

(Exact Name of Registrant As Specified In Its Charter)

Delaware	**73-1408526**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1025 Willa Springs Drive **Winter Springs, Florida** (Address of principal executive offices)	**32708** (Zip Code)

Registrant s telephone number, including area code: **(407) 677-8022**

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of Each Class	**Name of each exchange on which registered**
Common Stock, $0.0001 par value	Nasdaq Stock Market LLC (Nasdaq Capital Market)

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: **None**.

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

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

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

Indicate by checkmark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes o No x

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company o
	Emerging growth company x

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

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

As of June 30, 2017, the last business day of the registrant s most recently completed second fiscal quarter, the aggregate market value of its shares held by non-affiliates was approximately $38,713,175.

There were 10,604,648 shares outstanding of the registrant s common stock, par value $0.0001 per share, as of February 28, 2018. The registrant s common stock is listed on the Nasdaq Capital Market under the stock symbol IRMD.

Documents Incorporated by Reference: Information required by Items 10, 11, 12, 13 and 14 of Part III are incorporated by reference from the Proxy Statement for the registrant s 2018 Annual Meeting of Stockholders. Except with respect to information specifically incorporated by reference in the Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

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For the Fiscal Year Ended December 31, 2017

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CAUTIONARY STATEMENTS REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections entitled Business, Risk Factors and Management s Discussion and Analysis and Results of Operations. In some cases, you can identify forward-looking statements by the following words: may, will, could, would, should, expect, plan, anticipate, believe, estimate, predict, project, potential, continue, ongoing or the negative of these terms or other comparab although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

- our ability to receive 510(k) clearance for our products and product candidates, resolve various matters identified in the U.S. Food & Drug Administration (FDA) Warning Letter, complete inspections conducted by the FDA resulting in favorable outcomes, additional actions by or requests from the FDA (including a request to cease domestic distribution of products) and unanticipated costs or delays associated with the resolution of these matters;

- unexpected costs, expenses and diversion of management attention resulting from the FDA Warning Letter and other actions or requests posed to us by the FDA;

- our primary reliance on a limited number of products;

- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;

- our expectations regarding the sales and marketing of our products, product candidates and services;

- our expectations regarding the integrity of our supply chain for our products;

- the timing and likelihood of FDA approvals and regulatory actions on our product candidates and product marketing activities;

- the potential for adverse application of environmental, health and safety and other laws and regulations of any jurisdiction on our operations;

- our expectations for market acceptance of our new products;

- the potential for our marketed products to be withdrawn due to recalls, patient adverse events or deaths;

- our ability to establish and maintain intellectual property on our products and our ability to successfully defend these in cases of infringement;

- the implementation of our business strategies;

- the potential for exposure to product liability claims;

- our financial performance expectations and interpretations thereof by securities analysts and investors;

- our ability to compete in the development and marketing of our products and product candidates with other companies in our industry;

- difficulties or delays in the development, production, manufacturing and marketing of new or existing products and services, including difficulties or delays associated with obtaining requisite regulatory approvals or clearances associated with those activities;

- changes in laws and regulations or in the interpretation or application of laws or regulations, as well as possible failures to comply with applicable laws or regulations as a result of possible misinterpretations or misapplications;

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- cost-containment efforts of our customers, purchasing groups, third-party payers and governmental organizations;

- costs associated with protecting our trade secrets and enforcing our patent, copyright and trademark rights, and successful challenges to the validity of our patents, copyrights or trademarks;

- actions of regulatory bodies and other government authorities, including the FDA and foreign counterparts, that could delay, limit or suspend product development, manufacturing or sales or result in recalls, seizures, consent decrees, injunctions and monetary sanctions;

- costs or claims resulting from potential errors or defects in our manufacturing that may injure persons or damage property or operations, including costs from remediation efforts or recalls;

- the results, consequences, effects or timing of any commercial disputes, patent infringement claims or other legal proceedings or any government investigations;

- interruption in our ability to manufacture our products or an inability to obtain key components or raw materials or increased costs in such key components or raw materials;

- uncertainties in our industry due to the effects of government-driven or mandated healthcare reform;

- competitive pressures in the markets in which we operate;

- the loss of, or default by, one or more key customers or suppliers; and

- unfavorable changes to the terms of key customer or supplier relationships.

Forward-looking statements are not guarantees of future performance and are subject to substantial risks and uncertainties that could cause the actual results to differ materially from those that we predicted in the forward-looking statements. Investors should carefully review the information contained under the caption Risk Factors contained in Item 1A for a description of risks and uncertainties that could cause actual results to differ from those that we predicted. All forward-looking statements are based on information available to us on the date hereof, and we assume no obligation to update forward-looking statements, except as required by Federal Securities laws.

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PART I

ITEM 1. BUSINESS

Overview

IRADIMED CORPORATION (IRADIMED , the Company , we , us , our) develops, manufactures, markets and distributes Magnetic Resonan Imaging (MRI) compatible medical devices and accessories and services relating to them.

MRidium 3860+ MRI Compatible IV Infusion Pump System

We are the only known provider of a non-magnetic Intravenous (IV) infusion pump system that is specifically designed for safe use during MRI procedures. We were the first to develop an infusion delivery system that largely eliminates many of the dangers and problems present during MRI procedures. Standard infusion pumps contain magnetic and electronic components which can create radio frequency (RF) interference and are dangerous to operate in the presence of the powerful magnet that drives an MRI system. Our patented MRidium® MRI compatible IV infusion pump system has been designed with a non-magnetic ultrasonic motor, uniquely-designed non-ferrous parts and other special features in order to safely and predictably deliver anesthesia and other IV fluids during various MRI procedures. Our pump solution provides a seamless approach that enables accurate, safe and dependable fluid delivery before, during and after an MRI scan, which is important to critically-ill patients who cannot be removed from their vital medications, and children and infants who must generally be sedated in order to remain immobile during an MRI scan.

Each IV infusion pump system consists of an MRidium® MRI compatible IV infusion pump, non-magnetic mobile stand, proprietary disposable IV tubing sets and many of these systems contain additional optional upgrade accessories.

IRadimed 3880 MRI Compatible Patient Vital Signs Monitoring System

The 3880 MRI compatible patient vital signs monitoring system has been designed with non-magnetic components and other special features in order to safely and accurately monitor a patient s vital signs during various MRI procedures. The IRADIMED 3880 monitor is rated for operation in magnetic fields up to 30,000 gauss, which means it can operate virtually anywhere in the MRI scanner room. The IRADIMED 3880 has a compact, lightweight design, facilitating the transportation of patients from their critical care unit, to the MRI and back, resulting in increased patient safety through uninterrupted vital signs monitoring and decreasing the amount of time critically ill patients are away from critical care units. The features of the IRADIMED 3880 include: wireless ECG with dynamic gradient filtering; wireless SpO2 using Masimo® algorithms; respiratory CO2; non-invasive blood pressure; patient

temperature, and; optional advanced multi-gas anesthetic agent unit featuring continuous Minimum Alveolar Concentration measurements. The IRADIMED 3880 MRI compatible patient vital signs monitoring system has an easy-to-use design, small form factor and unique wireless tablet remote control that allows for the effective communication of patient vital signs information to clinicians located in the MRI control room. Our 3880 MRI compatible patient vital signs monitoring system received FDA 510(k) clearance in October 2017 and is currently available to domestic and international customers.

With the expanding use of MRI procedures, both traditional procedures and new intraoperative and interventional procedures, safe and reliable infusion delivery and patient monitoring in an MRI environment is becoming increasingly important to hospitals and other medical providers. Our founder, President, Chief Executive Officer and Chairman of the Board of Directors, Roger Susi, is a pioneer in the MRI compatible medical device industry, having invented the first MRI compatible patient monitoring system in 1986 and the first non-magnetic MRI compatible IV infusion system in 2004.

We were incorporated in Oklahoma in July 1992 and reincorporated in Delaware in April 2014.

We sell our products primarily to hospitals and acute care facilities, both in the United States and internationally. We currently employ a direct sales strategy in the United States and as of December 31, 2017, our direct sales force consisted of 18 field sales representatives, supported by 2 regional sales directors and supplemented by 3 clinical support representatives. Our goal is to continue to expand our U.S. sales force to between 22 and 24 field sales representatives and 6 clinical support representatives by the end of 2018. Internationally, we market our products into approximately 50 countries through the use of independent distributors.

As of December 31, 2017 we have sold approximately 4,500 MRI compatible IV infusion pump systems globally. In December 2016, we began shipping our 3880 Monitor in small quantities to certain of our international customers. In October 2017, we received FDA 510(k) clearance for our 3880 Monitor and immediately began our selling efforts in the United States.

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We generate revenue from the one-time sale of our MRI compatible medical devices and accessories. Recurring revenue is generated from ongoing service contracts and the sale of disposable products used with our devices. In fiscal year 2017, our revenue was $23.1 million and our operating profit was $1.3 million representing an operating margin of 5.6 percent. Refer to the information contained under the caption Financial Highlights and Outlook regarding our outlook for 2018.

Our internet website is www.iradimed.com. We make available on the Investors section of our website, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and Proxy Statements, and amendments to those reports, as soon as reasonably practicable after filing such documents with, or furnishing such documents to, the SEC. We include our website address throughout this filing for reference only. The information contained on our website is not incorporated by reference to this report.

History and Development

Mr. Susi founded Invivo Research Inc. in 1979 where he developed the first MRI compatible patient monitoring system. Mr. Susi served as the President of Invivo Research Inc. from 1979 until 1998, and as its Chairman of the Board of Directors from 1998 until 2000. Under Mr. Susi s leadership, Invivo Research matured from a start-up medical device company into a leading producer of vital signs monitoring devices used during MRI procedures. Invivo Research was acquired by Invivo Corporation in 1992, which began trading on the NASDAQ Stock Exchange in 1994. Mr. Susi served as a Director of Invivo Corporation from 1998 until 2000 and oversaw technical areas from 2000 to 2004. Invivo Corporation was acquired by Intermagnetics General Corporation in 2004. The Invivo MRI compatible vital signs monitoring system, currently owned by Koninklijke Philips NV (NYSE: PHG), continues to maintain a market-leading position.

Mr. Susi began exploring the market for an MRI compatible IV infusion pump while at Invivo. Invivo subsequently disclaimed any interest in the infusion pump and acknowledged that Mr. Susi was free to pursue the infusion pump development for his own account. Accordingly, Mr. Susi began the formal and detailed development of what subsequently has become our MRidium MRI compatible IV infusion pump system. This first generation MRI compatible IV infusion pump system and its associated proprietary IV tubing sets obtained FDA 510(k) market clearance in March 2005 after which we began our sales and marketing efforts.

We commenced international sales through a network of distributors and in 2006, we signed an exclusive distribution agreement with Mallinckrodt/Tyco Healthcare (now part of Medtronic plc (NYSE: MDT)) for domestic and Canadian distribution of our products including the MRidium 3850 MRI compatible IV infusion pump system (the predecessor to our current 3860+ model). The exclusive arrangement ended in 2010, allowing us to implement a direct marketing strategy with our own sales force in the U.S. and Canada.

In 2009, we introduced our second generation MRI compatible IV infusion pump system, the MRidium 3860+ which improved upon the previous 3850 version in a number of areas, including the addition of blood oxygen saturation monitoring (SpO2), and remote wireless monitoring capability. An SpO2 monitor can signal when an insufficient level of oxygen is being supplied to the body. Our MRidium 3860+ is the only MRI compatible IV infusion pump system on the market today.

In 2014, we began developing our own MRI compatible patient vital signs monitoring system (3880 Monitor). Through the use of current and new technologies, and our trade secrets, we believe our 3880 Monitor improves on the design of other MRI compatible vital signs monitors. Our 3880 Monitor has a compact and lightweight design, overcoming many of the workflow issues created by other larger and heavier MRI

compatible monitors currently in the market. In December 2016, we made our first shipments of the 3880 Monitor to international customers. In October 2017, we received FDA 510(k) clearance for our 3880 Monitor and immediately began our direct selling efforts in the United States.

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Industry

We currently compete in the MRI compatible medical device market.

Need for MRI Compatible IV Infusion Pumps and Vital Signs Monitors

MRI is a widely-used, non-invasive medical imaging technique to visualize vital organs, body function and to identify blockages, abnormalities and growths. MRI is generally considered safer than other scanning techniques that expose the body to radiation. This is particularly true for children. As such, hospitals and other medical facilities have been increasingly developing and using MRI for new procedures. These procedures include cardiac stress testing, intraoperative MRI and neurology MRI techniques. Our MRI compatible products offer a way to continuously deliver essential IV fluids safely and accurately while also monitoring the vital signs of critically ill or sedated patients, thereby allowing the expanded use of MRI procedures, better or quicker diagnoses and treatments that may lead to shorter hospital stays resulting in lower health care costs.

While the benefits and uses of interventional magnetic resonance (MR) are known, there are hazards intrinsic to the MR environment which must be respected. These hazards may be attributed to a powerful static magnetic field, pulsed gradient magnetic fields, and pulsed radio frequency fields. The MRI suite is a harsh place for medical devices, and safe and proper patient care requires specialty equipment that is specifically designed and built for the MR environment. Many of the dangers and problems present in the MR environment can be solved through use of non-magnetic equipment that have operational safeguards and that maintain performance standards within a harsh magnetic environment while simultaneously maintaining patient safety. Designing MRI compatible medical devices that operate safely and effectively in the MR environment requires overcoming significant technical hurdles.

Intravenous fluids and vital signs monitoring are needed during MRI procedures for many different reasons. Infusion pumps provide sedation to patients who are not able to remain immobile during an MRI scan and a continuous flow of critical medications to seriously ill patients. Given the benefits to patient safety, radiology departments performing the scan, anesthesia departments delivering sedation and critical care specialists responsible for delivering critical medications during MRI procedures often initiate requests for an MRI compatible IV infusion pump. Additionally, the Joint Commission on Accreditation of Healthcare Organizations requires monitoring of a patient s vital signs while under sedation. Further, vital signs monitoring is also required when the patient s condition prevents them from alerting clinicians when experiencing pain, respiratory problems, cardiac distress or other difficulties that may arise during an MRI scan.

Standard Infusion Pumps and Other Inadequate Alternatives

For those medical facilities that do not currently own an MRI compatible IV infusion pump, there are five general methods that are used to deal with patients undergoing an MRI who require IV medications during their imaging procedure: (1) do not offer MRI treatment to patients requiring IV delivered medications or sedation; (2) use standard (magnetic) pumps with long IV lines that extend outside the MRI scanner room; (3) proceed and accept patients for an MRI procedure but stop the flow of IV fluids during the procedure; (4) allow the gravity controlled free drip of IV fluids; and (5) attempt to shield a conventional IV infusion pump. All of these approaches have drawbacks, introduce safety risks and may result in deficient patient care.

Use of multiple lengths of extension tubing can cause infusion inaccuracies, unnecessary waste of costly medications and false alarms or, more seriously, delayed alarms for equipment issues such as occlusion, especially when low flow rates are being used. Such makeshift extension sets can also affect the effectiveness of fluid delivery. A clinician s adjustment of dosage and other settings may take longer to reach the patient due to the over-extended tubing.

Further, there are risks in using a standard IV infusion pump that is mistakenly believed to be at a safe distance from the MR scanner. The powerful magnetic fields may cause metal objects in the MR environment to be drawn with great force into the bore of the MR system, resulting in potentially deadly projectiles. Moreover, an MR scanner s gradient magnetic field and RF fields can send currents through cables and other conductive materials that are near the MR system and cause the cables to heat, which may result in burns if they come into contact with the patient or facility staff.

Other problems include devices malfunctioning if they are not properly designed for use in the harsh MR environment and low-quality MR images due to artifacts caused by RF interference emitted from ancillary equipment.

To deal with the harsh environment of MR, some manufacturers have offered a shielded box solution (also known as a Faraday cage) for use with their standard IV pumps, but the approach has not been widely accepted by customers. The major problem with this approach is that a highly magnetic standard IV infusion pump is still being introduced into a hazardous MRI environment which can lead to projectile accidents. Additionally, placing a highly magnetic standard IV infusion pump inside a shielded box

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hinders an operator s ability to determine the pump s status and creates inefficiencies when addressing an alarm or revising a pump s flow rate. Moreover, a Faraday cage with a standard IV infusion pump must be kept approximately 5 to 10 feet from the scanner, which may result in the use of long IV lines. By contrast, our MRI compatible IV infusion pump system can be safely placed anywhere in the scanner room including next to the scanner. We are not aware of any shielded box installations in use in the U.S. or any with a FDA 510(k) clearance and hence, we expect little current competition from this approach in the U.S.

We believe that our MRidium MRI compatible IV infusion pump system is the first and only product to provide an easy-to-operate, non-magnetic, safe and RF-quiet solution and hence a truly MRI compatible product.

Market Opportunities

Addressable Market

MRI Compatible IV Infusion Pump

We view our MRI compatible IV infusion pump primarily as a safety device. Accordingly, we do not actively market our IV infusion pump systems in countries that we believe do not have a minimum level of patient safety standards to warrant a device like ours. We estimate there are approximately 11,250 MRI scanners installed globally in acute care facilities of sufficient sophistication as to be considered supporting favorable market conditions for our MRI compatible IV infusion pump system. Of the facilities currently using our MRI compatible IV infusion pumps, many have elected to purchase more than one IV infusion pump system per MRI scanner installed. Based on our historical sales and customer pump purchases, we estimate that our current global market opportunity represents approximately 18,000 MRI compatible IV infusion pump systems, of which approximately 55 percent is located in the U.S.

MRI Compatible Patient Vital Signs Monitor

The market for MRI compatible multi-parameter vital signs monitors is well-developed and more subject to replacement cycles than new adoptions. Our current estimate of global annual sales of MRI multi-parameter vital signs monitors is approximately 1,000 to 1,200 units, of which we believe that approximately 70 percent to 80 percent is located in the U.S. We believe that annual unit sales are growing at approximately 6 percent. This unit count equates to a current annual market of approximately $70 million to $80 million, before including the associated accessories, disposables and services.

Additionally, this unit estimate is based on a ratio of one MRI patient vital signs monitor per MRI scanner, which is driven primarily by the large size and weight of existing MRI monitors currently available from competitors. Given the compact and lightweight design of our MRI monitor, which facilitates intra-hospital transport of patients while maintaining continuous monitoring of vital signs, we believe we have an advantage and can expand the market to achieve a ratio of greater than one of our 3880 Monitors per MRI scanner.

Expansion of Intra-Hospital Use of MRI Compatible Devices

Historically, we marketed our MRI compatible IV infusion pump primarily to the MRI departments of hospitals. We believe, however, that there is potential for expanded deployment of our MRI compatible IV infusion pumps and MRI compatible monitors within the Intensive Care Unit (ICU), Emergency Room (ER), and other critical care departments within the hospital where there is a high probability that MRI procedures will need to be performed on patients. Expanded use of our MRI compatible medical devices would serve as a type of transport package and allow for consistent and uninterrupted administration of IV fluids and monitoring of vital signs, allowing for easier and safer intra-hospital transport of patients to and from the MRI scanner. Accordingly, at the beginning of 2016, we implemented a critical care strategy whereby we began to market our MRI compatible IV infusion pumps to ICU and ER departments as well as our historical call points in radiology and anesthesiology. We implemented this same marketing strategy for our 3880 Monitor after receiving FDA 510(k) clearance in October 2017.

It is often necessary for a patient in a critical care department of the hospital who is connected to a standard vital signs monitor and a standard IV infusion pump that is delivering critical medications to be quickly moved to the MRI facility for immediate imaging. The presence of our MRI compatible medical devices in those critical care departments enables the orderly and rapid transfer between those standard medical devices to our 3880 Monitor and MRidium MRI compatible IV infusion pump in the critical care department prior to transporting the patient for an MRI. Seriously ill patients are generally at higher risk when they are away from the resources of critical care departments, and efficient transfers to MRI compatible devices while the patient is in the critical care environment minimizes the time the patient spends away from the critical care department.

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We believe there is a higher occurrence of equipment-related adverse events during the intra-hospital transport of critically ill patients. We therefore believe that placing our MRI compatible devices in critical care departments could reduce patient adverse events associated with vital signs monitors and IV pump transfers typically performed within MRI departments.

Some hospitals have begun to use MRI during surgical procedures. Neurosurgical interventions have been at the forefront of this development in image-guided surgery, followed by otolaryngological procedures. As MR-guided intervention during surgery has been deployed, the degree of complexity in supplemental devices has increased markedly. Much of the effort required for successful implementation of intraoperative MRI has been in development and testing of anesthesia equipment, patient monitoring devices, infusion pumps and surgical instruments and accessories, all of which need to be MRI compatible if used near the MRI scanner. Intraoperative MRI is expanding demand for our MRI compatible devices from the MRI suite to the surgical suite of the hospital.

Strategy

Company Objective

Our objective is to become the leader in providing safe and effective care for all patients undergoing MRI procedures through the development and commercialization of a portfolio of MRI compatible products. By increasing the safety parameters of equipment operating within the harsh magnetic environment of the MRI scanner room, we hope to enable hospitals and other healthcare providers to offer the MRI diagnostic procedures patients require. We believe our current products increase the safety of performing MRI diagnostics for critically ill patients and children by minimizing potential complications with IV infusions and vital signs monitoring.

We seek to grow our business by, among other things:

Driving market awareness of our MRI compatible IV infusion pump and the safety risks associated with using conventional IV pumps with long IV lines

We believe that the largest potential market for our MRI compatible IV infusion pumps is the segment of the market that is currently using workaround solutions. Such solutions include using conventional pumps outside the MRI scanner room and attaching multiple extension lines of IV tubing sets through the wall or under the door into the MRI scanner room to reach the patient. This practice of makeshift setups is fraught with risks to the patient and unnecessary costs and inefficiencies. These risks and inefficiencies include:

- Infection risk from running lengthy IV tubing sets with multiple extensions through the wall or under the door;

- Risk of inaccuracy from using a conventional IV infusion pump with multiple extension lines;

- Potential medication occlusion and lengthy alarm notification delays due to multiple extension lines, posing a great risk to a patient on critical medications;

- Excess medication costs due to the disposal of multiple extension IV tubing sets filled with unused medication at the end of the procedure; and

- Lost productivity and MRI scanning time due to the lengthy set up time required for multiple extension lines.

We believe that increased market awareness and education will be required for potential customers to appreciate the value for patients and the hospital of an efficient and patient-safe MRI environment which includes MRI compatible IV infusion pumps.

Driving market awareness of our MRI compatible patient vital signs monitoring system

We believe our 3880 MRI compatible patient vital signs monitoring system creates customer value by resolving significant workflow issues through the additional utilization that is not possible with other MRI monitors. Our 3880 Monitor s compact and lightweight design facilitates the transportation of patients from their critical care unit, to the MRI and back, resulting in increased patient safety through uninterrupted vital signs monitoring and decreasing the amount of time critically ill patients are away from critical care units. Because of the transport capabilities that only our 3880 Monitor offers, we believe multiple departments within a hospital will be interested in purchasing our device. Other MRI monitors are too large and heavy for use in patient transport scenarios are therefore typically only located in the MRI departments of hospitals. We began marketing our 3880 Monitor internationally in December 2016 and received FDA 510(k) clearance in October 2017. Upon receipt of FDA 510(k) clearance, we immediately began marketing the 3880 Monitor to domestic customers.

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Continuing to innovate with MRI compatible patient care products

Our management team collectively has more than 100 years of experience with MRI compatible products. We have entrenched relationships with many of the industry s top thought leaders and we have, and will continue to, closely collaborate with them to build upon IRADIMED s innovative MRI compatible technologies. We intend to leverage this experience and collaboration to innovate and commercialize other technologically-advanced MRI patient care products.

When reasonably available, acquiring synergistic MRI patient care companies, products or technology licenses to accelerate our product development and leverage our existing direct sales organization in the U.S.

We have an experienced team of engineering and operations managers committed to improving on existing MRI patient care designs through our internal development efforts and the acquisition of technologies and intellectual property of others. We have a developing and growing direct sales organization in the U.S. and a team of experienced international distributors that can effectively go to market with additional MRI patient care products. We continue to analyze such opportunities to improve our product mix and profitability.

Commercial Strategy

We believe that the MRI compatible IV infusion pump market continues to have growth potential given the low rate of market penetration, and we aim to drive increased awareness and adoption of our MRI compatible products by:

Expanding our MRI-focused U.S. direct sales force and our international sales efforts

We believe the most meaningful aspect of our commercialization strategy in the U.S. is the continued development and expansion of our direct sales force. Since there is no current direct competitor for an MRI compatible IV infusion pump, our focus is on expanding the market through better education on the advantages to patients, clinicians and hospitals of our infusion pump solution and the shortcomings of current workaround practices. Additionally, with the launch of our 3880 Monitor, we will now focuse on educating customers on the total workflow benefits our device offers and how our device increases patient safety through its transport capabilities.

Since 2011, our U.S. sales team has grown from one field sales representative to a team of 18 direct field sales representatives, 2 regional sales directors and 3 clinical support representatives. As business progress dictates, we intend to continue to add to our specialized, MRI product-focused sales team, including clinical support representatives. We believe that we can significantly increase sales of our MRI compatible medical devices by also calling on anesthesia and critical care departments, which may help influence hospitals purchasing decisions. We believe that this strategy will likely expand the number of acute care facilities using our MRI compatible products and increase the average number of MRI compatible IV infusion pumps and monitors per MRI scanner.

Internationally, our focus is to continue working with our distributors in key target markets, such as Europe and Japan, to expand the business and augment our market penetration rates. During 2018, we plan to begin the expansion of our internal capacity to serve these high potential markets by adding a dedicated regional sales manager located outside the U.S. to oversee our relationships at the local level.

Supporting commercial efforts with evidence-based information

We focus our sales team on educating customers on the safety and efficiency benefits of using our MRI compatible products. To assist in the education process, we have developed materials that document the risks and additional costs associated with using a workaround solution of running long lines from conventional IV pumps outside the MRI scanner room. We are also developing materials documenting the benefits of uninterrupted vital signs monitoring that allows for easy transfer of critically ill patients from ICU or ER to the MRI scanner room and back. We believe this kind of evidence-based documentation will help us to provide widespread education to the clinicians that are driving clinical practice. We also believe that documented evidence will serve to inform the quality and risk management leaders in these organizations, which in turn may help drive the overall adoption of our MRI compatible products.

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Providing best in class customer service and user experience

We believe that the expectations of our customers for service and a superior user experience have risen with the advancement of technology. Once a customer purchases our products, it is imperative that they receive first-class clinical education and support to encourage usage of our products. We devote a significant amount of time and training to ensure that this educational experience is a success. This training is performed most commonly by our sales staff and is augmented by our clinical support representatives; however, we intend to hire more clinical support specialists to strengthen our initial training experience and increase ongoing customer support. We believe that a positive user experience is critical to driving increased rates of utilization of our products.

Our Products

Typical MRI Scanner Room

The following diagram is representation of an aerial view of a typical MRI scanner room with a top-of-the-line 3T magnet. The gauss-lines illustrate the distance from the magnet where various types of medical devices can safely operate. Our MRidium MRI compatible IV infusion pump is the only pump on the market approved to operate safely and reliably near the patient (area shown in blue). All of the other pumps must either be placed at a distance from the MRI scanner, which may include being outside of the scanner room entirely. Additionally, our 3880 MRI compatible patient vital signs monitor is the only MRI monitor that can operate safely and reliably in very close proximity to the bore of the powerful magnet used to operate the MRI (area shown in red).

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We currently offer two primary product types: (1) a MRI compatible IV infusion pump system with associated disposable IV tubing sets, and (2) a MRI compatible patient vital signs monitoring system.

MRidium MRI Compatible IV Infusion Pump System

The patented MRidium MRI compatible IV infusion pump system is based upon a non-magnetic, ultrasonic motor and other uniquely-designed non-ferrous parts in order to provide accurate and dependable fluid delivery to patients undergoing an MRI procedure. Our MRidium MRI compatible IV infusion pump system has been designed to offer numerous advantages to hospitals, clinicians and patients. MRidium s strengths include the following:

- The only non-magnetic MRI compatible IV infusion pump system specifically designed and built for the MRI environment.

- A mobile, rugged, easy-to-operate, and reliable system with a strong safety record.

- Able to operate virtually anywhere in the MRI scanner room; approved for use in the presence of 0.2T to 3T magnets and fully operational up to the 10,000 gauss-line.

- Available with a Dose Error Reduction System (DERS) to reduce the risk of medication errors and simplify clinician monitoring.

- Available with a wireless remote display/control providing clinicians and technicians control and visibility from outside of the MRI scanner room.

- Available with an add-on channel allowing for the easy addition of a second IV line for patients requiring multiple IV medications at a low incremental cost to the hospital.

- Available with a built-in SpO2 monitor using Masimo SET® technology and a specially designed fiber optic SpO2 sensor allowing one device to monitor oxygen saturation levels while safely providing IV infusion during an MRI procedure.

Our MRI compatible IV infusion pump system includes the 3860+ MRI compatible IV infusion pump, proprietary single-use IV tubing sets, a non-magnetic pole and a lithium battery. In addition, we offer optional upgrade systems including the 3861 Side Car, 3865 Remote Display/Control, DERS and an SpO2 monitor as discussed below.

MRidium 3860+ MRI Compatible IV Infusion Pump

The MRidium 3860+ MRI compatible IV infusion pump system was introduced in 2009 and improved upon the performance and features of our first generation MRidium 3850 MRI compatible IV infusion pump system. Our pump system can operate dependably in the presence of 0.2T to 3T magnets and are fully operational up to the 10,000 gauss-line. This means they are highly versatile and can operate virtually anywhere in the MRI scanner room, including close to the MRI scanner. The MRidium 3860+ MRI compatible IV infusion pump system has a 10-key numeric input keypad making our system easy to accurately program and operate. Our pumping range of 0.1 mL per hour to 1,400 mL per hour provides a broad range of fluid flow control. Our broad range of infusion rates support differing patient needs including low levels for pediatric sedation, mid-levels for continued IV infusion of medications to critically-ill patients and high levels in the event of emergency situations. Our MRidium 3860+ MRI compatible IV infusion pump system offers a dose rate calculator, bolus dose programming, full alarm settings, and a rechargeable battery with a 12-hour battery life.

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MRidium 3860+ IV Tubing Sets

The MRidium 3860+ MRI compatible IV infusion pump system utilizes proprietary fluid delivery tubing sets, each known as an IV tubing set. Each use of our MRI compatible IV infusion pump requires a disposable IV tubing set. We offer a variety of IV tubing sets for varying MRI scenarios and these include our standard spike infusion set, syringe adapter infusion set and extension infusion set. Each of our IV tubing sets is latex-free and DEHP-free.

- *MRidium 1056 Standard Infusion Set.* Our standard spike infusion set features the ability to accurately deliver liquids from either a bottle or IV bag. Our standard infusion set contains two needle-free injection ports and is typically used when starting a new infusion from a bottle or bag.

- *MRidium 1057 Syringe Adapter Infusion Set.* Our syringe adapter IV set enables users to provide accurate delivery of IV fluids directly from standard syringes. The vented syringe adapter set benefits from a low priming volume of 4 ml, which minimizes inefficient waste of medication. This product is most commonly used for cardiac medications, anesthesia, and pediatric drug delivery.

- *MRidium 1058 Extension Infusion Set.* Our extension infusion set allows users to transfer a patient on a non-MRI infusion pump to our MRidium MRI compatible IV infusion pump. The user simply disconnects the existing IV tubing at the patient site and connects and primes the MRidium extension set to the existing IV tubing. Once removed from the conventional infusion pump and connected to our MRidium MRI compatible IV infusion pump, the user can program the pump and begin the infusion. The extension set includes one needle-free injection port and is typically used to provide uninterrupted critical medications to a severely ill patient during an MRI procedure.

MR IV Pole

We offer a fully-functional and weighted non-magnetic IV pole that is designed for mobility within the hospital and the MRI scanner room. The IV pole can support two MRidium MRI compatible IV infusion pumps, each with a 3861 Side Car Pump Module. The IV pole is 66 inches (1.68 meters) high, stabilized with a wide pole radius and mobilized with five casters designed to roll easily during transport. The IV pole is equipped with four hooks for holding fluid bags.

Optional Features

Our 3860+ MRI compatible IV infusion pump system gives customers the ability to adapt their systems to meet their specific needs. In addition to our standard product features, we also offer system upgrades which include a modular add-on second IV channel through our Side Car, a

wireless remote control/display, DERS and an imbedded SpO2 monitor. We also offer rechargeable lithium polymer battery packs which have 12-hour battery life when not connected to an electrical outlet.

3861 Side Car Pump Module

Our Side Car Pump Module can be attached to our 3860+ MRidium MRI compatible IV infusion pump to provide a second channel for infusion delivery. This flexible option allows hospitals to convert their single-channel infusion pump into a dual-channel system designed to deliver both large and small volume fluids in the MRI scanner room. The side car is fully functional with our 3865 MRidium Wireless Remote, allowing clinicians the ability to control both channels with one remote control unit outside of the MRI scanner room. The additional delivery line has all of the same features and benefits as the 3860+ MRidium MRI compatible IV infusion pump, as described above.

3865 MRidium Wireless Remote Display/Control

Our wireless remote control units allow for complete control and monitoring of the MRidium MRI compatible IV infusion pump system from the control room (outside of the MRI scan room). The 3865 MRidium Wireless Remote relays all commands and displays information bi-directionally between the MRI compatible IV infusion pump and the remote control unit. Utilizing the same user interface and large bright display as the MRidium pump, our wireless remote control unit permits clinicians to adjust all pump parameters, including SpO2 monitoring parameters, rates, dose, volume, pump run/stop, alarms (adjust or reset), as well as real-time titration. Our remote control unit utilizes a proven MRI compatible 2.4 GHz frequency hopping spread spectrum radio technology for artifact-free operation that does not disturb the MRI imaging process. Clinicians may also use the remote control unit to adjust a second pump channel when used in combination with our Side Car unit discussed above. Our 3865 MRidium Wireless Remote also functions as a battery charger for our MRidium battery pack.

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Dose Error Reduction System (DERS)

Our DERS software for use with our MRidium 3860+ MRI compatible IV infusion pump system incorporates the latest dosing safety features for patients. The DERS system enables users to create a unique drug library and establish nominal values and limits for dose and concentration for specified infusion protocols. With DERS, patient safety and user convenience are supported by user-programmed infusion hard limits (maximum and minimum) and soft limits (high and low limits that require user confirmation to exceed). The dose applied via DERS is displayed and can be adjusted directly on the running screen at any time during the infusion. The universal memory card port allows for easy archiving and updating of the drug library.

SpO2 Monitoring with Sensor and Accessories

Our MRidium 3860+ MRI compatible IV infusion pump system also offers state-of-the-art Masimo SET® SpO2 capability providing a unique ability to have SpO2 monitoring and IV delivery combined in one unit. This feature offers users the ability to start sedations outside of the MRI scanner room, transport to the scanner, and then back to recovery without having to discontinue SpO2 monitoring of the patient. In addition, our fiber optic MRI-SpO2 sensor and accessories provide a safe connection between the patient and our MRI compatible IV infusion pumps. This fiber optic-based SpO2 sensor delivers outstanding performance while avoiding potentially hazardous heating or image artifact during MR scans. The method of patient attachment uses a medical-grade silicone rubber sensor grip that allows easy and convenient attachment to the patient s hand or foot, and accommodates pediatric, adult, and infant patients with various size grips.

We believe our MRidium 3860+ MRI compatible IV infusion pump system and its customizable features comprehensively and uniquely address the needs of MRI departments within hospitals and other medical facilities.

MRI Compatible Patient Vital Signs Monitoring System

The 3880 Monitor has been designed with non-magnetic components and other special features in order to safely and accurately monitor a patient s vital signs during various MRI procedures. The 3880 Monitor system operates dependably in magnetic fields up to 30,000 gauss, which means it can operate virtually anywhere in the MRI scanner room, including in very close proximity to the MRI scanner bore (see above diagram).

Our 3880 Monitor has a compact, lightweight design allowing it to travel with the patient from their critical care unit, to the MRI and back, resulting in increased patient safety through uninterrupted vital signs monitoring and decreasing the amount of time critically ill patients are away from critical care units.

The basic configuration of the 3880 Monitor includes wireless ECG with dynamic gradient filtering; wireless SpO2 using Masimo® algorithms, and non-invasive blood pressure. Optional features include all or a combination of non-magnetic respiratory CO2; patient temperature, and/or;

optional advanced multi-gas anesthetic agent unit featuring continuous Minimum Alveolar Concentration measurements.

The MRI compatible patient vital signs monitoring system also includes: (1) an extended range remote tablet that allows for remote monitoring from outside the MRI scanner room; (2) a base station control center that facilitates printing, wireless communications between the remote tablet and the monitor, and acts as a battery charger for the remote tablet, and; (3) wireless ECG and SpO2 pods that facilitate the respective monitoring modalities. We are also currently working on additional features that will be offered as options in the future.

Intellectual Property

We protect our proprietary technology through a combination of patents, trade secrets and confidentiality agreements. During the development of our products, our founder, Roger Susi, obtained a number of patents regarding our MRI compatible IV infusion pump and related systems. Mr. Susi has irrevocably assigned these patents to us. We consider our patents important but do not believe our future success is materially dependent upon patents.

We have ten issued U.S. patents and four issued foreign patents with remaining lives that range from 5 to 14 years. Additionally, prior December 31, 2017, we were notified by the U.S. Patent and Trademark Office that the terms on two of our existing patents were to be extended as of January 2018. We also have a number of U.S. patent applications pending. These patents and patent applications relate to several of our products, including our MRI compatible IV infusion pump system and its components. We intend to file patent applications with respect to future patentable developments and improvements when we believe that such protection is in our best interest.

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We also rely on trade secret, copyright and other laws and on confidentiality agreements to protect our technology, but we believe that neither our patents nor other legal rights will necessarily prevent third parties from developing or using similar or related technology to compete against our products. Moreover, our technology may be viewed as improvements or adaptations of known MRI infusion technology, which might be duplicated or discovered through our patents, reverse engineering or both.

Sales and Marketing

We sell our MRI compatible products through our direct sales force in the U.S. and independent distributors internationally. In the U.S., we sell our products through our 18 direct field sales representatives, 2 regional sales directors and 3 clinical support representatives. We have distribution agreements for our products with independent distributors selling our products internationally. We have developed an experienced team of international distributors that have a strong MRI/radiology product portfolio and focus. Our international distributors are managed by our VP of International Sales, an industry veteran with over 20 years in the IV infusion pump business and over 10 years managing our international sales.

The percentage of total revenue generated by geographic region was as follows:

	Percent of Revenue Years Ended December 31,		
	2017	2016	2015
United States	84.5%	88.9%	91.3%
International	15.5%	11.1%	8.7%

The percentage of total revenue generated by product type was as follows:

	Percent of Revenue Years Ended December 31,		
	2017	2016	2015
Devices	67.0%	79.3%	83.4%
Disposable IV Sets and Services	33.0%	20.7%	16.4%

We define backlog as of a particular date to mean firm purchase orders from customers for which have we have not yet fulfilled. As part of our commitment to customer service, our goal is to ship products to meet the customers requested shipment dates. Our backlog is occasionally subject to cancellation or rescheduling by the customer on short notice with little or no penalty. Because of the uncertainty of order cancellations or rescheduling, we do not believe our backlog as of any particular date is indicative of actual sales for any future period and, therefore, should not be used as a measure of future revenue.

For the years ended December 31, 2017, 2016 and 2015, backlog was approximately:

(In millions)	Year ended December 31, 2017	2016	2015
Backlog	$ 2.7	$ 1.6	$ 13.9

Historical selling cycles for our devices have varied widely and are now typically three to six months in duration. To supplement the efforts of our sales and clinical support representatives, we produce and distribute videos that provide users of our MRidium products an easy means for learning clinical applications. These videos guide users through a detailed step-by-step process in using our MRI compatible IV infusion pump system, including initial product set-up, selection of infusion sets, loading the infusion pump, programming the pump, managing alarms and alerts and prompts, SpO2 monitoring, and other advanced functions. Users also benefit from our detailed operator manuals and 24/7 technical support via telephone. We intend to develop similar customer support materials for our 3880 MRI compatible patient vital signs monitoring system in the near future.

The principal customers for our MRI compatible products include hospitals and acute care facilities. The key decision maker in a purchase varies on the hospital department making the purchase. We serve these customers through our sales and service specialists and believe that our specialists are well-positioned to build upon these customer relationships. We communicate with our customers on a regular basis in an attempt to understand potential issues or concerns as well as to improve our products and services in response to their needs. Product orders and inquiries are handled by trained service representatives who communicate with customers after equipment shipments, installations and service repair calls. We have implemented various other programs which enable us to assess our customers needs. These programs include regular surveys and visits to customer sites.

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We enter into agreements with healthcare supply contracting companies, commonly referred to as Group Purchasing Organizations (GPOs) in the U.S., which enable us to sell and distribute our products to their member hospitals. GPOs negotiate volume purchase prices for hospitals, group practices, and other clinics that are members of a GPO. Our agreements with GPOs typically include the following provisions:

- Negotiated pricing for all group members;
- Volume discounts and other preferential terms on their members purchases from us;
- Promotion of our products by the GPO to its members; and
- Payment of administrative fees by us to the GPO, based on purchases of our products by group members.

Under these agreements, we are required to pay the GPOs a fee of three percent of the sales of our products to hospitals, group practices, and other acute care facilities that are members of the GPO. Our current GPO contracts effectively give us the ability to sell to more than 95 percent of all U.S. hospitals and acute care facilities.

Manufacturing and Suppliers

We assemble our products in our facilities in Winter Springs, Florida, from components and sub-assemblies purchased from outside suppliers. We perform final assembly, testing and packaging to control quality and manufacturing efficiency. We purchase components and sub-assemblies from qualified suppliers that are subject to our stringent quality specifications and inspections by us. We conduct quality audits of our key suppliers, several of which are experienced in the supply of components to manufacturers of finished medical devices or disposables for use with these medical devices. Our historical track record of producing MRI compatible products has been good; however, there can be no assurance that this trend will continue or that we will be able to produce sufficient units to reach our expected revenue growth rates.

Some of the raw materials and parts that are critical to the production and operation of our products are sourced from single suppliers. We have never encountered a significant supply interruption from any sole supplier and have received no indications that there might be disruptions of the supply of these raw materials or parts. We typically maintain no less than a three-month supply of raw materials and parts that are sourced from sole suppliers and make efforts to identify additional suppliers who may be able to provide such raw materials or parts. For example, the non-magnetic, ultrasonic motor which drives our MRI compatible IV infusion pump is sole-sourced from a major multinational Japanese manufacturing company with whom we have an excellent long-term relationship. This company has exclusively provided us with these motors since 2005, and we have an exclusive supply agreement with this company through 2019.

We place significant emphasis on providing quality products and services to our customers. Quality management and oversight play an essential role in understanding and meeting customer requirements, effectively resolving quality issues and improving our products and services. We have a network of quality systems throughout our facilities that relate to the design, development, assembly, packaging, sterilization, handling, distribution and labeling of our products.

To assess and facilitate compliance with applicable requirements, we periodically review our quality systems to determine their effectiveness and identify areas for improvement.

We also conduct compliance training programs for our sales and marketing personnel and perform assessments of our suppliers of raw materials, components and finished goods. In addition, we conduct quality management reviews designed to inform management of key issues that may affect the quality of our products. From time to time, we may determine that products manufactured or marketed by us do not meet our specifications, published standards or regulatory requirements. When a quality issue is identified, we investigate the issue and seek to take appropriate corrective action, such as withdrawal of the product from the market, correction of the product at the customer location, notice to the customer of revised labeling or a combination of these or other corrective actions.

In January 2007, we received ISO 13485 certification and met the requirements under the European Medical Device Directive to use the CE Mark, thereby allowing us to continue to market our products in the European Community. In January 2018 we underwent an audit to update our ISO 13485:2016 and Medical Device Single Audit Program certifications and currently await our certificates of compliance. These certificates will need renewal again in January 2019.

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Competition

The medical products industry is generally characterized by intense competition and extensive research and development. The market for medical products is subject to rapid change due to an increasingly competitive, cost-conscious environment and to government programs intended to reduce the cost of medical care. Many manufacturers and distributors of medical equipment are large, well-established companies whose resources, reputations and ability to leverage existing customer relationships might give them a competitive advantage over us. We believe that a company s reputation for producing accurate, reliable and technologically-advanced products, references from users, features (speed, safety, ease of use, patient convenience and range of applicability), product effectiveness and price are the principal competitive factors in the medical products industry.

Our SpO2 products, which measure blood oxygen saturation and included in our MRI compatible IV infusion pump and our MRI compatible vital signs monitor also compete indirectly with many other methods currently used to measure blood oxygen levels or the effects of low blood oxygen levels.

MRidium MRI Compatible IV Infusion Pump System

We do not believe there is currently any direct competition for our MRI compatible IV infusion pump system. Our only direct competitor in the MRI compatible IV infusion pump market, Bayer Radiology, formerly MEDRAD, Inc., announced during 2013 its decision to remove its competing Continuum pump system from the market, and discontinued support throughout the world in June 2015 due to ongoing regulatory issues. As a result, we believe that our MRidium 3860+ MRI compatible IV infusion pump is the only true MRI compatible IV infusion pump available today.

The medical device and IV infusion market is highly regulated and is typically one of the areas that the FDA scrutinizes closely for new market introductions. Because of this, the 510(k) FDA clearance process for new infusion pumps is usually long and requires significant testing and documentation. This long development timeline coupled with the low market penetration to date may discourage new competitors from undertaking a complex project like building an MRI compatible IV infusion pump. We believe that the market for MRI compatible IV infusion pump products is in relatively early stages of development and may become highly competitive if, and when, the market develops further.

Outside of the U.S., we also compete with manufacturers of shielded box solutions that are intended to permit use of conventional IV pumps inside the MRI scanner room. The providers of shielded boxes include B. Braun, Fresenius Kabi, MIPM Mammendorfer Institut für Physik und Medizin, and Arcomed.

Another potential competitor may be CareFusion Corporation (now part of Becton, Dickinson and Company (NYSE: BDX)). CareFusion is a major medical device manufacturer that has a dominant position in the conventional IV infusion pump market and made an investment in Caesarea Medical Electronics (CME) in December 2013. CME manufactured Bayer Radiology s Continuum Pump System, which was withdrawn from the U.S. market in 2014. CME markets this pump in international markets as MR compatible. In addition, B. Braun may seek to obtain FDA clearance for its SpaceStation MRI Trolley, currently only available outside the U.S., which allows traditional B. Braun IV infusion pumps to be used in the MR environment.

Many of our potential customers opt not to purchase our MRI compatible IV infusion pump systems and instead use makeshift workarounds, such as placing conventional IV infusion devices outside of the MRI scanning room and utilizing extension tubing to reach the patient. To this extent, we are in competition with conventional IV infusion pump manufacturers and distributors.

There are many manufacturers of conventional IV infusion pump devices, and if any of these manufacturers, or other potential competitors, decide to enter into the MRI compatible IV infusion pump market, they may have competitive advantages over us. Many of these potential competitors have established reputations, customer relationships and marketing, distribution and service networks. In addition, they have substantially longer histories in the medical products industry, larger product lines and greater financial, technical, manufacturing, management, and research and development budgets. Many of these potential competitors may have long-term product supply relationships with our potential customers.

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MRI Compatible Patient Vital Signs Monitoring System

There are several manufacturers that have developed competing MRI compatible vital signs monitoring systems that are currently on the market. We believe the dominant competitor with a market-leading position in MRI compatible vital signs monitoring is Invivo Research, Inc., which was founded by Roger Susi, our current founder, President, CEO and Chairman of the Board of Directors. Invivo is now owned by Koninklijke Philips NV (NYSE: PHG). Other large and well-known companies such as General Electric (NYSE: GE) and Schiller AG, also have competing products as do other smaller privately held companies. Each of these manufacturers have competitive advantages over us they may have established customer relationships, product supply agreements, longer histories in the MRI monitoring market and several have greater financial, technical, manufacturing, management, and research and development budgets. Additionally, our 3880 MRI compatible patient vital signs monitor is new to the market, which may result in customers being reluctant to switch from other well-known and established MRI compatible monitoring systems to ours.

Seasonality

Our business is seasonal. Our third quarter sales have typically been lower, compared to other fiscal quarters, principally because the fiscal quarter coincides with the summer vacation season, in the U.S., Europe, and Japan.

Segment Information and Geographic Data

Our business operates as one reportable segment. Financial information about geographic areas is presented in Note 13 in the Notes to Financial Statements of this Annual Report on Form 10-K.

Research and Development

Our research and development efforts focus on developing innovative products by utilizing our established core competencies in MRI compatible technologies and feedback from strategic relationships with hospitals, acute medical facilities and medical equipment manufacturers for new product ideas. Our research and development efforts are driven by the leadership of our founder, Roger Susi, assisted by engineers and technical professionals with significant experience in product design.

Our research and development expenses were $1.7 million or 7.5 percent of revenue in 2017, $1.3 million or 4.1 percent of revenue in 2016 and $1.8 million or 5.6 percent of revenue in 2015. During 2016, we capitalized $0.7 million of research and development costs associated with internally developed software that operates our new MRI compatible patient vital signs monitoring system.

Employees

As of December 31, 2017, we had 83 full-time employees, including 32 in manufacturing, 29 in sales and marketing and customer support services, 7 in regulatory affairs, 10 in finance and administration and 5 in research and development. No employees are represented by a labor union. We have not experienced any work stoppages and consider our relations with our employees to be good.

Regulatory Matters

Governmental Regulation and Other Matters

Our medical device products are subject to extensive, complex and increasing oversight and regulation by the U.S. Food & Drug Administration (FDA), and other domestic and foreign governmental authorities. Our manufacturing and other facilities, and those of our suppliers, are subject to periodic inspections to verify compliance with current FDA and other governmental regulatory requirements. If it were determined that we were not in compliance with these laws and regulations, we could be subject to criminal or civil liability, or both, and other material adverse effects. We have compliance programs in place to support and monitor compliance with these laws and regulations. All of our products and facilities and those of our suppliers are subject to drug and medical device laws and regulations promulgated by the FDA and national and supranational regulatory authorities outside the U.S., including, for example, Health Canada s Health Products and Foods Branch, the U.K. s Medicines and Healthcare Products Regulatory Agency, and Australia s Therapeutic Goods Agency. These authorities regulate a range of activities including, among other matters, manufacturing, post-marketing studies in humans, advertising and promotion, product labeling, post-marketing surveillance and adverse event reporting.

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Regulation of Medical Devices in the United States

The development, manufacture, sale and distribution of our medical device products are subject to comprehensive governmental regulation. Most notably, all of our medical devices sold in the United States are subject to the Food, Drug, and Cosmetic Act of 1938, as amended (FDC Act), as implemented and enforced by the FDA. The FDA, and in some cases other government agencies, such as the U.S. Federal Communications Commission (FCC), administer requirements covering the design, testing, safety, effectiveness, manufacturing, labeling, promotion and advertising, distribution and post-market surveillance of our products.

Unless an exemption applies, each medical device that we market must first receive either premarket notification clearance (by making what is commonly called a 510(k) submission) or premarket approval (by filing a premarket approval application (PMA) from the FDA pursuant to the FDC Act. In addition, certain modifications made to marketed devices also may require 510(k) clearance or approval of a PMA supplement. The FDA s 510(k) clearance process usually takes up to twelve months, but it can last longer. The process of obtaining PMA approval is much more costly, lengthy and uncertain. It generally takes from two to three years or even longer. All of our current products that are available in the U.S. were originally cleared through the 510(k) process. However, on September 2, 2014, we received a warning letter from the FDA requesting that we cease commercial distribution of our products and submit a new 510(k) for our MRI compatible IV infusion pump system. Refer to the section below captioned *FDA Facility Inspection and Warning Letter.* We cannot be sure that future products or modifications of current products, will qualify for the 510(k) pathway or whether 510(k) clearance or PMA approval will be obtained for any future product that we propose to market.

In December 2014, the FDA issued guidance entitled Infusion Pumps Total Product Life Cycle. This guidance established substantial additional pre-market requirements for new and modified infusion pumps. Through this guidance, the FDA indicated more data demonstrating product safety will be required for future 510(k) submissions for infusion pumps, including the potential for more clinical and human factors data. The impact of this guidance is likely to result in a more time consuming and costly process to obtain regulatory clearance to market infusion pumps. In addition, new requirements could result in longer delays for the clearance of new products, modification of existing infusion pump products or remediation of existing products in the market. Future delays in the receipt of, or failure to obtain, approvals could result in delayed or no realization of product revenues.

After a device is placed on the market, numerous regulatory requirements continue to apply. Those regulatory requirements include the following: product listing and establishment registration; adherence to the Quality System Regulation (QSR), which requires stringent design, testing, control, documentation and other quality assurance procedures; labeling requirements and FDA prohibitions against the promotion of off-label uses or indications; adverse event reporting; post-approval restrictions or conditions, including post-approval study commitments; post-market surveillance requirements; the FDA s recall authority, whereby it can ask for, or require, the recall of products from the market; and requirements relating to voluntary corrections or removals.

All aspects of our manufacturing and distribution of regulated products and those of our suppliers are subject to substantial governmental oversight. Facilities used for the production, packaging, labeling, storage and distribution of medical devices must be registered with the FDA and other regulatory authorities. All manufacturing activities for these products must be conducted in compliance with current good manufacturing practices (cGMPs). Our manufacturing facilities and those of our suppliers are subject to periodic, routine and for-cause inspections to verify compliance with cGMPs. If, upon inspection, the FDA or another regulatory agency finds that a manufacturer has failed to comply with cGMPs, it could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions, such as product recalls or seizures, monetary sanctions, consent decrees, injunctions to halt manufacturing and distributing products, civil or criminal sanctions, refusal to grant clearances or approvals or delays in granting such clearances or approvals, import detentions of products made outside of the United States, restrictions on operations or withdrawal or suspension of existing approvals. The FDA also has the authority to request repair, replacement or refund of the cost of any medical device manufactured or distributed by us. These actions could result in, among other

things, substantial modifications to our business practices and operations; a total or partial shutdown of production in one or more facilities while we or our suppliers remedy the alleged violation; the inability to obtain future pre-market clearances or approvals; and withdrawals or suspensions of current products from the market. Any of these events could disrupt our business and have a material adverse effect on our revenues, profitability and financial condition.

FDA Facility Inspection and Warning Letter

The FDA conducted a routine inspection of our prior facility between April 7 and April 16, 2014. This was the first FDA inspection of our facility since the voluntary product recall in August 2012 of certain infusion sets and the voluntary recall in July 2013 of our DERS software. The FDA issued a Form 483 on April 16, 2014 that identified eight observations. The majority of the observations related to procedural and documentation issues associated with the design, development, validation testing and documentation of software used in certain of our products. Other observations were related to the design validation of pump labeling, design analysis of tube stretching, procedures for post-market design review, and control and procedures related to handling certain

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reported complaints. We submitted responses to the Form 483 in May 2014 and June 2014 in which we described our proposed corrective and preventative actions to address each of the FDA s observations.

On September 2, 2014, we received a warning letter from the FDA relating to this inspection (the Warning Letter). The Warning Letter states that the FDA accepted as adequate several of our responses to Form 483 observations, identified two responses whose accuracy will be determined in the next scheduled inspection of our facility and identified issues for which our response was determined to be inadequate. The issues identified as inadequate concern our procedures for validating device design primarily related to software quality assurance.

Also, the Warning Letter raised a new issue. The Warning Letter states that modifications made to software on our previously cleared infusion pumps, the MRidium 3860 and MRidium 3850, were significant and required submission of new premarket notifications under Section 510(k) (a 510(k) submission) of the FDC Act. These modifications had been made over time. We believed they were insignificant and did not require premarket notification submissions. However, the FDA indicated that the modifications of the software for the MRidium 3860 and the software for the MRidium 3850 were significant modifications because they could significantly affect the safety or effectiveness of these devices. As a result, the Warning Letter states that the products being sold by us are adulterated and misbranded under the FDC Act. The Warning Letter also indicates that the MRidium 3860+ infusion pump requires separate FDA clearance from the MRidium 3860 and MRidium 3850.

The Warning Letter requested that we immediately cease activities that result in the misbranding or adulteration of the MRidium 3860 MRI infusion pump, MRidium 3850 MRI infusion pump, and the MRidium 3860+ MRI infusion pump, including the commercial distribution of the devices. We immediately complied with the Warning Letter and ceased sale and distribution of the identified products in the United States.

On September 4, 2014, we submitted to the FDA our initial response to the Warning Letter and on September 17, 2014 we sent an additional response that included supplemental information related to the Form 483 inspection observations for which the FDA considered our initial responses inadequate.

On November 25, 2014, we announced that we filed the 510(k) submission related to our MRidium 3860+ MRI IV infusion pumps and on December 12, 2014 we were notified that our 510(k) submission had been formally accepted for review by the FDA. On December 22, 2014, under FDA enforcement discretion, we announced that we resumed domestic distribution of our MRI compatible MRidium 3860+ MRI IV infusion pump systems, without the DERS option. On January 28, 2015, under FDA enforcement discretion, we announced that we resumed domestic distribution of our DERS option. On December 9, 2015, we met with the FDA to review responses to the agency s additional information letter.

Between July 11 and July 18, 2016, the FDA conducted a routine inspection of our facility. This was the first FDA inspection of our facility since the receipt of the Warning Letter. During this inspection, the updated documents and actions implemented in response to the Warning Letter findings were reviewed, and the FDA determined that no further actions were necessary.

On December 15, 2016, we received FDA 510(k) clearance for our MRidium 3860+ MRI IV infusion pump system, including the DERS software feature. As of December 31, 2017, the Warning Letter remains open.

Product Recalls and Software Updates

Dose Error Reduction System (DERS) Software Recall. Some of our MRidium 3860+ MRI compatible IV infusion pumps are equipped with a DERS. Due to a software issue observed on June 19, 2013, the drug dosage calculation indicated an incorrect recommended value for the flow rate when a specific key sequence was used during the infusion setup. As a result, a patient was infused with an incorrect flow rate. No harm to the patient was reported. On July 1, 2013, we issued an urgent medical device recall notice (the DERS Recall) and promptly made available to our customers a software update to resolve the error. On July 2, 2013, the subject of the recall was discussed with the FDA by phone. On July 12, 2013, we provided written notification to the FDA of the DERS Recall and submitted a Medical Device Report (MDR) with the FDA describing the incident, the investigative and corrective actions taken, the reason for the DERS Recall and the recall strategy. On September 18, 2013, we notified the FDA that all of the pumps sold with the DERS kits had been successfully upgraded with the software correction and reported that the DERS Recall was completed as of September 16, 2013. We requested that the FDA officially close the DERS Recall. On July 14, 2015, the FDA closed this recall and no further actions are necessary. We believe the financial expenses incurred related to the recall were not significant to our operations or financial results.

We have made substantial investments in quality systems and we will continue to make improvements to our products and systems to further reduce potential issues related to patient safety and avoid recalls in the future. Product quality plays a critical role in our success. While we believe that we have made significant improvements to our product quality and overall quality systems, further

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quality concerns, whether real or perceived, could adversely affect our results. Conversely, improving quality can be a competitive advantage and improve our results. For more information about risks related to these matters, see the section captioned *Defects or failures associated with our products and/or our quality control systems could lead to the filing of adverse event reports, recalls or safety alerts and negative publicity and could subject us to regulatory actions* in the Risk Factors section.

MRidium 3860+ Software Field Update. As a result of the Warning Letter, required 510(k) submission and subsequent 510(k) clearance as discussed above in the section entitled FDA Facility Inspection and Warning Letter we are required to field updated software for our MRidium 3860+ IV infusion pump to existing customers. Subsequent to the end of 2016, we began the software update efforts and expect to complete this action during the first half of 2018. We have accrued for all expected expenses related to this action and believe these expenses will not be significant to our operations or financial results.

Healthcare Fraud and Abuse Laws

As a manufacturer and distributor of medical devices to hospitals and other healthcare providers, we and our customers are subject to laws which apply to Medicare, Medicaid, and other federal and state healthcare programs in the U.S. One such law, the Anti-kickback Statute, prohibits the solicitation, offer, payment or receipt of remuneration in return for referral or purchase, or in return for the recommending or arranging for the referral or purchase, of products covered by the programs. The Anti-kickback Statute provides a number of exceptions or safe harbors for particular types of transactions. While we generally do not file claims for reimbursement from government payers, the U.S. federal government has asserted theories of liability against manufacturers under the Federal False Claims Act, which prohibits the submission of false claims to Medicare, Medicaid, and other state and federal programs. Many states have similar fraud and abuse laws which may apply to us. Violations of these fraud and abuse-related laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in healthcare programs such as Medicare and Medicaid and health programs outside the United States. We have developed and implemented business practices and processes to train our personnel to perform their duties in compliance with healthcare fraud and abuse laws. While we conduct informal oversight to detect and prevent these types of fraud and abuse, we lack formal written policies and procedures at this time. If we were unable to document and implement the controls and procedures required in a timely manner or otherwise violate such laws, we might suffer adverse regulatory consequences or face criminal sanctions, which could harm our operations, financial reporting or financial results.

Regulation of Medical Devices Outside of the United States

Medical device laws also are in effect in many of the non-U.S. markets in which we do business. These laws range from comprehensive device approval requirements for some or all of our products to requests for product data or certifications. Inspection of and controls over manufacturing, as well as monitoring of device-related adverse events, also are components of most of these regulatory systems. Most of our business is subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation balanced with a goal of optimizing international harmonization. For example, the European Union (EU), which currently relies on independent third parties, (called Notified Bodies) rather than governmental authorities to review and certify medium and high risk medical devices, is moving to more governmental oversight of medical devices. Currently, the regulatory requirements for a broad spectrum of medical devices are covered in three European Medical Device Directives (adopted in the 1990 s) with which manufacturers must comply in order to receive a CE Certificate of Conformity (CE Mark) from a Notified Body. Only certified medical devices bearing a CE Mark can be sold in the EU and European Free Trade Association (EFTA) countries and Turkey. EFTA includes Iceland, Norway, Principality of Liechtenstein and Switzerland.

In September 2012, the European Commission, (EC), proposed significant revisions to the regulatory framework for medical devices in the EU. The proposed changes include more oversight of Notified Bodies by governmental authorities, replacing the three European Medical Service Directives with two regulations and more stringent requirements for clinical evidence while also enhancing alignment with international guidelines to facilitate international trade. It is unknown how the proposed revisions will affect certification of future products or modifications of current products, but it is possible that more clinical data will be needed to support our applications, which would increase the costs and development time involved. We may lose our current quality system certification due to ISO Registrar difficulties as European authorities increase regulatory pressure or increased scrutiny resulting from the EU s Revised Medical Device Directive. The loss of the quality system certification may prevent product shipments to the EU and to other foreign markets, such as Canada. The EU has enacted legislation restricting the use of hazardous substances in electronic equipment (Directive 2011/65/EU, referred to as RoHS 2), such as our infusion pumps. The application of RoHS 2 to medical devices became effective as of July 22, 2014. Our MRidium 3860+ pumps systems are compliant with RoHS 2. If we are unable to remain compliant with RoHS 2, there may be an interruption of sales to the EU, which could significantly lower our revenues from foreign sales while we take remedial measures.

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Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the U.U., commonly referred to as Brexit. On March 29, 2017, the country formally notified the E.U. of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant portion of the regulatory framework in the United Kingdom is derived from E.U. directives and regulations, the referendum could materially impact the regulatory regime with respect to our products in the United Kingdom or the E.U. Any delay in obtaining, or an inability to obtain, any device certifications, product marketing approvals, or other regulatory authorizations as a result of Brexit or otherwise, could prevent us from commercializing our products in the United Kingdom and/or the E.U. and affect our operations and financial results.

Anti-Bribery Laws

Our global activities are subject to the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act, and other countries anti-bribery laws that have been enacted in support of the Organization for Economic Cooperation and Development s Anti-bribery Convention. These laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. government officials with the intent to inappropriately gain a business advantage. They also require companies to maintain accurate books and records and internal financial controls. The U.K. Bribery Act also prohibits commercial bribery and makes it a crime for a company to fail to prevent bribery. Companies have the burden of proving that they have adequate procedures in place to prevent bribery. The enforcement of such laws in the U.S. and elsewhere has increased dramatically in the past few years, and authorities have indicated that the pharmaceutical and medical device industry is a significant focus for enforcement efforts.

Because of the predominance of government-sponsored healthcare systems around the world, many of our customer relationships outside of the United States are with governmental entities. Our policies mandate strict compliance with the anti-bribery laws. We operate in many parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices.

Transparency Laws in the U.S. and Other Countries

There are numerous requirements imposed by states in the U.S. on the interaction of pharmaceutical and medical device companies with physicians. For example, several states and the District of Columbia either require the tracking and reporting of specific types of interactions with healthcare professionals or restrict such interactions. A similar requirement was imposed at the federal level under the sunshine provision of Patient Protection and Affordable Care Act, (the Sunshine Provisions), to track and report payments and transfers of value to U.S. physicians or teaching hospitals by manufacturers of medical products that are available for reimbursement by a federal insurer.

Other Laws

We are also subject to a variety of other laws, directives and regulations in and outside of the U.S., including those related to the following:

- environmental laws and regulations;

- the safety and health laws of the U.S. Occupational Safety and Health Act, which sets forth requirements for workplace conditions;

- California s Proposition 65, which sets forth a list of substances that are deemed by the State of California to pose a risk of carcinogenicity or birth defects; and

- various customs, export control, anti-boycott and trade embargo laws and regulations administered by U.S. and foreign government agencies, including the U.S. Customs and Border Protection, the Bureau of Industry and Security, the Department of Commerce and the Office of Foreign Assets Control Treasury Department, as well as others.

Despite our training and compliance program, our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents in violation of any of these laws.

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ITEM 1A. RISK FACTORS

Risks Relating to Our Business and Financial Condition

Our financial performance is significantly dependent on a single product, and disruptions in our ability to sell this product may have a material adverse effect on our business.

Our current revenue and profitability is significantly dependent on the sale of the MRidium 3860+ MRI compatible IV infusion pump system (a Class II medical device) and the ongoing sale of disposable tubing sets and related services. Sales of the MRidium 3860+ MRI compatible IV infusion pump system have historically comprised a substantial majority of our net revenue. Although we have recently launched our marketing efforts for our new 3880 MRI compatible patient vital signs monitor in the U.S., our near-term revenue and profitability will be dependent upon our ability to successfully market and sell the MRidium 3860+ MRI compatible IV infusion pump system.

In the past, the FDA has issued us a Warning Letter that impacted our ability to commercially distribute our MRidium 3860+ MRI compatible IV infusion pump system. Although we have resumed commercial distribution of the MRidium 3860+ MRI compatible IV infusion pump system, the Warning Letter remains open and there can be no guarantee that the FDA will not take similar action in the future. The FDA could require us to cease shipment of our products, notify health professionals and others that the devices present unreasonable risk or substantial harm to public health, order a recall, repair, replacement, or refund of the devices, detain or seize adulterated or misbranded medical devices, or ban the medical devices. The FDA may also issue further warning letters or untitled letters, refuse future requests for 510(k) submission or premarket approval, revoke existing 510(k) clearances or premarket approvals previously granted, impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices and assess civil or criminal penalties against our officers, employees, or us.

The MRidium 3860+ MRI compatible IV infusion pump could be rendered obsolete or economically impractical by numerous factors, many of which are beyond our control, including but not limited to:

- entrance of new competitors into our markets;
- technological advancements of MRI scanners;
- technological developments such as new imaging modalities which render MRI procedures obsolete or reduce the instances where MRI imaging is utilized;

- loss of key relationships with suppliers, group purchasing organizations, or end-user customers;
- manufacturing or supply interruptions;
- product liability claims;
- our reputation and product market acceptance; and
- product recalls or safety alerts.

Any major factor adversely affecting the sale of our MRidium 3860+ MRI compatible IV infusion pump would cause our revenues to decline and have a material adverse impact on our business, financial condition and our common stock.

We have been subject to securities class action litigation and derivative litigation and we may be subject to similar or other litigation in the future.

In the past, following adverse action by the FDA or volatility in our stock price, securities class action litigation has been brought against us. There can be no assurance that we will not face other securities litigation in the future. With respect to any litigation, our insurance may not reimburse us or may not be sufficient to reimburse us for the expenses or losses we may suffer in contesting and concluding such lawsuits. A decision adverse to our interests on these actions or resulting from these matters could result in the payment of substantial damages and could have a material adverse effect on our business, financial condition and our common stock. Regardless of the outcome, these claims may result in injury to our reputation, significant costs, diversion of management s attention and resources, and loss of revenue.

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There is no assurance that our internal and external sources of liquidity will at all times be sufficient for our cash requirements.

We must have sufficient sources of liquidity to fund our working capital requirements, our capital improvement plans, and execute on our strategic initiatives. Our recent decline in operating results has limited our capital resources, and could worsen if we are unable to increase revenues or adjust our costs appropriately. Further, our 3880 Monitor launch demands increased working capital before any return is realized from increased revenue. Our ability to achieve our business and cash flow plans is based on a number of assumptions which involve significant judgments and estimates of future performance, borrowing capacity and credit availability, which cannot at all times be assured. Accordingly, there is no assurance that cash flows from operations and other internal and external sources of liquidity will at all times be sufficient for our cash requirements. If necessary, we may need to consider actions and steps to improve our cash position and mitigate any potential liquidity shortfall, such as modifying our business plan, pursuing additional financing to the extent available, reducing capital expenditures, pursuing and evaluating other alternatives and opportunities to obtain additional sources of liquidity and other potential actions to reduce costs. There can be no assurance that any of these actions would be successful, sufficient or available on favorable terms. Any inability to generate or obtain sufficient levels of liquidity to meet our cash requirements at the level and times needed could have a material adverse impact on our business and financial position.

Our continued success depends on the integrity of our supply chain, including multiple single-source suppliers, the disruption of which could negatively impact our business.

Many of the component parts of our products are obtained through supply agreements with third parties. Some of these parts require our partners to engage in complex manufacturing processes and involve long lead times or delivery periods. In light of our dependence on third-party suppliers, several of which are single-source suppliers, we are subject to inherent uncertainties and risks related to their ability to produce or deliver parts on a timely basis, to comply with product safety and other regulatory requirements and to provide quality parts to us at a reasonable price.

For example, we are dependent upon a single vendor for the ultrasonic motor at the core of our MRidium MRI compatible IV infusion pump. If this vendor fails to meet our volume requirements, which we anticipate will increase over time, or if the vendor becomes unable or unwilling to continue supplying motors to us, this would impact our ability to supply our pumps to customers until a replacement source is secured. Our executed agreement with this vendor provides that the price at which we purchase products from the vendor is determined by mutual agreement from time to time or should material costs change. Although we have had a long history of stable pricing with this supplier, this provision may make it difficult for us to continue to receive motors from this vendor on favorable terms or at all if we do not agree on pricing in the future. In such event, it could materially and adversely affect our commercial activities, operating results and financial condition.

In the near term, we do not anticipate finding alternative sources for our primary suppliers, including single source suppliers. Therefore, if our primary suppliers become unable or unwilling to manufacture or deliver materials, or manufacture or deliver such materials later than anticipated, we could experience protracted delays or interruptions in the supply of materials which would ultimately delay our manufacture of products for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results and financial condition.

Additionally, any failure by us to forecast demand for, or to maintain an adequate supply of raw materials, parts, or finished products, could result in an interruption in the supply of certain products and a decline in our sales.

We rely on third-party suppliers for certain of our raw materials and components.

We rely on unaffiliated third-party suppliers for certain raw materials and components necessary for the manufacturing and operation of our products. Certain of those raw materials and components are proprietary products of those unaffiliated third-party suppliers and are specifically cited in our applications with regulatory agencies so that they must be obtained from that specific sole source or sources and could not be obtained from another supplier unless and until an appropriate application amendment is approved by the regulatory agency. For example, the non-magnetic ultrasonic motor which drives our MRI compatible IV infusion pump is sole-sourced from a major multinational Japanese manufacturing company.

Among the reasons we may be unable to obtain these raw materials and components include:

- a supplier s inability or unwillingness to continue supplying raw materials and/or components;

- regulatory requirements or action by regulatory agencies or others, including changes in international trade treaties and/or tariffs;

- adverse financial or other strategic developments at or affecting the supplier, including bankruptcy;

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- unexpected demand for or shortage of raw materials or components;

- failure to comply with quality standards which results in quality and product failures, product contamination and/or recall;

- discovery of previously unknown or undetected imperfections in raw materials or components;

- labor disputes or shortages, including from the effects of health emergencies and natural disasters; and

- political instability and actual or anticipated military or political conflicts.

These events could negatively impact our ability to satisfy demand for our products, which could have a material adverse effect on our product use and sales and our business and results of operations. We may experience these or other shortages in the future resulting in delayed shipments, supply constraints, contract disputes and/or stock-outs of our products.

The manufacture of our products requires strict adherence to regulatory requirements governing medical devices and if we or our suppliers encounter problems our business could suffer.

The manufacture of our products must comply with strict regulatory requirements governing Class II medical devices in the U.S. and other regulatory requirements in foreign locations. Problems may arise during manufacturing, quality control, storage or distribution of our products for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, manufacturing quality concerns, or problems with raw materials, electromechanical, software and other components, supplier issues, and natural disasters. If problems arise during production of our pump, the affected products may have to be discarded. Manufacturing problems or delays could also lead to increased costs, lost sales, damage to customer relations, failure to supply penalties, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches of products. If problems are not discovered before the product is released to the market, voluntary recalls, corrective actions or product liability related costs may also be incurred. Should we encounter difficulties in the manufacture of our products or be subject to a product recall, our business could suffer materially.

Our markets are very competitive and we sell certain of our products in a mature market.

The market for our 3880 MRI compatible patient vital signs monitoring system is well-developed and sales growth for our monitor in the U.S. could be slow. Our vital signs monitoring system could face difficult competition, including competitors offering lower prices, which could have an adverse effect on our revenue and margins. Our competitors may have certain competitive advantages, which include the ability to devote

greater resources to the development, promotion, and sale of their products. Consequently, we may need to increase our efforts, and related expenses for research and development, marketing, and selling to maintain or improve our position. We may not realize the per unit revenue we hav planned for and expect. Continued sales to our existing customers is expected to be significant to our revenue in the future, and if our existing customers do not continue to purchase from us, our revenue may decline.

We manufacture and store our products at a single facility in Florida.

We manufacture and store our products at a single facility in Winter Springs, Florida. If by reason of fire, hurricane or other natural disaster, or for any other reason, the facility is destroyed or seriously damaged or our access to it is limited, our ability to provide products to our customers would be seriously interrupted or impaired and our operating results and financial condition would be materially and negatively affected.

Our inability to collect on our accounts receivables held by significant customers may have an adverse effect on our business operations and financial condition.

We market our products to end users in the United States and to distributors internationally. Sales to end users in the United States are generally made on open credit terms. Management maintains an allowance for potential credit losses. From time to time, we have had accounts receivables from one or two customers that accounted for 10 percent or more of our gross accounts receivable. As a result, we may be exposed to a certain level of concentration of credit risk. If a major customer experiences financial difficulties, the effect on us could be material and have an adverse effect on our business, financial condition and results of operations.

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If we fail to maintain relationships with Group Purchasing Organizations, sales of our products could decline.

Our ability to sell our products to U.S. hospitals, acute care facilities and outpatient imaging centers depends in part on our relationships with Group Purchasing Organizations (GPOs). Many existing and potential customers for our products are members of GPOs. GPOs negotiate pricing arrangements and contracts, which are sometimes exclusive, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO s affiliated hospitals and other members. We pay the GPOs an administrative fee in the form of a percentage of the volume of products sold to their affiliated hospitals and other members. If we are not an approved provider selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products. Should a GPO negotiate a sole source or bundling contract covering a future or current competitor s products, we may be precluded from making sales of our competing products to members of that GPO for the duration of the contractual arrangement. For example, even if we have an existing contract with a GPO for sales of our MRidium 3860+ MRI compatible IV infusion pump, we may encounter difficulties in selling, or be unable to sell, our 3880 MRI compatible patient vital signs monitoring system to that GPO s affiliated hospitals and other members, which may result in a longer sales cycle or an inability. Our failure to renew contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. In the future, if another competitive supplier emerges, and we fail to keep our relationships and develop new relationships with GPOs, our competitive position would likely suffer.

Cost-containment efforts of our customers and purchasing groups could adversely affect our sales and profitability.

Our MRI compatible IV infusion pumps are considered capital equipment by many potential customers, and hence changes in the budgets of healthcare organizations and the timing of spending under these budgets and conflicting spending priorities can have a significant effect on the demand for our products and related services. Any decrease in expenditures by these healthcare facilities could decrease demand for our products and related services and reduce our revenue. Additionally, changes to reimbursement policies by third-party payors could also decrease demand for our products and related services and reduce our revenue.

Any failure in our efforts to educate clinicians, anesthesiologists, radiologists, and hospital administrators regarding the advantages of our products could significantly limit our product sales.

Our future success will require us to educate a sufficient number of clinicians, anesthesiologists, radiologists, hospital administrators and other purchasing decision-makers about our products and the costs and benefits of our products. If we fail to demonstrate the safety, reliability and economic benefits of our products to hospitals and acute medical facilities, our products may not be adopted and our expected and actual sales would suffer.

The lengthy sales cycle for medical devices could delay our sales.

The decision-making process of customers is often complex and time-consuming. Based on our experience, we believe the period between initial discussions concerning the MRidium 3860+ MRI compatible IV infusion pump and a purchase of a unit is typically three to six months and expect the same for our 3880 MRI compatible patient vital signs monitor. Sales cycles can also be delayed as a result of capital budgeting procedures. Moreover, even if one or two units are sold to a hospital, we believe that it will take additional time and experience with our products before other medical professionals routinely use them for other procedures and in other departments of the hospital. Such time would

delay potential sales of additional units and disposable products or additional optional accessories to that medical facility or hospital. These delays could have an adverse effect on our business, financial condition and results of operations.

Because we rely on distributors to sell our products outside of the U.S., our revenues could decline if our existing distributors do not continue to purchase products from us or if our relationship with any of these distributors is terminated.

We rely on distributors for all of our sales outside the U.S. and hence do not have direct control over foreign sales activities. These distributors also assist us with regulatory approvals and the education of physicians and government agencies. Our revenues outside the U.S. have historically represented approximately one-tenth to one-third of our net revenues. If our existing international distributors fail to sell our products or sell at lower levels than we anticipate, we could experience a decline in revenues or fail to meet our forecasts. We cannot be certain that we will be able to attract new international distributors nor retain existing ones that market our products effectively or provide timely and cost-effective customer support and service. None of our existing distributors are obligated to continue selling our products.

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If we do not successfully develop and commercialize enhanced products or new products that remain competitive, we could lose revenue opportunities and customers, and our ability to achieve growth would be impaired.

The medical device industry is characterized by rapid product development and technological advances, which places our products at risk of obsolescence. Our long-term success depends upon the development and successful commercialization of new products, new or improved technologies and additional applications for MRI compatible infusion, therapeutic, diagnostic and safety products and services. The research and development process is time-consuming and costly and may not result in products or applications that we can successfully commercialize. If we do not successfully adapt our technology, products and applications, we could lose revenue opportunities and customers. In addition, we may not be able to improve our products or develop new products or technologies quickly enough to maintain a competitive position in our markets and continue to grow our business.

We are highly dependent on our founder, CEO, President, Chairman and controlling shareholder, Roger Susi.

We believe that Mr. Susi will play a significant role in our continued success and in the development of new products. Our current and future operations could be adversely impacted if we were to lose his services. Accordingly, our success will be dependent on appropriately managing the risks related to executing a succession plan for Mr. Susi on a timely basis.

If we fail to attract and retain the talent required for our business, our business could be materially harmed.

Competition for highly skilled personnel is often intense in the medical device industry, and more specifically in the MRI compatible medical device industry. If our current employees with experience in the MRI compatible device industry leave our company, we may have difficulty finding replacements with an equivalent amount of experience and skill, which could harm our operations. Our future success will also depend in part on our ability to identify, hire and retain additional personnel, including skilled engineers to develop new products, and executives to oversee our marketing, sales, customer support and production staff. We may not be successful in attracting, integrating or retaining qualified personnel to meet our current growth plans or future needs. Our productivity may be adversely affected if we do not integrate and train our new employees quickly and effectively.

We may also have difficulty finding and retaining qualified Board members. Any failure to do so could be perceived negatively and could adversely affect our business.

Also, to the extent we hire personnel from competitors, we may be subject to allegations that we have improperly solicited, or that they have divulged proprietary or other confidential information, or that their former employers own their inventions or work product.

We may be unable to scale our operations successfully.

We are working to expand our size and scale via more penetration of existing markets and the launch of new complementary products. This growth, if it occurs as planned, will place significant demands on our management and manufacturing capacity, as well as our financial, administrative and other resources. We cannot guarantee that any of the personnel, systems, procedures and controls we put in place will be adequate to support the manufacture and distribution of our products. Our operating results will depend substantially on the ability of our officers and key employees to manage changing business conditions and to implement and improve our financial and administrative systems and manage other resources. If we are unable to respond to and manage changing business conditions, or the scale of our products, services and operations, then the quality of our services, our ability to retain key personnel and our business could be harmed.

We engage in related party transactions, which result in a conflict of interest involving our management.

We have engaged in the past, and continue to engage, in related party transactions, particularly between our company and Roger Susi and his affiliates. The only significant ongoing related party transaction is the lease agreement between our company and Susi, LLC, an affiliate of Roger Susi, with respect to our sole production and headquarters facility in Winter Springs, Florida. Related party transactions present difficult conflicts of interest, could result in disadvantages to our company and may impair investor confidence, which could materially and adversely affect us. Related party transactions could also cause us to become materially dependent on related parties in the ongoing conduct of our business, and related parties may be motivated by personal interests to pursue courses of action that are not necessarily in the best interests of our company and our stockholders.

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Any acquisitions of technologies, products and businesses, may be difficult to integrate, could adversely affect our relationships with key customers, and/or could result in significant charges to earnings.

We plan to periodically review potential acquisitions of technologies, products and businesses that are complementary to our products and that could accelerate our growth. However, our company has never completed an acquisition and there can be no assurance that we will be successful in finding any acquisitions in the future. The process of identifying, executing and realizing attractive returns on acquisitions involves a high degree of uncertainty. Acquisitions typically entail many risks and could result in difficulties in integrating operations, personnel, technologies and products. If we are not able to successfully integrate our acquisitions, we may not obtain the advantages and synergies that the acquisitions were intended to create, which may have a material adverse effect on our business, results of operations, financial condition and cash flows, our ability to develop and introduce new products and the market price of our stock.

The environment in which we operate makes it increasingly difficult to accurately forecast our business performance.

Significant changes and volatility in most aspects of the current business environment, including financial markets, consumer behavior, speed of technological, regulatory and competitive changes, make it increasingly difficult for us to predict our revenues and earnings into the future. Our quarterly sales and profits depend substantially on the volume and timing of orders fulfilled during the quarter, and such orders are difficult to forecast. Product demand is dependent upon the capital spending budgets of our customers and prospects as well as government funding policies, and matters of public policy as well as product and economic cycles that can affect the spending decisions of these entities. As a result, any revenue, earnings or financial guidance or outlook which we have given or might give may turn out to be inaccurate. Though we will endeavor to give reasonable estimates of future revenues, earnings and financial information at the time we give such guidance, based on then-current conditions, there is a significant risk that such guidance or outlook will turn out to be incorrect. Historically, companies that have overstated their operating guidance have suffered significant declines in their stock price when such results are announced to the public.

There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with United States GAAP. Furthermore, portions of GAAP require the use of fair value models which are variable in application and methodology from appraiser to appraiser. Any changes in estimates, judgments and assumptions used could have a material adverse effect on our business, financial position and operating results.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Such assumptions and estimates include those related to revenue recognition, accruals for product returns, valuation of inventory, impairment of intangibles and long-lived assets, accounting for income taxes and stock-based compensation and allowances for uncertainties. These factors are also influenced by regular changes to GAAP, some of which are material to most companies, such as recent changes to revenue recognition. These changes introduce risk to our financial report processes due to implementation and internal control implications.

We base the aforementioned estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as discussed in greater detail in the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations. Our actual operating results may differ and fall below our assumptions and the financial forecasts of securities analysts and investors, resulting in a significant decline in our stock price.

Additionally, as we work toward adopting and implementing the new revenue accounting standard, management will make judgments and assumptions based on our interpretation of the new standard. The new revenue standard is principle based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice, and guidance may evolve as we work toward implementing the new standard. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revised the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time,

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and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law.

Risks Related to Our Industry

We are subject to substantial government regulation that is subject to change and could force us to make modifications to how we develop, manufacture, market and price our products.

The medical device industry is regulated extensively by governmental authorities, principally the FDA in the U.S. and corresponding state and foreign regulatory agencies. The majority of our manufacturing processes are required to comply with quality systems regulations, including current good manufacturing practice requirements that cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging and shipping of our products. Failure to comply with applicable medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspensions of production, refusal of the FDA or other regulatory agencies to grant pre-market clearances or approvals for our products, withdrawals or suspensions of future or current clearances or approvals and criminal prosecution.

In addition, our products are subject to pre-clearance requirements by the FDA and similar international agencies that govern a wide variety of product activities from design and development to labeling, manufacturing, promotion, sales and distribution. Compliance with these regulations may be time consuming, burdensome and expensive for us. The failure to obtain, or the loss or suspension of any such pre-approval, would negatively affect our ability to sell our products, and harm our anticipated revenues.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we sell our products in foreign countries, we may be subject to rigorous regulation in the future. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated revenue.

If we fail to obtain, or experience significant delays in obtaining, FDA clearances or other necessary approvals to commercially distribute new products, our ability to maintain profitability or grow will suffer.

Our current products are Class II medical devices and hence require regulatory pre-market approval by the FDA and other federal and state authorities prior to their sale in the U.S. Similar approvals are required by foreign governmental authorities for sale of our products outside of the U.S. We are responsible for obtaining the applicable regulatory approval for the commercial distribution of our products. As part of our strategy, we plan to seek approvals for new MRI compatible products. The process of obtaining approvals, particularly from the FDA, is costly and time consuming, and there can be no assurance that we will obtain the required approvals on a timely basis, or at all. Failure to receive approvals for new products will hurt our ability to grow.

We are subject to risks associated with doing business outside of the U.S.

Sales to customers outside of the U.S. have historically comprised of approximately one-tenth to one-third of our net revenues and we expect that non-U.S. sales will contribute to future growth. A majority of our international sales originate from Europe and Japan, and we also make sales in Canada, Hong Kong, Australia, Mexico and certain parts of the Middle East. The risks associated with operations outside the U.S. include:

- foreign regulatory and governmental requirements that could change and restrict our ability to manufacture and sell our products;

- possible failure to comply with anti-bribery laws such as the U.S. Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions;

- foreign currency fluctuations that can impact our financial statements when foreign denominations are translated into U.S. dollars;

- different local product preferences and product requirements, which might increase with increasing nationalism;

- trade protection and restriction measures under international trade treaties and via tariffs, and import or export licensing requirements;

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- difficulty in establishing, staffing and managing non-U.S. operations;

- failure to maintain relationships with distributors, especially those who have assisted with foreign regulatory or government clearances;

- changes in labor, environmental, health and safety laws;

- potentially negative consequences from changes in or interpretations of tax laws;

- political instability and actual or anticipated military or political conflicts;

- economic instability, inflation, deflation, recession or interest rate fluctuations;

- uncertainties regarding judicial systems and procedures; and

- minimal or diminished protection of intellectual property.

These risks, individually or in the aggregate, could have an adverse effect on our results of operations and financial condition.

We may incur product liability losses, or become subject to other lawsuits related to our products, business, and insurance coverage could be inadequate or unavailable to cover these losses.

Our business is subject to potential product liability risks that are inherent in the design, development, manufacture and marketing of our medical devices and consumable products. We carry third party product liability insurance coverage to protect against such risks, but there can be no assurance that our policy is adequate. In the ordinary course of business, we may become the subject of product liability claims and lawsuits alleging that our products have resulted or could result in an unsafe condition or injury to patients. Any product liability claim brought against us, with or without merit, could be costly to defend and could result in settlement payments and adjustments not covered by or in excess of our product liability insurance. We currently have third-party product liability insurance with maximum coverage of $5,000,000; however, such coverage requires a substantial deductible that we must pay before becoming eligible to receive any insurance proceeds. The deductible amount is currently equal to $25,000 per occurrence and $125,000 in the aggregate. We will have to pay for defending product liability or other

claims that are not covered by our insurance. These payments could have a material adverse effect on our profitability and financial condition. Product liability claims and lawsuits, safety alerts, recalls or corrective actions, regardless of their ultimate outcome, could have a material adverse effect on our business, financial condition, reputation and on our ability to attract and retain customers. In addition, we may not be able to obtain insurance in the future on terms acceptable to us or at all.

Defects or failures associated with our products and/or our quality control systems could lead to the filing of adverse event reports, recalls or safety alerts and negative publicity and could subject us to regulatory actions.

Safety problems associated with our products could lead to a product recall or the issuance of a safety alert relating to such products and result in significant costs and negative publicity. An adverse event involving one of our products could require us to file an adverse event report with the FDA. Such disclosure could result in reduced market acceptance and demand for all of our products, and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our applications for new product approvals or clearances.

We may also voluntarily undertake a recall of our products or temporarily shut down production lines based on internal safety, quality monitoring and testing data. For example, in August 2012, we initiated a voluntary recall of a particular lot of MRidium Series 1000 MR Infusion Sets, Type 1058 MR IV, an extension set used with our MRidium MRI compatible IV infusion pumps, due to an out-of-specification dimension of one section of the IV set. We retrieved and destroyed all unused infusion sets subject to the recall. In July 2013, the FDA notified us that it had concluded its audit and confirmed that the recall was considered terminated. In July 2013, we issued a voluntary recall of our MRI compatible IV infusion pump systems equipped with MRidium 1145 DERS Drug Library due to their potential risk in providing an incorrect recommended value for the infusion rate during the pump s initial infusion setup. We updated the software in all product subject to the recall. In July 2015, the FDA notified us that it had concluded its audit and confirmed that the recall was terminated. To avoid future product recalls we have made and continue to invest in our quality systems, processes and procedures. We will continue to make improvements to our products and systems to further reduce issues related to patient safety.

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However, there can be no assurance our efforts or systems will be sufficient. Future quality concerns, whether real or perceived, could adversely affect our operating results.

Our products or product types, or MR imaging could be subject to negative publicity, which could have a material adverse effect on our financial position and results of operations and could cause the market value of our common stock to decline.

The market s perception of our products could be harmed if any of our products or similar products offered by others in our industry become the subject of negative publicity due to a product safety issue, withdrawal, recall, or are proven or are claimed to be harmful to patients. The FDA Warning Letter may harm the market perception of our company and products. The harm to market perception may have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Our products are designed for use around MRI scanners. MRI has been an important imaging diagnostic for some time now, however should MRI technology change materially or decline in useage due to new technologies or concerns about costs or efficacy of MR imaging, our products would suffer as MRI usage and installations declined. Such a matter may also have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Recent U.S. healthcare policy changes, including the Affordable Care Act and PPACA, may have a material adverse effect on our financial condition and results of operations.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the PPACA), enacted in 2010, implemented changes that are expected to significantly impact the medical device industry. Beginning on January 1, 2013, the Affordable Care Act imposed a 2.3 percent excise tax on sales of products defined as medical devices by the regulations of the FDA. We believe that all of our medical products are medical devices within the meaning of the FDA regulations. On December 18, 2015, under the Consolidated Appropriations Act of 2015, the medical device excise tax was suspended for two years beginning on January 1, 2016. New legislation passed in January 2018 further suspended the medical device excise tax through December 31, 2019. While this tax was suspended by legislation for 2018 and 2019, its return beginning on January 1, 2020 and potential increases from the 2.3 percent level in future years would negatively impact our operating results. We cannot currently foresee that the suspension will be reinstated.

Other significant measures contained in the PPACA include research on the comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The PPACA also includes significant new fraud and abuse measures, including required disclosures of financial payments to and arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, the PPACA established an Independent Payment Advisory Board (IPAB), to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce health care expenditures, which may have a negative impact on payment rates for services, including treatments and procedures which incorporate use of our products. The IPAB proposals may impact payments for treatments and procedures that use our technology beginning in 2016 and for hospital services beginning in 2020, and may indirectly reduce demand for our products.

In addition, it is possible that changes in administration policy, including the potential repeal of all or parts of the PPACA, resulting from recent U.S. presidential actions and congressional legislative efforts could result in additional proposals and continued developments with respect to healthcare reform. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

We are subject to healthcare fraud and abuse regulations that could result in significant liability, require us to change our business practices and restrict our operations in the future.

We and our customers are subject to various U.S. federal, state and local laws targeting fraud and abuse in the healthcare industry, including anti-kickback and false claims laws. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in healthcare programs such as Medicare and Medicaid, and Veterans Administration health programs and health programs outside the U.S. These laws and regulations are broad in scope and are subject to evolving interpretations, which could require us to alter one or more of our sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our sales, profitability and financial condition. Furthermore, since many of our customers rely on reimbursement from Medicare, Medicaid and other governmental programs to cover a substantial portion of their expenditures, if we or our customers are excluded from such programs as a result of a violation of these laws, it could have an adverse effect on our results of operations and financial condition. We have developed and implemented business practices and processes to train our personnel to perform their duties in compliance

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with healthcare fraud and abuse laws and conduct informal oversight to detect and prevent these types of fraud and abuse. However, we lack formal written policies and procedures at this time. If we are unable to formally document and implement the controls and procedures required in a timely manner or we are otherwise found to be in violation of such laws, we might suffer adverse regulatory consequences or face criminal sanctions, which could harm our operations, financial reporting or financial results.

We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws.

The U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We intend to adopt policies for compliance with these anti-bribery laws, which often carry substantial penalties.

We cannot assure you that our internal control policies and procedures always will protect us from reckless or other inappropriate acts committed by our affiliates, employees or agents. Violations of these laws, or allegations of such violations, could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

We and our suppliers and customers are required to obtain regulatory approvals to comply with regulations applicable to medical devices and infusion pumps, and these approvals could result in delays or increased costs in developing new products.

In December 2014, the FDA issued guidance entitled Infusion Pumps Total Product Life Cycle. This guidance established substantial additional pre-market requirements for new and modified infusion pumps. Through this guidance, the FDA indicated more data demonstrating product safety will be required for future 510(k) submissions for infusion pumps, including the potential for more clinical and human factors data. The process for obtaining regulatory approvals to market infusion pumps and related accessories have become more costly and time consuming. The impact of this guidance is likely to result in a more time consuming and costly process to obtain regulatory clearance to market infusion pumps. In addition, new requirements could result in longer delays for the clearance of new products, modification of existing infusion pump products or remediation of existing products in the market. Future delays in the receipt of, or failure to obtain, approvals could result in delayed or no realization of product revenues.

We and our suppliers and customers are required to maintain compliance with regulations applicable to medical devices and infusion pumps, and it could be costly to comply with these regulations and to develop compliant products and processes. Failure to comply with these regulations could subject us to sanctions and could adversely affect our business.

Even if we are able to obtain approval for introducing new products to the market, we and our suppliers may not be able to remain in compliance with applicable FDA and other material regulatory requirements once clearance or approval has been obtained for a product. These requirements include, among other things, regulations regarding manufacturing practices, product labeling, off-label marketing, advertising and post-marketing reporting, adverse event reports and field alerts. Compliance with these FDA requirements is subject to continual review and is monitored through periodic inspections by the FDA. For example, the FDA conducted routine inspections of our facility in Winter Springs,

Florida in July 2016. The FDA issued a Form 483 on July 18, 2016 resulting from an inspection of our facility between July 11 and July 18, 2016 that identified three observations. These observations were related to procedural and documentation issues associated with the CAPA system, vendor requirements and complaint investigation. This was the first FDA inspection of our facility since the receipt of the Warning Letter.

We submitted responses to the Form 483 in August 2016 and October 2016 in which we described our proposed corrective and preventative actions to address each of the observations. As part of our response, on October 13, 2016 we initiated a customer follow up to our August 2012 Safety Alert, and made available an updated instruction card for customers. As of December 31, 2017, we are in the process of closing this action.

During the July 2016 inspection, updated documents and actions implemented in response to the Warning Letter findings were reviewed, and the FDA determined that no further actions were necessary in response to the Warning Letter. As of December 31, 2017, the Warning Letter remains open.

In addition, manufacturing flaws, component failures, design defects, off-label uses or inadequate disclosure of product related information could result in an unsafe condition or the injury or death of a patient. All of these events could harm our sales, margins and profitability in the affected periods and may have a material adverse effect on our business. Any adverse regulatory action or action taken by us to maintain appropriate regulatory compliance, with respect to these laws and regulations could disrupt our business and have a material adverse effect on our sales, profitability and financial condition. Furthermore, an adverse regulatory action with respect to any of our products or operating procedure or to our or our suppliers manufacturing facility could materially harm our reputation in the marketplace.

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Our operations are subject to environmental laws and regulations, with which compliance is costly and which exposes us to penalties for non-compliance.

Our business, products, and product candidates are subject to federal, state, and local laws and regulations relating to the protection of the environment, worker health and safety and the use, management, storage, and disposal of hazardous substances, waste, and other regulated materials. These environmental laws and regulations could require us to pay for environmental remediation and response costs at third-party locations where we dispose of or recycle hazardous substances. The costs of complying with these various environmental requirements, as they now exist or as may be altered in the future, could adversely affect our financial condition and results of operations.

Risks Relating to our Intellectual Property

Our success depends on our ability to protect our intellectual property.

We intend to rely on a combination of patents, trademarks, trade secrets, know-how, license agreements and contractual provisions to establish and protect our proprietary rights to our technologies and products. We cannot guarantee that the steps we have taken or will take to protect our intellectual property rights will be adequate or that they will deter infringement, misappropriation or violation of our intellectual property. We may fail to secure patents that are important to our business, and we cannot guarantee that any pending U.S. trademark or patent application, if ultimately issued, will provide us some relative competitive advantage. Litigation may be necessary to enforce our intellectual property rights and to determine the validity and scope of our proprietary rights.

Any litigation could result in substantial expenses and may not adequately protect our intellectual property rights. In addition, the laws of some of the countries in which our products may in the future be sold may not protect our products and intellectual property to the same extent as U.S. laws, or at all. We may be unable to protect our rights in trade secrets and unpatented proprietary technology in these countries. If our trade secrets become known, we may lose our competitive advantages.

Even if we are able to secure necessary patents in the U.S., we may not be able to secure necessary patents and trademarks in foreign countries in which we sell our products or plan to sell our products. In March 2013, the U.S. transitioned to a first inventor to file system for patents in which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to a patent. We may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, inter parties review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights.

Our unpatented trade secrets, know-how, confidential and proprietary information, and technology may be inadequately protected.

We rely on unpatented trade secrets, know-how and technology. This intellectual property is difficult to protect, especially in the medical device industry, where much of the information about a product must be submitted to regulatory authorities during the regulatory approval process. We seek to protect trade secrets, confidential information and proprietary information, in part, by entering into confidentiality and invention assignment agreements with employees, consultants, and others. These parties may breach or terminate these agreements, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other confidential or proprietary information or result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets and our other confidential and proprietary information, we or our collaboration partners, board members, employees, consultants, contractors, or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors.

There is a risk that our trade secrets and other confidential and proprietary information could have been, or could, in the future, be shared by any of our former employees with, and be used to the benefit of, any company that competes with us.

If we fail to maintain trade secret protection or fail to protect the confidentiality of our other confidential and proprietary information, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able effectively to assert our trade secret protections against them, which could have a material adverse effect on our business.

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There can be no assurance of timely patent review and approval to minimize competition and generate sufficient revenues.

There can be no assurance that the Patent and Trademark Office will have sufficient resources to review our patent applications in a timely manner. Consequently, even if our patent applications are ultimately successful, our patent applications may be delayed, which would prevent intellectual property protection for our products. If we fail to successfully commercialize our products due to the lack of intellectual property protection, we may be unable to generate sufficient revenues to meet or grow our business according to our expected goals and this may have a materially adverse effect on our profitability, financial condition, and operations.

We may become involved in patent litigation or other intellectual property proceedings relating to our future product approvals, which could result in liability for damages or delay or stop our development and commercialization efforts.

The medical device industry has been characterized by significant litigation and other proceedings regarding patents, patent applications, and other intellectual property rights. The situations in which we may become parties to such litigation or proceedings may include any third parties (which may have substantially greater resources than we have) initiating litigation claiming that our products infringe their patent or other intellectual property rights; in such case, we will need to defend against such proceedings.

The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved and the uncertainty of litigation significantly increase the risks related to any patent litigation. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, making, or using products that use the disputed intellectual property;

- obtain a license from the intellectual property owner to continue selling, making, licensing, or using products, which license may require substantial royalty payments and may not be available on reasonable terms, or at all;

- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;

- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; or

- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and/or infeasible.

If any of the foregoing events occur, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition. As the number of participants in our industry grows, the possibility of intellectual property infringement claims against us increases.

Furthermore, the costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other intellectual property proceedings may also consume significant management time.

In the event that a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult, and time-consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time-consuming and could divert our management s attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patent or other intellectual property rights against a challenge. If we are unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could materially harm our business.

There may also be situations where we use our business judgment and decide to market and sell products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts (i.e., an at-risk launch). The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be increased up to three times. An adverse decision could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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In addition, we may indemnify our customers and distributors with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

We may be subject to claims that we, our board members, employees or consultants have used or disclosed alleged trade secrets or other proprietary information belonging to third parties and any such individuals who are currently affiliated with one of our competitors may disclose our proprietary technology or information.

As is commonplace in the medical device industry, some of our board members, employees and consultants are or have been associated with other medical device companies that compete with us. For example, Mr. Susi and a number of our other employees are former employees of Invivo Corporation and/or other medical device firms. While associated with such other companies, these individuals may have been exposed to research and technology similar to the areas of research, technology, sales methodology, pricing models and other such matters in which we are engaged. We may become subject to future claims that we, our employees, board members, or consultants have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of those companies. Litigation may be necessary to defend against such claims.

We have entered into confidentiality agreements with our executives and key consultants. However, we do not have, and are not planning to enter into, any confidentiality agreements with our non-executive directors because they have a fiduciary duty of confidentiality as directors.

There is the possibility that any of our former board members, employees, or consultants who are currently or who may be employed at, or associated with, one of our competitors may unintentionally or willfully disclose our proprietary technology or information.

Risks Related to Ownership of Our Common Stock

Our common stock price has been and will likely continue to be subject to significant fluctuations and volatility, and you may be unable to sell your shares at a fair price, or at all.

Our stock could be subject to wide fluctuations in price in response to various factors, including the following:

- a lack of liquidity in the public trading of our common stock;
- the commercial success or failure of our key products;

- delayed or reduced orders from our customers;
- manufacturing or supply interruptions;
- changes or developments in laws or regulations applicable to our products and product candidates;
- introduction of competitive products or technologies;
- poorly executed acquisitions or acquisitions whose projected potential is not realized;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed our own estimates and projections or the estimates and projections of securities analysts or investors;
- new or revised earnings estimates or guidance by us or securities analysts or investors;
- varying economic and market conditions in the U.S.;

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- negative developments impacting the medical device industry in general and changes in the market valuations of companies deemed similar to us;

- negative developments concerning our sources of manufacturing supply;

- disputes or other developments relating to patents, trademarks or other proprietary rights;

- litigation or investigations involving us, our industry, or both;

- issuances of debt, equity or convertible securities at terms deemed unfavorable by the market;

- major catastrophic events;

- sales of large blocks of our stock;

- exercise of the underwriters warrant that may lead to sales that put downward pressure on our stock price;

- changes in our Board of Directors, management or key personnel; or

- the other factors described in this Risk Factors section.

Any one of the factors above, or the cumulative effect of some of the factors referred to above, may result in significant fluctuations in our quarterly or annual operating results, fluctuations in our share price and investors perception of our business. If we fail to meet or exceed such expectations, our business and stock price could be materially adversely affected.

Our use of capital to repurchase shares of our common stock could have a material adverse effect on our stock price and our business.

Since we announced stock repurchase programs in 2016 and 2017, we have used a significant amount of cash to repurchase shares of common stock of our company. As part of our strategy, we intend to opportunistically repurchase additional shares of common stock from time to time at prices that we believe are attractive. There can be no assurance that we will be able to repurchase shares on favorable terms or that, if we do repurchase shares, that such repurchases will increase shareholder value. Additionally, if we use a significant portion of our capital to repurchase shares, our financial flexibility will be reduced and we may not be able to execute on other strategic initiatives or tolerate periods of operating losses. If we repurchase shares on unfavorable terms or if our use of capital to repurchase shares inhibits our ability to pursue other strategic initiatives or tolerate periods of operating losses, it could have a material adverse effect on our stock price and our business.

Future sales of our common stock may cause our stock price to decline.

On September 26, 2014, we filed a registration statement under Form S-8 to register all of the shares issuable upon exercise of options outstanding or reserved for future issuance under our equity compensation plans. In addition, on December 3, 2015 we filed a registration statement on Form S-3/A to register $40 million of shares of common stock that may be offered or sold by us. If any of the foregoing shares are sold by the Company, or if it is perceived that they will be sold, the trading price of our common stock could decline.

We may need or choose to raise additional capital in the future, which could result in dilution to our stockholders and adversely affect stock price.

While we believe that our cash and investment balances and prospective cash flow from our operations will provide us with adequate capital to fund operations for at least the next 12 months, we may need or choose to raise additional funds prior to that time. We may seek to sell additional equity or debt securities or to obtain a credit facility, which we may not be able to do on favorable terms, or at all. The sale of additional equity or convertible debt securities could result in additional dilution to our stockholders. If additional funds are raised through the issuance of debt securities or preferred stock, these securities could have rights that are senior to holders of common stock and any debt securities could contain covenants that would restrict our operations. The sale of such securities could hurt demand for our common stock and lead our share price to decline.

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Roger Susi, who serves as our Chairman of the Board of Directors and an executive officer, owns a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Mr. Susi, our founder, who serves as our Chairman of the Board of Directors, President and Chief Executive Officer, and his affiliates beneficially owns a majority of our outstanding common stock. Mr. Susi is able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. He may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock.

Mr. Susi s majority ownership also qualifies our company as a controlled company and allows us to opt out of compliance with numerous corporate governance listing requirements.

In addition, we qualify for the controlled company exemption under the corporate governance rules of the NASDAQ Stock Market until such a time as Mr. Susi does not control a majority of our outstanding common stock. As a controlled company, we would be permitted to opt out of compliance with the requirements that a majority of our board of directors consist of independent directors, that our Board of Directors compensation committee be comprised solely of independent directors, and that director nominees be selected or recommended to the Board of Directors for selection by independent directors. Notwithstanding the availability of these exemptions, we have elected not to rely upon any of the exemptions afforded to a controlled company under NASDAQ rules. A majority of our Board of Directors is comprised of independent directors, our compensation committee is comprised solely of independent directors, and our director nominees are recommended for selection to our Board of Directors by a majority of our independent directors in a vote in which only independent directors may participate. Our compliance is voluntary, however, and there can be no assurance that we will continue to comply with these standards in the future. We no longer require as a matter of policy that our Chairman of the Board be an independent director.

We do not intend to pay dividends for the foreseeable future.