IRADIMED CORP
Form 10-K
March 07, 2019
Table of Contents

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, 2018

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 check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 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	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, 2018, 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 $95,622,993.

There were 10,997,052 shares outstanding of the registrant s common stock, par value $0.0001 per share, as of February 28, 2019. 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.

Table of Contents

TABLE OF CONTENTS

IRADIMED CORPORATION.

TABLE OF CONTENTS TO ANNUAL REPORT ON FORM 10-K

For the Fiscal Year Ended December 31, 2018

PART I		1
ITEM 1.	BUSINESS	1
ITEM 1A.	RISK FACTORS	18
ITEM 1B.	UNRESOLVED STAFF COMMENTS	35
ITEM 2.	PROPERTIES	35
ITEM 3.	LEGAL PROCEEDINGS	35
ITEM 4.	MINE SAFETY DISCLOSURES	35
PART II		36
ITEM 5.	MARKET FOR REGISTRANT S COMMON STOCK, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	36
ITEM 6.	SELECTED CONSOLIDATED FINANCIAL DATA	39
ITEM 7.	MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	40
ITEM 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	51
ITEM 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	51
ITEM 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	53
ITEM 9A.	CONTROLS AND PROCEDURES	53
ITEM 9B.	OTHER INFORMATION	53
PART III		54
ITEM 10.	DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE	54
ITEM 11.	EXECUTIVE COMPENSATION	54
ITEM 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	54
ITEM 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	54
ITEM 14.	PRINCIPAL ACCOUNTING FEES AND SERVICES	54
PART IV		54
ITEM 15.	EXHIBITS AND FINANCIAL STATEMENT SCHEDULES	54
EXHIBIT INDEX		55
SIGNATURES		57
INDEX TO FINANCIAL STATEMENTS		F-1

Table of Contents

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 or other regulatory bodies;

- 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;

Table of Contents

- 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.

Table of Contents

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

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

Our 3880 MRI compatible patient vital signs monitoring system has been designed with non-magnetic components and other special features to safely and accurately monitor a patient s vital signs during various MRI procedures. The IRADIMED 3880 system operates dependably 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 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 features of the IRADIMED 3880 include: wireless ECG with dynamic gradient filtering; wireless SpO2 using Masimo® algorithms; non-magnetic respiratory CO2; invasive and 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 and allows for the effective communication of patient vital signs information to clinicians. 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 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, 2018, our direct sales force consisted of 24 field sales representatives, supported by 3 regional sales directors and supplemented by 5 clinical support representatives. Our goal is to continue to expand our U.S. sales force to between 30 and 32 field sales representatives and 6 clinical support representatives by the end of 2019. Internationally, we market our products into approximately 50 countries through the use of independent distributors.

As of December 31, 2018 we have sold approximately 5,000 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. As of December 31, 2018, we have sold approximately 261 of our 3880 MRI compatible patient vital signs monitoring systems.

Table of Contents

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 2018, our revenue was $30.4 million and our operating profit was $6.0 million representing an operating profit margin of 19.7 percent. Refer to the information contained under the caption Financial Highlights and Outlook regarding our outlook for 2019.

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, which was later acquired by Koninklijke Philips NV (NYSE: PHG).

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 is compact and lightweight, 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.

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, bodily 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, practitioners at 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.

Table of Contents

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, including those from critical care departments. 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 electrical 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 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.

Table of Contents

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 are 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 are 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 competitor MRI patient vital signs monitors. 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, based on feedback and early successes from certain customers, 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 marketing 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.

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.

Table of Contents

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, accessories and related services. 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 patients 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 great risks to patients 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 U.S. FDA 510(k) clearance in October 2017. Upon receipt of FDA 510(k) clearance, we immediately began marketing the 3880 Monitor to domestic customers.

Continuing to innovate with MRI compatible patient care products

Our management team collectively has more than 100 years of experience developing and commercializing MRI compatible products. We have entrenched relationships with several 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 compatible patient care products.

Table of Contents

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 compatible patient care products. While we have not completed an acquisition, 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 focus on educating customers on the total workflow benefits our devices offer and how our devices increase patient safety through their combined transport capabilities.

Since 2011, our U.S. sales team has grown from 1 field sales representative and 1 clinical support representative to a team of 24 direct field sales representatives, 3 regional sales directors and 5 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 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 2019, we plan to begin the expansion of our internal capacity to serve these high potential markets by adding a dedicated regional sales director 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 continuing the development of and enhancing our 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 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.

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.

Table of Contents

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 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). Additionally, 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 other pumps must be placed at a distance from the MRI scanner, which may include being outside of the scanner room entirely.

We currently offer two products for sale: (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:

Table of Contents

- The only non-magnetic MRI compatible IV infusion pump system specifically designed and built to operate inside the MR 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. The MRidium 3860+ pump system can operate dependably in the presence of 0.2T to 3T magnets and is fully operational up to the 10,000 gauss-line. This means our MRidium 3860+ is 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 life.

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. The 1056 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 1057 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 1058 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.

Table of Contents

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 3860+ 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 3861 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 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.

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 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 MRI 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.

Table of Contents

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 (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; invasive blood pressure; 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, SpO2 and invasive blood pressure pods that facilitate the respective monitoring modalities. We are also currently working on interoperability features that will be offered 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 12 issued U.S. patents and 4 issued foreign patents with remaining lives that range from 4 to 15 years. 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.

We also rely on trade secrets, 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 24 direct field sales representatives, 3 regional sales directors and 5 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,		
	2018	**2017**	**2016**
United States	80.5%	84.5%	88.9%
International	19.5%	15.5%	11.1%

Table of Contents

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

	Percent of Revenue Years Ended December 31,		
	2018	2017	2016
Devices	69.6%	67.0%	79.3%
Disposables and Services	25.4%	28.7%	19.7%
Amortization of extended warranty agreements	5.0%	4.3%	1.0%

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, 2018, 2017 and 2016, backlog was approximately:

	Years ended December 31,		
(In millions)	2018	2017	2016
Backlog	$ 2.6	$ 2.7	$ 1.6

Historical selling cycles for our devices have varied widely and are now typically three to six months in duration.

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 surveys and visits to customer sites.

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 member 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 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 facility 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.

Table of Contents

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. Our exclusive supply agreement with this company expired on January 25, 2019. We are currently in the process of renewing this supply agreement.

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 received our certificates in November 2018. These certificates will need renewal again in January 2022.

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. Historically, 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 FDA 510(k) 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.

Table of Contents

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.

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 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 as 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 Notes 2 and 4 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 $1.5 million or 5.0 percent of revenue in 2018, $1.7 million or 7.5 percent of revenue in 2017 and $1.3 million or 4.1 percent of revenue in 2016. During 2016, we capitalized $0.7 million of research and development costs associated with internally developed software that operates our 3880 MRI compatible patient vital signs monitor.

Table of Contents

Employees

As of December 31, 2018, we had 95 full-time employees, including 36 in manufacturing and service, 38 in sales, marketing and customer support services, 7 in regulatory affairs, 8 in finance and administration and 6 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.

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 beyond the 2014 guidance document 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.

Table of Contents

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. Most 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 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.

Table of Contents

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, 2018, the Warning Letter remains open.

Product Recalls and Software Updates

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 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 fielding updated software for our MRidium 3860+ IV infusion pump to existing customers. 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.

On January 16, 2019, we were notified by the U.K. Notified Body, UL International Ltd. (UL) that their recent technical file review of our 3880 MRI compatible patient vital signs monitoring system could not be completed as aspects of clinical evaluation reporting, as required by newly issued guidance from the European Union, was not acceptable, resulting in a technical non-conformity. Accordingly, UL issued a temporary EC Certificate that excludes our 3880 patient vital signs monitoring system. This temporary EC Certificate extends through July 27, 2019. We immediately suspended shipments of our 3880 patient vital signs monitor to all markets requiring a CE Mark. We are addressing the technical non-conformity, but there can be no assurance that these efforts will be successful.

Table of Contents

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, which could significantly lower our revenues from foreign sales while we take remedial measures.

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 devices. The application of RoHS 2 to medical devices became effective as of July 22, 2014. Our products 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.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the EU, commonly referred to as Brexit. The United Kingdom s departure from the EU is currently scheduled to take place on Friday, March 29, 2019. This referendum has created political and economic uncertainty, particularly in the United Kingdom and the EU, and this uncertainty may persist for years. Since a significant portion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, the referendum could materially impact the regulatory regime with respect to our products in the United Kingdom or the EU. 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 EU and affect our operations and financial results.

The ultimate effects of Brexit are uncertain and will depend on any agreements the United Kingdom makes to retain access to EU markets either during a transitional period or more permanently. Brexit could adversely affect European and worldwide economic and market conditions and could contribute to instability in global financial and foreign exchange markets. Uncertainty over the terms of the United Kingdom s departure from the EU could harm our business and financial results. In addition, other EU member countries may consider referendums regarding their EU membership. Any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business, results of operations and financial condition.

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.

Table of Contents

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.

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 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.

Our products 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;

Table of Contents

- product liability claims;

- our reputation and product market acceptance;

- loss of existing regulatory approvals or the imposition of new requirements to maintain such approvals; and

- product recalls or safety alerts.

Any major factor adversely affecting the sale of our products or services 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.

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 decline in operating results during 2017 limited our generation of capital resources and that situation could return if we are unable to continue to increase revenues or adjust our costs appropriately. Further, future new product launches may demand increased working capital before any long-term 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. Considering 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 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.

Table of Contents

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, but are not limited to:

- 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;

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

- failure of the supplier 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, 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.

Table of Contents

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 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 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 have 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 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, and may in the future have, accounts receivables from one or more 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.

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 to sell. 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 medical devices 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.

We believe 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.

Table of Contents

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 with customers regarding our products and a customer s purchase of our products is typically three to six months. Sales cycles can also be delayed because 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 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.

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, including in the MRI compatible medical device segment. 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.

Table of Contents

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.

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 Generally Accepted Accounting Principles (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 reporting processes due to implementation and internal control implications.

Table of Contents

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.

Our adoption and implementation of the new revenue accounting standard on January 1, 2018 included management s 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. If our initial judgments and assumptions require 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.

Changes in effective tax rates or adverse outcomes resulting from examination of our income or other tax returns could adversely affect our results.

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, 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, including potential U.S. state and foreign tax jurisdiction responses, is uncertain and our business and financial condition could be adversely affected.

In addition, we are subject to the continuous examination of our income tax returns by the Internal Revenue Service, or IRS, and other tax authorities. It is possible that tax authorities may disagree with certain positions we have taken, and any adverse outcome of such a review or audit could have a negative effect on our financial position and operating results. We regularly assess the likelihood of adverse outcomes resulting from these examinations to determine the adequacy of our provision for income taxes, but the determination of our provision for income taxes and other tax liabilities requires significant judgment by management, and there are transactions where the ultimate tax determination is uncertain. Although we believe that our estimates are reasonable, the ultimate tax outcome may differ from the amounts recorded in our financial statements and may materially affect our financial results in the period or periods for which such determination is made. There can be no assurance that the outcomes from continuous examinations will not have an adverse effect on our business, financial condition, and results of operations.

We are subject to various privacy and consumer protection laws.

Our privacy policy is posted on our website, and any failure by us or our vendor or other business partners to comply with it or with federal, state or international privacy, data protection or security laws or regulations could result in regulatory or litigation-related actions against us, legal liability, fines, damages and other costs. Substantial expenses and operational changes may be required in connection with maintaining compliance with such laws, and in particular certain emerging privacy laws are still subject to a high degree of uncertainty as to their interpretation and application. For example, in May 2018, the General Data Protection Regulation (the GDPR) began to fully apply to the processing of personal information collected from individuals located in the European Union. The GDPR has created new compliance obligations and has significantly increased fines for noncompliance. Although we take steps to protect the security of our customers personal

information, we may be required to expend significant resources to comply with data breach requirements if third parties improperly obtain and use the personal information of our customers or we otherwise experience a data loss with respect to customers personal information. A breach of our network security and systems could have negative consequences for our business and future prospects, including possible fines, penalties and damages, reduced customer demand for our products, and harm to our reputation and brand.

Table of Contents

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.

On January 16, 2019, we were notified by the U.K. Notified Body, UL International Ltd. (UL) that their recent technical file review of our 3880 MRI compatible patient vital signs monitoring system could not be completed as aspects of clinical evaluation reporting, as required by newly issued guidance from the European Union, was not acceptable, resulting in a technical non-conformity. Accordingly, UL issued a temporary EC Certificate that excludes our 3880 patient vital signs monitoring system. This temporary EC Certificate extends through July 27, 2019. We immediately suspended shipments of our 3880 patient vital signs monitor to all markets requiring a CE Mark. We are addressing the technical non-conformity and plan to be permitted to use the CE Mark on our 3880 patient vital signs monitoring system, but there can be no assurance that these efforts will be successful.

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;

Table of Contents

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

- 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, including U.S. state and foreign tax jurisdiction responses to recent changes in U.S. federal 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 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. 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.

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.

Table of Contents

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 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 usage 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.

U.S. healthcare policy and changes thereto, 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 significantly impacted 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 our current 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of PPACA. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of PPACA. The Budget Resolution is not a law; however, it was widely viewed as the first step toward the passage of legislation that would repeal certain aspects of PPACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In addition, with enactment of the Tax Cuts and Jobs Act of 2017, in December 2017, Congress repealed the individual mandate portion of PPACA. The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in January 2019. The potential impact of these efforts to repeal or defer and delay enforcement of PPACA on our business remains unclear. Congress also could consider subsequent legislation to replace elements of PPACA that are repealed. Because of the

continued uncertainty about the implementation of the PPACA, including the potential for further legal challenges or repeal of PPACA, we cannot quantify or predict with any certainty the likely impact of the PPACA or its repeal on our business, prospects, financial condition or results of operations.

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.

Table of Contents

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 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, 2018, the Safety Alert remains open.

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, 2018, 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.

Table of Contents

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 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 to effectively assert our trade secret protections against them, which could have a material adverse effect on our business.

Table of Contents

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.

Table of Contents

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.;

Table of Contents

- 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 underwriter s 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.

Any 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. Historically, we have opportunistically repurchased additional shares of common stock from time to time at prices that we believe are attractive. While our stock repurchase program has expired, should our Board of Directors authorize another stock repurchase program, there can be no assurance that we will be able to repurchase shares on favorable terms or, 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. If any of the foregoing shares are sold or if there is another future offering by the Company, or if it is perceived that they will be sold or there will be another future offering, 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.

Table of Contents

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 do not currently require that our Chairman of the Board be an independent director.

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

We do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our Board of Directors deems relevant. Investors seeking cash dividends should not purchase our common stock.

Accordingly, if you purchase shares, realization of a gain on your investment will depend solely on the appreciation of the price of our common stock, which may never occur.

The requirements of being a public company may strain our resources, divert management s attention and affect our ability to attract and retain executive management and qualified board members.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of the NASDAQ Stock Market and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. As a result, management s attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may need to hire more employees in the future or engage outside consultants to monitor and advise us regarding compliance, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are investing additional resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management s time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us, and our business may be adversely affected. These compliance requirements and costs will increase once we are no longer an emerging growth company as defined in the JOBS Act, which we anticipate will occur on December 31, 2019.

Table of Contents

We believe that being a public company and compliant with these new rules and regulations has made it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our Board of Directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

As a result of being a public company, we are obligated to establish and maintain adequate internal controls. Failure to develop and maintain adequate internal controls or to implement new or improved controls 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.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort. Our internal controls over financial reporting are designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. We are developing the system and processing documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act of 2002. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal controls over financial reporting, we will be unable to assert that our internal controls are effective.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act until we file our first Form 10-K following the date we are no longer an emerging growth company as defined in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in the future.

Our business practices have become more visible as a public company, and this could impact our competitive environment and our risk of potential litigation.

As a result of disclosure of information in filings required of a public company, our business and financial condition have become more visible potentially exposing us to new competition and threatened or actual litigation, including by competitors and other third parties. New competition could result in reduced sales of our products and adversely impact our profitability. If lawsuits prevail against us, our business and operating results could be adversely affected, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and operating results.

We may and have become involved in securities class action litigation that could divert management s attention from our business and adversely affect our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices of small capitalization medical device companies. These broad market fluctuations as well a broad range of other factors, including the realization of any of the risks described in this Risk Factors section, may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. We have become, and may in the future, become involved in this type of litigation. Litigation is expensive and could divert management s attention and resources from our

primary business, which could adversely affect our operating results. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require us to make significant payments. Such payment could have a material impact on how investors view our company and result in a decline in our stock price.

We are an emerging growth company, and we are not certain if the reduced reporting requirements applicable to emerging growth companies has made our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and intend to take advantage of certain exemptions from various reporting requirements. We cannot predict if investors will respond negatively to our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

Table of Contents

As an emerging growth company we have also chosen to take advantage of certain provisions of the JOBS Act that allow us to provide you with less information in our public filings than would otherwise be required. As a result it may be more difficult for you to evaluate an investment in our company. We anticipate that starting December 31, 2019, we will no longer be an emerging growth company and after that date we will no longer be able to avail ourselves of these exemptions.

If securities or industry analysts fail to initiate research coverage of our stock, downgrade our stock, or discontinue coverage, our trading volume might be reduced and our stock price could decline.

The trading market for our common stock depends, in part, on the research reports that securities or industry analysts publish about our business. If securities or industry analysts do not commence or continue coverage of our company, the trading market for our stock may not be robust and the price of our stock could likely be negatively impacted. In the event securities or industry analysts initiate coverage, and later downgrade our stock or discontinue such coverage, our stock price could decline.

Our charter documents and Delaware law have provisions that may discourage an acquisition of us by others and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our charter documents, as well as provisions of the Delaware General Corporation Law (DGCL), could depress the trading price of our common stock by making it more difficult for a third party to acquire us at a price favorable to our shareholders. These provisions include:

- authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval to defend against a takeover attempt; and

- establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. We are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our Board of Directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders, which could also affect the price that some investors are willing to pay for our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal offices are currently located in a leased facility of approximately 23,100 square feet located in Winter Springs, Florida. This facility has been leased from an entity controlled by our founder, President, CEO and Chairman of the Board of Directors, Roger Susi. Pursuant to the terms of our lease, the current monthly base rent is $34,133, adjusted annually for changes in the consumer price index. The term of the lease expires on May 31, 2019. The lease will automatically renew for two successive terms of five years each beginning in 2019 and again in 2024, and thereafter, will be renewed for successive terms of one year each.

We do not own any real property.

ITEM 3. LEGAL PROCEEDINGS

From time to time we are involved in legal proceedings arising in the ordinary course of business. We believe that adequate reserves for these liabilities have been made and that there is no litigation pending that could have a material adverse effect on our results of operations and financial condition.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents

PART II

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

Market Information

Our common stock trades on the NASDAQ Capital Market under the stock symbol IRMD. The following table summarizes, for the periods indicated, the high and low sale price per share of our common stock as reported by the NASDAQ:

	High	Low
Year ended December 31, 2018		
Fourth Quarter	$ 38.78	$ 19.88
Third Quarter	37.50	20.00
Second Quarter	20.75	14.00
First Quarter	15.85	12.51
Year ended December 31, 2017		
Fourth Quarter	$ 15.75	$ 9.60
Third Quarter	10.95	8.25
Second Quarter	10.80	7.85
First Quarter	12.53	7.85

The stock market in general has experienced significant stock price fluctuations in the past few years. In some cases, these fluctuations have been unrelated to the operating performance of the affected companies. Therefore, many companies have experienced dramatic volatility in the market prices of their common stock. We believe that a number of factors, both within and outside our control, could cause the price of our common stock to fluctuate, perhaps substantially. Factors such as the following could have a significant adverse impact on the market price of our common stock:

- Our financial position and results of operations;
- Our ability to obtain additional financing and, if available, the terms and conditions of the financing;
- Concern as to, or other evidence of, the reliability and efficiency of our proposed products or our competitors products;

- Announcements of innovations or new products by us or our competitors;

- Federal, state, and international governmental regulatory actions and the impact of such requirements on our business;

- The development of litigation against us;

- Period-to-period fluctuations in our operating results;

- Changes in estimates of our performance by any securities analysts;

- The issuance of new equity securities pursuant to a future offering or acquisition;

- Poorly executed acquisitions or acquisitions whose projected potential is not realized;

- Changes in interest rates;

- Competitive developments, including announcements by competitors of new products or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;

- Sales of large blocks of our stock;

- Exercise of the underwriter s warrant that may lead to sales that put downward pressure on our stock price;

Table of Contents

- Investor perceptions of our company; and

- General economic and other national and international conditions.

Stockholders

As of February 28, 2019, we had 7 stockholders of record. We estimate that there are approximately 2,485 benefinical owners of our common stock.

Dividends

We do not expect to declare or pay any cash dividends on our common stock in the foreseeable future, and we currently intend to retain future earnings, if any, to finance the expansion of our business. The decision whether to pay cash dividends on our common stock will be made by our board of directors, at its discretion, and will depend on our financial condition, operating results, capital requirements and other factors that the board of directors considers significant.

We have never paid or declared cash dividends on our capital stock.

Purchases of Equity Securities by the Issuer

In January 2016, the Board of Directors authorized the repurchase of up to $10 million of the Company s common stock pursuant to a stock repurchase program. This program was publicly announced on January 28, 2016 and expired on January 28, 2017. During the program period, we expended nearly all of the $10 million authorization.

In April 2017, the Board of Directors authorized a new stock repurchase program of up to $8 million of the Company s common stock pursuant to a stock repurchase program. This program was publicly announced on April 28, 2017 and expired on April 28, 2018. During the program period, we expended $1.8 million for such repurchases.

The following table provides information regarding repurchases of common stock for the year ended December 31, 2018.

	Total Number of Shares Purchased (1)		Average Price Paid per Share (2)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs		Maximum Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
January 1, 2018 January 31, 2018	289	$			$	6,181,458
February 1, 2018 February 28, 2018		$			$	6,181,458
March 1, 2018 March 31, 2018		$			$	6,181,458
April 1, 2018 April 30, 2018	216	$			$	6,181,458
May 1, 2018 May 31, 2018	41	$			$	
June 1, 2018 June 30, 2018	385	$			$	
July 1, 2018 July 31, 2018	39	$			$	
August 1, 2018 August 31, 2018		$			$	
September 1, 2018 September 30, 2018		$			$	
October 1, 2018 October 31, 2018	182	$			$	
November 1, 2018 November 30, 2018		$			$	
December 1, 2018 December 31, 2018	10,953	$			$	
Total	12,105	$			$	

(1) The number of shares purchased reflects shares withheld for taxes on vesting of restricted stock. There were no shares repurchased pursuant to the open market repurchase authorization.

(2) The average price paid per share does not include the withheld shares discussed in (1).

Transfer Agent

The transfer agent and registrar for our common stock is Corporate Stock Transfer, Inc.

Table of Contents

Equity Compensation Plan Information

Our equity compensation plan information is provided as set forth in Part III, Item 11 herein.

Additional Information

Copies of our annual reports, quarterly reports, current reports, and any amendments to those reports, are available free of charge on the Internet at www.sec.gov. All statements made in any of our filings, including all forward-looking statements, are made as of the date of the document, in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Stock Performance Graph

The following information of Part II Item 5 is being furnished and shall not be deemed to be soliciting material or to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, nor will it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that we specifically incorporate such information by reference thereto.

The following graph shows a comparison, from July 16, 2014, the date of our Initial Public Offering, through December 31, 2018, of cumulative total return for our common stock, the Russell 2000 Index and the NASDAQ Medical Equipment Index. Such returns are based on historical results and are not intended to suggest future performance. Data for the Russell 2000 Index and the NASDAQ Medical Equipment Index assumes reinvestment of dividends.

Table of Contents

ITEM 6. SELECTED FINANCIAL DATA

The following tables set forth certain selected financial data for each of the years in the five-year period ended December 31, 2018, and is derived from the audited Financial Statements of IRADIMED CORPORATION. The statements of operations data for each of the years in the three-year period ended December 31, 2018 are included elsewhere in this report. The statements of operations data for the years ended December 31, 2015 and 2014 and balance sheet data as of December 31, 2016, 2015 and 2014 are derived from our audited financial statements not included in this report. The selected financial data set forth below is qualified in its entirety by, and should be read in conjunction with, the Financial Statements and Notes thereto and Management s Discussion and Analysis and Results of Operations included elsewhere in this report.

	Years ended December 31,				
	2018	2017	2016	2015	2014
Statements of Operations Data:					
Revenue	$ 30,438,983	$ 23,081,592	$ 32,496,548	$ 31,593,720	$ 15,653,057
Cost of revenue	7,211,633	5,569,896	6,154,836	5,840,407	3,404,400
Gross profit	23,227,350	17,511,696	26,341,712	25,753,313	12,248,657
Operating expenses:					
General and administrative	8,710,882	9,001,164	8,795,703	7,769,881	4,816,973
Sales and marketing	6,995,586	5,502,959	5,278,448	4,705,977	3,297,120
Research and development	1,517,112	1,722,564	1,347,507	1,764,306	1,068,674
Total operating expenses	17,223,580	16,226,687	15,421,658	14,240,164	9,182,767
Income from operations	6,003,770	1,285,009	10,920,054	11,513,149	3,065,890
Other income (expense), net	193,537	111,377	32,680	121,385	(48,549)
Income before provision for income taxes	6,197,307	1,396,386	10,952,734	11,634,534	3,017,341
Provision for income tax (benefit) expense	(106,143)	896,622	3,738,189	4,104,614	966,975
Net income	$ 6,303,450	$ 499,764	$ 7,214,545	$ 7,529,920	$ 2,050,366
Net income per share:					
Basic	$ 0.59	$ 0.05	$ 0.67	$ 0.68	$ 0.23
Diluted	$ 0.52	$ 0.04	$ 0.60	$ 0.60	$ 0.20
Weighted-average shares outstanding:					
Basic	10,758,752	10,638,858	10,818,427	11,003,272	8,743,461
Diluted	12,110,117	11,720,316	11,989,681	12,556,887	10,219,143

	As of December 31,				
	2018	2017	2016	2015	2014
Balance Sheets Data:					
Cash and cash equivalents	$ 28,027,688	$ 18,205,976	$ 17,713,871	$ 19,368,114	$ 9,454,150
Investments	6,349,915	8,135,123	7,965,521	7,602,204	7,913,793
Working capital	39,852,197	31,029,638	30,194,520	30,913,633	19,775,355
Total assets	48,442,258	39,012,534	37,194,484	35,244,207	23,309,719
Total stockholders equity	41,945,733	32,930,877	31,889,125	31,933,025	20,890,696

Table of Contents

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

You should read this discussion and analysis together with our audited financial statements, the notes to such statements and the other financial information included in this Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under the section entitled Risk Factors and elsewhere in this Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. See CAUTIONARY STATEMENTS REGARDING FORWARD-LOOKING STATEMENTS for a discussion of the uncertainties, risks and assumptions associated with these statements.

Our Business

We develop, manufacture, market and distribute Magnetic Resonance Imaging (MRI) compatible medical devices and accessories and services relating to them.

We are a leader in the development of innovative MRI compatible medical devices and the only known provider of non-magnetic intravenous (IV) infusion pump systems that are specifically designed to be safe for 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 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.

Our 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; invasive and 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.

We generate revenue from the one-time sale of MRI compatible medical devices and accessories, ongoing service contracts and the sale of disposable products used with our devices. The principal customers for our MRI compatible products include hospitals and acute care facilities, both in the United States and internationally. In fiscal year 2012, we undertook a direct sales strategy in the United States. As of December 31, 2018, our direct sales force consisted of 24 field sales representatives, 3 regional sales directors and supplemented by 5 clinical support representatives. To extend our sales reach, we plan to expand our U.S. sales force to between 30 and 32 field sales representatives and 6 clinical support representatives by the end of 2019. We have distribution agreements with independent distributors selling our products internationally.

Historical selling cycles for our devices have varied widely and are now typically three to six months in duration. We also enter into agreements with healthcare supply contracting companies in the U.S., which enable us to sell and distribute our MRidium MRI compatible IV infusion pump system to their member hospitals. Under these agreements, we are required to pay these group purchasing organizations (GPOs) a fee of three percent of the sales of our products to their member hospitals. 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.

Table of Contents

U.S. Tax Reform

On December 22, 2017, the Tax Cuts and Jobs Act (2017 Act) was enacted. The 2017 Act represents major tax reform that, among other provisions, reduced the U.S. corporate tax rate. Certain income tax effects of the 2017 Act, including $0.5 million of tax expense recorded principally due to the write-down of our net deferred tax assets, are reflected in our Financial Statements in accordance with Staff Accounting Bulletin No. 118 (SAB 118), which provides SEC staff guidance regarding the application of Accounting Standards Codification (ASC) Topic 740, *Income Taxes*, in the reporting period in which the 2017 Act became law. See Note 11 to the Financial Statements for further information on the financial impact of the 2017 Act.

Financial Highlights and Outlook

Our revenue was $30.4 million in 2018, $23.1 million in 2017 and $32.5 million in 2016. Our diluted earnings per share was $0.52 in 2018, $0.04 in 2017 and $0.60 in 2016. Our cash from operations was $7.4 million in 2018, $3.4 million in 2017 and $9.4 million in 2016.

Our estimated installed base of medical devices is as follows:

	Years Ended December 31,		
	2018	**2017**	**2016**
IV Infusion Pump Systems	5,000	4,500	4,100
Patient Vital Signs Monitoring Systems	261	75	5

In 2019, we expect our revenues to increase due to higher sales of our medical devices and related accessories, disposables and services through the continued execution of our critical care strategy and headcount growth of our sales team.

We intend to continue targeting an increased number of hospitals and acute care facilities that have yet to adopt our technology and furthering our penetration into the Intensive Care Unit, Emergency Room and other critical care locations within hospitals where there is a high probability that interventional radiology procedures will need to be performed on patients. We expect operating expenses to increase in 2019 due to growth in the size of our sales team and higher sales person commission costs due to anticipated higher sales.

Application of Critical Accounting Policies

We prepare our financial statements in conformity with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and use assumptions that affect the reported amounts of assets, liabilities and related disclosures at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Our significant accounting policies are more fully described in Note 1 to the financial statements. However, we believe that the following critical accounting policies require the use of significant estimates, assumptions and judgments. The use of different estimates, assumptions and judgments could have a material effect on the reported amounts of assets, liabilities and related disclosures as of the date of the financial statements and revenue and expenses during the reporting period.

Revenue Recognition

On January 1, 2018, we adopted ASU 2014-09, Revenue from Contracts with Customers (Topic 606) using the modified retrospective method applied to contracts which were incomplete as of January 1, 2018. Results from reporting periods beginning after January 1, 2018 are presented under this new guidance, while prior period amounts are unadjusted and continue to be reported under previous revenue recognition guidance.

We generate revenue from the one-time sale of MRI compatible medical devices and accessories, extended warranty agreements, product maintenance and the sale of disposable products used with our devices. The principal customers for our MRI compatible products include hospitals and acute care facilities, both in the U.S. and internationally. In the U.S. we sell our products through our direct sales force and outside of the U.S. we sell our products through third-party distributors who resell our products to end users.

For most domestic sales, we enter into agreements with healthcare supply contracting companies, commonly referred to as Group Purchasing Organizations (GPOs), which enable us to sell and distribute our products to their member hospitals. Our agreements with GPOs typically include negotiated pricing for all group members established at time of GPO contract execution.

Table of Contents

We do not sell to GPOs. Hospitals, group practices and other acute care facilities that are members of a GPO, purchase products directly from us under the terms of our GPO agreements.

We recognize revenue when all of the following criteria are met: we have a contract with a customer that creates enforceable rights and obligations; promised products or services are identified; the transaction price, or the amount we expect to receive, is determinable and we have transferred control of the promised products or services to the customer. We consider transfer of control evidenced upon the passage of title and risks and rewards of ownership to the customer. We allocate the transaction price using the relative standalone selling price method. Customer sale prices for our MRI compatible IV infusion pump systems and related disposables and services are contractually fixed over the GPO contract term. We recognize a receivable at the point in time we have an unconditional right to payment. Payment terms are typically within 45 days after transferring control to U.S. customers. Most international distributors are required to pay a portion of the transaction price in advance and the remaining amount within 30 days of receiving the related products. Due to the short-term nature of these payment terms, we have elected to use the practical expedient that allows us to ignore the possible existence of a significant financing component within the contract.

We have elected to account for shipping and handling charges billed to customers as revenue and shipping and handling related expenses as cost of revenue.

In certain U.S. states we are required to collect sales taxes from our customers. We have elected to exclude the amounts collected for these taxes from revenue and record them as a liability until remitted to the taxing authority.

Contract Liabilities

We record contract liabilities, or deferred revenue, when we have an obligation to provide a product or service to the customer and payment is received in advance of our performance. When we sell a product or service with a future performance obligation, we defer revenue allocated to the unfulfilled performance obligation and recognize this revenue when, or as, the performance obligation is satisfied.

Our deferred revenue consists of advance payments received from customers prior to the transfer of products or services, shipments that are in-transit at the end of a period and sales of extended warranty agreements. Advanced payments received from customers and shipments in-transit are recognized in revenue at the time control of the related products has been transferred to the customer or services have been delivered. Amounts related to extended warranty agreements are deferred and recognized in revenue ratably over the agreement period, which is typically one to four years after control of the related products is transferred to the customer, as we believe this recognition pattern best depicts the transfer of services being provided.

Deferred revenue is classified as current or long-term deferred revenue in our Balance Sheets, depending on the expected timing of satisfying the related performance obligations.

Capitalized Contract Costs

We capitalize commissions paid to our sales managers related to contracts with customers when the associated revenue is expected to be earned over a period of time. Deferred commissions are primarily related to the sale of extended warranty agreements. Capitalized commissions are included in Prepaid Expenses and Other Current Assets in our Balance Sheets when the associated expense is expected to be recognized in one year or less, or in Other Assets when the associated expense is expected to be recognized in greater than one year. The associated expense is included in Sales and Marketing expenses in our Statements of Operations.

Variable Consideration

Most of our sales are subject to 30 to 60-day customer-specified acceptance provisions primarily for purposes of ensuring products were not damaged during the shipping process. Historically, we have experienced immaterial product returns and, when experienced, we typically exchange the affected products with new products. Accordingly, variable consideration from contracts with customers is immaterial to our financial statements.

Table of Contents

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable is recorded at the transaction price of the related products and services. We regularly assess the sufficiency of the allowance for estimated uncollectible accounts receivable. Estimates are based on historical collection experience and other customer-specific information, such as bankruptcy filings or known liquidity issues of our customers. When it is determined that an account receivable is uncollectible, it is written off and relieved from the allowance. Any future determination that the allowance for estimated uncollectible accounts receivable is not properly stated could result in changes in operating expense and results of operations.

Inventory

Inventory is stated at the lower of standard cost, which approximates actual cost on a first-in, first-out basis, or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. We may be exposed to a number of factors that could result in portions of our inventory becoming either obsolete or in excess of anticipated usage. These factors include, but are not limited to, technological changes, competitive pressures in products and prices, and the introduction of new product lines. We regularly evaluate our ability to realize the value of inventory based on a combination of factors, including historical usage rates, forecasted sales, product life cycles, and market acceptance of new products. When inventory that is obsolete or in excess of anticipated usage is identified, it is written down to net realizable value or an inventory valuation allowance is established.

The estimates we use in projecting future product demand may prove to be incorrect. Any future determination that our inventory is overvalued could result in increases to our cost of sales and decreases to our operating margins and results of operations.

Stock-based compensation

We apply the fair value recognition provisions of Financial Accounting Standards Board Accounting Standards Codification Topic 718, *Compensation Stock Compensation* (ASC 718). Determining the amount of stock-based compensation to be recorded for stock options that we grant requires us to develop estimates of the fair value as of the grant date. Calculating the fair value of stock option awards requires that we make highly subjective assumptions. We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. As we completed our IPO in July 2014, we utilize the historical stock price volatility from a representative group of public companies, which includes the Company, to estimate expected stock price volatility. We selected companies from the medical device industry with market capitalizations that are similar to ours. We intend to continue to utilize the historical volatility of the same or similar public companies to estimate expected volatility until a sufficient amount of historical information regarding the price of our publicly traded stock becomes available. We use the simplified method as prescribed by ASC 718 to calculate the expected term of stock options granted to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term of our stock option awards. The risk-free interest rate used for each grant is based on the U.S. Treasury yield curve in effect at the time of the grant for instruments with a similar expected life. We utilize a dividend yield of zero as we have no current intention to pay cash dividends.

On January 1, 2017, we adopted Accounting Standards Update (ASU) 2016-09, *Compensation Stock Compensation (Topic 718).* Resulting from the adoption of ASU 2016-09 and on a prospective basis, we record excess tax benefits and deficiencies in the Statement of Operations as a component of the provision for income taxes and presented as an operating activity in the Statements of Cash Flows. The payment of

withholding taxes on the net share settlement of equity awards is presented as a financing activity in the Statements of Cash Flows.

Also resulting from the adoption of ASU 2016-09, we elected to recognize forfeitures as they occur.

As stock-based compensation is an important part of our employee compensation reward strategy, we expect the future impact of stock-based compensation expense on our financial results to grow due to additional stock grants and increased headcount.

Table of Contents

Income taxes

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

On December 22, 2017, the 2017 Act was enacted. As a result of the 2017 Act, Iradimed was required to revalue its deferred tax assets and deferred tax liabilities to account for the future impact of lower corporate tax rates on these deferred amounts. The reduction in the federal corporate tax rate increased our income tax expense for the year ended December 31, 2017 due to the write-down of our net deferred tax assets. See Note 11 to the Financial Statements for further information on the financial impact of the 2017 Act.

We record net deferred tax assets to the extent we believe these assets will more likely than not be realized. In making such determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent financial operations. A valuation allowance is recorded to offset net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We recognize the tax benefit of uncertain tax positions in the financial statements based on the technical merits of the position. When the tax position is deemed more likely than not of being sustained, we recognize the largest amount of tax benefit that is greater than 50 percent likely of being ultimately realized upon settlement. We believe our tax positions are fully supportable.

JOBS Act Accounting Election

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act (JOBS Act), enacted in April 2012. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. The JOBS Act also permits us, as an emerging growth company, to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We chose to opt out of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by issuers. This decision to opt out of the extended transition period under the JOBS Act is irrevocable. Further, we anticipate that starting December 31, 2019, we will no longer be an emerging growth company and after that date we will no longer be able to avail ourselves of these reduced reporting requirements or exemptions.

Results of Operations

The following table sets forth for the periods indicated selected statements of operations data as a percentage of total revenue. Our historical operating results are not necessarily indicative of the results for any future period.

	Percent of Revenue Years Ended December 31,		
	2018	2017	2016
Revenue	100.0%	100.0%	100.0%
Cost of revenue	23.7	24.1	18.9
Gross profit	76.3	75.9	81.1
Operating expenses:			
General and administrative	28.6	39.0	27.1
Sales and marketing	23.0	23.8	16.2
Research and development	5.0	7.5	4.1
Total operating expenses	56.6	70.3	47.5
Income from operations	19.7	5.6	33.6
Other income, net	0.6	0.5	0.1
Income before provision for income taxes	20.4	6.0	33.7
Provision for income tax (benefit) expense	(0.3)	3.9	11.5
Net income	20.7%	2.2%	22.2%

Table of Contents

Comparison of the Years Ended December 31, 2018 and 2017

Revenue by Geographic Region

(In millions, except percent change)	Years Ended December 31, 2018	2017	Change
United States	$ 24.5	$ 19.5	25.7%
International	5.9	3.6	65.6%
Total Revenue	$ 30.4	$ 23.1	31.9%

Revenue by Type

(In millions, except percent change)	Years Ended December 31, 2018	2017	Change
Devices:			
MRI Compatible IV Infusion Pump Systems	$ 14.5	$ 13.6	6.7%
MRI Compatible Patient Vital Signs Monitoring Systems	6.7	1.9	260.0%
Total Devices Revenue	21.2	15.5	37.0%
Disposables and Services	7.7	6.6	16.9%
Amortization of extended warranty agreements	1.5	1.0	52.2%
Total Revenue	$ 30.4	$ 23.1	31.9%

Revenue increased $7.3 million, or 31.9 percent, to $30.4 million from $23.1 million for the same period in 2017. This increase is primarily due to an increase in the number of our MRI compatible medical devices that we recognized in revenue and higher revenue from our IV sets and services. The increase was partially offset by a lower average selling price for our infusion pump systems resulting from higher international sales as a percent of total sales in 2018 compared to 2017.

During the year ended December 31, 2018, we recognized revenue on 451 MRI compatible IV infusion pumps compared to 392 pumps in 2017. The average selling price of our MRI compatible IV infusion pump systems recognized in revenue during the year ended December 31, 2018 was approximately $32,200, compared to $34,700 for the same period in 2017. The decrease in average selling price is the result of higher international unit sales and an unfavorable product sales mix during 2018 when compared to 2017.

We recognized revenue on 186 MRI compatible patient vital signs monitoring systems during the year ended December 31, 2018, compared to 70 systems for the same period in 2017. The average selling price of our MRI compatible patient vital signs monitoring systems recognized in revenue was approximately $35,100 during the year ended December 31, 2018, compared to $25,200 for the same period in 2017. The increase in average selling price of our MRI compatible patient vital signs monitoring system is due to higher domestic unit sales in 2018 when compared to 2017.

Revenue from sales in the U.S. increased $5.0 million, or 25.7 percent, to $24.5 million from $19.5 million for the same period in 2017. Revenue from sales internationally increased $2.3 million, or 65.6 percent, to $5.9 million from $3.6 million for the same period in 2017. Domestic sales accounted for 80.5 percent of total revenue for the year ended December 31, 2018, compared to 84.5 percent for the same period in 2017.

Revenue from sales of devices increased $5.7 million, or 37.0 percent, to $21.2 million from $15.5 million for the same period in 2017. Revenue from sales of our disposables and services increased $1.1 million, or 16.9 percent, to $7.7 million from $6.6 million for the same period in 2017. Revenue from the amortization of our extended maintenance contracts increased $0.5 million, or 52.2 percent, to $1.5 million from $1.0 million for the same period in 2017.

Table of Contents

Cost of Revenue and Gross Profit

(In millions, except gross profit percentage)	Years Ended December 31, 2018	2017
Revenue	$ 30.4	$ 23.1
Cost of revenue	7.2	5.6
Gross profit	$ 23.2	$ 17.5
Gross profit percentage	76.3%	75.9%

Cost of revenue increased approximately $1.6 million, or 29.5 percent, to $7.2 million for the year ended December 31, 2018, from $5.6 million for the same period in 2017. Gross profit increased approximately $5.7 million, or 32.6 percent, to $23.2 million for the year ended December 31, 2018 from $17.5 million for the same period in 2017. The increase in cost of revenue and gross profit is due to higher sales during the year ended December 31, 2018, compared to the same period in 2017. Gross profit margin was 76.3 percent and 75.9 percent for the years ended December 31, 2018 and 2017, respectively. The increase in gross profit margin is the result of favorable overhead variance adjustments and higher domestic revenue as a percent of total revenue in 2018 compared to 2017.

Operating Expenses

(In millions, except percentage of revenue)	Years Ended December 31, 2018	2017
General and administrative	$ 8.7	$ 9.0
Percentage of revenue	28.6%	39.0%
Sales and marketing	$ 7.0	$ 5.5
Percentage of revenue	23.0%	23.8%
Research and development	$ 1.5	$ 1.7
Percentage of revenue	5.0%	7.5%

General and Administrative

General and administrative expense decreased approximately $(0.3) million, or (3.2) percent, to $8.7 million for the year ended December 31, 2018, from $9.0 million for the same period last year. This decrease is primarily due to lower stock compensation expense primarily related to a one-time charge for the modification of the underwriters warrants recognized in 2017, the write-off of non-trade accounts receivable during 2017 and lower consulting expenses during 2018, partially offset by higher expenses for payroll and benefits, computer software and supplies, legal and professional expenses.

Sales and Marketing

Sales and marketing expense increased approximately $1.5 million, or 27.1 percent, to $7.0 million for the year ended December 31, 2018, from $5.5 million for the same period in 2017. This is primarily the result of higher salary and commissions expenses resulting from the increased size of our sales team and higher sales during 2018 when compared to 2017, partially offset by lower stock compensation expense.

Research and Development

Research and development expense decreased approximately $(0.2) million, or (11.9) percent, to $1.5 million for the year ended December 31, 2018, from $1.7 million for the same period in 2017. This is primarily due to lower expenses for consulting and outside engineering services, partially offset by higher payroll and stock compensation expense.

Other Income, Net

Other income, net consists of interest income, foreign currency transactional gains and losses, and other miscellaneous income. We reported other income of approximately $194,000 and $111,000 for the years ended December 31, 2018 and 2017, respectively. This increase is primarily the result of higher interest income, partially offset by higher losses on maturities of investments during the year ended December 31, 2018 compared to the same period in 2017.

Table of Contents

Income Taxes

We recorded a provision for income tax benefit of approximately $(0.1) million for the year ended December 31, 2018. For the year ended December 31, 2017, we recorded a provision for income tax expense of approximately $0.9 million. Our effective tax rate for the year ended December 31, 2018 was (1.7) percent compared to 64.2 percent for the same period in 2017. The decrease in our provision for income taxes and effective tax rate is primarily the result of discrete items related to tax benefits associated with the exercise and sale of employee options and underwriters warrants during 2018 and $0.5 million of tax expense recorded during the year ended December 31, 2017 due to a one-time write-down of net deferred tax assets resulting from the 2017 Act, enacted on December 22, 2017. See Note 11 to the Financial Statements for further information on the financial statement impact of the 2017 Act.

Comparison of the Years Ended December 31, 2017 and 2016

Revenue by Geographic Region

	Years Ended December 31,		
(In millions, except percent change)	**2017**	**2016**	**Change**
United States	$ 19.5	$ 28.9	(32.5)%
International	3.6	3.6	(0.4)%
Total Revenue	$ 23.1	$ 32.5	(29.0)%

Revenue by Type

	Years Ended December 31,		
(In millions, except percent change)	**2017**	**2016**	**Change**
Devices:			
MRI Compatible IV Infusion Pump Systems	$ 13.6	$ 25.5	(46.6)%
MRI Compatible Patient Vital Signs Monitoring Systems	1.9	0.3	529.7%
Total Devices Revenue	15.5	25.8	(40.0)%
Disposables and Services	6.6	6.4	3.2%
Amortization of extended warranty agreements	1.0	0.3	233.3%
Total Revenue	$ 23.1	$ 32.5	(29.0)%

Revenue decreased $(9.4) million, or (29.0) percent, to $23.1 million from $32.5 million for the same period in 2016. This decrease is primarily due to a decrease in the number of MRI compatible IV infusion pump systems that we recognized in revenue, partially offset by an increase in sales of our MRI compatible patient vital signs monitors, higher revenue from our IV sets and services and a higher average selling price for our infusion pump systems resulting from a favorable product sales mix as we sold more higher priced optional pump features per pump sale on average in 2017 compared to 2016.

During the year ended December 31, 2017, we recognized revenue on 392 MRI compatible IV infusion pumps compared to 837 pumps in 2016. The average selling price of our MRI compatible IV infusion pump systems recognized in revenue during the year ended December 31, 2017 was approximately $34,700, compared to $30,500 for the same period in 2016.

We recognized revenue on 70 MRI compatible patient vital signs monitoring systems during the year ended December 31, 2017, compared to 5 systems for the same period in 2016. The average selling price of our MRI compatible patient vital signs monitoring systems recognized in revenue was approximately $25,200 during the year ended December 31, 2017, compared to $20,000 for the same period in 2016.

Revenue from sales in the U.S. decreased $(9.4) million, or (32.5) percent, to $19.5 million from $28.9 million for the same period in 2016. Revenue from sales internationally was consistent at $3.6 million for the years ended December 31, 2017 and 2016. Domestic sales accounted for 84.5 percent of total revenue for the year ended December 31, 2017, compared to 88.9 percent for the same period in 2016.

Revenue from sales of devices decreased $(10.3) million, or (40.0) percent, to $15.5 million from $25.8 million for the same period in 2016. Revenue from sales of our disposables and services increased $0.9 million, or 13.4 percent, to $7.6 million from $6.7 million for the same period in 2016. Revenue from the amortization of our extended maintenance contracts increased $0.7 million, or 233.3 percent, to $1.0 million from $0.3 million for the same period in 2016.

Table of Contents

Cost of Revenue and Gross Profit

(In millions, except gross profit percentage)	Years Ended December 31, 2017	2016
Revenue	$ 23.1	$ 32.5
Cost of revenue	5.6	6.2
Gross profit	$ 17.5	$ 26.3
Gross profit percentage	75.9%	81.1%

Cost of revenue decreased approximately $0.6 million, or (9.5) percent, to $5.6 million for the year ended December 31, 2017, from $6.2 million for the same period in 2016. Gross profit decreased approximately $8.8 million, or (33.5) percent, to $17.5 million for the year ended December 31, 2017 from $26.3 million for the same period in 2016. The decrease in cost of revenue and gross profit is due to lower sales during the year ended December 31, 2017, compared to the same period in 2016. Gross profit margin was 75.9 percent and 81.1 percent for the years ended December 31, 2017 and 2016, respectively. This is the result of unfavorable inventory adjustments due to lower production output, higher international sales as a percent of total revenue and the impact of sales of our MRI compatible patient vital signs monitor systems at introductory prices, partially offset by favorable sales mix for our MRI compatible IV infusion pumps.

Operating Expenses

(In millions, except percentage of revenue)	Years Ended December 31, 2017	2016
General and administrative	$ 9.0	$ 8.8
Percentage of revenue	39.0%	27.1%
Sales and marketing	$ 5.5	$ 5.3
Percentage of revenue	23.8%	16.2%
Research and development	$ 1.7	$ 1.3
Percentage of revenue	7.5%	4.1%

General and Administrative

General and administrative expense increased approximately $0.2 million, or 2.3 percent, to $9.0 million for the year ended December 31, 2017, from $8.8 million for the same period in 2016. This increase is primarily due to higher expenses for payroll and employee benefits resulting from higher headcount, stock compensation expense primarily related to a one-time charge for the modification of the underwriters warrants and the write-off of non-trade accounts receivable, partially offset by lower expenses for legal and professional fees, corporate franchise taxes and GPO administrative fees due to lower sales.

Sales and Marketing

Sales and marketing expense increased approximately $0.2 million, or 4.3 percent, to $5.5 million for the year ended December 31, 2017, from $5.3 million for the same period in 2016. This is primarily the result of higher salary and commissions expenses resulting from the increased size

of our sales team.

Research and Development

Research and development expense increased approximately $0.4 million, or 27.8 percent, to $1.7 million for the year ended December 31, 2017, from $1.3 million for the same period in 2016. This is primarily due to higher expenses for payroll resulting from higher headcount and consulting costs, partially offset by lower expenses for outside engineering services.

Other Income, Net

Other income, net consists of interest income, foreign currency transactional gains and losses, and other miscellaneous income. We reported other income of approximately $111,000 and $33,000 for the years ended December 31, 2017 and 2016, respectively. This increase is primarily the result of lower realized losses on the maturities of investments during the year ended December 31, 2017 compared to the same period in 2016.

Table of Contents

Income Taxes

We recorded income tax expense of approximately $0.9 million and $3.7 million for the years ended December 31, 2017 and 2016, respectively. The lower income tax expense for the year ended December 31, 2017 is due to lower income before provision for income taxes, partially offset by a higher effective tax rate when compared to the same period in 2016. Our effective tax rate for the year ended December 31, 2017 was 64.2 percent compared to 34.1 percent for the same period in 2016. The increase in our effective tax rate is primarily the result of $0.5 million of tax expense due to a one-time non-cash write-down of net deferred tax assets resulting from the 2017 Act, enacted on December 22, 2017. Additional causes for the higher effective tax rate are tax deficiencies associated with the exercise and vesting of certain stock compensation awards, stock compensation expense and U.S. state tax expense, partially offset by favorable provision to return adjustments, a higher domestic production activities deduction and research and development credits. See Note 11 to the Financial Statements for further information on the financial statement impact of the 2017 Act.

Liquidity and Capital Resources

Our principal sources of liquidity have historically been our cash and cash equivalents balances, our investments, cash flow from operations and access to the financial markets. Our principal uses of cash are operating expenses, working capital requirements and capital expenditures.

As of December 31, 2018, we had cash and cash equivalents and investments of $34.4 million, stockholders equity of $41.9 million, and working capital of $39.9 million compared to cash and cash equivalents and investments of $26.3 million, stockholders equity of $32.9 million, and working capital of $31.0 million as of December 31, 2017.

	For the Years Ended December 31,		
(In millions)	**2018**	**2017**	**2016**
Net cash provided by operating activities	$ 7.4	$ 3.4	$ 9.4
Net cash provided by (used in) investing activities	$ 1.5	$ (1.0)	$ (1.9)
Net cash provided by (used in) financing activities	$ 0.9	$ (1.9)	$ (9.1)

Comparison of the Years Ended December 31, 2018, 2017 and 2016

Operating Activities

For the year ended December 31, 2018, cash provided by operations increased $4.0 million to $7.4 million from $3.4 million in 2017. This increase is the result of higher net income and lower cash outflows for prepaid expenses and other current assets and accounts payable, partially offset by higher cash outflows for prepaid income taxes and lower cash inflows from deferred revenue.

For the year ended December 31, 2017, cash provided by operations decreased $(6.0) million to $3.4 million, compared to $9.4 million in 2016. This decrease is the result of lower net income and higher cash outflows for accrued income taxes, accounts payable and prepaid expenses and

other current assets, partially offset by lower cash outflows for inventory purchases and payroll. The sum of our net income and certain non-cash expense items, such as stock compensation expense, depreciation and amortization and the write-off of non-trade accounts receivable was $4.5 million in 2017, compared to $10.0 million in 2016.

Investing Activities

For the year ended December 31, 2018, cash provided by investing activities was $1.5 million, compared to cash used in investing activities of $(1.0) million in 2017. During 2018, $2.9 million of investments matured. This cash inflow was partially offset using $1.1 million to purchase corporate debt securities and $0.2 million to purchase property and equipment.

For the year ended December 31, 2017, cash used in investing activities was $1.0 million, compared to $1.9 million in 2016. During 2017, we used $2.7 million to purchase corporate debt securities and $0.8 million to purchase property and equipment. These cash outflows were partially offset by $2.7 million in maturities of investments.

Financing Activities

For the year ended December 31, 2018, cash provided by financing activities was $0.9, compared to cash used in financing activites of $(1.9) million in 2017. The increase in cash flow from financing activities primarily relates to $1.2 million of proceeds from the exercise of stock options and warrants during 2018 and the purchase of $1.8 million of treasury stock during 2017.

Table of Contents

For the year ended December 31, 2017, cash used in financing activities was $1.9 million and primarily related to the purchase of approximately $1.8 million of treasury stock, partially offset by taxes paid for the net share settlement of certain equity awards granted by the Company to employees.

Sales to end users in the United States are generally made on open credit terms. Management maintains an allowance for potential credit losses.

Our manufacturing operations and headquarters facility is approximately 23,100 square feet located in Winter Springs, Florida. This facility has been leased from Susi, LLC, an entity controlled by our President, CEO and Chairman, Roger Susi. Pursuant to the terms of our lease, the monthly base rent is $34,133, adjusted annually for changes in the consumer price index.

We believe our sources of liquidity, including cash flow from operations, existing cash, investments, and available financing sources will be sufficient to meet our projected cash requirements for at least the next 12 months from the date the financial statements are issued. Any equity financing may be dilutive to stockholders, and debt financing, if available, may involve restrictive covenants that increase our costs. We monitor our capital requirements to ensure our needs are in line with available capital resources. From time to time, we may explore additional financing sources to meet our working capital requirements, make continued investment in research and development, expand our business and acquire products or businesses that complement our current business. These actions would likely affect our future capital requirements and the adequacy of our available funds. Our future liquidity and capital requirements will depend on numerous factors, including the:

- Amount and timing of revenue and expenses;
- Extent to which our existing and new products gain market acceptance;
- Extent to which we make acquisitions;
- Cost and timing of product development efforts and the success of these development efforts;
- Cost and timing of selling and marketing activities; and
- Availability of borrowings or other means of financing.

Contractual Obligations

In the normal course of business, we enter into obligations and commitments that require future contractual payments. The commitments result primarily from purchase orders with vendors that supply components used in our medical devices and related disposables and commitments for our building and office equipment leases. The following table summarizes our contractual obligations and commercial commitments as of December 31, 2018:

			Payments due by Period		
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Unconditional purchase obligations	$ 2,674,691	$ 2,573,081	$ 101,610	$	$
Operating lease obligations	170,664	170,664			
Total	$ 2,845,355	$ 2,743,745	$ 101,610	$	$

Purchase obligations are defined as agreements to purchase goods or services that are enforceable and legally binding. Included in the purchase obligations category above are obligations related to purchase orders for inventory purchases under our standard terms and conditions and under negotiated agreements with vendors. We expect to receive consideration (products or services) for these purchase obligations. The purchase obligation amounts do not represent all anticipated purchases in the future, but represent only those items for which we are contractually obligated. The table above does not include obligations under employment agreements for services rendered in the ordinary course of business.

Off-Balance Sheet Arrangements

During the periods presented, we did not have and we do not currently have any off-balance sheet arrangements, as defined under SEC rules.

Table of Contents

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We develop our products in the U.S. and sell those products into more than 50 countries throughout the world. We also purchase certain components for our products from foreign vendors. Most of our sale and purchase transactions are denominated in the U.S. Dollar. As a result, our financial results could be affected by factors such as foreign currency exchange rates relative to the U.S. Dollar or weak economic conditions in foreign markets. In addition, changes in exchange rates may also affect the end-user prices of our products compared to those of our competitors, who may be selling their products in local currencies, making our products less competitive in some countries.

Foreign Currency Exchange Risk

We have foreign currency risks related to our revenue and cost of revenue denominated in currencies other than the U.S. Dollar, principally the Japanese yen (Yen). The volatility of the Yen depends on many factors that we cannot forecast with reliable accuracy. We have experienced and will continue to experience fluctuations in our net income as a result of transaction gains (losses) related to revaluing Yen denominated accounts payable balances. In the event our Yen denominated accounts payable or expenses increase, our operating results may be affected by fluctuations in the Yen exchange rate. If the U.S. Dollar uniformly increased or decreased in strength by 10 percent relative to the Yen, our net income would have correspondingly increased or decreased by an immaterial amount for the year ended December 31, 2018.

Interest Rate Risk

When able, we invest excess cash in bank money-market funds, corporate debt securities or discrete short-term investments. Our interest income is sensitive to changes in the general level of interest rates in the U.S. If market interest rates were to change by 100 basis points from levels at December 31, 2018, we expect a corresponding change of approximately $180,000 in interest income earned on our excess cash held in interest bearing accounts.

The fair value of our corporate bonds held as short-term investments is sensitive to changes in the general level of interest rates in the U.S., and the fair value of these investments will decline if market interest rates increase. As of December 31, 2018, our corporate bonds consisted of the following:

		Expected Maturity Dates			
	Fair Value	2019	2020	2021	2022
Corporate bonds:					
U.S. corporations	$ 5,429,336	$ 3,211,110	$	$ 1,735,661	$ 482,565
International corporations	920,579	447,543	473,036		
Total	$ 6,349,915	$ 3,658,653	$ 473,036	$ 1,735,661	$ 482,565

Our corporate bonds have fixed interest rates and semi-annual interest payment dates. If market interest rates were to change by 100 basis points from levels at December 31, 2018, we expect the corresponding change in fair value of our investments would be approximately $85,000. This is based on sensitivity analyses performed on our financial position as of December 31, 2018. Actual results may differ as our analysis of the effects of changes in interest rates does not account for, among other things, sales of securities prior to maturity and repurchase of replacement securities, the change in mix or quality of the investments in the portfolio, and changes in the relationship between short-term and long-term

interest rates.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Financial Statements and Supplementary Data required by this Item 8 are incorporated by reference to information beginning on Page F-1 of this Form 10-K.

Table of Contents

Selected Quarterly Financial Data (Unaudited)

The following tables present our operating results for each of the eight quarters in the period ending December 31, 2018. The information for each of these quarters is unaudited and has been prepared on the same basis as our audited financial statements appearing elsewhere in this report.

In the opinion of our management, all necessary adjustments, including normal recurring adjustments, have been included to present fairly the unaudited quarterly results when read in conjunction with our audited Financial Statements and the related notes appearing elsewhere in this report. These operating results are not necessarily indicative of the results of any future period.

	Quarters Ended			
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
Revenue	$ 8,339,392	$ 7,614,655	$ 7,376,785	$ 7,108,151
Cost of revenue	1,982,492	1,826,716	1,710,890	1,691,535
Gross profit	6,356,900	5,787,939	5,665,895	5,416,616
Operating expenses:				
General and administrative	2,147,155	2,181,839	2,078,356	2,303,532
Sales and marketing	2,049,188	1,784,418	1,516,044	1,645,936
Research and development	367,715	373,583	395,988	379,826
Total operating expenses	4,564,058	4,339,840	3,990,388	4,329,294
Income from operations	1,792,842	1,448,099	1,675,507	1,087,322
Other income, net	83,072	42,555	27,838	40,072
Income before provision for income taxes	1,875,914	1,490,654	1,703,345	1,127,394
Provision for income tax expense (benefit)	168,901	(909,619)	348,377	286,198
Net income	$ 1,707,013	$ 2,400,273	$ 1,354,968	$ 841,196
Net income per share:				
Basic	$ 0.16	$ 0.22	$ 0.13	$ 0.08
Diluted	$ 0.14	$ 0.20	$ 0.11	$ 0.07
Weighted-average shares outstanding:				
Basic	10,946,149	10,824,421	10,651,619	10,608,387
Diluted	12,224,505	12,195,870	12,011,475	11,879,889

	Quarters Ended			
	December 31, 2017	September 30, 2017	June 30, 2017	March 31, 2017
Revenue	$ 6,704,944	$ 5,689,724	$ 5,524,364	$ 5,162,560
Cost of revenue	1,640,197	1,307,767	1,234,314	1,387,618
Gross profit	5,064,747	4,381,957	4,290,050	3,774,942
Operating expenses:				
General and administrative	2,152,692	2,551,290	2,189,925	2,107,257
Sales and marketing	1,562,743	1,251,901	1,323,539	1,364,776
Research and development	349,559	382,704	449,011	541,290
Total operating expenses	4,064,994	4,185,895	3,962,475	4,013,323
Income (loss) from operations	999,753	196,062	327,575	(238,381)
Other income, net	32,000	28,715	21,138	29,524
	1,031,753	224,777	348,713	(208,857)

Income (loss) before provision for income taxes				
Provision for income tax expense (benefit)	848,115	32,384	(8,360)	24,483
Net income (loss)	$ 183,638	$ 192,393	$ 357,073	$ (233,340)
Net income (loss) per share:				
Basic	$ 0.02	$ 0.02	$ 0.03	$ (0.02)
Diluted	$ 0.02	$ 0.02	$ 0.03	$ (0.02)
Weighted-average shares outstanding:				
Basic	10,563,860	10,565,598	10,687,746	10,740,979
Diluted	11,788,023	11,643,044	11,727,473	10,740,979

Table of Contents

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain a set of disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. In accordance with Rule 13a-15(b) of the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K, an evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures, as of the end of the period covered by this Annual Report on Form 10-K, were effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining a system of internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles (U.S. GAAP). All internal control systems, no matter how well designed, have inherent limitations.

We conducted an assessment of the effectiveness of our system of internal control over financial reporting as of December 31, 2018, the last day of our fiscal year. This assessment was based on criteria established in the framework Internal Control-Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission and included an evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment. Based on our assessment, management has concluded that our internal control over financial reporting was effective as of the end of the fiscal year to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with U.S. GAAP. We reviewed the results of management s assessment with the Audit Committee of our Board of Directors.

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act (JOBS Act), enacted in April 2012. As an emerging growth company our independent registered public accounting firm is not yet required to, nor have they been engaged to express, nor have they expressed, an opinion on the effectiveness of our internal control over financial reporting.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the year ended December 31, 2018 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Controls

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives as specified above. Management does not expect, however, that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

ITEM 9B. OTHER INFORMATION

Not applicable.

Table of Contents

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The information required by this Item 10 will be included in the Proxy Statement to be filed within 120 days after the fiscal year covered by this annual report on Form 10-K and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 will be included in the Proxy Statement, and such information is incorporated herein by reference.

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

The information required by this Item 12, including Equity Compensation Plan Information, will be included in the Proxy Statement, and such information is incorporated herein by reference.

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

The information required by this Item 13 will be included in the Proxy Statement, and such information is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 will be included in the Proxy Statement, and such information is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. Financial Statements: See Index to Financial Statements in Part II, Item 8 of this annual report on Form 10-K.
2. Financial Statement Schedule: Not applicable.
3. Exhibits: The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this Form 10-K.

Table of Contents

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit A to the Company s Definitive Information Statement on Schedule 14C (File No. 001-36534), filed on October 9, 2015).
3.2	Bylaws of Iradimed Corporation, as amended and restated as of September 13, 2018 (incorporated herein by reference to Exhibit 3.2 to the Company s Current Report on Form 8-K (File No. 001-36534), filed on September 19, 2018).
4.1	Specimen common stock certificate (incorporated herein by reference to Exhibit 4.1 to the Company s Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-196875), filed on July 9, 2014).
10.1+	iRadimed Corporation 2005 Incentive Stock Plan adopted February 1, 2005 (incorporated herein by reference to Exhibit 10.1 to the Company s Registration Statement on Form S-1 (File No. 333-196875), filed on June 18, 2014).
10.2+	Form of Stock Option Agreement for iRadimed Corp. 2005 Incentive Stock Plan (incorporated herein by reference to Exhibit 10.2 to the Company s Registration Statement on Form S-1 (File No. 333-196875), filed on June 18, 2014).
10.3+	Iradimed Corporation 2014 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Company s Registration Statement on Form S-1 (File No. 333-196875), filed on June 18, 2014).
10.4+	Form of Stock Option Agreement for iRadimed Corporation 2014 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the Company s Registration Statement on Form S-1 (File No. 333-196875), filed on June 18, 2014).
10.5+	Form of Restricted Stock Award Agreement for iRadimed Corporation 2014 Equity Incentive Plan (incorporated herein by reference to Exhibit 4.6 to the Company s Registration Statement on Form S-8 (File No. 333-198971), filed on September 26, 2014).
10.6+	Form of Restricted Stock Unit Agreement (Time-Vesting) for iRadimed Corporation 2014 Equity Incentive Plan (incorporated herein by reference to Exhibit 4.7 to the Company s Registration Statement on Form S-8 (File No. 333-198971), filed on September 26, 2014).
10.7+	Form of Restricted Stock Unit Agreement (Performance-Vesting) for iRadimed Corporation 2014 Equity Incentive Plan (incorporated herein by reference to Exhibit 4.8 to the Company s Registration Statement on Form S-8 (File No. 333-198971), filed on September 26, 2014).
10.8	Lease Agreement regarding 1025 Willa Springs Dr. dated January 17, 2014 between Susi, LLC and the Registrant (incorporated herein by reference to Exhibit 10.7 to the Company s Registration Statement on Form S-1 (File No. 333-196875), filed on June 18, 2014).
10.9+	Employment Agreement between the Registrant and Christopher K. Scott dated December 16, 2013 (incorporated herein by reference to Exhibit 10.8 to the Company s Registration Statement on Form S-1 (File No. 333-196875), filed on June 18, 2014).
10.10+	Employment Agreement between the Registrant and Roger Susi dated April 14, 2014 (incorporated herein by reference to Exhibit 10.9 to the Company s Registration Statement on Form S-1 (File No. 333-196875), filed on June 18, 2014).
10.11+	Employment Agreement between the Registrant and Brent Johnson dated December 7, 2011 (incorporated herein by reference to Exhibit 10.10 to the Company s Registration Statement on Form S-1 (File No. 333-196875), filed on June 18, 2014).
10.12	Supply Agreement between dated January 26, 2014 (incorporated herein by reference to Exhibit 10.11 to the Company s Registration Statement on Form S-1 (File No. 333-196875), filed on June 18, 2014).

55

Table of Contents

Exhibit No.	Description
10.13+	Employment Agreement between the Registrant and John McCreery dated March 28, 2017 (incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K (File No. 001-36534), filed on March 30, 2017).
10.14	Amendment to Warrant to Purchase Common Stock dated as of July 17, 2017 by and between the Company and Roth Capital Partners, LLC (incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K (File No. 001-36534), filed on July 21, 2017).
10.15	Amendment to Warrant to Purchase Common Stock dated as of July 17, 2017 by and between the Company and Monarch Capital Group, LLC (incorporated herein by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K (File No. 001-36534), filed on July 21, 2017).
10.16	Amendment to Warrant to Purchase Common Stock dated as of July 17, 2017 by and between the Company and Lisa Walters-Hoffert (incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K/A (File No. 001-36534), filed on November 3, 2017).
10.17+	Employment Agreement Modification, dated as of September 14, 2018 by and between Iradimed Corporation and John McCreery (incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K (File No. 001-36534), filed on September 24, 2018).
10.18+	Employment Agreement, dated as of September 18, 2018 by and between Iradimed Corporation and Louis Waldman (incorporated herein by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K (File No. 001-36534), filed on September 24, 2018).
10.19+	Employment Agreement, dated as of September 21, 2018 by and between Iradimed Corporation and Francis Casey (incorporated herein by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K (File No. 001-36534), filed on September 24, 2018).
23.1	Consent of RSM US LLP, Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on signature page)
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 I.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extensions Schema Document
101.CAL	XBRL Taxonomy Extension Label Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates a management contract or compensatory plan or arrangement.

Confidential treatment has been granted for portions of this exhibit. These portions have been omitted from the exhibit filed with the Securities and Exchange Commission and submitted separately to the Securities and Exchange Commission.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Winter Springs, State of Florida, on March 7, 2019.

IRADIMED CORPORATION
(Registrant)

Dated: March 7, 2019

/s/ Roger Susi
By: Roger Susi
Chairman of the Board, Chief Executive Officer and President
(Principal Executive Officer)

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Roger Susi and Chris Scott as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Roger Susi Roger Susi	Chairman of the Board, Chief Executive Officer and President (Principal Executive Officer)	March 7, 2019
/s/ Chris Scott Chris Scott	Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	March 7, 2019
/s/ Monty Allen Monty Allen	Director	March 7, 2019
/s/ Anthony Vuoto Anthony Vuoto	Director	March 7, 2019
/s/ Jonathan Kennedy Jonathan Kennedy	Director	March 7, 2019

Table of Contents

IRADIMED CORPORATION FINANCIAL STATEMENTS

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets	F-3
Statements of Operations	F-4
Statements of Comprehensive Income	F-5
Statements of Stockholders Equity	F-6
Statements of Cash Flows	F-7
Notes to Financial Statements	F-8

Table of Contents

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of IRADIMED CORPORATION

Opinion on the Financial Statements

We have audited the accompanying balance sheets of IRADIMED CORPORATION (the Company) as of December 31, 2018 and 2017, the related statements of operations, comprehensive income, stockholders equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes to the financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ RSM US LLP

We have served as the Company s auditor since 2013.

Orlando, Florida
March 7, 2019

Table of Contents

IRADIMED CORPORATION

BALANCE SHEETS

	As of December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,027,688	$ 18,205,976
Accounts receivable, net	4,209,992	3,778,929
Investments	6,349,915	8,135,123
Inventory, net	4,059,443	4,210,846
Prepaid expenses and other current assets	526,787	648,881
Prepaid income taxes	1,367,892	127,855
Total current assets	44,541,717	35,107,610
Property and equipment, net	1,869,561	1,868,851
Intangible assets, net	832,519	885,502
Deferred income taxes, net	1,088,702	950,375
Other assets	109,759	200,196
Total assets	$ 48,442,258	$ 39,012,534
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 772,470	$ 656,723
Accrued payroll and benefits	1,802,321	1,512,336
Other accrued taxes	133,000	109,502
Warranty reserve	74,524	60,538
Deferred revenue	1,798,784	1,617,571
Other current liability	108,421	108,571
Accrued income taxes		12,731
Total current liabilities	4,689,520	4,077,972
Deferred revenue	1,807,005	2,003,685
Total liabilities	6,496,525	6,081,657
Stockholders equity:		
Common stock; $0.0001 par value; 31,500,000 shares authorized; 10,989,111 shares issued and outstanding as of December 31, 2018 and 10,596,566 shares issued and outstanding as of December 31, 2017	1,099	1,060
Additional paid-in capital	15,317,335	12,623,181
Retained earnings	26,669,491	20,355,545
Accumulated other comprehensive loss	(42,192)	(48,909)
Total stockholders equity	41,945,733	32,930,877
Total liabilities and stockholders equity	$ 48,442,258	$ 39,012,534

See accompanying notes to financial statements.

Table of Contents

IRADIMED CORPORATION

STATEMENTS OF OPERATIONS

	For the Years Ended December, 31		
	2018	**2017**	**2016**
Revenue	$ 30,438,983	$ 23,081,592	$ 32,496,548
Cost of revenue	7,211,633	5,569,896	6,154,836
Gross profit	23,227,350	17,511,696	26,341,712
Operating expenses:			
General and administrative	8,710,882	9,001,164	8,795,703
Sales and marketing	6,995,586	5,502,959	5,278,448
Research and development	1,517,112	1,722,564	1,347,507
Total operating expenses	17,223,580	16,226,687	15,421,658
Income from operations	6,003,770	1,285,009	10,920,054
Other income, net	193,537	111,377	32,680
Income before provision for income taxes	6,197,307	1,396,386	10,952,734
Provision for income tax (benefit) expense	(106,143)	896,622	3,738,189
Net income	$ 6,303,450	$ 499,764	$ 7,214,545
Net income per share:			
Basic	$ 0.59	$ 0.05	$ 0.67
Diluted	$ 0.52	$ 0.04	$ 0.60
Weighted-average shares outstanding:			
Basic	10,758,752	10,638,858	10,818,427
Diluted	12,110,117	11,720,316	11,989,681

See accompanying notes to financial statements.

Table of Contents

IRADIMED CORPORATION

STATEMENTS OF COMPREHENSIVE INCOME

	For the Years Ended December, 31		
	2018	**2017**	**2016**
Net income	$ 6,303,450	$ 499,764	$ 7,214,545
Other comprehensive income (loss):			
Change in fair value of available-for-sale securities, net of tax benefit of $1,168, $10,039 and $19,406 respectively	(3,554)	(16,655)	(34,764)
Realized loss on available-for-sale securities reclassified to net income, net of tax benefit of $7,269, $2,162 and $30,757 respectively	20,767	4,595	53,200
Other comprehensive income (loss)	17,213	(12,060)	18,436
Comprehensive income	$ 6,320,663	$ 487,704	$ 7,232,981

See accompanying notes to financial statements.

Table of Contents

IRADIMED CORPORATION

STATEMENTS OF STOCKHOLDERS EQUITY

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive (Loss) Income	Stockholders Equity
	Shares	Amount				
Balances, December 31, 2015	11,175,125	$ 1,118	$ 19,332,023	$ 12,655,169	$ (55,285)	$ 31,933,025
Net income				7,214,545		7,214,545
Other comprehensive income					18,436	18,436
Stock-based compensation			1,841,901			1,841,901
Tax benefits credited to equity			603,553			603,553
Exercise of stock options and warrants	116,763	11	247,122			247,133
Purchases and retirement of treasury stock	(569,213)	(57)	(9,969,411)			(9,969,468)
Balances, December 31, 2016	10,722,675	$ 1,072	$ 12,055,188	$ 19,869,714	$ (36,849)	$ 31,889,125
Net income				499,764		499,764
Other comprehensive loss					(12,060)	(12,060)
Stock-based compensation			2,454,363			2,454,363
Net share settlement of restricted stock units	50,759	5	(158,145)			(158,140)
Exercise of stock options and warrants	33,054	3	76,363			76,366
Purchases and retirement of treasury stock	(209,922)	(20)	(1,818,521)			(1,818,541)
Cumulative effect from adoption of accounting standard update			13,933	(13,933)		
Balances, December 31, 2017	10,596,566	$ 1,060	$ 12,623,181	$ 20,355,545	$ (48,909)	$ 32,930,877
Net income				6,303,450		6,303,450
Other comprehensive income					17,213	17,213
Stock-based compensation			1,764,319			1,764,319
Net share settlement of restricted stock units	77,352	8	(309,569)			(309,561)
Exercise of stock options and warrants	315,193	31	1,239,404			1,239,435
Cumulative effect from adoption of accounting standard update				10,496	(10,496)	
Balances, December 31, 2018	10,989,111	$ 1,099	$ 15,317,335	$ 26,669,491	$ (42,192)	$ 41,945,733

See accompanying notes to financial statements.

Table of Contents

IRADIMED CORPORATION

STATEMENTS OF CASH FLOWS

	For the Years Ended December, 31		
	2018	2017	2016
Operating activities:			
Net income	$ 6,303,450	$ 499,764	$ 7,214,545
Adjustments to reconcile net income to net cash provided by operating activities:			
Change in allowance for doubtful accounts	15,833	(7,083)	12,636
Change in provision for excess and obsolete inventory	111,790	69,199	94,186
Depreciation and amortization	1,105,003	1,308,738	955,809
Write-off of non-trade accounts receivable		205,444	
Excess tax benefit on the exercise of stock options			(603,553)
Stock-based compensation	1,764,319	2,454,363	1,841,901
Deferred income taxes, net	(144,430)	(150,657)	(570,910)
Loss on maturity of investments	28,036	6,757	83,957
Changes in operating assets and liabilities:			
Accounts receivable	(446,896)	(201,591)	75,297
Inventory	(121,591)	(334,113)	(1,483,361)
Prepaid expenses and other current assets	(407,461)	(1,161,964)	(702,573)
Other assets	65,135	(13,860)	(117,235)
Accounts payable	34,161	(523,449)	1,113
Accrued payroll and benefits	289,985	477,070	(252,982)
Other accrued taxes	23,498	(9,592)	88,407
Warranty reserve	13,986	19,633	6,824
Deferred revenue	(5,885)	944,632	1,723,918
Other current liability	(150)	(12,063)	120,634
Prepaid income taxes, net of accrued income taxes	(1,252,768)	(155,310)	917,707
Net cash provided by operating activities	7,376,015	3,415,918	9,406,320
Investing activities:			
Purchases of investments	(1,124,512)	(2,693,739)	(4,992,626)
Proceeds from maturity of investments	2,905,000	2,495,004	4,575,140
Purchases of property and equipment	(228,315)	(775,574)	(780,809)
Capitalized intangible assets	(36,350)	(49,189)	(743,486)
Net cash provided by (used in) investing activities	1,515,823	(1,023,498)	(1,941,781)
Financing activities:			
Proceeds from stock option and warrant exercises	1,239,435	76,366	247,133
Taxes paid for the net share settlement of restricted stock units	(309,561)	(158,140)	
Income tax benefits credited to equity			603,553
Purchases of treasury stock		(1,818,541)	(9,969,468)
Net cash provided by (used in) financing activities	929,874	(1,900,315)	(9,118,782)
Net increase (decrease) in cash and cash equivalents	9,821,712	492,105	(1,654,243)
Cash and cash equivalents, beginning of year	18,205,976	17,713,871	19,368,114
Cash and cash equivalents, end of year	$ 28,027,688	$ 18,205,976	$ 17,713,871
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$ 1,375,714	$ 1,205,028	$ 3,392,722

See accompanying notes to financial statements.

Table of Contents

IRADIMED CORPORATION

NOTES TO FINANCIAL STATEMENTS

1 Organization and Significant Accounting Policies

Organization

IRADIMED CORPORATION (IRADIMED , the Company , we , our) was incorporated in Oklahoma in July 1992 and reincorporated in Delaware in April 2014. We develop, manufacture, market and distribute a Magnetic Resonance Imaging (MRI) compatible intravenous (IV) infusion pump system and MRI compatible patient vital signs monitoring systems and related accessories and services.

We are a leader in the development of innovative MRI compatible medical devices and the only known provider of non-magnetic IV infusion pump systems that are specifically designed to be safe for 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 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.

Our 3880 MRI compatible patient vital signs monitoring system (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. 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. Other MRI compatible patient vital signs monitors are large and heavy, creating workflow issues for users. The features of the IRADIMED 3880 Monitor include: wireless ECG with dynamic gradient filtering; wireless SpO2 using Masimo® algorithms; non-magnetic respiratory CO2; invasive and non-invasive blood pressure; patient temperature, and; optional advanced multi-gas anesthetic agent unit featuring continuous Minimum Alveolar Concentration measurements. The 3880 Monitor has an easy-to-use design and allows for the effective communication of patient vital signs information to clinicians.

Our headquarters is located in Winter Springs, Florida.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities in the financial statements and the reported amount of revenue and expenses during the reporting period. Such estimates include allowances for potentially uncollectible accounts receivable, valuation of inventory, intangible assets, allocation of the transaction price to the performance obligations in contracts with our customers, stock-based compensation, deferred income taxes, reserves for warranty obligations, and the provision for income taxes. Actual results could differ from those estimates.

FDA 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. Most 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 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.

Table of Contents

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, 2018, the Warning Letter remains open.

Revenue Recognition

On January 1, 2018, we adopted Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606)* using the modified retrospective method applied to contracts which were incomplete as of January 1, 2018. Results from reporting periods beginning after January 1, 2018 are presented under this new guidance, while prior period amounts are unadjusted and continue to be reported under previous revenue recognition guidance.

We generate revenue from the one-time sale of MRI compatible medical devices and accessories, extended warranty agreements, product maintenace and the sale of disposable products used with our devices. The principal customers for our MRI compatible products include hospitals and acute care facilities, both in the U.S. and internationally. In the U.S. we sell our products through our direct sales force and outside of the U.S. we sell our products through third-party distributors who resell our products to end users.

For most domestic sales, we enter into agreements with healthcare supply contracting companies, commonly referred to as Group Purchasing Organizations (GPOs), which enable us to sell and distribute our products to their member hospitals. Our agreements with GPOs typically include negotiated pricing for all group members established at time of GPO contract execution.

Table of Contents

We do not sell to GPOs. Hospitals, group practices and other acute care facilities that are members of a GPO, purchase products directly from us under the terms of our GPO agreements.

We recognize revenue when all of the following criteria are met: we have a contract with a customer that creates enforceable rights and obligations; promised products or services are identified; the transaction price, or the amount we expect to receive, is determinable and we have transferred control of the promised products or services to the customer. We consider transfer of control evidenced upon the passage of title and risks and rewards of ownership to the customer. We allocate the transaction price using the relative standalone selling price method. Customer sale prices for our MRI compatible IV infusion pump systems and related disposables and services are contractually fixed over the GPO contract term. We recognize a receivable at the point in time we have an unconditional right to payment. Payment terms are typically within 45 days after transferring control to U.S. customers. Most international distributors are required to pay a portion of the transaction price in advance and the remaining amount within 30 days of receiving the related products. Accordingly, we have elected to use the practical expedient that allows us to ignore the possible existence of a significant financing component within the contract.

We have elected to account for shipping and handling charges billed to customers as revenue and shipping and handling related expenses as cost of revenue.

In certain U.S. states we are required to collect sales taxes from our customers. We have elected to exclude the amounts collected for these taxes from revenue and record them as a liability until remitted to the taxing authority.

Contract Liabilities

We record contract liabilities, or deferred revenue, when we have an obligation to provide a product or service to the customer and payment is received in advance of our performance. When we sell a product or service with a future performance obligation, we defer revenue allocated to the unfulfilled performance obligation and recognize this revenue when, or as, the performance obligation is satisfied.

Our deferred revenue consists of advance payments received from customers prior to the transfer of products or services, shipments that are in-transit at the end of a period and sales of extended warranty agreements. Advanced payments received from customers and shipments in-transit are recognized in revenue at the time control of the related products has been transferred to the customer or services have been delivered. Amounts related to extended warranty agreements are deferred and recognized in revenue ratably over the agreement period, which is typically one to four years after control of the related products is transferred to the customer, as we believe this recognition pattern best depicts the transfer of services being provided.

Deferred revenue is classified as current or long-term deferred revenue in our Balance Sheets, depending on the expected timing of satisfying the related performance obligations.

Capitalized Contract Costs

We capitalize commissions paid to our sales managers related to contracts with customers when the associated revenue is expected to be earned over a period of time. Deferred commissions are primarily related to the sale of extended warranty agreements. Capitalized commissions are included in Prepaid Expenses and Other Current Assets in our Balance Sheets when the associated expense is expected to be recognized in one year or less, or in Other Assets when the associated expense is expected to be recognized in greater than one year. The associated expense is included in Sales and Marketing expenses in our Statements of Operations.

Variable Consideration

Most of our sales are subject to 30 to 60-day customer-specified acceptance provisions primarily for purposes of ensuring products were not damaged during the shipping process. Historically, we have experienced immaterial product returns and, when experienced, we typically exchange the affected products with new products. Accordingly, variable consideration from contracts with customers is immaterial to our financial statements.

Cash Equivalents

All highly liquid instruments purchased with an original maturity of three months or less are classified as cash equivalents.

Table of Contents

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable is recorded at the transaction price of the related products and services. We regularly assess the sufficiency of the allowance for estimated uncollectible accounts receivable. Estimates are based on historical collection experience and other customer-specific information, such as bankruptcy filings or known liquidity problems of our customers. When it is determined that an account receivable is uncollectible, it is written off and relieved from the allowance. Any future determination that the allowance for estimated uncollectible accounts receivable is not properly stated could result in changes in operating expense and results of operations. As of December 31, 2018 and 2017, our allowance for doubtful accounts was $42,443 and $37,225, respectively.

Investments

Our investments consist of corporate debt securities and are considered available-for-sale. The specific identification method is used to determine the cost basis of investments sold. Our investments are recorded in our Balance Sheets at fair value. We classify our investments as current based on the nature of the investments and their availability for use in current operations. Unrealized gains and losses on our investments are included in accumulated other comprehensive income (loss), net of tax. Realized gains or losses and impairment losses that are determined to be other-than-temporary are recorded in other income, net in our Statements of Operations.

Fair Value Measurements

Fair value is the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. A three-level valuation hierarchy requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

The valuation hierarchy is based upon the transparency of inputs to the valuation of an asset or liability on the measurement date. The three levels of inputs are:

- Level 1 quoted prices (unadjusted) in active markets for an identical asset or liability.

- Level 2 quoted prices for a similar asset or liability in an active market or model-derived valuations in which all significant inputs are observable for substantially the full term of the asset or liability.

- Level 3 unobservable and significant to the fair value measurement of the asset or liability.

Financial instruments include cash and cash equivalents, investments, accounts receivable, accounts payable and accrued expenses. Cash and cash equivalents and investments are reported at their respective fair values on the balance sheet dates. The recorded carrying amount of accounts receivable, accounts payable and accrued expenses approximates their fair values due to their short-term maturities.

Inventory

Inventory is stated at the lower of standard cost, which approximates actual cost on a first-in, first-out basis, or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. We may be exposed to a number of factors that could result in portions of our inventory becoming either obsolete or in excess of anticipated usage. These factors include, but are not limited to, technological changes, competitive pressures in products and prices, and the introduction of new product lines. We regularly evaluate our ability to realize the value of inventory based on a combination of factors, including historical usage rates, forecasted sales, product life cycles, and market acceptance of new products. When inventory that is obsolete or in excess of anticipated usage is identified, it is written down to net realizable value or an inventory valuation allowance is established.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is computed using the straight-line method over estimated useful lives of the respective assets, which are three to five years for computer software and hardware; five to seven years for furniture, fixtures, machinery and equipment. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the improvements.

Repair and maintenance costs that do not extend the useful life of our property and equipment are expensed as incurred.

Table of Contents

Intangible Assets

Intangible assets include application and legal costs incurred to obtain patents. We capitalize these costs when we determine that probable future economic benefits exist. In making this determination, we consider the projected future operating results associated with the patents, industry and economic trends, and the entry of new products in the market. Costs incurred prior to this determination are expensed in the period they are incurred. We amortize capitalized patent costs using the straight-line method over their useful lives, which is typically 17 years. Periodic costs incurred to maintain existing patents are expensed as incurred.

Research & Development and Capitalized Software Development Costs

Research and development costs are expensed as incurred. Some of our products include embedded software which is essential to the products functionality. Costs incurred in the research and development of new software components and enhancements to existing software components are expensed as incurred until technological feasibility has been established. We capitalize software development costs when the project reaches technological feasibility and cease capitalization when the project is ready for release. Capitalized software development costs are included in intangible assets and are amortized on a straight-line basis over the estimated useful life of the product and included in cost of revenue. Amortization begins when the product is available for general release to the customer.

Long-lived Assets

Long-lived assets are tested for impairment whenever changes in circumstances indicate the carrying value of these assets may be impaired. Impairment indicators include, but are not limited to, technological obsolescence, unfavorable court rulings, significant negative industry and economic trends, and significant underperformance relative to historical and projected future operating results. Impairment is considered to have occurred when the estimated undiscounted future cash flows related to the asset groups are less than its carrying value. Estimates of future cash flows involve consideration of many factors including the marketability of new products, product acceptance and lifecycle, competition, appropriate discount rates, and operating margins. An impairment is recognized as the amount by which the carrying value is greater than the fair value of the asset or asset group.

Warranty

We provide for the estimated cost of product warranties at the time revenue is recognized. While we engage in product quality programs and processes, including actively monitoring and evaluating the quality of our suppliers, the estimated warranty obligation is affected by ongoing product failure rates, material usage costs and direct labor incurred in correcting a product failure. Actual product failure rates, material usage costs and the amount of labor required to repair products that differ from estimates result in revisions to the estimated liability. We warrant for a limited period of time that our products will be free from defects in materials and workmanship. We estimate warranty allowances based on historical warranty experience. The estimates we use in projecting future product warranty costs may prove to be incorrect. Any future determination that our provision for product warranty is understated could result in increases to our cost of revenue and a reduction in our operating profits and results of operations. Historically, warranty expenses have not been material to our financial statements.

Advertising and Marketing

For the years ended December 31, 2018, 2017 and 2016, these costs were $123,451, $118,975 and $136,170, respectively. Advertising and marketing costs are expensed as incurred and included in sales and marketing expense.

Medical Device Excise Taxes

Prior to January 1, 2016, we were subject to the Medical Device Excise Tax applicable to sales of listed medical devices under the Patient Protection and Affordable Care Act (ACA) enacted in 2010. The ACA required us to pay 2.3 percent of the taxable sales value of devices sold. 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 that further suspended the medical device excise tax through December 31, 2019.

Table of Contents

Stock-Based Compensation

Historically, we have granted two types of employee equity awards, stock options and restricted stock units.

We recognize stock-based compensation expense associated with employee equity awards on a straight-line basis over the requisite service period for the entire award, which is generally four years for employees and two years for the board of directors.

The maximum contractual life of our stock options is ten years from the grant date. We utilize the Black-Scholes option pricing model to estimate the grant date fair value of those awards. The Black-Scholes option pricing model requires the input of certain assumptions including stock price, dividend yield, expected volatility, risk-free interest rate, and expected option life. Changes in these assumptions can materially affect the estimated fair value of our employee stock options.

The grant date stock price was based on our closing stock price on the date of grant; dividend yield was based on our expectation of dividend payments over the expected life of the option; expected volatility was based on a study of our volatility and comparable, publicly traded companies with similar products and product life cycles; risk-free interest rate was the rate available on zero coupon U.S. government obligations with a term approximating the expected option life; the expected option life was calculated using the simplified method.

The grant date fair value of our restricted stock units is based on the closing price of our common stock on the date of grant.

We issue new shares of common stock upon exercise of stock options or vesting of restricted stock units.

On January 1, 2017, we adopted ASU 2016-09, *Compensation Stock Compensation (Topic 718).* Resulting from the adoption of ASU 2016-09 and on a prospective basis, we record excess tax benefits and deficiencies in the Statement of Operations as a component of the provision for income taxes and presented as an operating activity in the Statements of Cash Flows. The payment of withholding taxes on the net share settlement of equity awards is presented as a financing activity in the Statements of Cash Flows.

Also resulting from the adoption of ASU 2016-09, we elected to recognize forfeitures as they occur.

Income Taxes

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates

in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

On December 22, 2017, the Tax Cuts and Jobs Act (2017 Act) was enacted. As a result of the 2017 Act, we were required to revalue our deferred tax assets and deferred tax liabilities to account for the future impact of lower corporate tax rates on these deferred amounts. The reduction in the federal corporate tax rate increased our income tax expense for the year ended December 31, 2017. See Note 11 for further information on the financial impact of the 2017 Act.

We record net deferred tax assets to the extent we believe these assets will more likely than not be realized. In making such determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent financial operations. A valuation allowance is recorded to offset net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We recognize the tax benefit of uncertain tax positions in the financial statements based on the technical merits of the position. When the tax position is deemed more likely than not of being sustained, we recognize the largest amount of tax benefit that is greater than 50 percent likely of being ultimately realized upon settlement.

Foreign Currency

Gains and losses from transactions denominated in currencies other than our functional currency are included in other income (expense), net. Foreign currency gains and losses result primarily from fluctuations in the exchange rate between the U.S. Dollar and the Japanese Yen.

Table of Contents

Comprehensive Income

Comprehensive income includes net income and other comprehensive income items that are excluded from net income under U.S. GAAP. Comprehensive income includes unrealized gains and losses on our investments classified as available for sale.

Basic and Diluted Net Income per Share

Basic net income per share is based on the weighted-average number of common shares outstanding during the period. Diluted net income per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. The Underwriters warrants, stock options and restricted stock units granted by us represent the only dilutive effect reflected in diluted weighted-average shares outstanding.

The following table presents the computation of basic and diluted net income per share:

	For the Years Ended December, 31		
	2018	**2017**	**2016**
Net income	$ 6,303,450	$ 499,764	$ 7,214,545
Weighted-average shares outstanding Basic	10,758,752	10,638,858	10,818,427
Effect of dilutive securities:			
Underwriters warrants	92,486		94,169
Stock options	1,137,270	1,067,072	1,074,804
Restricted stock units	121,609	14,386	2,281
Weighted-average shares outstanding Diluted	12,110,117	11,720,316	11,989,681
Basic net income per share	$ 0.59	$ 0.05	$ 0.67
Diluted net income per share	$ 0.52	$ 0.04	$ 0.60

Stock options and warrants to purchase shares of our common stock and restricted stock units excluded from the calculation of diluted net income per share because the effect would have been anti-dilutive are as follows:

	As of December, 31		
	2018	**2017**	**2016**
Anti-dilutive stock options and restricted stock units	21,488	478,882	100,338

Certain Significant Risks and Uncertainties

We market our products to end users in the United States and to third-party 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.

We have deposited our cash and cash equivalents with various financial institutions. Our cash and cash equivalents balances exceed federally insured limits throughout the year. We have not incurred any losses related to these balances.

Our products require clearance from the Food and Drug Administration and international regulatory agencies prior to commercialized sales. Our future products may not receive required approvals. If we were denied such approvals, or if such approvals were revoked or delayed, it would have a materially adverse impact on our business, results of operations and financial condition.

Certain key components of our products essential to their functionality are sole-sourced. Any disruption in the availability of these components would have a materially adverse impact on our business, results of operations and financial condition.

Recent Accounting Pronouncements

Accounting Pronouncements Implemented in 2018

In May 2014, the FASB issued ASU 2014-09, *Revenue Contracts with Customers (Topic 606)*. This update provides guidance on the recognition of revenue based upon the entity s contracts with customers to transfer goods or services at an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. This update also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. This update is effective for annual periods beginning after December 15, 2017, including interim periods within that reporting period. We adopted this guidance effective January 1, 2018 using the modified retrospective method to contracts that were incomplete as of January 1, 2018.

Table of Contents

We evaluated each of the five steps in the new revenue recognition model, which are: 1) Identify the contract with the customer; 2) Identify the performance obligations in the contract; 3) Determine the transaction price; 4) Allocate the transaction price to the performance obligations; and 5) Recognize revenue when, or as, performance obligations are satisfied. We concluded that the adoption of this guidance does not require any adjustment to the opening balance of retained earnings and did not have a material impact to our financial statements. Additionally, our method and timing for recognizing revenue after the implementation of this guidance did not vary significantly from our revenue recognition practices under the previous revenue recognition guidance.

In May 2017, the FASB issued ASU 2017-09, *Compensation Stock Compensation (Topic 718)*. This update clarifies the scope of modification accounting and when it should be applied to a change in terms or conditions of a share-based payment award. Under this update, modification accounting is required for all changes to share-based payment awards, unless all of the following are met: 1) there is no change to the fair value of the award, 2) the vesting conditions have not changed, 3) the classification of the award as an equity instrument or a debt instrument has not changed. This update is effective for annual periods beginning after December 15, 2017, including interim periods within that reporting period. We adopted this guidance effective January 1, 2018. There was no impact to our financial statements resulting from the implementation of this guidance.

In February 2018, the FASB issued ASU 2018-02, *Income Statement Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects From Accumulated Other Comprehensive Income*. This update addresses a specific consequence of the Tax Cuts and Jobs Act (2017 Act). This update allows a reclassification from accumulated other comprehensive income to retained earnings for the stranded tax effects resulting from the 2017 Act. The update eliminates the stranded tax effects that were created as a result of the reduction of historical U.S. federal corporate income tax rate to the newly enacted U.S. federal corporate income tax rate. The accounting update is effective January 1, 2019, with early adoption permitted, and is to be applied either in the period of adoption or retrospectively to each period in which the effect of the change in the U.S. federal corporate income tax rate in the 2017 Act is recognized. We adopted this guidance effective January 1, 2018. As a result of the adoption, $10,496 was reclassified from accumulated other comprehensive income to retained earnings.

Accounting Pronouncements Implemented in 2017

In July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory (Topic 330)*. The amendments in this update require that inventory within the scope of this ASU be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The amendments in this ASU do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured at first-in, first-out (FIFO) or average cost. The update is effective for annual periods beginning after December 15, 2016, including interim periods within that reporting period. We adopted this guidance effective January 1, 2017 on a prospective basis. The adoption of this guidance did not impact our financial condition, results of operations or cash flows.

In November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes (Topic 740)*. The amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments in the update apply to all entities that present a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in this update. The update is effective for annual periods beginning after December 15, 2016, including interim periods within that reporting period. We adopted this guidance effective January 1, 2017 on a retrospective basis. As a result of the adoption, $311,871 of deferred taxes was reclassified from current to noncurrent assets, as of December 31, 2016.

In March 2016, the FASB issued ASU 2016-09, *Compensation Stock Compensation (Topic 718)*. This update identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the recognition of excess tax benefits and deficiencies, the classification of excess tax benefits on the statement of cash flows, classification of awards as either equity or liabilities and an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur. This update is effective for annual and interim periods beginning after December 15, 2016. We adopted this guidance effective January 1, 2017.

Beginning January 1, 2017, excess tax benefits and deficiencies are reflected in the Statement of Operations as a component of the provision for income taxes, whereas they were previously recognized as additional paid-in capital on the Balance Sheet. Adoption of this guidance resulted in the recognition of a net tax deficiency of $74,904 in our provision for income taxes, with the effect of increasing our income tax expense for the year ended December 31, 2017.

Table of Contents

Additionally, beginning on January 1, 2017, and on a prospective basis, the guidance now requires excess tax benefits and deficiencies be presented in the Statement of Cash Flows as an operating activity rather than as a financing activity, while the payment of withholding taxes on the net share settlement of equity awards be presented as a financing activity. The implementation of this guidance did not have a material impact on the Statement of Cash Flows for the year ended December 31, 2017. Prior period amounts were not retrospectively adjusted.

Effective January 1, 2017, we elected to recognize forfeitures as they occur rather than continue to estimate forfeitures expected to occur. This change in accounting policy resulted in an immaterial cumulative-effect adjustment to retained earnings for the year ended December 31, 2017.

The remaining updates required by this standard did not have a material impact to our interim unaudited condensed financial statements.

Recently Issued Accounting Pronouncements to be Implemented

On February 25, 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. ASU 2016-02 supersedes existing lease guidance, including ASC 840 - *Leases*. Among other things, ASU 2016-02 requires recognition of a right-of-use asset and liability for future lease payments for contracts that meet the definition of a lease and requires disclosure of certain information about leasing arrangements. ASU 2016-02 will be effective January 1, 2019, although early adoption is permitted. On July 30, 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which, among other things, allows companies to elect an optional transition method to apply the new lease standard through a cumulative-effect adjustment in the period of adoption. We adopted the standard on January 1, 2019 using the optional transition method. We have made substantial progress in executing our implementation plan and revising our controls and processes to address the lease standard.

We are electing the package of practical expedients, which, among other things, allows us to carry forward our prior lease classifications under ASC 840. We are also electing to adopt the hindsight practical expedient to determine the lease terms.

Adoption of the standard is expected to impact our statement of financial position by approximately $3.2 million for the addition of right-of-use assets and liabilities related to operating leases. ASU 2016-02 also requires expanded disclosure regarding the amounts, timing and uncertainties of cash flows related to a company s lease portfolio. We are evaluating these disclosure requirements and are incorporating the collection of relevant data into our processes in preparation for disclosure in 2019. We do not expect ASU 2016-02 to have a material impact on our annual results of operations or cash flows.

2 Revenue

Disaggregation of Revenue

We disaggregate revenue from contracts with customers by geographic region and revenue type as we believe it best depicts the nature, amount, timing and uncertainty of our revenue and cash flow.

Revenue information by geographic region is as follows:

	For the Years Ended December 31,		
	2018	2017	2016
United States	$ 24,508,026	$ 19,500,680	$ 28,902,911
International	5,930,957	3,580,912	3,593,637
Total revenue	$ 30,438,983	$ 23,081,592	$ 32,496,548

Table of Contents

Revenue information by type is as follows:

	For the Years Ended December 31,		
	2018	2017	2016
Devices:			
MRI Compatible IV Infusion Pump System	$ 14,536,998	$ 13,621,769	$ 25,491,720
MRI Compatible Patient Vital Signs Monitoring Systems	6,655,618	1,848,616	293,552
Total Devices revenue	21,192,616	15,470,385	25,785,272
Disposables and Services	7,728,624	6,613,999	6,412,081
Amortization of extended warranty agreements	1,517,743	997,208	299,195
Total revenue	$ 30,438,983	$ 23,081,592	$ 32,496,548

Contract Liabilities

Our contract liabilities consist of:

	As of December 31,	
	2018	2017
Advance payments from customers	$ 180,425	$ 251,087
Shipments in-transit	9,582	13,326
Extended warranty agreements	3,415,782	3,356,843
Total	$ 3,605,789	$ 3,621,256

Changes in the contract liabilities during the period are as follows:

	Deferred Revenue
Contract liabilities, December 31, 2016	$ 2,676,624
Increases due to cash received from customers	3,040,963
Decreases due to recognition of revenue	(2,096,331)
Contract liabilities, December 31, 2017	$ 3,621,256
Increases due to cash received from customers	2,222,217
Decreases due to recognition of revenue	(2,237,684)
Contract liabilities, December 31, 2018	$ 3,605,789

Capitalized Contract Costs

Our total capitalized contract costs as of December 31, 2018 and December 31, 2017 were $181,248 and $168,757, respectively. Expense for the years ended December 31, 2018, 2017 and 2016 related to the amortization of capitalized contract costs were immaterial to our financial statements.

3 Inventory

Inventory consists of:

	As of December 31,	
	2018	**2017**
Raw materials	$ 3,408,158	$ 3,593,136
Work in process	305,562	280,443
Finished goods	557,566	537,466
Inventory before allowance for excess and obsolete	4,271,286	4,411,045
Allowance for excess and obsolete	(211,843)	(200,199)
Total	$ 4,059,443	$ 4,210,846

Table of Contents

4 Property and Equipment

Property and equipment consist of:

	As of December 31,	
	2018	2017
Computer software and hardware	$ 555,292	$ 490,272
Furniture and fixtures	901,415	655,518
Leasehold improvements	202,026	191,139
Machinery and equipment	2,184,015	2,046,808
Tooling in-process	58,263	46,970
	3,901,011	3,430,707
Accumulated depreciation	(2,031,450)	(1,561,856)
Total	$ 1,869,561	$ 1,868,851

Depreciation and amortization expense of property and equipment was $470,395, $362,872 and $230,282 for the years ended December 31, 2018, 2017 and 2016, respectively.

Property and equipment, net by geographic region is as follows:

	As of December 31,	
	2018	2017
United States	$ 1,439,545	$ 1,349,897
International	430,016	518,954
Total property and equipment, net	$ 1,869,561	$ 1,868,851

Long-lived assets held outside of the United States consist principally of tooling, which is a component of property and equipment, net.

5 Intangible Assets

The following table summarizes the components of intangible asset balances:

	As of December 31,	
	2018	2017
Patents in use	$ 304,270	$ 168,383
Patents in process	73,164	116,260
Internally developed software in use	867,569	867,569
Internally developed software in process	13,723	
Trademarks	23,017	23,017

		1,281,743		1,175,229
Accumulated amortization		(449,224)		(289,727)
Total	$	832,519	$	885,502

Amortization expense of intangible assets was $89,333, $82,399 and $18,017 for the years ended December 31, 2018, 2017 and 2016, respectively.

Expected annual amortization expense for the next five years related to intangible assets is as follows (excludes in-process intangible assets):

2019	$	89,963
2020	$	89,963
2021	$	89,963
2022	$	89,963
2023	$	88,740

Table of Contents

6 Investments

Our investments consisted of corporate bonds that we have classified as available-for-sale and are summarized in the following tables:

	As of December 31, 2018			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds:				
U.S. corporations	$ 5,487,645	$	$ 58,309	$ 5,429,336
International corporations	918,417	2,162		920,579
Total	$ 6,406,062	$ 2,162	$ 58,309	$ 6,349,915

	As of December 31, 2017			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds:				
U.S. corporations	$ 7,244,771	$ 746	$ 63,575	$ 7,181,942
International corporations	971,087	707	18,613	953,181
Total	$ 8,215,858	$ 1,453	$ 82,188	$ 8,135,123

As of December 31, 2018, the scheduled maturities of our investments are as follows:

	Cost	Fair Value
Less than 1 year	$ 3,676,236	$ 3,658,653
1 to 3 years	2,237,851	2,208,697
3 to 5 years	491,975	482,565
Total	$ 6,406,062	$ 6,349,915

7 Fair Value Measurements

The fair value of our assets and liabilities subject to recurring fair value measurements are as follows:

	Fair Value at December 31, 2018			
	Fair Value	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Corporate bonds:				
U.S. corporations	$ 5,429,336	$	$ 5,429,336	$
International corporations	920,579		920,579	

Total	$ 6,349,915	$	$ 6,349,915	$

	Fair Value at December 31, 2017			
	Fair Value	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Corporate bonds:				
U.S. corporations	$ 7,181,942	$	$ 7,181,942	$
International corporations	953,181		953,181	
Total	$ 8,135,123	$	$ 8,135,123	$

Our corporate bonds are valued by the third-party custodian at closing prices from national exchanges or pricing vendors on the valuation date.

There were no transfers into or out of any Levels during the years ended December 31, 2018 or 2017.

Table of Contents

8 Accumulated Other Comprehensive Loss

The only component of accumulated other comprehensive loss relates to unrealized gains and (losses) on our investments and activity is as follows:

	Unrealized Gains (Losses) on Available-For-Sale Securities
Balance at December 31, 2015	$ (55,285)
Losses, net	(34,764)
Reclassification realized in net earnings	53,200
Balance at December 31, 2016	$ (36,849)
Losses, net	(16,655)
Reclassification realized in net earnings	4,595
Balance at December 31, 2017	$ (48,909)
Losses, net	(3,554)
Reclassification realized in net earnings	20,767
Adoption of ASU 2018-02	(10,496)
Balance at December 31, 2018	$ (42,192)

9 Stock-Based Compensation

In April 2014, our Board of Directors adopted and our shareholders approved the 2014 Equity Incentive Plan (2014 Plan). Upon adoption and approval of the 2014 Plan, the previous equity incentive plan was terminated and the remaining shares available for future awards were canceled. The 2014 Plan reserved 1,000,000 shares of our common stock for awards of incentive stock options, non-qualified stock option, stock appreciation rights, restricted stock, restricted stock units, performance awards and other stock-based and cash awards. As of December 31, 2018, there were 412,752 shares available for future awards under the 2014 Plan.

Stock-based compensation was recognized as follows in the Statements of Operations:

	For the Years Ended December 31,		
	2018	2017	2016
Cost of revenue	$ 279,221	$ 214,325	$ 147,400
General and administrative	1,000,002	1,670,015	1,144,207
Sales and marketing	329,644	441,931	493,362
Research and development	155,452	128,092	56,932
Total stock-based compensation expense	$ 1,764,319	$ 2,454,363	$ 1,841,901

Stock Options

The following table presents a summary of our stock option activity as of and for the year ended December 31, 2018:

	Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (Yrs.)	Aggregate Intrinsic Value
Outstanding beginning of period	1,430,962	$ 2.60	5.3	$ 18,136,810
Options granted				
Options exercised	(295,624)	3.53		
Options cancelled	(1,875)	17.39		
Options expired	(4,000)	15.97		
Outstanding end of period	1,129,463	$ 2.29	4.2	$ 25,052,908
Exercisable	1,119,214	$ 2.13	4.2	$ 24,999,743

Table of Contents

As of December 31, 2018, we had $64,230 of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 0.9 years. The total grant date fair value of stock options that vested during the year ended December 31, 2018 was $554,165. The total intrinsic value of options exercised during the year ended December 31, 2018, 2017 and 2016 was $6,071,319, $268,053 and $2,112,426, respectively.

No options were granted during the year ended December 31, 2018. The weighted-average grant-date fair value of options granted during the years ended December 31, 2017 and 2016 was $11.10 and $12.64, respectively. For the years ended December 31, 2017 and 2016, we estimated the fair value of options granted using a Black-Scholes option pricing model with the following weighted average assumptions:

	For the Years Ended December, 31	
	2017	2016
Volatility	92.0%	61.5%
Expected term (years)	6.3	6.3
Risk-free interest rate	1.4%	1.6%
Dividend yield	0.0%	0.0%

Prior to our IPO, historical valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. In the absence of a public trading market, we considered all relevant facts and circumstances known at the time of valuation, made certain assumptions based on future expectations and exercised significant judgment to determine the fair value of our common stock. The factors considered in determining the fair value include, but are not limited to, the following:

- Retrospective and contemporaneous third-party valuation of our common stock;
- Our historical financial results and estimated trends and projections of our future operating and financial performance;
- The market performance of comparable, publicly traded companies; and
- The overall economic and industry conditions and outlook.

Restricted Stock Units

The following table presents a summary of our restricted stock unit activity as of and for the year ended December 31, 2018:

	Restricted Stock Units		Weighted-Average Grant Date Fair Value
Unvested at December 31, 2017	252,733	$	13.04
Granted	65,736	$	23.96
Vested	(89,457)	$	13.76
Cancelled	(2,511)	$	16.35
Unvested at December 31, 2018	226,501	$	15.89

As of December 31, 2018, we had $3,315,392 of unrecognized compensation cost related to the unvested restricted stock units, which is expected to be recognized over a weighted-average period of 2.7 years.

Warrants

Associated with our IPO completed on July 21, 2014, we issued Underwriters Warrants (the Warrants) to purchase up to a total of 201,600 shares of our common stock. The grant date aggregate fair value of the Warrants was $611,000. The Warrants were exercisable, in whole or in part, commencing July 21, 2015 through July 21, 2017. The Warrants were exercisable at $8.125 per share, or 130 percent of the public offering price per share of our common stock in the IPO. On the grant date, we classified the Warrants as equity and incremental direct costs associated with our IPO. Accordingly, the issuance of the Warrants had no impact our financial statements.

Table of Contents

The exercise price and number of Warrant shares may be adjusted (1) voluntarily at our discretion, or (2) if we undertake a stock split, stock dividend, recapitalization or reorganization of our common stock into a lesser / greater number of shares, the Warrant exercise price will be proportionately reduced / increased and the number of Warrant shares will be proportionately increased / decreased. The Warrant may only be settled through the issuance of our common stock in exchange for cash.

On July 17, 2017, our Board of Directors approved a modification to the Warrants. This modification extended the expiration date of the Warrants from July 17, 2017 to July 17, 2019 and revised the strike price from $8.125 to $10.05. The fair value of the amended Warrants was $2.42 per share as measured using the Black-Scholes options pricing model. Related to this modification, we recognized a $380,452 charge to earnings during the year ended December 31, 2017. This charge is included in general and administrative expense in our Statements of Operations. During the year ended December 31, 2018, 19,569 warrants were exercised. As of December 31, 2018, Warrants to purchase 162,031 shares of our common stock remained outstanding.

10 Other Income, Net

Other income, net consists of:

	For the Years Ended December 31,		
	2018	2017	2016
Interest income	$ 238,106	$ 122,575	$ 126,419
Realized losses on maturities of investments	(29,308)	(6,761)	(83,957)
Foreign currency exchange losses	(15,261)	(4,437)	(7,734)
Other			(2,048)
Total other income, net	$ 193,537	$ 111,377	$ 32,680

11 Income Taxes

On December 22, 2017, the Tax Cuts and Jobs Act (2017 Act) was enacted. The 2017 Act includes a number of changes to existing U.S. tax laws that impact us, most notably a reduction of the U.S. corporate income tax from 34.0 percent to 21.0 percent effective January 1, 2018. The 2017 Act also provides for the acceleration of depreciation for certain assets placed into service after September 27, 2017 as well as prospective changes that began in 2018, including repeal of the domestic production activities deduction, acceleration of tax revenue recognition, capitalization of research and development expenditures and additional limitations on the deductibility of executive compensation.

The SEC staff issued Staff Accounting Bulletin No. 118 (SAB 118), which provides guidance on accounting for the tax effects of the 2017 Act. SAB 118 provides for a measurement period that should not extend beyond one year from the 2017 Act enactment date for companies to complete the accounting relating to the 2017 Act under ASC 740. In accordance with SAB 118, we must reflect the income tax effects of those aspects of the 2017 Act for which the accounting under ASC 740 is complete. To the extent that our accounting for certain income tax effects of the 2017 Act is incomplete but we are able to determine a reasonable estimate, we must record a provisional estimate in our financial statements. If we cannot determine a provisional estimate to be included in our financial statements, we should continue to apply ASC 740 on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the 2017 Act.

The following table presents the impact of the 2017 Act as an increase (decrease) reflected in the noted line item in the Statements of Operations and Balance Sheet:

		Year Ended December 31, 2017 Reduction of U.S. Corporate Tax Rate
Provision for income tax expense	$	473,899
Effective tax rate		33.9%

		As of December 31, 2017 Reduction of U.S. Corporate Tax Rate
Deferred income taxes, net	$	(473,899)

During 2018, we completed our accounting for the income tax effects of the 2017 Act and no material adjustments were required to the provisional amounting initially recorded.

Table of Contents

The changes to existing tax laws as a result of the 2017 Act, which we believe have the most significant impact on our federal income taxes is the reduction of the U.S. corporate income tax rate. We measure deferred tax assets and deferred tax liabilities using the enacted tax rates that will apply in the years in which the temporary differences are expected to reverse. Accordingly, our deferred tax assets and deferred tax liabilities were remeasured to reflect the reduction in the U.S. corporate income tax rate from 34.0 percent to 21.0 percent, resulting in a $473,899 increase in income tax expense for the year ended December 31, 2017 and a corresponding decrease in net deferred tax assets as of December 31, 2017.

The components of the provision for income taxes are as follows:

	For the Years Ended December 31,		
	2018	2017	2016
Current taxes:			
U.S. federal	$ 740	$ 862,725	$ 3,674,645
State	37,547	186,993	634,453
Total current tax expense	38,287	1,049,718	4,309,098
Deferred taxes:			
U.S. federal	(128,905)	(92,788)	(509,404)
State	(15,525)	(60,308)	(61,505)
Total deferred tax benefit	(144,430)	(153,096)	(570,909)
Provision for income tax (benefit) expense	$ (106,143)	$ 896,622	$ 3,738,189

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred taxes are as follows:

	As of December 31,	
	2018	2017
Deferred income tax assets (liabilities):		
Stock compensation	$ 927,282	$ 985,261
Deferred revenue	499,307	405,264
Reserves and allowances	197,355	165,014
Research and development credits carryforward	43,391	
Net operating loss carryforward	26,767	
Other, net	5,869	20,990
Reserves and allowances		(10,968)
Depreciation and amortization	(611,269)	(615,186)
Total deferred income taxes, net	$ 1,088,702	$ 950,375

A reconciliation of the statutory U.S. federal tax rate to our effective rate is as follows:

	For the Years Ended December 31,		
	2018	2017	2016
Statutory U.S. federal tax rate	21.0%	34.0%	34.0%
Tax Cuts and Jobs Act		33.9	
Tax (windfalls) deficiencies on exercise and vesting of equity awards	(21.8)	5.4	
Stock compensation expense	(0.2)	5.3	(0.8)

State taxes, net of federal benefit	(0.1)	5.1	4.2
Permanent items	0.5	4.4	0.4
Provision to return adjustments	(0.3)	(9.5)	0.2
Domestic production activities deduction		(7.2)	(2.9)
Research and development credits	(0.8)	(7.2)	(1.0)
Effective rate	(1.7)%	64.2%	34.1%

As of December 31, 2018 and December 31, 2017, we had not identified or accrued for any uncertain tax positions. We are currently unaware of any uncertain tax positions that could result in significant payments, accruals or other material deviations in this estimate over the next 12 months.

Table of Contents

We file tax returns in the United States Federal jurisdiction and many U.S. state jurisdictions. Our returns are not currently under examination by the Internal Revenue Service (IRS). During the year ended December 31, 2018, the IRS examined our 2016 Federal Income Tax Return and concluded that no adjustments were necessary. The Company remains subject to income tax examinations for our United States Federal and certain U.S. state income taxes for 2015 and subsequent years and various other U.S. state income taxes for 2014 and subsequent years.

12 Employee Benefit Plan

We sponsor a 401(k) tax-deferred savings plan under which eligible employees may elect to have a portion of their salary deferred and contributed to the plan. Employer matching contributions are determined by management and are discretionary. Employer matching contributions were $293,669, $232,129 and $259,731, respectively, for the years ended December 31, 2018, 2017 and 2016. Employer contributions vest immediately.

13 Commitments and Contingencies

Leases. We have entered into noncancelable operating leases for our facilities.

In January 2014, we entered into a lease, commencing July 1, 2014, for a new facility in Winter Springs, Florida owned by Susi, LLC, an entity controlled by our president and CEO, Roger Susi. Pursuant to the terms of our lease for this property, the monthly base rent is $34,133, adjusted annually for changes in the consumer price index. The term of the lease expires on May 31, 2019. The lease will automatically renew for two successive terms of five years each beginning in 2019 and again in 2024, and thereafter, will be renewed for successive terms of one year each.

Rent expense for the years ended December 31, 2018, 2017 and 2016 was $418,772, $409,378 and $405,081, respectively. Minimum lease payments for each of our operating leases are even throughout their respective lease term.

Future minimum lease payments under noncancelable operating leases as of December 31, 2018 are as follows:

		Operating Leases
2019	$	170,664
2020		
2021		
2022		
2023		
Thereafter		
Total minimum lease payments	$	170,664

Purchase commitments. We had various purchase orders for goods or services totaling approximately $2,674,691 at December 31, 2018. No amounts related to these purchase orders have been recognized in our balance sheet.

Indemnifications. Under our amended and restated bylaws, we have agreed to indemnify our officers and directors for certain events or occurrences arising as a result of the officer or director serving in such capacity. We have a director and officer liability insurance policy that limits our exposure under these indemnifications and enables us to recover a portion of any future loss arising out of them.

In addition, in the normal course of business, we enter into contracts that contain indemnification clauses whereby the Company indemnifies our customers against damages associated with product failures. We have determined that these agreements fall within the scope of ASC 460, *Guarantees*. We have obtained liability insurance providing coverage that limits our exposure for these indemnified matters. We have not incurred costs to defend lawsuits or settle claims related to these indemnities. We believe the estimated fair value of these indemnities is minimal and have not recorded a liability for these agreements as of December 31, 2018.

Legal matters. We may from time to time become a party to various legal proceedings or claims that arise in the ordinary course of business.

Table of Contents

14 Capital Stock

The rights and privileges of our Series A Preferred Stock and Common Stock are as follows:

Series A Preferred Stock

We are authorized to issue 3,500,000 shares of preferred stock, of which 800,000 of these shares shall be designated as Series A Preferred Stock (Preferred Stock) with a par value of $0.0001 per share. As of December 31, 2018, there was no preferred stock issued or outstanding.

Voting and Dividends. The holder of each share of Preferred Stock has the right to one vote for each share of Common Stock into which such Preferred Stock could then be converted. The holders of the Preferred Stock are entitled to receive dividends from legally available assets prior to any declaration or payment of dividends to Common Stock holders. Dividends on each share of Preferred Stock are initially at $0.06429 per year payable when and as declared by the Board and are non-cumulative. After payment of such dividends, any additional dividends or distributions are distributed among all holders of Common Stock and Preferred Stock in proportion to the number of shares of Common Stock that would be held by each holder if all shares of Preferred Stock were converted to Common Stock at the then effective conversion rate. To date, no dividends have been declared.

Liquidation. In the event of any liquidation, dissolution or winding up of our Company, either voluntary or involuntary, the holders of the Preferred Stock are entitled to receive, prior and in preference to any distribution of the proceeds resulting from such liquidation event to holders of the Common Stock, an amount equal to $1.07143 plus declared but unpaid dividends. If, upon occurrence of such liquidation event, the proceeds are insufficient to permit the payment of the aforementioned amount in full, then the entire proceeds shall be distributed ratably among all holders of the Preferred Stock in proportion to the full amount each holder would otherwise receive.

Conversion. Each share of Preferred Stock is convertible at any time, at the option of the holder, into such number of fully paid non-assessable shares of Common Stock as is determined by dividing the original issue price of each share of Preferred Stock by the applicable conversion price. The initial conversion price per share is $1.07143. Adjustments to the initial conversion price may result from a recapitalization event or changes in the number of common shares outstanding. Each share of Preferred Stock automatically converts into shares of fully paid non-assessable shares of Common Stock, at the then applicable conversion rate, upon the date specified by written consent or agreement of the holders of a majority of the then outstanding shares of Preferred Stock, voting as a single class on an as-converted basis.

Redemption. Upon a majority vote of the then outstanding shares of Preferred Stock, we may, at our discretion, redeem or purchase shares of Preferred Stock. We also have a first right of refusal to repurchase shares of the Preferred Stock arising from a holder s proposal to sell such Preferred Stock.

Common Stock

We are authorized to issue 31,500,000 shares of Common Stock with a par value of $0.0001 per share.

Voting and Dividends. Each outstanding share of Common Stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders of the Company for their vote except for matters related to potential amendments to our Certificate of Incorporation or matters that solely relate to the terms of one or more outstanding series of our Preferred Stock. Holders of our Common Stock are entitled to receive, when, as and if declared by the Board, dividends pro rata based on the number of shares of Common Stock held. These dividend rights are junior to those of the Preferred Stock holders rights to dividends.

Liquidation. Liquidation preference of the Common Stock holders is junior to that of the Preferred Stock holders.

Redemption. The Common Stock is not redeemable.

Share Repurchase

On April 27, 2017 (the Authorization Date), our Board of Directors approved a share repurchase program, authorizing the repurchase of up to $8.0 million of our common stock through April 28, 2018. During the program period, we used $1,818,541 to acquire 209,922 shares of our common stock. We retired to treasury all of the repurchased shares.

Table of Contents

In January 2016, the Board of Directors authorized the repurchase of up to $10 million of the Company s common stock pursuant to a stock repurchase program. This program was publicly announced on January 28, 2016 and expired on January 28, 2017. During the program period, we used $9,969,468 to acquire 569,213 shares of our common stock. We retired to treasury all of the repurchased shares.

15 Subsequent Events

On January 16, 2019, we were notified by the U.K. Notified Body, UL International Ltd. (UL) that their recent technical file review of our 3880 MRI compatible patient vital signs monitoring system could not be completed as aspects of clinical evaluation reporting, as required by newly issued guidance from the European Union, was not acceptable, resulting in a technical non-conformity. Accordingly, UL issued a temporary EC Certificate that excludes our 3880 patient vital signs monitoring system. This temporary EC Certificate extends through July 27, 2019. We immediately suspended shipments of our 3880 patient vital signs monitor to all markets requiring a CE Mark. We are addressing the technical non-conformity, but there can be no assurance that these efforts will be successful.