UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

(Mark One)

☒ **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

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

Commission File Number: 001-37725

ViewRay, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**42-1777485**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2 Thermo Fisher Way Oakwood Village, OH	**44146**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (440) 703-3210

Securities registered pursuant to section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.01	**The Nasdaq Global Market**

Securities registered pursuant to Section 12(g) of the Exchange 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 ☐ No ☒

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

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

Indicate by check mark whether the Registrant has submitted electronically 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 ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See 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	☐	Accelerated filer	☒
Non-accelerated filer	☐	Small reporting company	☒
		Emerging growth company	☒

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

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

At June 30, 2018, the aggregate market value of the Registrant's common stock held by non-affiliates of the Registrant was $404,955,660 based on the closing sale price as reported on the Nasdaq Global Market. As of March 5, 2019, the Registrant had 96,669,649 shares of common stock, $0.01 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement to be delivered to stockholders in connection with the 2019 annual meeting of stockholders are incorporated by reference in Part III of this Form 10-K where indicated.

VIEWRAY, INC.
FORM 10-K
ANNUAL REPORT

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or this Report, contains forward-looking statements, including, without limitation, in the sections captioned "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and elsewhere. Any and all statements contained in this Report that are not statements of historical fact may be deemed forward-looking statements. Terms such as "will", "may," "might," "would," "should," "could," "project," "estimate," "pro forma," "predict," "potential," "strategy," "anticipate," "attempt," "develop," "plan," "help," "believe," "continue," "intend," "expect," "future" and terms of similar import (including the negative of any of the foregoing) may be intended to identify forward-looking statements. However, not all forward-looking statements may contain one or more of these identifying terms. Forward-looking statements in this Report may include, without limitation, statements regarding (i) the plans and objectives of management for future operations, including plans or objectives relating to the development of products, (ii) a projection of income (including income/loss), earnings (including earnings/loss) per share, capital expenditures, dividends, capital structure or other financial items, (iii) our future financial performance, including any such statement contained in a discussion and analysis of financial condition by management or in the results of operations included pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC, and (iv) the assumptions underlying or relating to any statement described in points (i), (ii) or (iii) above.

The forward-looking statements are not meant to predict or guarantee actual results, performance, events or circumstances and may not be realized because they are based upon our current projections, plans, objectives, beliefs, expectations, estimates and assumptions and are subject to a number of risks and uncertainties and other influences, many of which we have no control over. Actual results and the timing of certain events and circumstances may differ materially from those described by the forward-looking statements as a result of these risks and uncertainties. Factors that may influence or contribute to the inaccuracy of the forward-looking statements or cause actual results to differ materially from expected or desired results may include, without limitation:

- market acceptance of magnetic resonance imaging ("MRI") guided radiation therapy;
- the benefits of MR Image-Guided radiation therapy;
- our ability to successfully sell and market MRIdian® in our existing and expanded geographies;
- the performance of MRIdian in clinical settings;
- competition from existing technologies or products or new technologies and products that may emerge;
- the pricing and reimbursement of MR Image-Guided radiation therapy;
- the implementation of our business model and strategic plans for our business and MRIdian;
- the scope of protection we are able to establish and maintain for intellectual property rights covering MRIdian;
- our ability to obtain regulatory approval in targeted markets for MRIdian;
- our ability to procure materials and components in connection with the manufacture and installation of MRIdian;
- estimates of our future revenue, expenses, capital requirements and our need for additional financing;
- our financial performance;
- our expectations related to the MRIdian linear accelerator technology, or MRIdian Linac;
- developments relating to our competitors and the healthcare industry; and
- other risks and uncertainties, including those listed under the section titled "Risk Factors."

Any forward-looking statements in this Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Item 1A, titled "Risk

Factors" and discussed elsewhere in this Report. Given these uncertainties, you are cautioned not to place undue reliance on these forward-looking statements. We disclaim any obligation to update the forward-looking statements contained in this Report to reflect any new information or future events or circumstances or otherwise, except as required by law.

This Report also contains estimates, projections and other information concerning our industry, our business, and the markets for certain devices, including data regarding the estimated size of those markets. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

PART I

Item 1. BUSINESS

In this report, "ViewRay", the "Company", "we", "us" and "our" refer to ViewRay, Inc. and its wholly-owned subsidiary, ViewRay Technologies, Inc.

Company Overview

We design, manufacture and market the ViewRay MRIdian®. The MRIdian is an innovative system that integrates high quality radiation therapy with simultaneous magnetic resonance imaging (MRI). There are two generations of the MRIdian: the first generation MRIdian with Cobalt-60 based radiation beams and the second generation MRIdian Linac, with more advanced linear accelerator or 'linac' based radiation beams.

The MRIdian combines MRI and external-beam radiation therapy to simultaneously image and treat cancer patients. MRI is a broadly used imaging tool that has the ability to clearly differentiate between types of soft tissue. In contrast, X-ray or computed tomography (CT), the most commonly used imaging technologies in radiation therapy today, are often unable to distinguish soft tissues such as the tumor and critical organs. MRIdian integrates MRI technology, radiation delivery and our proprietary software to clearly ***See*** the soft tissues, ***Shape*** the dose to accommodate for changes in anatomy and ***Strike*** the target precisely using real-time targeting throughout the treatment. The MRIdian system is ***Sized*** to fit into standard radiation therapy vaults without having to remove ceiling or walls. These capabilities allow MRIdian to deliver radiation to the tumor accurately, while reducing the radiation amount delivered to nearby healthy tissue, as compared to other radiation therapy treatments currently available. We believe this will lead to improved patient outcomes and reduced treatment-related side effects.

Both generations of the MRIdian have received 510(k) marketing clearance from the US Food and Drug Administration, or FDA, and permission to affix the CE mark.

- We received initial 510(k) marketing clearance from the US Food and Drug Administration, or FDA, for our treatment planning and delivery software in January 2011.
- We received 510(k) marketing clearance for MRIdian, with Cobalt-60 as the radiation source, in May 2012. We received permission to affix the CE mark to MRIdian with Cobalt-60 in November 2014, allowing MRIdian with Cobalt-60 to be sold within the European Economic Area, or EEA. In August 2016, we received regulatory approval from the Japanese Ministry of Health, Labor and Welfare to market MRIdian with Cobalt-60 in Japan. In August 2016, we also received approval from the China Food and Drug Administration to market MRIdian with Cobalt-60 in China.
- In September 2016, we received the CE mark for MRIdian Linac (with a linear accelerator as the radiation source) in the EEA. In February 2017, we received 510(k) clearance from the FDA to market MRIdian Linac. In June 2017, we received 510(k) clearance to market RayZR™, our high-resolution beam-shaping multi-leaf collimator, or MLC. We also received MRIdian Linac regulatory approval in Taiwan and Canada in August 2017, and in Israel in November 2017. In March 2018, we received regulatory approval from the Japanese Ministry of Health, Labor and Welfare to market MRIdian Linac in Japan. In February 2019, we received 510(k) clearance to market new soft tissue visualization capabilities for MRIdian system. We are also seeking required MRIdian Linac approvals in other countries such as China.

MRIdian is the first radiation therapy solution that enables simultaneous radiation treatment delivery and real-time MRI imaging of a patient's internal anatomy. It generates high-quality images that differentiate between the targeted tumor, surrounding soft tissue and nearby critical organs. MRIdian also records the level of radiation dose that the treatment area has received, enabling physicians to adapt the prescription between treatments, as needed. We believe this improved visualization and accurate dose recording will enable better treatment, improve patient outcomes and reduce side effects. Key benefits to users and patients include: improved imaging and patient alignment; the ability to adapt the patient's radiation treatments to changes while the patient is still on the treatment table, or "on-table adaptive treatment planning"; MRI-based motion management; and an accurate recording of the delivered radiation dose. Physicians have already used MRIdian to treat a broad spectrum of radiation therapy patients with more than 45 different types of cancer, as well as patients for whom radiation therapy was previously not an option.

We currently market MRIdian through a direct sales force in North America and are developing a sales force to assist distributors in the rest of the world. As of December 31, 2018, we had installed or delivered 28 MRIdian systems worldwide and had a backlog with total value of $212.3 million. We generated revenue of $81.0 million, $34.0 million, and $22.2 million for the years ended December 31, 2018, 2017 and 2016, respectively. We had net losses of $76.4 million, $72.2 million and $50.6 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Cancer and Radiation Therapy Market

Incidence of Cancer

Cancer is a leading cause of death globally and the second leading cause of death in the United States behind cardiovascular disease. According to the American Cancer Society, nearly 1.7 million people are expected to be diagnosed with cancer in the United States during 2019 and approximately 0.6 million are expected to die from cancer, which translates to about 1,660 deaths per day. As a result of a growing and aging population, the International Agency for Research on Cancer (IARC), part of the World Health Organization, reported that the worldwide cancer burden has risen to 18.1 million new cases and 9.6 million cancer deaths in 2018.

Cancer Therapy

The primary goal of cancer therapy is to kill cancerous tissues, while minimizing damage to healthy tissues. There are three main ways to treat cancer: surgery, chemotherapy and radiation therapy. Surgery attempts to remove the tumor from the body, while minimizing trauma to healthy tissue and preventing the spread or translocation of the disease to other parts of the body. Surgery is particularly effective because the surgeon can see the tumor and surrounding healthy tissue directly throughout the course of the procedure and can adapt his or her planned removal approach mid-procedure accordingly. Chemotherapy uses drugs to kill cancer cells. Unlike surgery, most forms of chemotherapy circulate throughout the patient's body to reach cancer cells almost anywhere in the body systemically. Chemotherapy is most effective at destroying microscopic levels of disease. Radiation therapy is typically used as a local treatment, directed at a tumor and surrounding areas where microscopic cancerous cells are assumed to have spread. Radiation may be used as the primary treatment modality, or in combination with either chemotherapy or surgery or both. Radiation therapy works by damaging genetic material in cells and other cell components through interaction with ionizing energy. Effective radiation therapy balances destroying cancer cells with minimizing damage to normal cells. It can be used at high doses to ablate a tumor, an effect similar to surgery, or at moderate doses to target local microscopic disease, as is done with chemotherapy. Other, more recently developed ways of treating cancer, include hormone therapy and targeted therapy, such as immunotherapy.

Radiation Therapy

Radiation therapy has become widespread, with nearly two-thirds of all treated cancer patients in the United States receiving some form of radiation therapy during the course of their cancer treatments, according to estimates by American Society for Radiation Oncology, ASTRO. For most cancer types treated with radiation therapy, at least 75% of the patients are treated with the intent to cure the cancer. For lung and brain cancers, that number is somewhat lower, with 59% of lung cancer patients and 50% of brain cancer patients being treated with the goal of curing cancer. The remainder of cases are treated with palliative intent to relieve pain or other tumor related symptoms. The type of radiation therapy delivered by linac or Cobalt 60 based devices is a non-invasive outpatient procedure with little or no recovery time and can be used on patients who are unable to undergo conventional

surgery. According to IMV, 97% of patients receiving radiation therapy in the United States are treated using a linac.

Radiation is used to kill cancer cells primarily by damaging their DNA but can also kill healthy cells in the same way or cause them to become cancerous themselves. As a result, the goal of curative radiation therapy is to balance delivery of a sufficiently high dose of radiation to a tumor to kill the cancer cells while, at the same time, minimizing damage to healthy cells, particularly those in critical organs. Normal cells are better able to repair themselves after radiation than tumor cells, so doses of radiation are often fractionated, or delivered in separate sessions with rest periods in between. As a result, standard radiation therapy is often given once a day, five times a week, for one to nine weeks. According to a 2017 IMV report, patients made an estimated 20.2 million radiation therapy treatment visits in the United States from March 2016 to March 2017.

Radiation Therapy Equipment Market

According to Markets and Markets 2015 Radiotherapy Market Global Forecasts 2020 report, the global radiotherapy market is estimated to grow to approximately $6.3 billion by 2020. According to IAEA Human Health Campus, there are nearly 12,000 linacs installed at over 7,300 centers worldwide. In the United States, there are over 4,000 linacs installed at over 2,100 centers. The annual market for linacs is estimated to be 1,000 units per year globally, the majority of which are replacements for older machines.

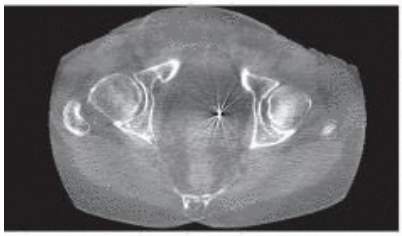
In the radiation therapy market, new technologies have historically been adopted at a rapid rate. According to IMV, the percentage of centers performing intensity modulated radiation therapy, or IMRT, grew from 30% in 2002 to 96% in 2012. The percentage of sites utilizing image-guided radiation therapy, or IGRT, grew even more quickly: from 15% in 2004 to 83% in 2012. The majority of IGRT procedures use on-board X-ray systems. As leading cancer centers adopt and study MR Image-Guided radiation therapy, we believe that our current-generation linac based MRI system will also follow a rapid adoption curve in the broader linac replacement market.

Limitations of Traditional Radiation Therapy

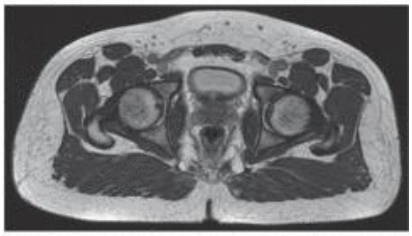
Limitations with traditional radiation therapy result from imaging technologies that make accurate visualization of a tumor and its relation to critical organs difficult or impossible during the treatment delivery. Most current traditional systems take images of the tumor before and after treatments, but, none do so continuously during the treatments in real time. As a result, treatments may not be delivered with the precision assumed by the physician and may not result in the necessary efficacy or reduction in local tumor recurrence. Also, healthy tissues may be exposed to radiation levels different from those predicted by the planning system and can result in patient injury.

- ***Inability to accurately SEE a tumor for treatment alignment.*** To locate a tumor, current radiation therapy systems rely on CT scans taken while the patient is on the delivery unit treatment table, or "on-table." Because it is difficult to differentiate between the tumor and nearby soft tissues with CT images, clinicians use surrogate registration markers, including existing bone structures, external marks and surgically implanted fiducials, to align a patient's tumor to the treatment beams prior to commencing treatment.

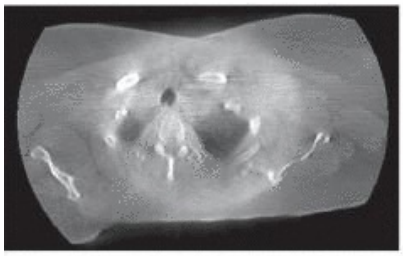
Comparison of On-Table CT Images to On-Table MRIdian Images



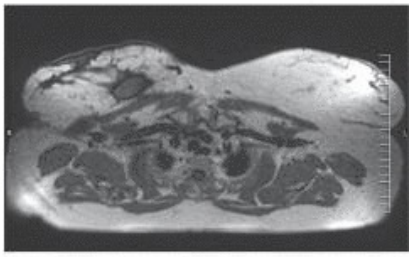
Prostate cancer, on-table CT image



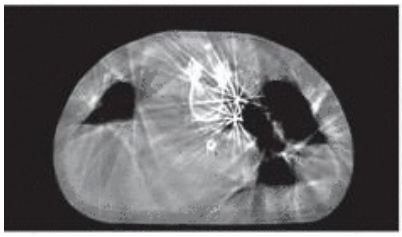
Prostate cancer, on-table MRIdian image



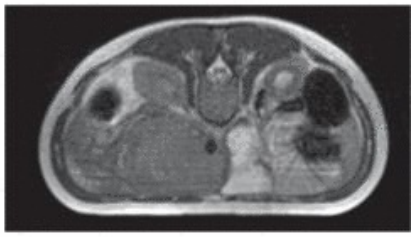
Breast cancer, on-table CT image



Breast cancer, on-table MRIdian image



Abdominal cancer, on-table CT image



Abdominal cancer, on-table MRIdian image

However, the spatial relationship between tumors and the registration markers used to locate them often changes between the time of the patient's initial imaging and the time of his or her first treatment session. This is particularly true for tumors which are located in soft tissue. By relying on a marker as a proxy for the tumor location, rather than on the tumor itself, clinicians risk missing the tumor when they deliver radiation beams into the patient's body. In addition, placement of surgically implanted fiducial markers comes with inherent risks: the procedures are invasive; there is a risk of pain, infection, bleeding and lung collapse; and fiducials may change location and even migrate inside the body. Despite placement of fiducials, physicians are often unable to track changes in tumor shape. Also, fiducials made of dense metals, such as gold, may cause artifacts which interfere with imaging.

- ***Inability to SHAPE and adapt treatment on-table.*** A physician designs a treatment plan and dose prescription based on images that are captured days or even weeks prior to initiation of radiation therapy. Creating a treatment plan can take up to several weeks in complex cases, and treatment itself can take up to nine weeks. However, during the course of therapy, tumors often change size, orientation or shape, and patient anatomy can change for a variety of reasons such as weight loss or gain. These changes can alter the planned radiation exposure to both the targeted regions and nearby healthy organs; this has the potential to increase the risk of local tumor recurrence and to reduce the safety of the radiation delivery. Adjusting for these changes on conventional delivery units requires re-planning, which includes getting new patient images needed to create a new treatment plan. This process may take several days and is highly resource intensive. As a result of these limitations, re-planning is infrequently performed.

  Due to limitations in imaging technologies, physicians may actually be unaware of changes in the tumor and surrounding anatomy. Consequently, they may continue to administer radiation dose according to the original treatment plan, without realizing its potential to reduce the effectiveness of the tumor treatment and to increase the risk of patient injury.

- ***Inability to STRIKE and track tumor and organ motion accurately.*** In addition to the difficulty of locating a tumor accurately in a patient's body at the time treatment begins, a further challenge is accounting for ongoing tumor movement that takes place during treatment. Tumors have been shown to move multiple centimeters relative to surrogate registration markers over the course of only a few seconds. Breathing and other normal bodily functions, such as changes in the bladder or bowel during treatment, can cause significant tumor motion. Although physicians use internal markers, external cameras and blocks placed on the patients' body to track respiratory and other motion, they are typically unable to track the tumor itself. As a result, physicians usually enlarge the total region to be irradiated. This limitation increases the probability of missing the targeted treatment area and exposing healthy tissues to unnecessary radiation.

Each of these limitations increases the risk of missing a tumor and hitting healthy tissue during treatment. If a tumor is insufficiently irradiated, it may not respond to treatment, resulting in a greater probability of local tumor recurrence and reduced overall survival for the patient. The ability to avoid irradiating healthy tissue has been shown to reduce side effects. If healthy tissues, particularly critical organs, are irradiated, the side effects can be severe, including: scarring of lung tissue; fibrosis and cardiotoxicity in lung and breast cancers; incontinence and sexual dysfunction in pelvic and prostate cancers; infertility in pediatric cancers; memory loss, seizures and necrosis in brain cancer; secondary cancers, and in serious cases, death.

Although MR technology is an imaging tool broadly used to differentiate between types of soft tissue in diagnostic settings, MR technology had not been available in the radiation treatment delivery room before the launch of ViewRay's MRIdian System. In the past, MR was not used with radiation therapy because the technologies interfered with each other: the magnetic field generated by an MRI interfered with the linac beam, while the radiofrequencies produced by the linac distorted the MR images. Current forms of CT have improved over time, but issues with radiation dose and image quality limit the utility of these technologies. Fluoroscopy and cone-beam CT, which is a form of on-board CT, involve the use of X-rays, a form of ionizing radiation, and pose an increased risk of radiation-induced cancer to the patient.

Our Solution

We developed MRIdian to address the key limitations of existing external-beam radiation therapy technologies. MRIdian employs MRI-based technology to provide real-time imaging that clearly defines the targeted tumor from the surrounding soft tissue and other critical organs, both before and during radiation treatment delivery. We believe

this combination of enhanced anatomy visualization and accurate dose calculation and delivery will significantly improve the safety and efficacy of radiation therapy, leading to better outcomes for patients suffering from cancer.

Over the past decade, significant technological advances in radiotherapy have come into clinical practice including improved treatment planning, better tumor localization, and individualized motion management. While life-saving developments continue, limitations such as poor soft tissue contrast, the use of surrogates to identify anatomy, and having no real-time imaging during beam-on have constrained the possibility to safely deliver higher, potentially more effective radiation doses.

In order for clinicians to deliver high precision adaptive radiotherapy, the MRIdian Linac was designed with a purpose-built magnet, high precision double stacked double focused MLC, a high dose rate linear accelerator, and a Treatment Planning and Delivery System (TPDS) software suite built from the ground up. We believe that MRIdian provides the following clinical and commercial benefits to physicians, hospitals and patients:

- ***The ability to See: SmartVISION®*** – Unlike MRI systems used for diagnostic radiology, MRIdian's SmartVISION MR imaging was purpose-built for radiation oncology and MRI-Guided ROAR delivery. Most importantly, SmartVISION provides diagnostic-quality, multi-sequence MR imaging while being completely interoperable with the linear accelerator. SmartVISION's patented imaging technology was specifically designed to not interfere with high-fidelity beam delivery while significantly reducing the risk of skin toxicities, trapped or distorted dose, and other concerns which may occur when high magnetic fields interact with radiation beams. With a patented split-magnet MR design exclusive to SmartVISION, MRIdian provides a unique unobstructed beam path enabling a source-axis-distance (SAD) capable of supporting sophisticated beam dosimetry, exceptionally sharp penumbra tailored for stereotactic radiosurgery, or SRS and stereotactic body radiation therapy, or SBRT, and high dose rate beam delivery.

- ***The ability to Shape: SmartADAPT®*** – Normal bodily function regularly results in significant changes to the daily shape and position of both the tumor and surrounding healthy tissues. Using MRIdian's SmartADAPT software, clinicians can now generate daily on-table MR setup scans in seconds and leverage high-contrast, high-definition detail to detect and rapidly reshape dose delivery to accommodate the subtle anatomical changes that occur each day throughout the course of treatment. Taking advantage of groundbreaking advances in computing technology, SmartADAPT calculates new individualized Monte Carlo plans in seconds based on the exact anatomy at that time - all while the patient is in the treatment position.

- ***The ability to Strike: SmartTARGET®*** – Gas bubbles emerge, bladders fill, and respiratory motion constantly occurs. As a result, tumors and surrounding critical structures can rapidly change position and shape during beam delivery. Utilizing MR imaging to detect the slightest intra-fraction motion, MRIdian's SmartTARGET allows oncologists to non-invasively visualize the tumor's edges and surrounding organ position in real-time using a non-ionizing streaming video perspective. When tumors move or deform, or organs-at-risk abruptly change position, SmartTARGET instantly reacts, automatically turning radiation beams both on and off, providing greater confidence prescribed doses reach the target while avoiding critical structures.

- ***The ability to Size: SmartSITE®*** – MRIdian's compact SmartSITE footprint addresses common physical space limitations and challenges associated with large-scale vaults and the need for a custom built solution. SmartSITE is designed to fit within almost any existing standard linear accelerator vault and shielding configuration, avoiding excessive delays, interruptions and costs necessary to build custom, large-scale vaults. SmartSITE is able to fit through conventional vault doorways, there is no need to remove walls, raise ceilings, or dig trenches.

MRIdian can treat a broad spectrum of radiation therapy indications and disease sites with its ability to perform three-dimensional conformal radiation therapy, or 3D-CRT, IMRT, IGRT, SBRT and SRS. MRIdian treatments are supported by existing radiation therapy reimbursement codes. We believe MRIdian's increased tumor target accuracy will allow physicians to treat patients with higher radiation doses over fewer treatment fractions; this potentially enables the clinic to treat more patients with greater overall efficiency and patient throughput.

We believe the ability to image with MRI and treat cancer patients with radiation simultaneously will lead to improved patient outcomes.

Our Strategy

We are dedicated to making MR Image-Guided radiation delivery the standard of care for radiation therapy. To achieve our objective of providing clinicians new and innovative ways to deliver radiation therapy, we are focused on delivering on an integrated plan that incorporates a bold commercial strategy, a relentless focus on operational excellence, the pursuit of the highest customer satisfaction and therapy adoption. We are also committed to attracting, retaining and developing the best talent across all functions. We believe this will allow us to expand the market and target more customers, accelerate our sales cycle, and significantly improve the customer's overall experience.

- ***Investment in the commercial organization.*** We are continuing to expand our sales force for the United States and Canada, while developing a direct sales force to assist distributors in EMEA and Japan, which collectively makes up about 70% of the global market opportunity according to Markets and Markets 2015 Radiotherapy Market Global Forecasts 2020 report. We intend to build a commercial presence that is highly competitive and expect to see significant improvements in execution from this developing commercial team.

- ***Operational excellence.*** While focusing external efforts on building the customer pipeline, we are also committed to achieving internal operational excellence in parallel. We will seek to create efficiencies across the organization to reduce the purchase order to revenue recognition cycle time. This goal will be driven by the proactive engagement with customers to achieve vault readiness; driving supplier quality enhancements; and developing more robust and efficient manufacturing capabilities.

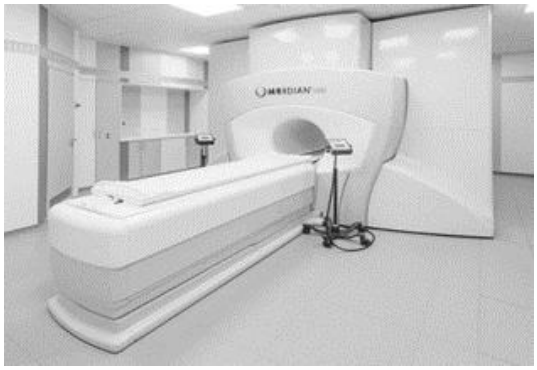
- ***Customer service.*** Key to our value system is pursuing the highest customer satisfaction. We will measure this by continuously quantifying customer satisfaction and loyalty, and adjusting our priorities accordingly. By hearing the voices of the radiation oncologists, the medical physicists and radiation oncology dosimetrists, therapists and administrators, we will continue to improve and refine the capabilities and resulting benefits of MRIdian over competitive radiation therapy systems. Current priorities are focused on addressing service and technical support, clinical workflow enhancements, the development of clinical data and maintaining our competitive lead in MR Image-Guided radiation therapy through continued innovation.

- ***MRIdian therapy adoption.*** We believe that MRIdian adoption will accelerate as we leverage three key drivers: innovation, clinical data and training.
    - ***Innovation.*** Innovation is one of our greatest strengths as an organization, a strength that we fully intend to capitalize on. We intend to continue to invest in our technology to maintain our leadership position in the emerging MR Image-Guided radiation therapy market. In the next year, we intend to introduce enhancements to the system and software to provide improved capabilities for MRIdian users and patients. As we continue to build a strong intellectual property portfolio, our pipeline includes projects to address treatment delivery speed, machine vision and biological imaging. We will work proactively with key opinion leaders, clinicians, hospitals and free standing centers to refine and improve MRIdian's features, optimize clinical workflow and maximize patient throughput while incorporating our advanced features.
    - ***Clinical data***. MRIdian customers continue to develop an impressive compendium of clinical data. Over the last five year, over 45 ICD 10 diagnoses codes have been treated on MRIdian systems. Radiation oncologists and medical physicists have expanded treatment to areas such as beating heart, central lung and non-invasive heart ablations.
    - ***Training.*** Training remains paramount to adoption. We plan to invest in peer-to-peer symposia and training courses to facilitate sharing of the best practices of key opinion leaders with new customers. We also plan to invest in our clinical field team. In order to drive awareness and adoption, we will continue to work with current customers and their respective institutions to host visiting physicians, train new users in best-practices, and engage in outreach events worldwide.

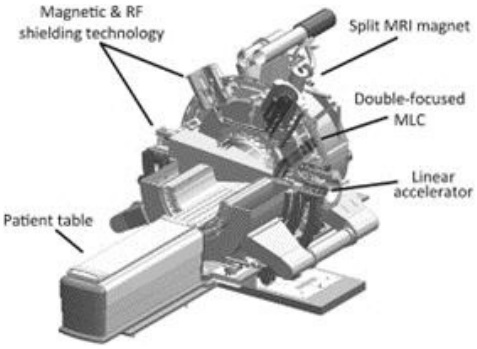
The MRIdian System

The MRIdian is comprised of three major components, (i) the MRI system, (ii) the radiation delivery system, and an (iii) integrated treatment planning and delivery software.

Photo of an Installed MRIdian (University of Heidelberg)



MRIdian System Components



MRIdian MRI System

The MRI system is the component of MRIdian that captures soft tissue images of the patient's body. To address the technical complications that arise from combining an MRI with an external-beam radiation delivery unit, we have designed a proprietary split superconducting magnet that will allow radiation doses to be delivered through a central gap, which eliminates MRI components from the path of the beam. Our MRI system captures and displays live, high-quality images in one plane, four times per second or in three planes, two times per second. These real-time images automatically track selected structures and control radiation treatment beam delivery.

We have engineered our MRI system to be able to produce clear images using a low-field strength 0.35 Tesla magnet, which enables us to avoid image and radiation dose distortions that result when higher field strength magnets are used. In addition, MRIdian's 0.35 Tesla field strength prevents over-heating of the patient during uninterrupted imaging, which could occur when a higher field strength magnet is used for fast imaging during radiation delivery. Over-heating can require interruption or termination of the imaging or of the overall treatment.

MRIdian Radiation Delivery System

In the first-generation MRIdian, which we no longer make available for sale, radiation was delivered from three Cobalt-60 radiation therapy heads symmetrically mounted on a rotating ring gantry, providing full 360-degree coverage and simultaneous dose delivery.

In the second generation MRIdian, our currently available system, we developed solutions to two long-standing problems that had prevented compact integration of a linac beam with an MRI system: 1) linac radiofrequency interference with the operation of the MRI; and 2) MRI magnetic interference with the operation of the linac. First, linacs utilize high-powered microwave generators similar to equipment used in radar at airports. These "radar stations" inside the linac create radiofrequency emissions, or "noise" that can corrupt the delicate signals measured from the patient's body to generate MR images. ViewRay solved this problem by introducing technology similar to that used in stealth aircraft. Airplanes built with stealth technology can hide from radar by using a coating that absorbs microwaves, thus preventing radar beams that strike the aircraft from bouncing back to the radar station. In a similar manner, we absorb the output of the linac "radar station" to hide it from the MRI, producing images as noise-free as those created without an integrated linac.

Second, MRIs utilize high-powered superconducting magnets required to image the patient's tissues that must be placed close to the linac components used for radiation therapy. But many linac components will not operate properly when placed close to or inside these strong magnetic fields. ViewRay overcame this challenge by creating magnetic shielding shells that create voids in the magnetic field, without significantly disturbing the magnetic field

used for imaging. This allows the linac to operate on the MRIdian gantry as if there were no magnetic field present. MRIdian Linac uses the same split-magnet MRI system used in the first generation MRIdian system. It is specifically designed to fit in standard radiotherapy vaults so that customers do not need to build new vaults in order to replace an X-ray guided linear accelerator with a MRIdian. Existing first generation MRIdian systems currently in use can be upgraded to the MRIdian Linac in the field.

Integrated Treatment Planning and Delivery Software

Our proprietary treatment planning and delivery software work with the integrated patented split-magnet MRI System and unobstructed radiation beam path and optimal source-axis-distance (SAD) of the Radiation Delivery System to unlock beam dosimetry, sharp SRS and SBRT-tailored penumbra, and high dose rate beam delivery.

Installed Base and Clinical Use

At December 31, 2018, seven MRIdian with Cobalt-60 and 17 MRIdian Linac systems are in operation at 22 cancer centers (10 in the United States and 12 outside the United States). Four MRIdian Linacs have already been delivered to customers and are expected to be installed in 2019.

New Orders and Backlog

New orders are defined as the sum of gross product orders, representing MRIdian contract price, recorded in backlog during the period. Backlog is the accumulation of all orders for which revenue has not been recognized and which we consider valid. Backlog includes customer deposits or letters of credit, except when the sale is to a customer where a deposit is not deemed necessary or customary. Deposits received are recorded as customer deposit, which is a liability on the balance sheet. Orders may be revised or cancelled according to their terms or upon mutual agreement between the parties. Therefore, it is difficult to predict with certainty the amount of backlog that will ultimately result in revenue. The determination of backlog includes objective and subjective judgment about the likelihood of an order contract becoming revenue. We perform a quarterly review of backlog to verify that outstanding orders in backlog remain valid, and based upon this review, orders that are no longer expected to result in revenue are removed from backlog. Among other criteria we use to determine whether a transaction to be in backlog, we must possess both an outstanding and effective written agreement for the delivery of a MRIdian signed by a customer with a minimum customer deposit or a letter of credit requirement, except when the sale is to a customer where a deposit is not deemed necessary or customary (i.e. sale to a government entity, a large hospital, group of hospitals or cancer care group that has sufficient credit, sales via tender awards, or indirect channel sales that have signed contracts with end-customers). We decide whether to remove or add back an order from or to our backlog by evaluating the following criteria: changes in customer or distributor plans or financial conditions; the customer's or distributor's continued intent and ability to fulfill the order contract; changes to regulatory requirements; the status of regulatory approval required in the customer's jurisdiction, if any; and other reasons for potential cancellation of order contracts.

We received new orders for MRIdian systems, totaling $140.7 million, $113.6 million and $77.0 million in fiscal years 2018, 2017 and 2016, respectively. Based on our assessment, we removed $53.5 million and $11.1 million from the backlog for fiscal year 2018 and 2017 respectively; none were removed for fiscal year 2016. At December 31, 2018, we had a backlog with a total value of $212.3 million. There can be no assurance that backlog will result in revenue in any particular time period or at all.

Installation Process

Following execution of an order contract, it generally takes nine to 15 months for a customer to prepare an existing facility or construct a new vault, although in some cases customers may request installation for a date later in the future to meet their own clinical or business requirements. After the customer completes its vault customization, it typically takes approximately ninety days to complete the installation and on-site testing of the system, including the completion of acceptance test procedures. MRIdian is designed to fit into a typical radiation therapy vault, similar to other replacement linear accelerators. MRIdian's components all fit through standard hospital vault entrances for assembly. On-site training takes approximately one week and can be conducted concurrent with installation and acceptance testing.

Our customers are responsible for removing any outgoing linear accelerator equipment and preparing the room for the MRidian system unless otherwise stipulated within the contract with the customer. This includes ensuring

adequate radiation and radio frequency shielding, preparing the floor for the mounting plate, and upgrading facility utilities to meet system requirements.

Clinical Development

To date, we have primarily relied on clinical symposia and case studies presented at ASTRO and the European Society for Radiotherapy and Oncology, or ESTRO, to raise awareness of MR Image-Guided radiation therapy and to market MRIdian to leading cancer centers. In order to promote broader adoption rates at other cancer centers and hospitals, we plan to work with our customers to collect and publish data on clinical efficacy, treatment times and clinical results for patients who have been treated on a MRIdian. Outcomes data presented at the 2017 Annual Meeting of ASTRO highlighted potentially compelling early results using the Company's MRIdian system for the treatment of inoperable, locally advanced pancreatic cancer. These initial results will be explored further in a multi-center, prospective, single-arm clinical trial for inoperable, locally advanced or borderline resectable pancreatic cancer. The trial is being conducted by ViewRay and the first patient was enrolled in December, 2018.

Additionally, Washington University has published a prospective study on Magnetic Resonance Image Guided Radiation Therapy for External Beam Accelerated Partial-Breast Irradiation using a one-week course of treatment. This study demonstrated that on-board MR image-guidance allowed for a greater than 50% reduction of margins while maintaining the same dose to the tumor with patients reporting 100% Excellent/Good Cosmesis.

While we do not currently have statistically significant, prospective evidence that MRIdian improves patient outcomes or decreases healthcare costs relative to CT-based radiotherapy, we believe sponsoring and supporting studies will demonstrate the benefits of MR Image-Guided radiation therapy and adaptive treatment planning. As data accumulate from the use of MRIdian, we plan to work with professional healthcare organizations to support further global marketing efforts, additional product clearances, approvals and/or registrations and potential improvements in reimbursement.

Selling and Marketing

We currently market MRIdian through a direct sales force in North America and continue to expand our global footprint by going direct and adding additional distributors to our network in key markets. We market MRIdian to a broad range of worldwide customers, including university research and teaching hospitals, community hospitals, private practices, government institutions and freestanding cancer centers. As with the traditional linac market, our sales and revenue cycles vary based on the particular customer and can be lengthy, sometimes lasting up to 18 to 24 months (or more) from initial customer contact to order contract execution.

To sell MRIdian globally, we use a combination of sales executives, sales directors and a network of international third-party distributors with internal support from sales operations, product management and application specialists. A targeted group of fourteen senior sales directors are responsible for selling MRIdian within the North America. Our product management function helps market MRIdian and works with our engineering group to identify and develop upgrades and enhancements. We also have a team of application specialists who provide post-sales support.

We engage in various physician-targeted advertising efforts, and our selling and marketing practices include participating in trade shows and symposia.

Competition

We compete directly with companies marketing IGRT devices for the treatment of cancer using MRI, CT, ultrasound, optical tracking and X-ray imaging. We also compete with companies developing next-generation IGRT devices, specifically those developing MR Image-Guided devices, amongst others. We expect the following to drive worldwide competitive market dynamics; technological advances, including the ability to provide real-time imaging; clinical outcomes; reimbursement; system size, price, and operational complexity; and operational efficiency.

Our major competitors with devices approved for distribution in the United States or globally include Accuray Incorporated, or Accuray, Elekta AB, or Elekta, and Varian Medical Systems, Inc., or Varian. Many of our direct competitors have greater financial, sales and marketing, service infrastructure and research and development capabilities than we do, as well as more established reputations and current market share. The main limitation of currently approved non MRI-based devices is the lack of clear images with soft tissue contrast before and during the treatment.

Elekta is the only competitor which also markets an MRI device combined with a linear accelerator. Elekta Unity received FDA clearance in early December of 2018.

Other Image Guided therapy devices. The University of Sydney, Ingham Institute and the University of Queensland have formed a partnership to develop an MRI-linac. MagnetTX, which licensed its technology from the university of Alberta's Cross Cancer Institute, is working on a MRI-linac as well. Although these academic research centers and very early stage companies may not pose as immediate commercial competition, if they were to form a partnership or other relationship with one of our competitors, it could impact our sales negatively.

The limited capital expenditure budgets of our customers result in all suppliers to these entities competing for a limited pool of funds. Our customers may be required to select between two items of capital equipment. For example, some of our potential customers are considering expensive proton therapy systems, which could consume a significant portion of their capital expenditure budgets.

Manufacturing

We have adopted a model in which we rely on subsystem manufacturing, assembly and testing by our key suppliers. The MRIdian subsystems are then fully integrated at the customer site. Through this approach, we avoid the majority of the fixed cost structure of manufacturing facilities. We purchase major components and subsystems for MRIdian from national and international third-party original equipment manufacturers, or OEM, suppliers and contract manufacturers. These major components include the magnet, MRI electronics, ring gantry, radiation therapy heads, Cobalt-60 sources, linear accelerator, multi-leaf collimators, patient-treatment table and computers. We also purchase minor components and manufacture parts directly ourselves. For sales for which we are responsible for installation, we assemble and integrate these components with our proprietary software and perform multiple levels of testing and qualification at the customer site. The system undergoes a final acceptance test, which is performed in conjunction with the customer.

Many of the major subsystems and components of MRIdian are currently procured through single and sole source suppliers. Among these are the magnet, MRI electronics, MRI coils, ring gantry, Cobalt-60 sources, linear accelerator and the patient-treatment table. We have entered into multi-year supply agreements for most of our major components and subsystems.

We manage our supplier relationships with scheduled business reviews and periodic program updates. We closely monitor supplier quality and delivery performance to ensure compliance with all MRIdian system specifications. We believe our supply chain has adequate capacity to meet our projected sales over the next several years.

Intellectual Property

The proprietary nature of, and protection for, MRIdian components, new technologies, processes and know-how are important to our business. Our policy is to seek patent protection in the United States and in certain foreign jurisdictions for our MRIdian systems and other technology where available and when appropriate. We also in-license technology, inventions and improvements we consider important to the development of our business.

We hold a license to four issued U.S. patents, 18 issued foreign patents (eight of which were issued in Great Britain, Germany, France and the Netherlands as a result of two patent applications filed and allowed through the European Patent Office), one pending U.S. application and four pending foreign applications as of January 15, 2019. We own an additional 24 issued U.S. patents, 52 issued foreign patents (15 of which were issued in Great Britain, Germany, France, Italy and the Netherlands as a result of three patent applications filed and allowed through the European Patent Office), 25 pending U.S. applications and 108 pending foreign applications as of January 15, 2019. Assuming all required fees are paid, individual patents or patent applications owned or licensed by us will expire between 2021 and 2039. We also have a joint ownership interest with Case Western Reserve University in one issued patent and one U.S. application.

Our portfolio includes patents and patent applications directed to system-wide aspects of MRIdian and to key aspects of its subsystems and components. The initial licensed patents for our core technology broadly cover the simultaneous use of MR imaging and isotopic external-beam radiation therapy. These patents have been granted in the United States, Europe, Hong Kong, Australia, China, Canada and Japan, and additional related patent applications remain pending in Canada, the United States, Australia and Japan. We have issued U.S. and foreign patents and pending continuation applications of the licensed patents that extend this core technology to alternate beam technologies. Additionally, we have patents and patent applications that cover critical design elements

including, among others, our approach to Cobalt IMRT, our methods for integrating MRI with the radiation delivery system, and the design of our disassemblable, or "pop apart," magnet which enables the MRI sub-system to fit into most standard radiation therapy vaults. The U.S. patent application on our approach to Cobalt IMRT has been issued, the patent application on our split gradient coil has been issued in the United States, Japan, Australia and China and numerous applications on other design elements are pending in the United States and foreign jurisdictions. In addition, we have U.S., Chinese, European and Australian patents and U.S. and foreign patent applications that cover the use of MR- imaging at a frequency sufficient to account for real-time organ motion to provide video-rate tissue tracking in disciplines outside of radiation therapy. Many of the patents and applications in our portfolio covering aspects of the MRIdian with Cobalt-60 system also cover the MRIdian Linac. In addition, we have patents issued in the U.S., Europe, Australia, Japan and China, and additional applications pending in the U.S. and foreign jurisdictions, specifically directed to technology enabling the MRIdian Linac combination of MRI and linear accelerator technology.

We continue to review new technological developments in our system and in the field as a whole, in order to make decisions about what filings would be most appropriate for us. An additional key component of our intellectual property is our proprietary software used in planning and delivering MRIdian's therapeutic radiation dose.

In December 2004, we entered into a licensing agreement with the University of Florida Research Foundation, Inc., or UFRF, whereby UFRF granted us a worldwide exclusive license to certain of UFRF's patents in exchange for 33,653 shares of common stock and a royalty from sales of products developed and sold by us utilizing the licensed patents. We were obligated to meet certain product development and commercialization milestones by various dates through December 31, 2014. The significant milestones met prior to December 31, 2013 included: (i) completion of a business plan and Small Business Technology Transfer grant application; (ii) securing a minimum of $20.0 million venture financing; (iii) successful relocation and build out of our headquarters; (iv) receipt of the first magnet from an OEM partner; (v) hiring of a chief executive officer with industry experience in developing and commercializing similar products; and (vi) filing for FDA approval. The final milestone, which required us to recognize the first commercial sale of the MRIdian system to retail customers by December 31, 2014, was met during the year ended December 31, 2013. If these milestones had not been accomplished, UFRF would have had the right to terminate the licensing agreement. Royalty payments are based on 1% of net sales, defined as the amount collected on sales of licensed products and/or licensed processes after deducting trade and/or quantity discounts, credits on returns and allowances, outbound transportation costs paid and sales tax. Minimum quarterly royalty payments of $50,000 commenced with the quarter ended March 31, 2014 and are payable in advance. Minimum royalties paid in any calendar year will be credited against earned royalties for that calendar year. The royalty payments continue until the earlier of (i) the date that no licensed patents remain enforceable; or (ii) the payment of earned royalties, once begun in 2014, cease for more than four consecutive calendar quarters.

In addition to our patents, we also rely upon trade secrets, know-how, trademarks, copyright protection and continuing technological and licensing opportunities to develop and maintain our competitive position. We have periodically monitored and continue to monitor the activities of our competitors and other third parties with respect to their use of intellectual property. We require our employees, consultants and outside scientific collaborators to execute confidentiality and invention assignment agreements upon commencing employment or consulting relationships with us. Despite these safeguards, any of our know-how or trade secrets not protected by a patent could be disclosed to, or independently developed by, a competitor.

Coverage and Reimbursement

We believe that reimbursement rates in the United States have generally supported a favorable return on investment for the purchase of new radiotherapy equipment, including MRIdian. Payments for standard radiation therapy treatments using MRIdian, including 3D-CRT, IMRT and SBRT, are generally covered and reimbursed under existing Current Procedural Terminology, or CPT, codes and coverage policies currently in place. User experience to date indicates that our initial customers have treated a wide spectrum of different patients and treatment modalities using MRIdian. Physicians use the MRIdian system's on-board MRI for distinct procedures which can be billed by physicians using existing CPT codes, including: complex simulation weekly IMRT or daily for SBRT; special physics consult; and adaptive re-planning. Each of these are distinct procedures which can be billed by physicians using existing CPT codes, so long as these procedures are reimbursed and so long as they meet medical necessity and other documentation and coverage criteria established by government or other third-party payors.

Third-party payors, including governmental healthcare programs such as Medicare and Medicaid, establish coverage policies and reimbursement rates for diagnostic examinations and therapeutic procedures performed by physicians in hospitals and free-standing clinics. Private insurers often model their payment rates and coverage policies based on those established by the government. The U.S. Congress from time to time considers various Medicare and other healthcare reform proposals that could affect both private and public third-party payor coverage and reimbursement for healthcare services provided in hospitals and clinics. In addition, third-party payors regularly update reimbursement amounts, including annual updates to payments to physicians, hospitals and clinics for medical procedures, including radiation treatments using MRIdian.

The Centers for Medicare & Medicaid Services, or CMS, also publishes annual updates to the hospital outpatient prospective payment system, or HOPPS. These payments are bundled amounts received by our hospital customers for hospital outpatient services, including conventional radiation therapy and IMRT, which may result in lower reimbursement to our customers for procedures performed using MRIdian.

Foreign Reimbursement Regulations

Internationally, reimbursement and healthcare payment systems vary from country to country and include single-payor, and government managed systems as well as systems in which private payors and government-managed systems exist side-by-side. In general, the process of obtaining coverage approvals is slower outside of the United States. Our ability to achieve adoption of MRIdian, as well as significant sales volume in international markets we enter will depend in part on the availability of reimbursement for procedures performed using MRIdian.

Research and Development

Continued innovation and development of advanced technologies is critical to our goal of making MR Image-Guided radiation therapy the standard of care for cancer treatment. Our current development activities include improvements in and expansion of product capabilities, continued clinical workflow refinements, design improvements to reduce system costs and improvements in reliability.

The modular design of MRIdian enables the development of new capabilities and performance enhancements by generally allowing each subsystem to evolve within the overall platform design. Access to regular MRIdian upgrades protects customer investment in MRIdian and facilitates the adoption of new features and capabilities among existing installed base customers.

In addition, we believe our existing and expanding IP portfolio will enable us to continuously develop innovative technologies to further strengthen the differentiation of MRIdian in the marketplace. Magnetic resonance imaging is a powerful and versatile measurement technique and is widely used throughout radiology and medicine because of its ability to generate information about tissues and disease states.

Government Regulation

U.S. Medical Device Regulation and Nuclear Materials Regulation

As a manufacturer and seller of medical devices and devices that deliver radiation, we and some of our suppliers and distributors are subject to extensive and rigorous regulation by the FDA, the Nuclear Regulatory Commission, or the NRC, other federal, state and local authorities in the United States and foreign regulatory authorities. The U.S. Food, Drug, and Cosmetic Act, or FDCA, and the regulations promulgated by the FDA relating to medical devices and radiation-producing devices govern, among other things, the following activities that we perform or that are performed on our behalf, and that we will continue to perform or have performed on our behalf:

- product design, development and testing;
- manufacturing;
- approval or clearance;
- packaging, labeling and storage;
- marketing, advertising and promotion, sales;
- distribution, including importing and exporting;

- installation;
- possession and disposal;
- record keeping;
- service and surveillance, including post-approval monitoring and reporting;
- complaint handling; and
- repair or recall of products and issuance of field safety corrective actions.

FDA Clearance and Approval of Medical Devices

The FDA regulates medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. Unless an exemption applies, the FDA requires that all new medical devices and all marketed medical devices that have been significantly changed, or that will be marketed with a new indication for use, obtain either clearance via a 510(k) premarket notification or approval via a Premarket Approval, or PMA, application before the manufacturer may commercially market or distribute the product in the United States.

The FDA classifies medical devices into one of three classes. Devices deemed to pose the lowest risk are placed in Class I.

Moderate risk devices are placed in Class II, for which safety and effectiveness can be reasonably assured by adherence to: (i) a set of regulations referred to as General Controls, which require compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, (ii) Special Controls, which can include performance standards, guidelines and post-market surveillance; and (iii) regulations regarding facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Most Class II devices are subject to 510(k) premarket review and clearance by the FDA.

Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) devices are placed in Class III. Class III devices require FDA approval of a PMA prior to marketing.

Both generations of the MRIdian System have been classified as Class II medical devices subject to the 510(k) clearance process.

510(k) clearance process. Most Class II devices are subject to premarket review and clearance by the FDA, which is accomplished through the 510(k) premarket notification process. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent" to a "predicate" device, which is a legally marketed similar device that is not subject to PMA requirements.

To be "substantially equivalent," the proposed device must have the same intended use as the predicate device and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. The FDA is in the process of evaluating and implementing significant reforms to the device premarket review process, such as encouraging 510(k) applicants to use newer predicate devices to demonstrate substantial equivalence, and other policies that are intended to promote the use of modern technologies, improve the efficiency of the review process, and protect the public health.

The process of obtaining 510(k) clearance usually takes from three to 12 months from the date the application is filed and generally requires submitting supporting design and test data, which can be extensive and can prolong the process for a considerable period of time. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in the intended use of the device, may require a new 510(k) clearance or, depending on the modification, could require approval of a PMA. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with the manufacturer's decision, it may retroactively require the manufacturer to submit a request for 510(k)

clearance or PMA approval and can require the manufacturer to cease marketing and/or recall the product in the United States until 510(k) clearance or PMA approval is obtained.

We received 510(k) clearances for the treatment planning and delivery software system in January 2011 and for MRIdian in May 2012. Since obtaining 510(k) clearances in 2011 and 2012, we have made changes to MRIdian that we believe do not require new 510(k) clearance.

In February 2017, we received 510(k) clearance from the FDA to market the MRIdian Linac system. We received 510(k) clearance from the FDA for a modification of the MRIdian Linac system in June 2017.

Premarket application approval process. Submission and approval of a PMA is required before marketing of a Class III product may proceed. The PMA must contain sufficient valid scientific evidence to assure that the device is safe and effective for its intended use. The PMA process is the FDA's most stringent premarket review process for devices, typically requiring the submission of extensive information including clinical study data. None of our products have been subject to the PMA approval process, and we have no plans for any indication, system improvements or extensions that we believe would require a PMA.

Clinical trials. Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) clearance. Clinical trials are subject to extensive monitoring, record keeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board, or IRB, for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical trial, the patient's informed consent must be obtained in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. The clinical trial sponsor, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and effectiveness of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product.

Continuing FDA regulation. Any devices we manufacture or distribute pursuant to 510(k) clearance or PMA approval by the FDA are subject to pervasive and continuing regulation by the FDA and certain state agencies. These include product listing and establishment registration requirements, which help facilitate FDA inspections and other regulatory actions.

In addition, our manufacturing operations for medical devices and those of our suppliers must comply with the FDA's Quality System Regulation, or QSR. The QSR requires that each manufacturer, including third party manufacturers, establish and implement a quality system by which the manufacturer monitors the manufacturing process and maintains records that show compliance with FDA regulations and the manufacturer's written specifications and procedures. Among other things, the QSR requires that manufacturers establish performance requirements before production and follow stringent requirements applicable to the device design, testing, production, control, record keeping, documentation, labeling and installation, as well as supplier/contractor selection, complaint handling and other quality assurance procedures during all aspects of the manufacturing process. Compliance with the QSR is necessary to be able to continue to market medical devices that have received FDA approval or clearance, and to receive FDA clearance or approval to market new or significantly modified medical devices. The FDA makes announced and unannounced inspections of medical device manufacturers, and these inspections may include the manufacturing facilities of subcontractors. Following an inspection, the FDA may issue a FDA Form 483 report that describes the conditions or practices that the FDA investigator believes are in violation of FDA's requirements. FDA may also issue warning letters documenting regulatory violations observed during an inspection, for failure to adequately address inspectional observations, or for other violations of the FDCA. The manufacturer's failure to adequately and promptly respond to such reports or warning letters may result in further FDA enforcement action against the manufacturer and related consequences, including, among other things, fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, FDA refusal to grant 510(k) clearance or PMA approval, withdrawal of existing clearances or approvals, and criminal prosecution.

Manufacturers must also comply with post-market surveillance regulations, including medical device reporting regulations, which require that manufacturers review and report to the FDA any incident in which their device may have caused or contributed to a death or serious injury, or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. In addition, corrections and removals reporting regulations require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health. The FDA may also order a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death.

The FDA and the Federal Trade Commission, or FTC, also regulate the promotion and advertising of MRIdian. In general, we may not promote or advertise MRIdian for uses not within the scope of our clearances or approvals or make unsupported safety and effectiveness claims.

Failure to comply with applicable FDA requirements, including delays in or failures to report incidents to the FDA or for promoting devices for unapproved or uncleared uses, can result in enforcement action by the FDA, such as:

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

Radiological health. We are also regulated by the FDA under the Electronic Product Radiation Control provisions of the FDCA because MRIdian contains radiation producing components, and because we assemble these components during manufacturing and service activities. The Electronic Product Radiation Control provisions require radiation producing products to comply with certain regulations and applicable performance standards. Manufacturers are required to certify in product labeling and reports to the FDA that their products comply with all necessary standards as well as maintain manufacturing, testing and sales records for their products. The Electronic Product Radiation Control provisions also require manufacturers to report product defects and affix appropriate labeling to covered products. Failure to comply with these requirements could result in enforcement action by the FDA, which can include any of the sanctions described above.

Nuclear Regulatory Commission and U.S. State Agencies

In the United States, as a manufacturer of medical devices and devices utilizing radioactive byproduct material (i.e. depleted uranium shielding and Cobalt-60 sources), we are subject to extensive regulation by not only federal governmental authorities, such as the NRC, but also by state and local governmental authorities, such as the Ohio Department of Health, to ensure such devices are safe and effective. In Ohio, the Department of Health, by agreement with the NRC, regulates the possession, use, and disposal of radioactive byproduct material as well as the manufacture of devices containing radioactive sealed sources to ensure compliance with state and federal laws and regulations. We have received sealed source device approval from the Ohio Department of Health for MRIdian and have entered into a standby letter of credit with PNC for $103,000 to provide certification of financial assurance for decommissioning Cobalt-60 radioactive materials in accordance with Ohio Department of Health regulations. We and/or our supplier of radiation sources must also comply with NRC and U.S. Department of Transportation regulations on the labeling and packaging requirements for shipment of radiation sources to hospitals or other users of MRIdian. Compliance with NRC, state and local requirements is required for distribution, installation, use and service within each state that we intend to install MRIdian systems.

Existing radiation therapy facilities practicing nuclear medicine, brachytherapy or Gamma Knife therapy are already required to have necessary NRC and/or state licenses and a radiation safety program requiring compliance to various provisions under NRC regulations at Part 35 of Title 10 of the Code of Federal Regulations (“Medical uses of byproduct material”). Use of MRIdian is regulated under Section 35.1000 of the NRC’s regulations (“Other medical

uses of byproduct material or radiation from byproduct material"). In 2013, the NRC released licensing guidance under its regulations to guide our customers in the NRC requirements applicable to the use of MRIdian. We believe that this guidance is favorable in that it is consistent with clinical use of existing image-guided radiation therapy devices.

Moreover, our use, management, and disposal of certain radioactive substances and wastes are subject to regulation by several federal and state agencies depending on the nature of the substance or waste material. We believe that we are in compliance with all federal and state regulations for this purpose.

Outside the United States, various laws apply to the import, distribution, installation and use of MRIdian, in consideration of the nuclear materials within MRIdian. We do not believe that the MRIdian Linac falls under these regulations.

U.S. Privacy and Security Laws

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Further, "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity are also subject to certain HIPAA privacy and security standards. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

U.S. Fraud and Abuse Laws and Regulations

The healthcare industry is also subject to a number of fraud and abuse laws and regulations, including physician anti-kickback, false claims and physician payment transparency laws. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in federal healthcare programs and significant monetary penalties, among others. These laws, among other things, constrain the sales, marketing and other promotional activities of manufacturers of medical products, such as us, by limiting the kinds of financial arrangements we may have with hospitals, physicians and other potential purchasers of medical products who may seek reimbursement from a federal or state health care program such as Medicare or Medicaid.

Anti-kickback laws. The federal Anti-Kickback Statute makes it a criminal offense to knowingly and willfully solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase, order, lease of any good, facility, item or service, that are reimbursable by a state or federal health care program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to the purchase of medical devices from a particular manufacturer or the referral of patients to a particular supplier of diagnostic services utilizing such devices. Although, there are established statutory exceptions and regulatory safe harbors that define certain financial transactions and practices that are not subject to the Anti-Kickback Statute, the exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances.

Generally, courts have taken a broad interpretation of the scope of the Anti-Kickback Statute, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals or purchases. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Violations of this law are punishable by up to five years in prison, and can also result in criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. Many states have also adopted statutes similar to the federal Anti-Kickback Statute, some of which apply to payments in connection with the referral of patients for healthcare items or services reimbursed by any source, not only governmental payor programs.

False Claims Act. The federal civil False Claims Act prohibits anyone from knowingly and willfully presenting, or causing to be presented, claims for payment, that are false or fraudulent, such as claims for payment of services not provided as claimed. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud called a "relator". Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government is ultimately successful in obtaining redress in the matter or if the relator succeeds in obtaining redress without the government's involvement, then the relator is typically entitled to receive a percentage of the recovery. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties ranging from $11,181 to $22,363 for each separate false claim, and may be excluded from participation in federal health care programs, and, although the federal False Claims Act is a civil statute, violations may also implicate various federal criminal statutes. Several states have also adopted comparable state false claims act, some of which apply to all payors.

Civil monetary penalties laws. The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Other fraud and abuse laws. HIPAA also created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, the intent standard for certain healthcare fraud statutes under HIPAA was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Physician payment transparency laws. There has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers and entities. The Affordable Care Act, among other things, imposed new reporting requirements on certain manufacturers, including certain device manufacturers, for payments provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties of up to an aggregate of $169,170 per year and up to an aggregate of $1,127,799 per year for "knowing failures." Device manufacturers must submit reports by the 90th day of each calendar year.

Certain states also mandate implementation of compliance programs, impose restrictions on device manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare providers and entities.

The laws and regulations and their enforcement are constantly undergoing change, and we cannot predict what effect, if any, changes may have on our business. In addition, new laws and regulations may be adopted which adversely affect our business. There has been a trend in recent years, both in the United States and internationally, toward more stringent regulation and enforcement of requirements applicable to medical device manufacturers and requirements regarding protection and confidentiality of personal data.

State Certificate of Need Laws

In some states, a certificate of need, or CON, or similar regulatory approval is required by hospitals and other healthcare providers prior to the acquisition of high-cost capital items, including MRIdian, or the provision of new services. These laws generally require appropriate state agency determination of public need and approval prior to the acquisition of such capital items or addition of new services. CON requirements may preclude our customers from acquiring, or significantly delay acquisition of, MRIdian and/or from performing treatments using MRIdian. CON laws are the subject of ongoing legislative activity, and a significant increase in the number of states regulating the offering and use of MRIdian through CON or similar requirements could adversely affect us.

Healthcare Reform

In the United States and foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system seeking, among other things, to reduce healthcare costs that could affect our results of operations.

By way of example, in the United States, the Affordable Care Act was signed into law in March 2010.Among other things, the Affordable Care Act:

- imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States which, due to subsequent legislative amendments, has been suspended through January 1, 2020; and
- implemented payment system reforms; and
- created an independent payment advisory board.

There is uncertainty with respect to the Affordable Care Act and changes that the current presidential administration and the U.S. Congress may implement. Any changes will likely take time to unfold and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for MRIdian or additional pricing pressure.

Foreign Regulation of Medical Devices

Our activities outside the United States are subject to regulatory requirements that vary from country to country and frequently differ significantly from those in the United States. Failure to obtain and maintain regulatory approval or clearance in any foreign country in which we market or plan to market MRIdian and MRIdian Linac may have a negative effect on our ability to generate revenue and harm our business.

In general, MRIdian and MRIdian Linac are regulated outside the United States as medical devices by foreign governmental agencies similar to the FDA and the FTC. In addition, in foreign countries where we have operations or sell MRIdian, we are subject to laws and regulations applicable to manufacturers of medical devices, radiation producing devices and to the healthcare industry, and laws and regulation of general applicability relating to environmental protection, safe working conditions, manufacturing practices and other matters. These laws and regulations are often comparable to, or more stringent than U.S. laws and regulations. Our sales of MRIdian in foreign countries are also subject to regulation of matters such as product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. We rely in some countries on our foreign distributors to assist us in complying with applicable regulatory requirements.

Regulation in the EU

In the European Union, or EU, we are required under the European Medical Device Directive (Council Directive 93/42/EEC) to affix the CE mark to our MRIdian systems in order to sell the MRIdian systems in member countries of the EU. The CE mark is an international symbol that represents adherence to certain essential principles of safety and effectiveness mandated in the European Medical Device Directive (the so-called “essential requirements”). Once affixed, the CE mark enables a product to be sold within the EEA, which is composed of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein.

To demonstrate compliance with the essential requirements, we must undergo a conformity assessment procedure which varies according to the type of medical device and its classification. Except for certain low risk medical devices where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a Member State of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This Certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

We received the CE Certificate of Conformity from our Notified Body in November 2014, allowing us to affix the CE mark to MRIdian in order to sell it throughout the EEA. In September 2016, we received approval for CE mark in the European Union for our MRIdian Linac.

If we modify MRIdian we may need to undergo a new conformity assessment procedure to be able to affix the CE mark to the modified product. Additionally, we will need to undergo new conformity assessments for any new products that we may develop in the future before we are able to affix the CE mark to these new products. We cannot be certain that the outcome of these conformity assessments will be positive and that we will be able to affix the CE mark for modified or new products or that we will continue to meet the quality and safety standards required to maintain the CE marks that we already have or may have in the future. In addition, if we are unable to affix the CE mark to our future products, we would be unable to sell them in EU member countries.

In September 2012, the European Commission published proposals for the revision of the EU regulatory framework for medical devices. The proposals would replace the Medical Devices Directive and the Active Implantable Medical Devices Directive with two new regulations: the Medical Devices Regulation and the In-Vitro Diagnostic Medical Devices Regulation. Unlike directives, which must be implemented into the national laws of the EU Member States, the regulations would be directly applicable, i.e., without the need for adoption of EU Member State laws implementing them, in all EEA Member States and are intended to eliminate current differences in the regulation of medical devices among EEA Member States.

The Medical Devices Regulation will apply to ViewRay starting on May 26, 2020. Once applicable, the new regulation will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number; and
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU.

Regulation in Other Countries

We will be subject to additional regulations in foreign countries in which we intend to market, sell and import MRIdian. We or our distributors must receive all necessary approvals or clearance prior to marketing and importing MRIdian in those international markets. We received a license and permission to import MRIdian into the United Arab Emirates in December 2014. We received regulatory approval for MRIdian with Cobalt-60 in Italy in January 2015, Korea in September 2015, as well as Japan and China in August 2016. We also received regulatory approval for MRIdian Linac in Israel in November 2017. We will seek approvals in other countries as may be required in the future.

The International Standards Organization promulgates internationally recognized standards, including those for the requirements of quality systems. We are certified to the ISO 13485:2016 standard, which specify the quality system requirements for medical device manufacturers. To support our ISO certifications, we are subject to surveillance

audits by a Notified Body yearly and recertification audits every three years that assess our continued compliance with the relevant ISO standards. Our most recent recertification audit occurred in March 2017.

Employees

At December 31, 2018, we had 221 full-time employees, 49 of whom were engaged in research and development, and 172 in sales and marketing, business development, finance, human resources, facilities and general management and administration. None of our employees are covered by a collective bargaining agreement, and we have not experienced any work stoppages. We consider our relations with our employees to be good.

General

We make our periodic and current reports, including our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements and any amendments to those reports, available free of charge, on our website as soon as practicable after such material is electronically filed or furnished with the Securities and Exchange Commission (the "SEC"). Our website address is www.viewray.com and the reports are filed under "SEC Filings", on the Company – Investor Relations portion of our website. Our Code of Business Conduct and Ethics, Corporate Governance Guidelines and the charters of the Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee are also available under "Corporate Governance", on the Investor Relations portion of our website. Investors and others should note that we announce material financial and operational information to our investors using our investor relations website (http://investors.viewray.com/), press releases, SEC filings and public conference calls and webcasts. Please note that information on, or that can be accessed through, our website is not deemed "filed" with the SEC and is not to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended (the "Securities Act"), or the Securities Exchange Act of 1934, as amended (the "Exchange Act").

We operate our business as one segment as defined by U.S. generally accepted accounting principles. Our financial results for the years ended December 31, 2018, 2017 and 2016 are discussed in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 8. Financial Statements and Supplementary Data" of this Annual Report.

We commenced operations as a Florida corporation in 2004 and subsequently reincorporated in Delaware in 2007. Our corporate headquarters are located at 2 Thermo Fisher Way, Oakwood Village, Ohio 44146. Our telephone number is (440) 703-3210, and our website address is www.viewray.com.

Item 1A. RISK FACTORS

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K and other filings we have made and make in the future with the Securities and Exchange Commission, or the SEC. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected.

Risks Related to Our Business and Strategy

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. In the future, these factors may raise substantial doubt about our ability to continue as a going concern.

We have historically incurred substantial net losses, including net losses of $76.4 million, $72.2 million and $50.6 million during the years ended December 31, 2018, 2017 and 2016, respectively. At December 31, 2018, we had an accumulated deficit of $399.0 million. We expect our net losses to continue as a result of ongoing investments in product development and expansion of our commercial operations, including increased manufacturing, and sales and marketing. These net losses have had, and will continue to have, a negative impact on our working capital, total assets and stockholders' equity. Because of the numerous risks and uncertainties associated with our development and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would harm our business, financial condition, results of operations and cash flows.

Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance quarter-to-quarter and year-to-year, due to factors including the timing of product approval, commercial ramp, clinical trials, any litigation that we may file or that may be filed against us, the execution of collaboration, licensing or other agreements and the timing of any payments we make or receive under them. These factors may raise substantial doubt about our ability to continue as a going concern.

If clinicians do not widely adopt MR Image-Guided radiation therapy or MRIdian Linac fails to achieve and sustain sufficient market acceptance, we will not generate sufficient revenue and our growth prospects, financial condition and results of operations could be harmed.

Our MR Image-Guided radiation therapy system, MRIdian, may never gain significant acceptance in the marketplace and, therefore, may never generate substantial revenue or allow us to achieve or maintain profitability. Widespread adoption of MR Image-Guided radiation therapy depends on many factors, including: acceptance by clinicians that MR Image-Guided radiation therapy is clinically-effective and cost-effective in treating a wide range of cancers; demand by patients for MR Image-Guided treatment; successful education of clinicians on the various aspects of this therapeutic approach; and coverage and adequate reimbursement for procedures performed using MR Image-Guided radiation therapy. If we are not successful in conveying to clinicians and hospitals that MR Image-Guided radiation therapy provides equivalent or superior radiation therapy compared to existing technologies, we may experience reluctance or refusal on the part of clinicians and hospitals to order, and third-party payors to pay for, performing a treatment in which MRIdian is utilized. Our ability to achieve commercial market acceptance for MRIdian or any other future products also depends on the strength of our sales, marketing and distribution organizations. In addition, our expectations regarding clinical benefits and cost savings from using MRIdian may not be accurate. These hurdles may make it difficult to demonstrate to physicians, hospitals and other healthcare providers that MRIdian is an appropriate option for radiation therapy, and may be both superior to available radiation therapy systems and more cost-effective than alternative technologies.

Furthermore, we may encounter difficulty in gaining inclusion in cancer treatment guidelines and gaining broad market acceptance by healthcare providers, third-party payors and patients. Healthcare providers may have difficulty in obtaining adequate reimbursement from government and/or third-party payors for cancer treatment, which may negatively impact adoption of MRIdian.

We may not be able to generate sufficient revenue from the commercialization of our MRIdian systems to achieve and maintain profitability.

We rely entirely on the commercialization of MRIdian Linac to generate revenue. During the year ended December 31, 2018, we recognized revenue of $76.6 million from installation or delivery of 13 MRIdian Linac systems and

two systems upgrades; $3.9 million from service revenue at certain customer sites; and $0.5 million from distribution rights revenue. In order to successfully commercialize MRIdian Linac, we will need to: continue to expand our marketing efforts to develop new relationships and expand existing relationships with customers; continue to expand our commercial footprint via direct sales and distribution network; receive clearance or approval for MRIdian systems in additional countries; achieve and maintain compliance with all applicable regulatory requirements; and develop and commercialize new features for MRIdian systems. We cannot assure you that we will be able to achieve or maintain profitability. If we fail to successfully commercialize MRIdian systems, we may never receive a return on the substantial investments in product development, sales and marketing, regulatory compliance, manufacturing and quality assurance that we have made, as well as further investments we intend to make.

In addition, potential customers may decide not to purchase MRIdian systems, or our customers may decide to cancel orders due to changes in treatment offerings, research and product development plans, difficulties in obtaining coverage or reimbursement for MR Image-Guided radiation therapy treatment, complications with facility build-outs, utilization of MR Image-Guided radiation therapy or other cancer treatment methods developed by other parties, lack of financing or the inability to obtain or delay in obtaining a certificate of need from state regulatory agencies or zoning restrictions, all of which are circumstances outside of our control.

In addition, demand for MRIdian systems may not increase as quickly as we predict, and we may be unable to increase our revenue levels as we expect. Even if we succeed in increasing adoption of MRIdian systems by hospitals and other healthcare providers, maintaining and creating relationships with our existing and new customers and developing and commercializing new features for MRIdian systems, we may not be able to generate sufficient revenue to achieve or maintain profitability.

We are an early, commercial-stage company and have a limited history commercializing MRIdian, which may make it difficult to evaluate our current business and predict our future performance.

We are an early, commercial-stage company and have a limited operating history. We commenced operations as a Florida corporation in 2004 and subsequently reincorporated in Delaware in 2007. However, we did not begin commercial operations until 2013. Our limited history commercializing MRIdian may make it difficult to evaluate our current business and predict our future performance. Any assessment as to if or when we may become profitable or predictions about our future success or viability, are subject to significant uncertainty. We have encountered and will continue to encounter risks and difficulties frequently experienced by early, commercial-stage companies in rapidly evolving industries. If we do not address these risks successfully, our business could be harmed.

If MRIdian does not perform as expected, or if we are unable to satisfy customers' demands for additional product features, our reputation, business and results of operations will suffer.

Our success depends on the market's confidence that MRIdian can provide reliable, high-quality MR Image-Guided radiation therapy. At December 31, 2018, there were seven MRIdian with Cobalt-60 and 21 MRIdian Linacs installed or delivered. Consequently, we have limited statistics regarding the efficacy or reliability of MRIdian. We believe that our customers are likely to be particularly sensitive to product defects and errors, including functional downtime that limits the number of patients that can be treated using the system or a failure that is costly to repair. We cannot assure that similar product defects or other errors will occur in the future. This could also include the mistreatment of a patient with MRIdian caused by human error on the part of MRIdian's operators or prescribing physicians or as a result of a machine malfunction. We may be subject to regulatory enforcement action or legal claims arising from any defects or errors that may occur. Any failure of MRIdian to perform as expected could harm our reputation, business and results of operations.

In addition, our customers are technologically well informed and at times have specific demands or requests for additional functionality. If we are unable to meet those demands through the development of new features for MRIdian or future products, or those new features or products do not function at the level that our customers expect, or we are unable to increase patient throughput as expected or we are unable to obtain regulatory clearance or approval of those new features or products, where applicable, our reputation, business and results of operations could be harmed.

The safety and efficacy of MRIdian systems for certain uses is not currently supported by long-term clinical data, and may therefore be less safe and effective than initially anticipated.

To date, we have not been required to complete long-term clinical studies in connection with the sale of MRIdian with Cobalt-60 or MRIdian Linac. As a result, we currently lack the breadth of published long-term clinical data supporting the efficacy of MRIdian with Cobalt-60 or MRIdian Linac and the benefits each offers that might have been generated in connection with other marketing authorization processes. In addition, because only a few MRIdian systems have been installed at customer sites, we have limited complication or patient survival rate data with respect to treatments using the systems. If future patient studies or clinical testing do not support our belief that MRIdian with Cobalt-60 or MRIdian Linac offers a more advantageous treatment for a wide variety of cancer types, market acceptance of these systems could fail to increase or could decrease and our business could be harmed.

If we choose to, or are required to, conduct additional studies, the results of these studies or experience could reduce the rate of coverage and reimbursement by both public and private third-party payors for procedures that are performed with MRIdian with Cobalt-60 or MRIdian Linac, slow the market adoption of our product by physicians, significantly reduce our ability to achieve expected revenues and prevent us from becoming profitable. In addition, if future studies and experience indicate that MRIdian with Cobalt-60 or MRIdian Linac causes unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls or suspension or withdrawal of FDA clearance, and our reputation with physicians, patients and healthcare providers may suffer.

There have been instances of patients' severe injury or death due to a variety of factors, including operator error, misuse, radiation therapy product or customer system malfunctions, and other factors. If our redundant safety systems do not operate as we expect, or any of these or other causes arose in the use of our products, MRIdian with Cobalt-60 or MRIdian Linac could severely injure or kill a patient. This could result in lawsuits, fines or damage to our reputation.

We may be delayed or prevented from implementing our long-term sales strategy if we fail to educate clinicians and patients about the benefits of MRIdian.

In order to increase revenue, we must increase awareness of the range of benefits that we believe MRIdian offers to both existing and potential customers, primarily cancer clinicians. An important part of our sales strategy involves educating and training clinicians to utilize the entire functionality of MRIdian. In addition, we must further educate clinicians about the ability of MRIdian to treat a wide range of cancer types effectively and efficiently. If clinicians are not properly educated about the use of MRIdian for radiation therapy, they may be unwilling or unable to take advantage of the full range of functionality that we believe MRIdian offers, which could have a negative impact on MRIdian sales. Clinicians may decide that certain tumors can be adequately treated using traditional radiation therapy systems, notwithstanding the benefits of MRIdian. We must also succeed in educating customers about the potential for reimbursement for procedures performed using MRIdian. In addition, we need to increase awareness of MRIdian among potential patients, who are increasingly educated about cancer treatment options and therefore impact adoption of new technologies by clinicians. If our efforts to expand sales of MRIdian in the long-term are not successful, our business and results of operations will be harmed.

We may not be able to gain the support of leading hospitals and key opinion leaders, or to publish the results of our clinical trials in peer-reviewed journals, which may make it difficult to establish MRIdian as a standard of care and achieve market acceptance.

Our strategy includes developing relationships with leading hospitals and key opinion leaders in our industry. If these hospitals and key industry thought leaders determine that MRIdian is not clinically effective or that alternative technologies are more effective, or if we encounter difficulty promoting adoption or establishing MRIdian as a standard of care, our ability to achieve market acceptance of MRIdian could be significantly limited.

We believe that publication of scientific and medical results in peer-reviewed journals and presentation of data at leading conferences are critical to the broad adoption of MRIdian. Publication in leading medical journals is subject to a peer-review process, and peer reviewers may not consider the results of studies involving MRIdian sufficiently novel or worthy of publication.

We have limited experience in marketing and selling MRIdian, and if we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of MRIdian and we may never generate sufficient revenue to achieve or sustain profitability.

We have limited experience in marketing and selling MRIdian. We have only been selling MRIdian since 2013 and have seven MRIdian with Cobalt-60 and 21 MRIdian Linac installed or delivered at December 31, 2018. Our devices have only been used to treat patients since early 2014. MRIdian is a new technology in the radiation therapy systems sector and our future sales will largely depend on our ability to increase our sales and marketing efforts and adequately address our customers' needs. We believe it is necessary to maintain a sales force that includes sales representatives with specific technical backgrounds that can address those needs as part of the sales cycle. Competition for these types of employees is intense and we may not be able to attract and retain sufficient personnel to maintain an effective sales and marketing force. If we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of MRIdian and we may never generate sufficient revenue to achieve or sustain profitability.

The long sales cycle and low unit volume sales of MRIdian, as well as other factors, may contribute to substantial fluctuations in our operating results and stock price and make it difficult to compare our results of operations to prior periods and predict future financial results.

Because of the relatively small number of systems we expect to install in any period, each installation of a MRIdian may represent a significant percentage of our revenue for a particular period. Additionally, customer site construction, certificate of need and additional zoning and licensing permits are often required in connection with the sale of a MRIdian, any of which may further delay the installation process. When we are responsible for installing a system, we only recognize revenue from the sale of a MRIdian after the system has been installed and accepted by the customer. When a qualified third party is responsible for the installation, we recognize revenue when title is transferred. Therefore, if we do not install a MRIdian or transfer title when anticipated, our operating results will vary significantly from our expectations. We have had experiences with customers postponing installation of MRIdian systems due to delays in facility build-outs, which are often lengthy and costly processes for our existing and potential customers. In addition, if our customers delay or cancel purchases, we may be required to modify or terminate contractual arrangements with our suppliers, which may result in the loss of deposits. Due to future fluctuations in revenue and costs, as well as other potential fluctuations, you should not rely upon our operating results in any particular period as an indication of future performance. In addition to the other risks described, the following factors may also contribute to these fluctuations:

- timing of when we are able to recognize revenue associated with sales of MRIdian;
- actions relating to regulatory matters, including regulatory requirements in some states for a certificate of need prior to the installation of a MRIdian;
- delays in shipment due to, for example, unanticipated construction delays at customer locations where MRIdian is to be installed, labor disturbances or natural disasters;
- delays in our manufacturing processes or unexpected manufacturing difficulties;
- timing of the announcements of contract executions or other customer and commercial developments;
- timing of the announcement, introduction and delivery of new products or product features by us and by our competitors;
- timing and level of expenditures associated with expansion of sales and marketing activities and our overall operations;
- fluctuations in our gross margins and the factors that contribute to such fluctuations, as described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" elsewhere in this Annual Report;
- our ability to effectively execute on our strategic and operating plans;

- the extent to which MRIdian gains market acceptance and the timing of customer demand for MRIdian;
- our ability to protect our proprietary rights and defend against third-party challenges;
- disruptions in the supply or changes in the costs of raw materials, labor, product components or transportation services; and
- changes in third-party coverage and reimbursement, government regulation or in a customer's ability to obtain financing.

These factors are difficult to forecast and may contribute to fluctuations in our reported revenue and results of operations and variation from our expectations, particularly during the periods in which our sales volume is low. Any fluctuations in our financial results may cause volatility in our stock price.

Each MRIdian is a major capital equipment item and is subject to a lengthy sales cycle. The time from initial customer contact to execution of a contract can take 18 to 24 months or more. Following execution of a contract, it generally takes nine to 15 months for a customer to customize an existing facility or construct a new vault. During this time, facilities support and transitioning, as well as permitting, are typically required, which can take several months. The time required to customize an existing facility prior to installation, including modifications of a standard vault to accommodate an MRI, is typically currently two to three months. If a customer does not have an existing vault available, it may take longer to construct a new vault. In some cases, customers may request installation for a date later in the future to meet their own clinical or business requirements. Upon the commencement of installation at a customer's facility, it typically takes approximately 60 to 90 days to complete the installation and on-site testing of the system, including the completion of acceptance test procedures. If a small number of customers defer installation of a MRIdian for even a short period, recognition of a significant amount of revenue may be deferred to a subsequent period. Because our operating costs are relatively fixed, our inability to recognize revenue in a particular period may impact our profitability in that period. The inability to recognize revenue in a particular period may also make it difficult to compare our operating results with prior periods. The price of a MRIdian requires a portion of our target customers to obtain outside financing before committing to purchase a MRIdian. This financing may be difficult for our customers to obtain in any given period, if at all. The requirement of site-specific modifications or construction may also delay adoption or overall demand. In addition, while we believe that our backlog of orders provides a better measure at any particular point in time of the long-term performance prospects of our business than our operating results for a particular period, investors may attribute significant weight to our operating results for a particular period, which may be volatile and as a result, cause fluctuations in our stock price.

A large portion of our revenue in any given reporting period may be derived from a small number of contracts.

Given that a significant portion of the purchase price for MRIdian will generally be recognized as revenue in a single reporting period, we expect a small number of contracts in any given reporting period to account for a substantial portion of our revenue in any period. Any decrease in revenue from these contracts could harm our operating results. Accordingly, our revenue and results of operations may vary from period to period. We are also subject to credit risk associated with the concentration of our accounts receivable from our customers. If one or more of our customers at any given time were either to terminate their contracts with us, cease doing business with us or fail to pay us on a timely basis, our business, financial condition and results of operations could be harmed.

The payment structure we use in our customer arrangements may lead to fluctuations in operating cash flows in a given period.

While our customers typically provide a deposit upon entering into an order contract with us, the substantial majority of the payment owed for a MRIdian is not due until the time of shipment of a MRIdian or following final acceptance by the customer upon installation. If we miss targeted shipments or our customers do not actively work towards completing installation, our receipt of payments and our operating cash flows could be impacted. In addition, if customers do not adhere to our payments terms, our operating cash flows could be impacted in any given period. Due to these fluctuations in operating cash flows and other potential fluctuations, you should not rely upon our operating results in any particular period as an indication of future performance.

Amounts included in backlog may not result in actual revenue and are an uncertain indicator of our future earnings.

We define backlog as the accumulation of all orders for which revenue has not been recognized and we consider valid. The determination of backlog includes, among other factors, our subjective judgment about the likelihood of an order becoming revenue and the regulatory approval required in the customer's jurisdiction, if any. Our judgments in this area have been, and in the future, may be, incorrect and we cannot assure you that, for any order included in backlog, we will recognize revenue with respect to it. In addition, orders can be delayed for a number of reasons, many of which are beyond our control, including supplier delays, which may cause delays in our manufacturing process, customer delays in commencing or completing construction of its facility, delays in obtaining zoning or other approvals and delays in obtaining financing. We may not be aware of these delays affecting our suppliers and customers and as a result may not consider them when evaluating the contemporaneous effect on backlog. Moreover, orders generally do not have firm dates by when a customer must take delivery or accept our systems, and certain customers may not provide a deposit or letter of credit with the contract, either of which could allow a customer greater flexibility to delay the order without cancelling the contract. Further, our backlog could be reduced due to cancellation of orders by customers. Should a cancellation occur, our backlog and anticipated revenue would be reduced unless we were able to replace it. Reductions in our backlog could negatively impact our future results of operations or the price of our common stock.

We evaluate our backlog at least quarterly to determine if the orders continue to meet our criteria for inclusion in backlog. We may adjust our reported backlog to account for any changes in: customer or distributor plans or financial conditions; the customer's or distributor's continued intent and ability to fulfill the order contract; regulatory requirements; the status of regulatory approval required in the customer's jurisdiction (or other factors); or due to changes in our judgment about the likelihood of completing an order contract. Because revenue will not be recognized until we have fulfilled our obligations to a customer, there may be a significant amount of time from signing a contract with a customer or shipping a system and revenue recognition. We cannot assure you that our backlog will result in revenue on a timely basis or at all, or that any cancelled contracts will be replaced.

Our ability to achieve profitability depends substantially on increasing our gross margins by standardizing the selling price, reducing costs of MRIdian and improving our economies of scale, which we may not be able to achieve.

We are not, and never have been, profitable. The MRIdian purchase contracts we have entered into to date have been at a range of selling prices. Generally, earlier contracts have been at lower prices and more recent contracts have been at higher prices. Our ability to enter into contracts at higher selling prices depends on a number of factors including:

- our ability to achieve commercial market acceptance for our system;
- the pricing of competitors' systems;
- availability of coverage and adequate reimbursement by commercial and government payors; and
- our ability to manufacture and install our systems in a timely and cost-effective manner.

We bear the risk of warranty claims on all products we supply, including equipment and component parts manufactured by third parties. We cannot assure you that we will be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or that any recovery from the vendor or supplier would be adequate. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against the suppliers expires, which could result in additional costs to us. There is a risk that warranty claims made against us will exceed our warranty reserve and our business, financial condition and results of operations could be harmed.

Our customer contracts provide that our customers commit to purchase a MRIdian system for a fixed price, and a MRIdian system will generally not be delivered for nine to 15 months. In some circumstances, delivery can be postponed several months due to customer delays related to construction, vault preparation or concurrent facility expansion, and the cost of product supplies may increase significantly in the intervening time period. In addition, inflation may generally reduce the real value of the purchase price payable upon the achievement of future progress

payment milestones. Either of these occurrences could cause our gross margins to decline or cause us to lose money on the sale of a MRIdian.

Moreover, our gross margins may decline in a given period due in part to significant replacement rates for components, resulting in increased warranty expense, negative profit margins on service contracts and customer dissatisfaction. If we are unable to reduce our product costs and improve or maintain quality and reliability, our gross margin may be negatively impacted. Additionally, we may face increased demands for compensation from customers who are not satisfied with the quality and reliability of MRIdian, which could increase our service costs or require us to issue credits against future service payments and negatively impact future product sales. For example, we may have to extend a warranty period due to our failure to meet up-time requirements. We continually work to reduce the cost of our MRIdian product; however, we may be unable to reduce our product cost as quickly as we anticipate and, in some instances, may experience increases in costs from our suppliers.

Even if we are able to implement cost reduction and quality improvement efforts successfully, our service operations may remain unprofitable given the relatively small size and geographic dispersion of our installed base, which prevents us from achieving significant economies of scale for the provision of services. If we are unable to achieve increasingly higher gross margins on our MRIdian systems, we may never become profitable.

We may not be able to develop new products or enhance the capabilities of MRIdian to keep pace with our industry's rapidly changing technology and customer requirements.

Our industry is characterized by rapid technological changes, new product introductions and enhancements and evolving industry standards. Our business prospects depend on our ability to develop new products and applications for our technology in new markets that develop as a result of technological and scientific advances, while improving the performance and cost-effectiveness of MRIdian. New technologies, techniques or products could emerge that might offer better combinations of price and performance than MRIdian systems. The market for radiation therapy treatment products is characterized by rapid innovation and advancement in technology. It is important that we anticipate changes in technology and market demand, as well as physician, hospital and healthcare provider practices to successfully develop, obtain clearance or approval, if required, and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis. Nevertheless, we must carefully manage our introduction of new products. If potential customers believe that new products will offer enhanced features or be sold for a more attractive price, they may delay purchases until they are available. We may also have excess or obsolete inventory as we transition to new products, and we have no experience in managing product transitions. If we do not successfully innovate and introduce new technology into our anticipated product lines, or effectively manage the transitions of our technology to new product offerings, our business, financial condition and results of operations could be harmed.

We face competition from numerous companies, many of whom have greater resources than we do or offer alternative technologies at lower prices than our MRIdian systems, which may make it more difficult for us to achieve significant market penetration and profitability.

The market for radiation therapy equipment is characterized by intense competition and pricing pressure. In particular, we compete with a number of existing therapy equipment companies, including Elekta AB, Varian Medical Systems, Inc. and Accuray Incorporated. Many of these competitors are large, well-capitalized companies with significantly greater market share and resources than we have. As a result, these companies may be better positioned than we are to spend more aggressively on marketing, sales, intellectual property and other product initiatives and research and development activities. In addition, we may compete with certain MRI-linear accelerator research projects that are currently in development and may be commercialized.

Existing technologies may offer certain advantages compared to the MRI technology used by our MRIdian system. For example, computed tomography, or CT, is known to hold certain potential advantages over MRI technology for use in radiation therapy. Diagnostic CT is currently the most widely adopted imaging modality for treatment planning, and can be used to directly measure the electron density of patient tissues, which enables more accurate dose computation. In addition, CT imaging provides superior imaging of bones and boney anatomy than MRI, which is advantageous when imaging those structures for planning and alignment for treatment. Finally, CT is a less expensive technology than MRI and might be preferred by customers seeking a lower cost solution.

Our current competitors or other potential competitors may develop new products at any time or may receive approval or clearance in new jurisdictions; for example, Elekta received FDA 510k clearance in the United States for its Unity product in December 2018. In addition, competitors may be able to respond more quickly and

effectively than we can to new or changing opportunities, technologies, standards or customer requirements. If we are unable to develop products that compete effectively against the products of existing or future competitors, our future revenue could be negatively impacted. Some of our competitors may compete by changing their pricing model or by lowering the price of their therapy systems. If these competitors' pricing techniques are effective, it could result in downward pressure on the price of all therapy systems. If we are unable to maintain or increase our selling prices in the face of competition, we may not improve our gross margins.

In addition to the competition that we face from technologies performing similar functions to MRIdian, competition also exists for the limited capital expenditure budgets of our customers. A potential purchaser may be forced to choose between two items of capital equipment. Our ability to compete may also be negatively impacted when purchase decisions are based largely upon price, because MRIdian is a premium-priced system relative to other capital expenditures and alternative radiation therapy technologies. In certain circumstances, a purchaser may decide that an alternative radiation therapy system priced below MRIdian may be sufficient for its patient population given the relative upfront cost savings.

Negative press regarding MR Image-Guided radiation therapy for the treatment of cancer could harm our business.

The comparative efficacy and overall benefits of MR Image-Guided radiation therapy are not yet well understood, particularly with respect to certain types of cancer. These types of reports could negatively impact the market's acceptance of MR Image-Guided radiation therapy, and therefore our ability to generate revenue could be negatively impacted.

We may acquire other businesses, form joint ventures or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

We may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our proprietary technology and industry experience to expand our offerings or distribution. We have no experience with acquiring other companies and limited experience with forming strategic partnerships. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a negative impact on our cash flows, financial condition and results of operations. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could harm our financial condition and results of operations. We may not realize the anticipated benefits of any acquisition, strategic alliance or joint venture.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

To finance any acquisitions or joint ventures, we may choose to issue shares of common stock as consideration, which could dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration.

Risks Related to Our Reliance on Third Parties

We rely on a limited number of third-party suppliers and, in some cases, sole suppliers, for the majority of our components, subassemblies and materials and may not be able to find replacements or immediately transition to alternative suppliers.

We rely on a number of suppliers, including several sole suppliers such as Japan Superconductor Technology, Inc., Siemens AG, Best Theratronics Ltd., Tesla Engineering Limited and Quality Electrodynamics, LLC, for components of MRIdian. For us to be successful, our suppliers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. We have experienced and may in the future experience

delays in obtaining components and materials from suppliers which could impede our ability to manufacture, assemble and install MRIdian on our expected timeline, which could result in order cancellations or contractual penalties. For example, in August 2018, in response to a worldwide shortage of liquid helium, our liquid helium supplier imposed on all its customers, including our company, a reduction in helium allocation amounts. The reduction in allocation covered the remainder of 2018 and has extended into 2019.

If we are required to transition to new third-party suppliers for certain components of MRIdian, we believe that there are only a few other manufacturers that are currently capable of supplying the necessary components. In addition, the use of components or materials furnished by these alternative suppliers could require us to alter our operations. Furthermore, if we are required to change the manufacturer of a critical component of MRIdian, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture MRIdian in a timely manner. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of MRIdian or could require that we modify the design of MRIdian. If the change in manufacturer results in a significant change to MRIdian, a new 510(k) clearance from the FDA or similar international regulatory authorization may be necessary, which could cause substantial delays. The occurrence of any of these events could harm our ability to meet the demand for MRIdian in a timely manner or cost-effectively.

An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these components and materials and we cannot assure you that we will be able to secure alternative equipment and materials we require for MRIdian. Any such interruption could harm our reputation, business, financial condition and results of operations.

In addition, we are in early stages of developing suppliers for components that are specific to MRIdian Linac. The inability of these suppliers to produce reliable components and to sufficiently scale up manufacturing could harm our ability to install MRIdian Linac systems in a timely or cost-effective manner.

We depend on third-party distributors to market and distribute MRIdian in international markets.

We expect a significant amount of our revenue to come from international sales and we depend on a number of distributors for sales in certain international markets. Our distributors may not be able to successfully market and sell MRIdian and may not devote sufficient time and resources to support the marketing and selling efforts that enable the product to develop, achieve or sustain market acceptance. In some jurisdictions, we rely on our distributors to manage the regulatory process, and we are dependent on their ability to do so effectively. In addition, if a dispute arises with a distributor or if a distributor is terminated by us or goes out of business, it may take time to locate an alternative distributor, to seek appropriate regulatory approvals and to train that distributor's personnel to market MRIdian; our ability to sell and service MRIdian in the region formerly serviced by the terminated distributor could be harmed. Any of our distributors could become insolvent or otherwise become unable to pay amounts owed to us when due. Any of these factors could reduce our revenue from affected international markets, increase our costs in those markets or damage our reputation. In addition, if we are unable to attract additional international distributors, our international revenue may not grow.

Failures by our third-party distributors to deliver or install MRIdian properly and on time could harm our reputation.

We rely on arrangements with third-party distributors for sales and installation of MRIdian in certain international markets. As a result of our reliance on third-party distributors, we may be subject to disruptions and increased costs due to factors beyond our control, including labor strikes, third-party error and other issues. If the services of any of these distributors become unsatisfactory, including their failure to properly install MRIdian, we may experience delays in meeting our customers' product demands and we may not be able to find a suitable replacement on a timely basis or on commercially reasonable terms. Any failure to deliver, install or service products in a timely manner may damage our reputation and could cause us to lose current or potential customers.

We rely on third parties to store our inventory and to perform spare parts shipping and other logistics functions on our behalf. A failure or disruption with our logistics providers could harm our business.

Customer service is a critical element of our sales strategy. Third-party logistics providers store most of our spare parts inventory in depots around the world and perform a significant portion of our spare parts logistics and shipping activities. If any of our logistics providers suffers an interruption in its business or experiences delays, disruptions or

quality control problems in its operations or we have to change and qualify alternative logistics providers for our spare parts, shipments of spare parts to our customers may be delayed and our reputation, business, financial condition and results of operations could be negatively harmed.

If third-party payors do not provide coverage and adequate reimbursement to our customers, it could negatively impact sales of MRIdian.

In the United States, hospitals and other healthcare providers who purchase MRIdian generally rely on third-party payors to reimburse all or part of the costs and fees associated with the treatments performed with our system. Accordingly, sales of MRIdian depend, in part, on whether coverage and adequate reimbursement for standard planning methodologies are available to our customers from third-party payors, such as government healthcare insurance programs, including the Medicare and Medicaid programs, private insurance plans, health maintenance organizations and preferred provider organizations. In general, third-party payors in the United States have become increasingly cost-conscious, which has limited coverage for, and reimbursement of, certain procedures such as MR Image-Guided radiation therapy. Third-party payors have also increased utilization controls related to the use of products such as ours by healthcare providers.

Furthermore, there is no uniform policy on coverage and reimbursement for MR Image-Guided radiation therapy among third-party payors. Payors continue to review their coverage policies carefully for existing and new therapies and can, without notice, deny coverage for treatments that include the use of MRIdian.

The Medicare program is increasingly used as a model for how private payors and other governmental payors develop their coverage and reimbursement policies for medical services and procedures. Medicare coverage of advanced and conventional radiation therapies using MRIdian currently varies depending upon the geographic location in which the services are provided. The Centers for Medicare & Medicaid Services, or CMS has not adopted national coverage determination for such therapies that would determine coverage nationally. In the absence of a national coverage determination, Medicare Administrative Contractors, or MACs, with jurisdiction over specific geographic regions have the discretion to determine whether and when the use of MR Image-Guided radiation therapy will be considered medically necessary and covered in their respective regions. A number of MACs have adopted or proposed local coverage determinations covering MR Image-Guided radiation therapy. However, these local coverage determinations do not ensure that coverage will be available for MR Image-Guided radiation therapy for all types of cancer, as the coverage policies may limit coverage to only certain types of cancer.

Even if MR Image-Guided radiation therapy is covered and reimbursed by third-party payors, adverse changes in payors' coverage and reimbursement policies that affect MRIdian could harm our ability to market and sell MRIdian. We cannot be sure that third-party payors will reimburse our customers for procedures using MRIdian at a level that will enable us to achieve or maintain adequate sales and price levels for MRIdian. Without coverage and adequate reimbursement from third-party payors, the market for MRIdian may be limited.

Third-party payors regularly update reimbursement amounts and also, from time to time, revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments to physicians, hospitals and ambulatory surgery centers for the radiation treatments performed with MRIdian. Generally, because the cost of MRIdian is recovered by the healthcare provider as part of the payment for performing the treatment and not separately reimbursed, these updates could directly impact the demand for MRIdian. An example of payment updates is the Medicare program's updates to hospital and physician payments, which are done on an annual basis using a prescribed statutory formula.

Historically, under the Medicare Physician Fee Schedule, or MPFS, when the application of the formula resulted in lower payment, Congress passed interim legislation to prevent the reductions. In April 2015, however, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, was signed into law, which repealed and replaced the statutory formula for Medicare payment adjustments to physicians. MACRA provided a permanent end to the annual interim legislative updates that had previously been necessary to delay or prevent significant reductions to payments under the Medicare Physician Fee Schedule. MACRA provided for a 0.5% update from July 1, 2015 through December 31, 2015, and for each calendar year through 2019, after which there will be a 0% annual update each year through 2025. In addition, MACRA required the establishment of the Merit-Based Incentive Payment System, beginning in 2019, under which physicians may receive performance-based payment incentives or payment reductions based on their performance with respect to clinical quality, resource use, clinical improvement activities and meaningful use of electronic health records. MACRA also required CMS, beginning in 2019, to provide incentive payments for physicians and other eligible professionals that participate in alternative payment models,

such as accountable care organizations, that emphasize quality and value over the traditional volume-based fee-for-service model. It is unclear what impact, if any, MACRA will have on our business and operating results, but any resulting decrease in payment may result in reduced demand for our services.

CMS also publishes annual updates to HOPPS. These payments are bundled amounts received by our hospital customers for hospital outpatient services, including conventional radiation therapy and IMRT, which may result in lower reimbursement to our customers for procedures performed using MRIdian.

In addition, in 2016, CMS implemented changes to the reimbursement of certain services performed in the freestanding center setting which, to date, have not had any material impact on the services delivered with our products.

Any significant cuts in reimbursement rates or changes in reimbursement methodology or administration for MR Image-Guided radiation therapy, or concerns or proposals regarding further cuts or changes in methodology or administration, could further increase uncertainty, influence our customers' decisions, reduce demand for MRIdian, cause customers to cancel orders and impact our revenue and harm our business.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that adequate reimbursement will be made available with respect to MRIdian under any foreign reimbursement system.

Our employees, consultants and commercial partners may engage in misconduct or other improper activities, including insider trading and non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, consultants, distributors, and commercial partners may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities that violate the regulations of the FDA and non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

Risks Related to Our Financial Condition and Capital Requirements

We may need to raise additional capital to fund our existing commercial operations, develop and commercialize new features for MRIdian and new products and expand our operations.

Based on our current business plan, we expect that our existing cash and cash equivalents will enable us to conduct our planned operations for at least the next 12 months. If our available cash balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, we may, from time to time, seek to raise capital through a variety of sources, including the public equity market, private equity financing, and/or public or private debt.

We may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- increase our sales and marketing efforts to increase market adoption of MRIdian and address competitive developments;
- provide for supply and inventory costs associated with plans to accommodate potential increases in demand for MRIdian systems;
- fund development and marketing efforts of any future products and technologies or additional features to then-current products;
- acquire, license or invest in new technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth and improve gross margins;
- our rate of progress in establishing coverage and reimbursement arrangements with domestic and international commercial third-party payors and government payors;
- the cost of expanding our operations and offerings, including our sales and marketing efforts;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of MRIdian;
- the cost of research and development activities;
- the effect of competing technological and market developments;
- costs related to international expansion; and
- the potential cost of and delays in product development as a result of any regulatory oversight applicable to MRIdian.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, dilution to our stockholders will result. Any equity securities issued also could provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to certain components contained within MRIdian, or grant licenses on terms that are not wholly favorable to us.

We have incurred, and will continue to incur significant costs as a result of operating as a public company and our management expects to continue to devote substantial time to public company compliance programs.

As a public company, we have incurred, and will continue to incur significant legal, accounting and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC, and the Nasdaq Stock Market. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our management and other personnel have devoted, and will continue to devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and as a result of the new corporate governance and executive compensation related rules, regulations and guidelines prompted by the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, and further regulations and disclosure obligations expected in the future, and we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will continue to cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

To comply with the requirements of being a public company, we may need to undertake various actions, including implementing new internal controls and procedures and hiring additional accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Securities Exchange Act of 1934, or the Exchange Act, is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls could negatively impact the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we may be required to include in our periodic reports we will file with the SEC under Section 404 of the Sarbanes-Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, our common stock may not be able to remain eligible for quotation on The Nasdaq Global Market.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company" as defined in the JOBS Act. If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, which could harm our business.

Regulations related to "conflict minerals" may force us to incur additional expenses, may result in damage to our business reputation and may adversely impact our ability to conduct our business.

The Dodd-Frank Wall Street Reform and Consumer Protection Act and the rules promulgated by the SEC under such act require companies, including us, to disclose the existence in their products of certain metals, including

tantalum, tin, gold, tungsten and their derivatives, that originate from the Democratic Republic of the Congo and adjoining countries. Under these rules, we are required to obtain sourcing data from suppliers, perform supply chain due diligence, and file annually with the SEC a specialized disclosure report on Form SD covering the prior calendar year. These requirements could adversely affect the sourcing, availability, and pricing of minerals used in the manufacture of components used in MRIdian. We may face reputational harm if we determine that certain of our components contain minerals not determined to be conflict free or if we are unable to alter our processes or sources of supply to avoid using such materials. Additionally, we may also encounter customers who require that all of the components of our products be certified as conflict free. If we are not able to meet this requirement, such customers may choose not to purchase our products, which could adversely impact sales of our products, and impact our results of operations. In addition, we have incurred and expect to incur additional costs to comply with these disclosure requirements, including costs related to determining the source of any of the relevant minerals and metals used in MRIdian.

Our loan and security agreement with Silicon Valley Bank (SVB), contains operating and financial covenants that may restrict our business and financing activities.

At December 31, 2018, we had $56.0 million in outstanding debt to SVB. Borrowings under our loan and security agreement with SVB are secured by substantially all of our personal property, except that the collateral does not include any intellectual property held by the Company, provided, however, the collateral shall include all accounts and proceeds of such intellectual property. Our loan and security agreement restrict our ability to, among other things:

- dispose of or sell our assets;
- make material changes in our business;
- merge with or acquire other entities or assets;
- incur additional indebtedness;
- create liens on our assets;
- pay dividends;
- make investments; and
- pay off subordinated indebtedness.

The operating and financial restrictions and covenants in our loan and security agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under our loan and security agreement. If not waived, future defaults could cause all of the outstanding indebtedness under our loan and security agreement to become immediately due and payable and terminate all commitments to extend further credit.

If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

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

At December 31, 2018, we had federal net operating loss carryforwards, or NOLs, of $330.8 million, which begin to expire in the year ending December 31, 2024, and $198.1 million related to state net operating loss carryforwards, which begin to expire in the year ending December 31, 2019. We also had federal and state research and development tax credit carryforwards of $4.6 million and $2.0 million, respectively, which expire at various dates through the year ending December 31, 2024. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We believe we have experienced two ownership changes in the past, none of which had a corresponding limitation of tax attributes. However, future owner or equity changes including changes that may be outside of our control, could result in limitations on net operating loss and credit carryforwards. Our NOLs may also be limited under similar provisions of state law. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future tax benefits of such assets.

We face risks related to the current global economic environment, which could delay or prevent our customers from obtaining financing to purchase MRIdian and implement the required facilities, which could harm our business, financial condition and results of operations.

The state of the global economy continues to be uncertain. The current global economic conditions and uncertain credit markets and concerns regarding the availability of credit pose a risk that could impact customer demand for MRIdian, as well as our ability to manage normal commercial relationships with our customers, suppliers and creditors, including financial institutions. If the current global economic environment deteriorates, our business could be negatively affected.

Risks Related to Administrative, Organizational and Commercial Operations and Growth

We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy.

We anticipate growth in our business operations. This future growth could create a strain on our organizational, administrative and operational infrastructure, including manufacturing operations, supply chain, quality control, technical support and customer service, sales force management and general and financial administration. We may not be able to maintain the quality of or installation timelines of MRIdian or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. We may implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain and failure to complete this in a timely and efficient manner could harm our business.

If we are unable to support demand for MRIdian and our future products, including ensuring that we have adequate resources to meet increased demand, or we are unable to successfully manage the evolution of our MR Image-Guided radiation technology, our business could be harmed.

As our commercial operations and sales volume grow, we will need to continue to increase our workflow capacity for manufacturing, customer service, billing and general process improvements and expand our internal quality assurance program, among other things. We will also need to purchase additional equipment, some of which can take several months or more to procure, set up and validate, and increase our manufacturing, maintenance, software and computing capacity to meet increased demand. We cannot assure you that any of these increases in scale, expansion of personnel, purchase of equipment or process enhancements will be successfully implemented.

The loss of or our inability to attract and retain key personnel, including highly skilled executives, scientists and salespeople, could negatively impact our business.

The loss or incapacity of existing members of our executive management team could negatively impact our operations if we experience difficulties in hiring qualified successors. Our executive officers have employment agreements; however, the existence of an employment agreement does not guarantee the retention of the executive officer for any period of time.

Our commercial, manufacturing and research and development programs and operations depend on our ability to attract and retain highly skilled engineers, scientists and salespeople. We may not be able to attract or retain qualified personnel in the future due to the competition for qualified personnel among medical device businesses, including in California and Ohio. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. Recruiting and retention difficulties can limit our ability to support our commercial, manufacturing and research and development programs. All of our employees are at-will, which means that either we or the employee may terminate his or her employment at any time.

We have a limited history of manufacturing, assembling and installing MRIdian in commercial quantities and may encounter related problems or delays that could result in lost revenue.

The pre-installation manufacturing processes for MRIdian include sourcing components from various third-party suppliers, subassembly, assembly, system integration and testing. We must manufacture and assemble MRIdian in compliance with regulatory requirements and at an acceptable cost in order to achieve profitability. We have only a limited history of manufacturing, assembling and installing MRIdian and, as a result, we may have difficulty manufacturing, assembling and installing MRIdian in sufficient quantities in a timely manner. To manage our manufacturing and operations with our suppliers, we forecast anticipated product orders and material requirements to predict our inventory needs up to 18 months in advance and enter into purchase orders on the basis of these requirements. Our limited manufacturing history may not provide us with sufficient data to accurately predict future component demand and to anticipate our costs effectively.

Likewise, we have experienced and may in the future experience delays in the assembly and installation of MRIdian at customer sites on our expected timeline associated with contractor timing delays, which could result in order cancellations or contractual penalties. For example, one of our end customers has informed us that they believe we are late on delivery of one system and that we will be subject to penalties as a result. While we have disputed that claim, there can be no assurance that we will be successful, and penalties could adversely affect our results of operations. In another instance, one of our end customers experienced flooding at its site on two occasions, which has delayed our ability to complete installation and which may adversely affect our results of operations.

Alternatively, delays or postponements of scheduled customer installations could lead to excess inventory due to our limited flexibility to postpone or delay component shipments from suppliers. Accordingly, we may encounter difficulties in production of MRIdian, including problems with quality control and assurance, component supply shortages or surpluses, increased costs, shortages of qualified personnel and difficulties associated with compliance with local, state, federal and foreign regulatory requirements. In addition, if we are unable to maintain larger-scale manufacturing capabilities, our ability to generate revenue will also be limited and our reputation could be harmed. If we cannot achieve the required level and quality of production, we may need to make changes in our supply chain or enter into licensing and other arrangements with third parties who possess sufficient manufacturing facilities and capabilities in compliance with regulatory requirements. Even if we outsource necessary production or enter into licensing or other third-party arrangements, the associated cost could reduce our gross margin and harm our financial condition and results of operations.

If we were sued for product liability or professional liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of MRIdian could lead to the filing of product liability claims were someone to allege that MRIdian did not effectively treat the conditions its users were intending to target, caused serious medical conditions or injury, or failed to perform as designed. We may also be subject to liability for errors in, a misunderstanding of or inappropriate reliance upon the information we provide in the ordinary course of our business activities, such as customer support or operating instructions. A product liability claim could result in substantial damages and be costly and time-consuming for us to defend.

We maintain product liability insurance, but the amounts of insurance coverage may not fully protect us from the financial impact of defending against product liability claims (and we have significant deductibles). Any product liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could lead to regulatory investigations, product recalls or withdrawals, damage our reputation or cause current vendors, suppliers and customers to terminate existing agreements and potential customers and partners to seek other suppliers of radiation therapy systems, any of which could negatively impact our results of operations.

The results of the United Kingdom's referendum on withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business.

In June 2016, a majority of voters in the United Kingdom, or the U.K., elected to withdraw from the EU in a national referendum, also known as Brexit. The U.K. is currently negotiating the terms of its exit from the EU. The effects of Brexit will depend on any agreements the U.K. reaches to retain access to EU markets either during a transitional period or more permanently. Nevertheless, the referendum has created significant uncertainty about the future relationship between the U.K. and the EU, including with respect to the laws and regulations that will apply as the U.K. determines which EU laws to replace or replicate in the event of a withdrawal, including those governing manufacturing, labor, environmental, data protection/privacy, competition, medical sales and advertising and other matters applicable to the medical device industry. The referendum has also given rise to calls for the governments of other EU member states to consider withdrawal. These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict our access to capital, which could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our securities.

We face risks associated with our international business.

In addition to our marketing and sales of MRIdian in the United States, we also market MRIdian in other regions, with contracts signed with customers and distributors in those regions. Our international business operations are subject to a variety of risks, including:

- difficulties in staffing and managing foreign and geographically dispersed operations;
- effective compliance with various U.S. and international laws, including export control laws and the U.S. Foreign Corrupt Practices Act of 1977, or the FCPA, and anti-money laundering laws;
- effective compliance with privacy, data protection and information security laws, such as the European Union General Data Protection Regulation (GDPR) and the Cybersecurity Law of the People's Republic of China;
- differing regulatory requirements for obtaining clearances or approvals to market MRIdian and future product enhancements for MRIdian;
- changes and uncertainties relating to foreign rules and regulations that may impact our ability to sell MRIdian, perform services or repatriate profits to the United States;
- tariffs, export or import restrictions, restrictions on remittances abroad, imposition of duties or taxes that limit our ability to move MRIdian out of these countries or interfere with the import of essential materials into these countries;
- limitations on our ability to enter into cost-effective arrangements with distributors of MRIdian, or at all;
- fluctuations in foreign currency exchange rates;
- imposition of limitations on production, sale or export of MRI-guided radiation therapy systems in foreign countries;
- imposition of limitations on or increase of withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures;

- differing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- imposition of differing labor laws and standards;
- economic, political or social instability in foreign countries and regions;
- dependence on, and potential disruptions to, our international supply chain, including as a result of changes in foreign laws and regulations, tariffs, export or import restrictions, political, economic and social instability or otherwise;
- an inability, or reduced ability, to protect our intellectual property, including any effect of compulsory licensing imposed by government action; and
- availability of government subsidies or other incentives that benefit competitors in their local markets that are not available to us.

We expect that we will begin expanding into more markets; however, we cannot assure you that our expansion plans will be realized, or if realized, be successful. We expect each market to have particular regulatory and funding hurdles to overcome and future developments in these markets, including the uncertainty relating to governmental policies and regulations, could harm our business. If we expend significant time and resources on expansion plans that fail or are delayed, our reputation, business and financial condition may be harmed.

International tariffs, including tariffs applied to our MRIdian systems sold into China, could materially and adversely affect our business operations and financial condition.

Our global business could be negatively affected by trade barriers and other governmental protectionist measures, any of which can be imposed suddenly and unpredictably. For example, in June 2018, the U.S. Government announced 25% tariffs on radiation therapy equipment imported from China, and in August 2018, China retaliated by announcing 25% tariffs on medical or surgical x-ray equipment, which may include MRIdian systems. The imposition of tariffs on MRIdian systems imported into China or elsewhere could require us to raise prices, which may negatively impact the demand for our products in the affected market and/or reduce our gross margins. In addition, any of our competitors that are based outside the United States or that are otherwise not subject to tariffs that affect us might gain a competitive advantage as a result. Given the uncertainty regarding the scope and duration of trade actions by the U.S., China and other countries, the impact of these trade actions or any other trade barriers, tariffs or similar measures on our business operations or financial condition remains uncertain.

Our results may be impacted by changes in foreign currency exchange rates.

Currently, the majority of our international order contracts are denominated in U.S. dollars. We pay certain of our suppliers in a foreign currency under the terms of their supply agreements, and we may pay other suppliers in the future in foreign currency. As a result, an increase in the value of the U.S. dollar relative to foreign currencies could require us to reduce our selling price or risk making MRIdian less competitive in international markets or could cause our costs to increase. Also, if our international sales increase, we may enter into a greater number of transactions denominated in non-U.S. dollars, which could expose us to foreign currency risks, including changes in currency exchange rates. We do not currently engage in any hedging transactions. If we are unable to address these risks and challenges effectively, our international operations may not be successful and our business could be harmed.

We could be negatively impacted by violations of applicable anti-corruption laws or violations of our internal policies designed to ensure ethical business practices.

We operate in a number of countries throughout the world, including in countries that do not have as strong a commitment to anti-corruption and ethical behavior that is required by U.S. laws or by corporate policies. We are subject to the risk that we, our U.S. employees or our employees located in other jurisdictions or any third parties such as our sales agents and distributors that we engage to do work on our behalf in foreign countries may take action determined to be in violation of anti-corruption laws in any jurisdiction in which we conduct business, including the FCPA and the Bribery Act of 2010, or the U.K. Anti-Bribery Act. In addition, we operate in certain countries in which the government may take an ownership stake in an enterprise and such government ownership may not be readily apparent, thereby increasing potential anti-corruption law violations. Any violation of the FCPA

and U.K. Anti-Bribery Act or any similar anti-corruption law or regulation could result in substantial fines, sanctions, civil and/or criminal penalties and curtailment of operations in certain jurisdictions and might harm our business, financial condition or results of operations. In addition, we have internal ethics policies with which we require our employees to comply in order to ensure that our business is conducted in a manner that our management deems appropriate. If these anti-corruption laws or internal policies were to be violated, our reputation and operations could also be substantially harmed. Further, detecting, investigating and resolving actual or alleged violations is expensive and can consume significant time and attention of our senior management.

We are subject to export restrictions and laws affecting trade and investments, and the future sale of our MRIdian system may be further limited or prohibited in the future by a government agency or authority.

As a global company headquartered in the United States, our MRIdian system is subject to U.S. laws and regulations that may limit, restrict or require a license to export (and re-export from other countries) our MRIdian system and related product and technical information due to MRIdian's use of hazardous materials, including MRIdian with Cobalt's use of Cobalt-60, lead and depleted uranium. We are also subject to the export and import laws of those foreign jurisdictions to which we sell or from which we re-export our MRIdian system. Compliance with these laws and regulations could significantly limit our operations and our sales in the future and failure to comply, even indirectly, could result in a range of penalties, including restrictions on exports of our MRIdian system for a specified time period, or forever, and severe monetary penalties. In certain circumstances, these restrictions may affect our ability to interact with any of our future foreign subsidiaries and otherwise limit our trade with third parties, including suppliers and customers, operating inside and outside the United States. In addition, if we introduce new products, we may need to obtain licenses or approvals from the United States and other governments to ship them into foreign countries. Failure to receive the appropriate approvals may mean that our commercial efforts and expenses related to such efforts may not result in any revenue, which could harm our business.

We depend on our information technology systems, and any failure of these systems could harm our business.

We depend on information technology and telecommunications systems for significant elements of our operations. We have developed proprietary software for the management and operation of MRIdian by our customers. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including for example, systems handling human resources, financial controls and reporting, contract management, inventory management, regulatory compliance and other infrastructure operations. In addition to the aforementioned business systems, we intend to extend the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design and the automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including sales and marketing, manufacturing operations, customer service support, billing and reimbursement, research and development activities and general administrative activities.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from providing maintenance and support services to our customers, conducting research and development activities and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could harm our business.

Our operations are vulnerable to interruption or loss due to natural or other disasters, power loss, strikes and other events beyond our control.

We conduct a significant portion of our activities, including administration and data processing, at facilities located in California, Ohio and other areas that have experienced major earthquakes, tornadoes and other natural disasters. A major earthquake, tornado or other disaster (such as a major fire, hurricane, flood, tsunami, volcanic eruption or terrorist attack) affecting our facilities, or those of our suppliers, could significantly disrupt our operations, and delay or prevent product shipment or installation during the time required to repair, rebuild or replace our suppliers' damaged manufacturing facilities; these delays could be lengthy and costly. If any of our suppliers' or customers'

facilities are negatively impacted by a disaster, shipments of MRIdian could be delayed. Additionally, customers may delay purchases of MRIdian until operations return to normal. Even if we are able to quickly respond to a disaster, the ongoing effects of the disaster could create some uncertainty in the operations of our business. In addition, our facilities may be subject to a shortage of available electrical power and other energy supplies. Any shortages may increase our costs for power and energy supplies or could result in blackouts, which could disrupt the operations of our affected facilities and harm our business. Further, MRIdian is typically shipped from a limited number of ports, and any disaster, strike or other event blocking shipment from these ports could delay or prevent shipments and harm our business. In addition, concerns about terrorism, the effects of a terrorist attack, political turmoil or an outbreak of epidemic diseases, such as Ebola or influenza, could have a negative effect on our operations, those of our suppliers and customers and the ability to travel, which could harm our business, financial condition and results of operations.

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

On December 22, 2017, President Trump signed into law the "Tax Cuts and Jobs Act," or the TCJA, which significantly amends the Internal Revenue Code of 1986. The TCJA, among other things, reduces the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limits the tax deduction for interest expense to 30% of adjusted earnings, eliminates net operating loss carrybacks, imposes a one-time tax on offshore earnings at reduced rates regardless of whether they are repatriated, allows immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifies or repeals many business deductions and credits. We have completed our evaluation of the impact of these changes on our effective tax rate and reflected the amounts in our financial statements. However, the overall impact of the TCJA also depends on the future interpretations and regulations that may be issued by U.S. tax authorities, and it is possible that future guidance could adversely impact us.

Risks Related to Intellectual Property

Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling MRIdian or impact our stock price.

There is considerable intellectual property litigation and contested patent disputes in the medical device area. Third parties may, in the future, assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize MRIdian in its current or an updated form, launch new products and enter new markets, we expect that competitors may claim that MRIdian infringes their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. Although we are presently unaware of any basis by which a third-party would be justified in making such claims, in the future, we may receive letters or other threats or claims from third parties inviting us to take licenses under, or alleging that we infringe, their patents. Third parties may have obtained, and may in the future obtain, patents under which such third parties may claim that the use of our technologies constitutes patent infringement.

Moreover, we may become party to future adversarial proceedings regarding our patent portfolio or the patents of third parties. Such proceedings could include contested post-grant proceedings such as oppositions, inter parties review, reexamination, interference or derivation proceedings before the U.S. Patent and Trademark Office or foreign patent offices. The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

We could incur substantial costs and divert the attention of our management and technical personnel in defending ourselves against any of these claims or in any of such proceedings. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a negative impact on our cash position and stock price. Furthermore, parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement or misappropriation against us, we may be required to pay damages, obtain one or more licenses from third parties or be prohibited from selling certain products, all of which could have a negative impact on our cash position, business and financial condition.

In addition, we may be unable to obtain these licenses at a reasonable cost, if at all. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Moreover, we could encounter delays in product introductions while we attempt to develop alternative methods or products. Defense of any lawsuit or adversarial proceeding or failure to obtain any of these licenses on favorable terms could prevent us from commercializing products, and the prohibition of sale of MRIdian or future products could impact our ability to grow and maintain profitability and could harm our business.

If we are unable to adequately protect our proprietary technology or maintain issued patents that are sufficient to protect MRIdian, others could compete against us more directly, which could harm our business, financial condition and results of operations.

Our commercial success will depend in part on our success in obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

Specifically, we hold a license to four issued U.S. patents, 18 issued foreign patents (eight of which were issued in Great Britain, Germany, France and the Netherlands as a result of two patent applications filed and allowed through the European Patent Office), one pending U.S. patent application and four pending foreign patent applications as of January 15, 2019. We own an additional 24 issued U.S. patents, 52 issued foreign patents (15 of which were issued in Great Britain, Germany, France, Italy and the Netherlands as a result of three patent applications filed and allowed through the European Patent Office), 25 pending U.S. patent applications and 108 pending foreign patent applications as of January 15, 2019. Assuming all required fees are paid, individual patents or patent applications owned or licensed by us will expire between 2021 and 2039. We also have a joint ownership interest with Case Western Reserve University in one issued patent and one U.S. patent application. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect MRIdian, any additional features we develop for MRIdian or any new products. Other parties may have developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. U.S. patents and patent applications may also be subject to supplemental examination or contested post-grant proceedings such as inter parties review, reexamination, interference or derivation proceedings before the U.S. Patent and Trademark Office and challenges in district court. Patents may be subjected to opposition, post-grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own or exclusively license may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third-party receiving the patent right sought by us, which in turn could affect our ability to commercialize MRIdian.

Furthermore, though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We

may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, agents, distributors, suppliers, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If any of these developments were to occur, they each could have a negative impact on our results of operations and business.

Our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering MRIdian are invalidated or found unenforceable, our financial position and results of operations could be negatively impacted. In addition, if a court found that valid, enforceable patents held by third parties covered MRIdian, our financial position and results of operations could be harmed.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect MRIdian or any other products;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize MRIdian on a substantial scale before our relevant patents expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or products that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

We rely, in part, upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us and have non-compete agreements with some, but not all, of our consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

If we are not able to meet the requirements of our license agreement with the University of Florida Research Foundation, Inc., we could lose access to the technologies licensed thereunder and be unable to manufacture, market or sell MRIdian.

We license patents and patent applications from the UFRF, covering our combination of MRI and radiation therapy, and other key technologies, incorporated into MRIdian under a license agreement that requires us to pay royalties to UFRF. In addition, the license agreement obligates us to pursue an agreed development plan and to submit periodic reports and restricts our ability to take actions to defend the licensed patents. The license agreement terminates when the underlying patents expire in 2025, although UFRF has the right to unilaterally terminate the agreement if we do not meet our royalty payment obligations, including minimum royalty payments of $50,000 per quarter, or if we fail to satisfy other development and commercialization obligations related to our utilization of the technology. If UFRF were to terminate the agreement or if we were to otherwise lose the ability to exploit the licensed patents, our competitive advantage could be reduced, we may not be able to find a source to replace the licensed technology and we may be prevented from selling MRIdian. The license agreement reserves to UFRF the initial right to defend or prosecute any claim arising with respect to the licensed technology. If UFRF does not vigorously defend the patents, we may be required to engage in expensive patent litigation to enforce our rights and any competitive advantage we have based on the licensed technology may be hampered. Any of these events could harm our business, financial condition and results of operations.

Changes in U.S. patent laws may limit our ability to obtain, defend or enforce our patents.

Past or future patent reform legislation or precedent could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also affect patent litigation. The first to file provisions of the Leahy-Smith Act limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention.

The Leahy-Smith Act also created an administrative tribunal known as the Patent Trial and Appeal Board, or PTAB, that provides a venue for companies to challenge the validity of a competitor's patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long-term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could therefore increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them. Moreover, if such challenges occur with regard to our UFRF-licensed patents, as indicated above, we have only limited rights to control the defense.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

In addition to patent protection, we also rely upon copyright and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In

addition, many countries limit the enforceability of patents against certain third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may, in the future, make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. These agreements provide that we must negotiate certain commercial rights with collaborators with respect to joint inventions or inventions made by our collaborators that arise from the results of the collaboration. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a third-party collaborator's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a collaborator's technology, we may be limited in our ability to capitalize on the market potential of these intellectual property rights. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in that intellectual property. Either outcome could harm our business.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities or other medical device companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

A network or data security incident may allow unauthorized access to our products, our network or our data and also that of our customers, resulting in disruption of critical information systems, harm to our reputation and creation of additional liability that could adversely impact our financial results.

Increasingly, companies are subject to a wide variety of attacks on their products, networks and systems on an ongoing basis. In addition to traditional computer "hackers," malicious code (such as viruses and worms), employee theft or misuse, and denial-of-service attacks, sophisticated nation-state and nation-stated supported actors now engage in attacks (including advanced persistent threat intrusions). Despite significant efforts to create security barriers to such threats, it is virtually impossible to entirely mitigate these risks. If we do not allocate and effectively manage the resources necessary to build and sustain the proper infrastructure in our business technology or in our product design, we could be subject to, among other things: transaction errors; processing inefficiencies; the loss of customers; business disruptions; the loss of or damage to intellectual property through a security breach; or the inability to comply with applicable laws.

If a breach of data security were to occur at a customer site through one of our products as a result of third-party action, employee error, malfeasance or otherwise, and the confidentiality, integrity or availability of our customers' data, including patient health information (PHI) and personally identifiable information (PII) were disrupted, we could incur significant liability to our customers and to individuals or businesses whose information was being stored by our customers. Our systems may be perceived as less desirable, which could negatively affect our business and damage our reputation. In addition, a network or security breach could result in the loss of customers and make it more challenging to acquire new customers. Because techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and generally are not recognized until launched against a target, we may be unable to anticipate these techniques or to implement adequate preventive measures. In addition, security breaches impacting our network could result in a risk of loss or unauthorized disclosure of customers' data, which, in turn, could lead to litigation, governmental audits and investigations and possible liability, damage our relationships with our existing customers, and have a negative impact on our ability to attract and retain new customers. In addition, the costs associated with the investigation, remediation and potential notification of the breach to customers and counter-parties could be material.

Third parties may attempt to fraudulently induce employees or customers into disclosing sensitive information such as user names, passwords or other information or otherwise compromise the security of our internal networks, electronic systems and/or physical facilities in order to gain access to our data or our customers' data, which could result in significant legal and financial exposure, interruptions or malfunctions in our operations, and, ultimately, harm to our future business prospects and revenue. We may be required to expend significant capital and financial resources to protect against threats such as these, or to alleviate problems caused by breaches in security.

Risks Related to Regulatory Matters

MRIdian and our operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.

MRIdian is a medical device that is subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- premarket clearance and approval;
- record keeping procedures;
- advertising and promotion;
- recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market approval studies; and
- product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the FDCA or approval of a premarket approval, or PMA, application from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, in order to clear the proposed device for marketing. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

Certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance, or possible PMA approval. The 510(k) clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. Despite the time, effort and cost, we cannot assure you that any particular device will be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business.

In the United States, we have obtained 510(k) premarket clearance from the FDA to market MRIdian for the provision of stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation treatment is indicated. An element of our strategy is to continue to upgrade MRIdian to incorporate new software and hardware enhancements. We expect that such upgrades, as well as other future modifications, may require new 510(k) clearance; however, future upgrades may be subject to the substantially more costly, time-consuming and uncertain PMA process. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or cancelled, which could cause our sales to decline. In August 2016, we filed for FDA 510(k) clearance for the MRIdian Linac and received FDA clearance in February 2017. In June 2017, we received 510(k) clearance to market RayZR, our high-resolution MLC.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that MRIdian is substantially equivalent to the proposed predicate device or safe and effective for its intended use;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared product on a timely basis. For example, the FDA issued guidance ("Deciding When to Submit a 510(k) for a Change to an Existing Device" and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device") on October 25, 2017 to assist industry in determining when a change to a previously 510(k)-cleared product requires a new premarket notification to be submitted to the FDA. These guidance documents replaced the 1997 guidance on the same topic. In November 2018, the FDA announced plans to significantly revise aspects of the 510(k) program to reduce reliance on older predicate devices (e.g., predicates that are less than 10 years old). In January 2019, the FDA also finalized guidance on an alternative 510(k) pathway, the "Safety and Performance Based Pathway," which relies on modern performance-based criteria and current technological principles to demonstrate substantial equivalence rather than on direct comparisons to older predicates; the draft guidance was published earlier in 2018. With the changes to the 510(k) pathway, the FDA expects increased use of the de novo pathway, which is for the review of novel, low to moderate risk devices for which there is no existing predicate to use in determining substantial equivalence. The FDA intends these reform actions to improve the efficiency and transparency of the clearance process, as well as bolster patient safety. The FDA's proposed changes to the 510(k) pathway and these guidance documents could impose additional regulatory requirements upon us that could: increase the costs of compliance; restrict our ability to maintain our current clearances; and delay our ability to obtain 510(k) clearances.

Even after we have obtained the proper regulatory clearance or approval to market a product, we have ongoing responsibilities under FDA regulations. The failure to comply with applicable regulations could jeopardize our ability to sell MRIdian and result in enforcement actions such as:

- warning letters;
- fines;
- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- refusal to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of MRIdian; and
- in the most serious cases, criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and harm our reputation, business, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. The Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Uncertainty at the FDA or if the FDA were under-staffed, could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

In order to sell MRIdian in member countries of the European Economic Area, or EEA, MRIdian must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC). Compliance with these requirements is a prerequisite to be able to affix the CE mark to MRIdian, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-

risk medical devices, where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a Member State of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. We have the right to affix the CE mark to MRIdian with Cobalt-60 since November 2014 and MRIdian Linac since September 2016. If we fail to remain in compliance with applicable European laws and directives, we would not be able to continue to affix the CE mark to MRIdian with Cobalt-60 and MRIdian Linac, which would prevent us from selling MRIdian with Cobalt-60 or MRIdian Linac within the EEA. We will also need to obtain regulatory approval in other foreign jurisdictions in which we plan to market and sell MRIdian with Cobalt-60 and MRIdian Linac.

Modifications to MRIdian and our future products may require new 510(k) clearances or PMA approvals, or may require us to cease marketing or recall the modified products until clearances are obtained.

In the United States, we have obtained 510(k) premarket clearance from the FDA to market MRIdian for the provision of stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation treatment is indicated. Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA.

In February 2017, we received a 510(k) premarket clearance from the FDA to market the MRIdian system that contains MRIdian Linac. As we make other changes or enhancements to our MRIdian system, we will need to determine whether additional FDA clearance is required or not. However, the FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have made modifications to MRIdian in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510(k) clearances or PMA approvals were not required. We may make similar modifications or add additional features in the future that we believe do not require a new 510(k) clearance or approval of a PMA. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMA applications for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Furthermore, the FDA's ongoing review of and proposed changes to the 510(k) clearance process may make it more difficult for us to make modifications to our previously cleared products, either by imposing more strict requirements on when a new 510(k) notification for a modification to a previously cleared product must be submitted, or applying more onerous review criteria to such submissions. More recently, the FDA issued guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device" and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device") on October 25, 2017 (replacement of a 1997 guidance document) to assist industry in determining when a change to a previously 510(k)-cleared product requires a new pre market notification to be submitted to the FDA. In November 2018, the FDA announced plans to significantly revise aspects of the 510(k) program to reduce reliance on older predicate devices (e.g., predicates that are less than 10 years old). In January 2019, the FDA also finalized guidance on an alternative 510(k) pathway, the "Safety and Performance Based Pathway," which relies on modern performance-based criteria and current technological principles to demonstrate substantial equivalence rather than on direct comparisons to older predicates; the draft guidance was published earlier in 2018. In addition, FDA issued guidance "Postmarket Management of Cybersecurity in Medical Devices" on December 28, 2016 and on October 18 2018, the FDA published related draft guidance, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". These new guidance documents could impose additional regulatory requirements upon us that could: increase the costs of compliance; restrict our ability to maintain our current clearances; and delay our ability to obtain 510(k) clearances. We cannot guarantee

whether the FDA's approach in future guidance will result in substantive changes to existing policy and practice regarding the assessment of whether a new 510(k) is required for changes or modifications to existing devices. The FDA continues to review its 510(k) clearance process, which could result in additional changes to regulatory requirements or guidance documents, which could increase the costs of compliance or restrict our ability to maintain current clearances.

If treatment guidelines for cancer radiation therapies change or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for MRIdian.

If treatment guidelines for cancer radiation therapies or the standard of care evolves, we may need to redesign MRIdian and seek new clearances or approvals from the FDA for MRIdian. Our 510(k) clearance from the FDA is based on current treatment guidelines. If treatment guidelines change so that different treatments become desirable, the clinical utility of MRIdian could be diminished and our business could suffer. For example, competition by other forms of cancer treatment, in particular personalized medicine approaches in targeting drugs and biologics, could reduce the use of radiation therapy as a standard of care in certain indications.

The misuse or off-label use of MRIdian with Cobalt-60 or MRIdian Linac may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Clinicians or physicians may misuse MRIdian with Cobalt-60 or MRIdian Linac or use improper techniques if they are not adequately trained or otherwise, potentially leading to injury and an increased risk of product liability. If MRIdian with Cobalt-60 or MRIdian Linac is misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance. In addition, any of the events described above could harm our business and lead to regulatory action.

In addition, MRIdian with Cobalt-60 and MRIdian Linac have been cleared by the FDA for specific treatments. We train our marketing and direct sales force to not promote MRIdian with Cobalt-60 and MRIdian Linac for uses outside of the FDA-cleared indications for use, known as "off-label uses." For example, MRIdian with Cobalt and MRIdian Linac have not been indicated for diagnostic use. We cannot, however, prevent a physician from using MRIdian with Cobalt-60 or MRIdian Linac off-label, when in the physician's independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use MRIdian with Cobalt-60 or MRIdian Linac off-label. Furthermore, the use of MRIdian with Cobalt-60 or MRIdian Linac for indications other than those cleared by the FDA or authorized by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

Our MRIdian systems may cause or contribute to adverse medical events that we are required to report to regulatory bodies outside of the U.S. and to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our MRIdian systems, or a recall of our MRIdian systems either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that MRIdian may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse

events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of MRIdian. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of MRIdian or delay in clearance of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects, repeated misuse or other deficiencies or failures to comply with applicable regulations. We cannot assure you that similar or more significant product defects or other errors will not occur in the future. Recalls involving MRIdian could be particularly harmful to our business, financial condition and results of operations because it is currently our only product.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA or other regulatory bodies. We may initiate voluntary withdrawals or corrections for MRIdian in the future that we determine do not require notification of the FDA or other regulators in the US and around the world. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales.

Any actual or perceived failure by us to comply with legal or regulatory requirements related to privacy or data security in one or multiple jurisdictions could result in proceedings, actions or penalties against us.

Many jurisdictions have enacted or are considering enacting privacy and/or data security legislation, including laws and regulations applicable to the collection, use, storage, transfer, disclosure and/or processing of personal information. For example, the U.S. Department of Health and Human Services has promulgated rules governing the privacy and security of individually identifiable health information under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH. These privacy and security rules protect medical records and other patient health information (PHI) by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information, limiting most uses and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose, and requiring administrative, technical and physical safeguards. Although we are not a covered entity under HIPAA, we have entered into agreements with certain covered entity customers, such as health care providers, under which we are considered to be a "business associate" under HIPAA. As a business associate, we are contractually bound and may also be directly responsible under HIPAA, as amended by HITECH, to implement policies, procedures and reasonable and appropriate security measures to protect any individually identifiable health information we may create, receive, maintain or transmit on behalf of covered entities. We may also be subject to state laws protecting the confidentiality of medical records where those state laws have stricter provisions than HIPAA.

The costs of compliance with, and other burdens imposed by, such laws and regulations that are applicable to the businesses of our customers may limit the use and adoption of our products and reduce overall demand for them. These privacy and data security related laws and regulations are evolving and may result in increasing regulatory and public scrutiny and escalating levels of enforcement and sanctions. Although we are working to comply with those federal, state, and foreign laws and regulations, industry standards, contractual obligations and other legal obligations that apply to us, those laws, regulations, standards and obligations are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another, other requirements or legal obligations, our practices or the features of our platform. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, industry standards, contractual obligations or other legal obligations, or any actual or suspected security incident, whether or not resulting in unauthorized access to, or acquisition, release or transfer of personal information or other data, may result in governmental enforcement actions and prosecutions, private litigation, fines and penalties or adverse publicity and could cause our customers to lose trust in us, which could have an adverse effect on our reputation and business.

Any inability to adequately address privacy and security concerns, even if unfounded, or comply with applicable laws, regulations, policies, industry standards, contractual obligations, or other legal obligations could result in additional cost and liability to us, damage our reputation, inhibit sales, and adversely affect our business.

We also expect that there will continue to be new proposed laws, regulations and industry standards concerning privacy, data protection and information security in the United States, the European Union and other jurisdictions, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self-regulatory standards that my place additional burdens on us. New laws, amendments to or re-interpretations of existing laws and regulations, industry standards, contractual obligations and other obligations may require us to incur additional costs and restrict our business operations. Such laws and regulations may require companies to implement privacy and security policies, inform individuals of security breaches that affect their personal information, and, in some cases, obtain individuals' consent to use personal information for certain purposes.

Our failure to comply with applicable laws and regulations could result in enforcement action against us, including fines and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill (both in relation to existing customers and prospective customers), any of which could harm our business, results of operations and financial condition.

If we or our distributors do not obtain and maintain international regulatory registrations or approvals for MRIdian, we will not be able to market and sell MRIdian outside of the United States.

Sales of our devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling MRIdian or only require notification, others require that we or our distributors obtain the approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or approvals, can be expensive and time-consuming, and we cannot be certain that we or our distributors will receive regulatory approvals in each country in which we plan to market MRIdian or that we will be able to do so on a timely basis. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for FDA clearance, and requirements for such registrations or approvals may significantly differ from FDA requirements. If we modify MRIdian, we or our distributors may need to apply for additional regulatory approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we or our distributors have received. If we or our distributors are unable to maintain our authorizations in a particular country, we will no longer be able to sell MRIdian in that country, which could harm our business.

Regulatory clearance or approval by the FDA does not ensure marketing authorization by regulatory authorities in other countries, and authorization for marketing by one or more foreign regulatory authorities does not ensure marketing authorization will be granted by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining marketing authorization in one country may have a negative effect on the regulatory process in others.

We must manufacture MRIdian in accordance with federal and state regulations, and we could be forced to recall our installed systems or terminate production if we fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of MRIdian must comply with the FDA's QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of MRIdian. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. MRIdian is also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

We cannot guarantee that we or any subcontractors will take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of MRIdian. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with MRIdian or manufacturing processes could result in, among other things:

- warning letters or untitled letters;
- fines, injunctions or civil penalties;
- suspension or withdrawal of approvals or clearances;
- seizures or recalls of MRIdian;
- total or partial suspension of production or distribution;
- administrative or judicially imposed sanctions;
- FDA's refusal to grant pending or future clearances or approvals for MRIdian;
- clinical holds;
- refusal to permit the import or export of MRIdian; and
- criminal prosecution of us or our employees.

Any of these actions could significantly and negatively impact supply of MRIdian. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and suffer reduced revenue and increased costs.

Legislative or regulatory reforms in the United States or the EU may make it more difficult and more costly for us to obtain regulatory clearances or approvals for MRIdian or to produce, market or distribute MRIdian after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices or the reimbursement thereof. In addition, the FDA or the NRC regulations and guidance are often revised or reinterpreted by the FDA or NRC in ways that may significantly affect our business and our MRIdian systems In addition, as part of Food and Drug Administration Safety and Innovation Act, or FDASIA, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms, which are further intended to clarify and improve medical device regulation both pre- and post-clearance or approval. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to manufacture, market or distribute MRIdian or future products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- additional testing prior to obtaining clearance or approval;
- changes to manufacturing methods;
- recall, replacement or discontinuance of MRIdian or future products; or
- additional record keeping.

Any of these changes could require substantial time and cost and could harm our business and our financial results.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation, which repealed and replaced the Medical Devices Directive. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation will become applicable three years after publication. Once applicable, the new regulations will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU;
- strengthen rules for the assessment of certain high-risk devices, which may have to undergo an additional check by experts before they are placed on the market.

These modifications may have an impact on the way we conduct our business in the EEA.

Our business involves the use of hazardous materials and we and our third-party manufacturers must comply with environmental laws and regulations, which may be expensive and restrict how we do business.

Our third-party manufacturers' activities and our own activities involve the controlled storage, use and disposal of hazardous materials, including Cobalt-60, lead and depleted uranium. We and our manufacturers are subject to federal, state, local and foreign laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these hazardous materials. We currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials, but we do reserve funds to address these claims at both the federal and state levels. Although we believe that our safety procedures for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, state or federal or other applicable authorities may curtail our use of these materials and interrupt our business operations. In addition, if an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines. If such unexpected costs are substantial, this could significantly harm our financial condition and results of operations.

We are subject to federal and state fraud and abuse laws and health information privacy and security laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our relationships with providers and hospitals are subject to scrutiny under these laws. We may also be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act; Some states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;

- HIPAA, which created federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters.

Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, which is defined broadly to include other healthcare providers and teaching hospitals and ownership and investment interests held by physicians and their immediate family members;

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers;

- state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and

- state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

These laws, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of medical devices. We have a variety of arrangements with our customers that could implicate these laws. Due to the breadth of these laws, the narrowness of statutory exceptions and safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could harm our business, financial condition and results of operations.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could negatively impact our ability to operate our business and our results of operations.

Healthcare policy changes, including legislation reforming the U.S. healthcare system, could harm our cash flows, financial condition and results of operations.

In March 2010, the Affordable Care Act was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other things, the Affordable Care Act requires each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, which, due to subsequent legislative amendments, has been suspended until January 1, 2020;

We expect that the current presidential administration and U.S. Congress will seek to modify, repeal, or otherwise invalidate all or certain provisions of, the Affordable Care Act. There is uncertainty with respect to the impact the current presidential administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for MRIdian or additional pricing pressure.

Risks Related to Ownership of Our Common Stock

The price of our common stock may be volatile and may be influenced by numerous factors, some of which are beyond our control.

Factors that could cause volatility in the market price of our common stock include, but are not limited to:

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors or market expectations;
- commercial success and market acceptance of MRIdian;
- success of our competitors in discovering, developing or commercializing products;
- ability to commercialize or obtain regulatory approvals for MRIdian, or delays in commercializing or obtaining regulatory approvals;
- strategic transactions undertaken by us;
- additions or departures of key personnel;
- product liability claims;
- prevailing economic conditions;
- disputes concerning our intellectual property or other proprietary rights;
- FDA or other U.S. or foreign regulatory actions affecting us or the healthcare industry;
- healthcare reform measures in the United States;
- sales of our common stock by our officers, directors or significant stockholders;
- future sales or issuances of equity or debt securities by us;
- business disruptions caused by earthquakes, tornadoes or other natural disasters; and
- changes in the manner that investors and securities analysts who provide research on us to the marketplace analyze the value of our common stock.

In addition, the stock markets in general, and the markets for medical device companies in particular, have experienced extreme volatility that have been often unrelated to the operating performance of the issuer. These broad market fluctuations may negatively impact the price or liquidity of our common stock. In the past, when the price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business.

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

We are an "emerging growth company," as defined in the JOBS Act, and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, Section 102 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. An "emerging growth company" can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private

companies. However, we chose to "opt out" of such extended transition period, and as a result, we comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

Future sales of our common stock or securities convertible or exchangeable for our common stock may cause our stock price to decline.

If our existing stockholders or option holders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after any applicable legal restrictions on resale lapse, the price of our common stock could decline. The perception in the market that these sales may occur could also cause the price of our common stock to decline. At December 31, 2018, we have outstanding a total of 96,332,023 shares of common stock.

In addition, at December 31, 2018, based on the number of shares subject to outstanding awards under our 2008 Stock Option and Incentive Plan, or 2008 Plan, and 2018 Inducement Plan, or 2018 Plan, 1,167,158 shares and 5,620,000 shares, respectively, of common stock are subject to outstanding options; based on the number of shares subject to outstanding awards or available for issuance under our 2015 Equity Incentive Award Plan, or 2015 Plan, and 2015 Employee Stock Purchase Plan, or 2015 ESPP, 8,582,917 shares and 1,780,020 shares, respectively, of common stock are subject to outstanding options or reserved for future issuance. These shares will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act, which includes, for shares held by directors, executive officers and other affiliates, volume limitations under Rule 144 under the Securities Act. The 2015 Plan contains provisions for the annual increase of the number of shares reserved for issuance under such plan. If the shares we may issue from time to time under the 2008 Plan, 2015 Plan, 2018 Plan or 2015 ESPP are sold, or if it is perceived that they will be sold, by the award recipients in the public market, the price of our common stock could decline.

You may experience dilution of your ownership interests because of the future issuance of additional shares of our common or preferred stock or other securities that are convertible into or exercisable for our common or preferred stock.

In the future, we may issue our authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our present stockholders and the purchasers of our common stock. We are authorized to issue an aggregate of 300,000,000 shares of common stock and 10,000,000 shares of "blank check" preferred stock. We may issue additional shares of our common stock or other securities that are convertible into or exercisable for our common stock in connection with hiring or retaining employees, future acquisitions, future sales of our securities for capital raising purposes, or for other business purposes. The future issuance of any such additional shares of our common stock may create downward pressure on the trading price of the common stock. We may need to raise additional capital in the near future to meet our working capital needs, and there can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with these capital raising efforts, including at a price (or exercise prices) below the price you paid for your stock.

Our operating results for a particular period may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to fluctuations. Our operating results will be affected by numerous factors, including:

- variations in the level of expenses related to MRIdian systems or future development programs;
- level of underlying demand for MRIdian and any other products we develop;
- addition or termination of clinical trials or funding support;
- receipt, modification or termination of government contracts or grants, and the timing of payments we receive under these arrangements;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved; and
- regulatory developments affecting MRIdian with Cobalt-60, MRIdian Linac or our competitors.

If our operating results for a particular period fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that comparisons of our financial results from various reporting periods are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Based on the beneficial ownership of our common stock at December 31, 2018, our officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially own approximately 46% of our common stock. Accordingly, these stockholders will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. Further, pursuant to one of the Securities Purchase Agreements related to the October 2017 Direct Registered Offering discussed elsewhere in this Report, we agreed to (a) appoint a representative of Fosun International Limited ("Fosun") as a non-voting observer to our board of directors and (b) after the date, if ever, that Fosun beneficially owns at least 15% of our then-outstanding shares of common stock, appoint a representative of Fosun as a director upon Fosun's request. Fosun's rights expire on the first date that Fosun ceases to own at least 90% of the shares it purchased in the October 2017 Direct Registered Offering discussed elsewhere in this Report. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change in control of the Company, even if such a change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the Company or our assets and might affect the prevailing price of our common stock. The significant concentration of stock ownership may negatively impact the price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Provisions of our charter documents or Delaware law could delay or prevent an acquisition of the Company, even if such an acquisition would be beneficial to our stockholders, which could make it more difficult for you to change management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include:

- a classified board of directors so that not all directors are elected at one time;
- a prohibition on stockholder action through written consent;
- no cumulative voting in the election of directors;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director;
- a requirement that special meetings of stockholders be called only by the board of directors, the chairman of the board of directors, the chief executive officer or, in the absence of a chief executive officer, the president;
- an advance notice requirement for stockholder proposals and nominations;
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine; and
- a requirement of approval of not less than 66 2/3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our certificate of incorporation.

In addition, Delaware law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns, or within the last three years has owned, 15% or more of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed

manner. Accordingly, Delaware law may discourage, delay or prevent a change in control of the Company. Furthermore, our certificate of incorporation specifies that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable in such action.

Provisions in our charter documents and other provisions of Delaware law could limit the price that investors are willing to pay in the future for shares of our common stock.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future; therefore, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. In addition, our current loan and security agreement with CRG contains, and our future loan arrangements may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our stock price could decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price could decline. If one or more of these analysts cease coverage of the Company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

Risks Related to Information Security and Cybersecurity

An information security incident, including a cybersecurity breach, could have a negative impact to the Company's business or reputation.

To meet business objectives, we rely on both internal information technology (IT) systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research, business plans, financial information, intellectual property, and personal data that may be subject to legal protection. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these IT systems and networks, and the confidentiality, integrity, and availability of our sensitive data. We assess these threats and makes investments to increase internal protection, detection, and response capabilities, as well as ensure that our third-party providers have required capabilities and controls, to address this risk. To date, we have not experienced any material impact to the business or operations resulting from information or cybersecurity attacks; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential that we could be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action.

* * *

This Annual Report contains forward-looking statements that involve unknown risks, uncertainties and other factors that may cause the actual results, financial condition, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Factors that might cause such a difference include, but are not limited to, those set out above.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Facilities

Our corporate headquarters are located in Oakwood Village, Ohio, where we lease and occupy approximately 19,800 square feet of office space. The current term of our Oakwood Village lease expires on October 31, 2019, with an option to extend the term through October 31, 2021. We also maintain two offices in Mountain View, California. For the first office, we lease and occupy approximately 25,500 square feet of office space. The current term of this Mountain View lease expires on July 31, 2025. In connection with this lease, we entered into a standby letter of credit with PNC Bank, National Association for $0.8 million, which is still outstanding at December 31, 2018. In April 2018, we entered into a lease agreement to lease approximately 24,600 square feet of additional office space for our second office in Mountain View, California. This lease expires on the seventh anniversary of the commencement date, and the Company has the option to extend the term of the lease for a period of up to five years.

We have analyzed our current facilities in light of our anticipated requirements and have determined to increase our foot-print in other states to meet the needs of our operations; we are currently seeking additional space on commercially reasonable terms.

Item 3. LEGAL PROCEEDINGS

We are not currently involved in any material litigation. From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and one or more unfavorable outcomes in any claim or litigation against us could have a material adverse effect for the period in which they are resolved and on our business generally. In addition, regardless of their merits or their ultimate outcomes, lawsuits and legal proceedings are costly, divert management attention and may materially adversely affect our reputation, even if resolved in our favor.

The information under the caption “Commitments and Contingencies” in Note 6 of the consolidated financial statements of this Annual Report on Form 10-K is incorporated herein by reference.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Our common stock is traded on the Nasdaq Global Market under the symbol “VRAY”, which listing was completed on March 30, 2016.

As of March 5, 2019, there were 92 stockholders of record of our common stock, although we believe that there are a significantly larger number of beneficial owners of our common stock.

We have never paid cash dividends on our capital stock and do not anticipate paying cash dividends in the foreseeable future. We intend to retain future earnings to fund ongoing operations and future capital requirements. Any future determination to pay cash dividends will be at the discretion of our board of directors and will be dependent upon financial condition, results of operations, capital requirements and such other factors as the board of directors deems relevant.

For equity compensation plan information, please refer to Item 12 in Part III of this Annual Report

Recent Sales of Unregistered Securities

During the year ended December 31, 2018, there were no sales of unregistered equity securities by the Company.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

The Company does not have a stock repurchase program and did not make any share repurchases during the year ended December 31, 2018.

Item 6. SELECTED FINANCIAL DATA

The following selected financial data are qualified in their entirety by, and should be read in conjunction with, the more detailed information contained in the consolidated financial statements, the notes thereto and the information set forth in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(in thousands, except share and per share amounts)				
Consolidated Statements of Operations Data:					
Revenue:					
Product	$ 76,626	$ 30,458	$ 20,555	$ 9,620	$ 5,988
Service	3,861	3,109	1,504	530	411
Distribution rights	475	475	178	—	—
Grant	—	—	—	240	—
Total revenue	80,962	34,042	22,237	10,390	6,399
Cost of revenue:					
Product	66,522	25,488	23,897	12,673	8,176
Service	7,837	2,222	1,969	1,871	975
Total cost of revenue	74,359	27,710	25,866	14,544	9,151
Gross margin	6,603	6,332	(3,629)	(4,154)	(2,752)
Operating expenses:					
Research and development(1)	16,520	14,709	11,442	10,449	9,404
Selling and marketing(1)	15,062	8,412	5,601	5,139	4,681
General and administrative(1)	50,113	31,375	23,503	21,685	14,742
Total operating expenses	81,695	54,496	40,546	37,273	28,827
Loss from operations	(75,092)	(48,164)	(44,175)	(41,427)	(31,579)
Interest income	8	5	2	2	1
Interest expense	(7,701)	(7,247)	(5,951)	(3,452)	(2,243)
Other income (expense), net	6,389	(16,770)	(512)	(117)	21
Loss before provision for income taxes	$ (76,396)	$ (72,176)	$ (50,636)	$ (44,994)	$ (33,800)
Provision for income taxes	—	—	—	1	—
Net loss and comprehensive loss	$ (76,396)	$ (72,176)	$ (50,636)	$ (44,995)	$ (33,800)
Amortization of beneficial conversion feature related to Series A convertible preferred stock	(2,728)	—	—	—	—
Deemed capital contribution on repurchase of Series A preferred stock	—	—	—	—	9
Net loss attributable to common stockholders, basic and diluted	$ (79,124)	$ (72,176)	$ (50,636)	$ (44,995)	$ (33,791)
Net loss per share attributable to common stockholders, basic and diluted(2)	$ (0.98)	$ (1.23)	$ (1.26)	$ (2.58)	$ (37.87)
Weighted-average common shares used in computing net loss per share attributable to common stockholders, basic and diluted(2)	81,123,140	58,457,868	40,068,307	17,432,434	892,315

(1) Includes stock-based compensation expense as follows:

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(in thousands)				
Research and development	$ 1,411	$ 952	$ 593	$ 262	$ 85
Selling and marketing	700	303	120	50	15
General and administrative	12,058	4,064	2,194	754	218
Total stock-based compensation expense	$ 14,169	$ 5,319	$ 2,907	$ 1,066	$ 318

(2) See Note 16 to our consolidated financial statements for an explanation of the method used to calculate our basic and diluted net loss per share attributable to common stockholders.

	December 31,				
	2018	2017	2016	2015	2014
	(in thousands)				
Consolidated Balance Sheets Data:					
Cash and cash equivalents	$ 167,432	$ 57,389	$ 14,198	$ 20,667	$ 11,129
Total assets	294,970	135,711	48,764	52,157	34,105
Deferred revenue, current and noncurrent portion	19,475	23,389	10,433	5,961	7,361
Long-term debt	55,364	44,504	44,290	29,016	14,642
Total liabilities	127,661	133,724	92,417	59,114	39,618
Total stockholders' equity (deficit)	167,309	1,987	(43,653)	(6,957)	(150,623)

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

The following management's discussion and analysis should be read in conjunction with the financial statements and the related notes thereto contained in this Annual Report. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements are subject to risks and uncertainties, including those under "Risk Factors" in this Annual Report that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. See "Cautionary Note Regarding Forward-Looking Statements" in this Annual Report.

Unless otherwise indicated, references in this section to "ViewRay," "we," "us," "our," "the Company" and "our Company" refer to ViewRay, Inc. and its consolidated subsidiary, ViewRay Technologies, Inc.

As a result of the merger of ViewRay, Inc. and ViewRay Technologies, Inc. in July 2015, or the Merger, and the change in business and operations of the Company, a discussion of the past financial results of the Company is not pertinent, and under applicable accounting principles the historical financial results of ViewRay Technologies, Inc., the accounting acquirer, prior to the Merger are considered the historical financial results of the Company.

The following discussion highlights our results of operations and the principal factors that have affected our financial condition as well as our liquidity and capital resources for the periods described, and provides information that management believes is relevant for an assessment and understanding of the statements of financial condition and results of operations presented herein. The following discussion and analysis are based on our consolidated financial statements contained in this Annual Report, which we have prepared in accordance with United States generally accepted accounting principles. You should read this discussion and analysis together with such consolidated financial statements and the related notes thereto.

Company Overview

We design, manufacture and market the ViewRay MRIdian®. The MRIdian is an innovative system that integrates high quality radiation therapy with simultaneous resonance imaging (MRI). There are two generations of the MRIdian: the first generation MRIdian with Cobalt-60 based radiation beams and the second generation MRIdian Linac, with more advanced linear accelerator or 'linac' based radiation beams.

Both generations of the MRIdian have received 510(k) marketing clearance from the United States Food and Drug Administration, or FDA, and permission to affix the CE mark.

MRIdian is the first radiation therapy system that enables simultaneous radiation treatment delivery and real-time MRI imaging of a patient's internal anatomy. It generates high-quality images that differentiate between the targeted tumor, surrounding soft tissue and nearby critical organs. MRIdian also records the level of radiation dose that the treatment area has received, enabling physicians to adapt the prescription between treatments, as needed. We believe this improved visualization and accurate dose recording will enable better treatment, improve patient outcomes and reduce side effects. Key benefits to users and patients include: improved imaging and patient alignment; the ability to adapt the patient's radiation treatments to changes while the patient is still on the treatment table, or "on-table adaptive treatment planning"; MRI-based motion management; and an accurate recording of the delivered radiation dose. Physicians have already used MRIdian to treat a broad spectrum of radiation therapy patients with more than 45 different types of cancer, as well as patients for whom radiation therapy was previously not an option.

At December 31, 2018, we had seven MRIdian with Cobalt-60 systems and 17 MRIdian Linac systems installed at 22 cancer centers worldwide (10 in the United States and 12 outside the United States). Four MRIdian Linacs have already been delivered and are expected to be installed in 2019.

We currently market MRIdian through a direct sales force in North America and continue to expand our global footprint by going direct and adding additional distributors to our network in key markets. We market MRIdian to a broad range of worldwide customers, including university research and teaching hospitals, community hospitals, private practices, government institutions and freestanding cancer centers. As with the traditional linac market, our sales and revenue cycles vary based on the particular customer and can be lengthy, sometimes lasting up to 18 to 24 months (or more) from initial customer contact to order contract execution. Following execution of an order contract, it generally takes nine to 15 months for a customer to customize an existing facility or construct a new

vault. Upon the commencement of installation at a customer's facility, it typically takes approximately 60 to 90 days for us to install MRIdian and perform on-site testing of the system, including the completion of acceptance test procedures.

We generated product, service and distribution rights revenues of $81.0 million, $34.0 million and $22.2 million, and had net losses of $76.4 million, $72.2 million and $50.6 million during the years ended December 31, 2018, 2017 and 2016, respectively.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- add personnel to support our product development and commercialization efforts;
- continue our research and development efforts;
- seek regulatory approval for MRIdian in certain foreign countries; and
- operate as a public company.

Accordingly, we may seek to fund our operations through public or private equity, debt financings or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop enhancements to and integrate new technologies into MR Image-Guided radiation therapy systems.

August 2018 Public Offering of Common Stock

On August 14, 2018, we entered into an underwriting agreement with Morgan Stanley & Co. LLC and Jefferies LLC, as representatives of several underwriters, or the Underwriters, in connection with the issuance and sale of 16,216,217 shares of our common stock at a public offering price of $9.25 per share, or the August 2018 Public Offering of Common Stock. In addition, we granted the Underwriters a 30-day option to purchase up to 2,432,432 additional shares of common stock on the same terms, which the Underwriters exercised in full. We completed the offering on August 17, 2018 and received aggregate net proceeds of approximately $161.9 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

March 2018 Direct Registered Offering

In February 2018, we entered into a securities purchase agreement pursuant to which we sold (i) 4,090,000 shares of our common stock; (ii) 3,000,581 shares of our Series A convertible preferred stock and (iii) warrants to purchase 1,418,116 shares of our common stock, or the 2018 Offering Warrants, for total gross proceeds of $59.1 million, or the March 2018 Direct Registered Offering. We completed the March 2018 Direct Registered Offering on March 5, 2018. The 2018 Offering Warrants have an exercise price of $8.31 per share, became exercisable upon issuance and expire in March 2025. All outstanding shares of Series A convertible preferred stock were converted into common stock at a conversion ratio of 1:1 on April 19, 2018.

October 2017 Direct Registered Offering

In October 2017, we entered into Securities Purchase Agreements pursuant to which we sold an aggregate of 8,382,643 shares of common stock for total gross proceeds of $49.9 million, or the October 2017 Direct Registered Offering. We completed the closing of the October 2017 Direct Registered Offering on October 25, 2017.

2017 Private Placement

In January 2017, we entered into a Securities Purchase Agreement pursuant to which we sold an aggregate of 10,323,101 shares of common stock consisting of 8,602,589 shares of common stock and warrants to purchase 1,720,512 shares of common stock, or the 2017 Placement Warrants, for total gross proceeds of $26.1 million, or the 2017 Private Placement. We completed the closing of the 2017 Private Placement on January 18, 2017. The 2017 Placement Warrants have a per share exercise price of $3.17 per share, and became exercisable in July 2017 and expire seven years from the date of issuance.

2016 Private Placement

On August 19, 2016, we entered into a Securities Purchase Agreement pursuant to which we sold an aggregate of 5,983,251 shares of common stock consisting of 4,602,506 shares of common stock and warrants to purchase 1,380,745 shares of common stock, or the 2016 Placement Warrants, for aggregate proceeds of $13.2 million, net of offering cost, or the 2016 Private Placement. We completed the initial closing of the 2016 Private Placement on August 22, 2016 with the final closing on September 9, 2016. The 2016 Placement Warrants have an exercise price of $2.95 per share, are exercisable at any time at the option of the holder and expire seven years from the date of issuance.

SVB Term Loan

In December 2018, we entered into a term loan agreement, or the SVB Term Loan, with Silicon Valley Bank, for a principal amount of $56.0 million. The SVB Term Loan has a maturity date of December 1, 2023 and bears interest at a rate of 6.30% per annum to be paid monthly over the term of the loan. Beginning on December 1, 2020 (or June 1, 2021, if the Company achieves a trailing twelve-month revenue of at least $215.0 million from January 1, 2019 to December 1, 2020 and elects to apply such later date), the Company will make thirty-six equal monthly payments of principal (or thirty equal payments, if the Company so elects). In addition, upon repayment of the SVB Term Loan in full, the Company will make a final payment equal to 3.15% of the original aggregate principal amount of the SVB Term Loan.

The SVB Term Loan is secured by substantially all our assets, except that the collateral does not include any intellectual property held by us, provided, however, the collateral shall include all accounts and proceeds from the sale or license of such intellectual property.

Additional details regarding the SVB Term Loan are included in the section entitled “Notes to Consolidated Financial Statements – Note 5 – Debt” in the consolidated financial statements included elsewhere in this Form 10-K.

CRG Term Loan

In June 2015, we entered into our long-term debt facility from Capital Royalty II L.P., Capital Royalty Partners II—Parallel Fund “A” L.P., Capital Royalty Partners II (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P., or together with their successors by assignment, CRG, and such loan, the CRG Term Loan, for up to $50.0 million, of which $30.0 million was made available to us upon closing with the remaining $20.0 million to be available on or before June 26, 2016 upon meeting certain milestones. We drew down the first $30.0 million on the closing date in June 2015. In March 2016, the CRG Term Loan was amended with regard to the conditions for borrowing the remaining $20.0 million available under the CRG Term Loan. We achieved one milestone at March 31, 2016 and borrowed an additional $15.0 million in May 2016.

In December 2018, we used the proceeds of the SVB Term Loan and cash on hand to repay in full our obligations under the outstanding CRG Term Loan and no amounts remain outstanding as of December 31, 2018.

At-The-Market Offering of Common Stock

In January 2017, we filed a registration statement with the SEC which covers the offering, issuance and sale of up to a maximum aggregate offering price of $75.0 million of our common stock, preferred stock, debt securities, warrants, purchase contracts and/or units; and we entered into a sales agreement with FBR Capital Markets & Co., or FBR, under which we may sell up to $25.0 million of our common shares pursuant to an at-the-market offering program in accordance with Rule 415(a)(4) under the Securities Act. FBR acted as sales agent on a best efforts basis and used commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us, consistent with its normal trading and sales practices, on mutually agreed terms between FBR and us. There is no arrangement for funds to be received in any escrow, trust or similar arrangement. In May 2018, we agreed to sell up to an additional $25.0 million of our common stock in accordance with the terms of a sales agreement with FBR and pursuant to an at-the-market offering program in accordance with Rule 415(a)(4) under the Securities Act. FBR is entitled to compensation of up to 3.0% of the gross sales price per share sold.

During fiscal year 2017, we sold an aggregate of approximately 6.6 million shares of our common stock at an average market price of $6.10 per share under the at-the-market offering program, resulting in aggregate gross proceeds of approximately $40.1 million. During fiscal year 2018, we sold 33,097 shares of our common stock at an

average market price of $8.41 under the at-the-market offering program, resulting in aggregate gross proceeds of approximately $0.3 million. As of December 31, 2018, there was approximately $9.5 million left under this program for future stock issuance.

In January 2019, we filed a registration statement with the SEC which covers the offering, issuance and sale of up to a maximum aggregate offering price of $250.0 million of our common stock, preferred stock, debt securities, warrants, purchase contracts and/or units, including up to $100.0 million of our common shares pursuant to our at-the-market offering program with FBR.

New Orders and Backlog

New orders are defined as the sum of gross product orders, representing MRIdian contract price, recorded in backlog during the period. Backlog is the accumulation of all orders for which revenue has not been recognized and which we consider valid. Backlog includes customer deposits or letters of credit, except when the sale is to a customer where a deposit is not deemed necessary or customary. Deposits received are recorded in a customer deposit liability account on the balance sheet. Orders may be revised or cancelled according to their terms or upon mutual agreement between the parties. Therefore, it is difficult to predict with certainty the amount of backlog that will ultimately result in revenue. The determination of backlog includes objective and subjective judgment about the likelihood of an order contract becoming revenue. We perform a quarterly review of backlog to verify that outstanding orders in backlog remain valid, and based upon this review, orders that are no longer expected to result in revenue are removed from backlog. Among other criteria to consider for a transaction to be in backlog, we must possess both an outstanding and effective written agreement for the delivery of a MRIdian signed by a customer with a minimum customer deposit or a letter of credit requirement except when the sale is to a customer where a deposit is not deemed necessary or customary (i.e. sale to a government entity, a large hospital, group of hospitals or cancer care group that has sufficient credit, sales via tender awards, or indirect channel sales that have signed contracts with end-customers). We decide whether to remove or add back an order from or to our backlog by evaluating the following criteria: changes in customer or distributor plans or financial conditions; the customer's or distributor's continued intent and ability to fulfill the order contract; changes to regulatory requirements; the status of regulatory approval required in the customer's jurisdiction, if any; the length of time the order has been on our backlog; and other reasons for potential cancellation of order contracts.

During the years ended December 31, 2018, 2017 and 2016, our new orders were $140.7 million, $113.6 million and $77.0 million, respectively. Based on our assessment, we removed $53.5 million and $11.1 million from the backlog for fiscal year 2018 and 2017 respectively; none were removed for fiscal year 2016. At December 31, 2018 and 2017, we had backlog with a total value of $212.3 million and $203.6 million, respectively.

Components of Statements of Operations

Revenue

Product Revenue. Product revenue consists of revenue recognized from sales of MRIdian systems, as well as optional components, such as additional planning workstations and body coils.

Following execution of an order contract, it generally takes nine to 15 months for a customer to customize an existing facility or construct a new vault for the purchased system. Upon the commencement of installation at a customer's facility, it typically takes approximately 60 to 90 days to complete the installation and on-site testing of the system, including the completion of acceptance test procedures. On-site training takes approximately one week and can be conducted concurrently with installation and acceptance testing. Order contracts generally include customer deposits upon execution of the agreement, and in certain cases, additional amounts due at shipment or commencement of installation, and final payment due generally upon customer acceptance.

Revenue recognition for MRIdian systems that we install generally occurs when the customer acknowledges that the system operates in accordance with standard product specifications, the customer accepts the installed unit and the control of the system is transferred to the customer. For sales of MRIdian systems for which we are not responsible for installation, revenue is recognized when the entire system is delivered, which is when the control of the system is transferred to the customer.

Service Revenue. Our contracts typically include service warranty at no additional costs for one year. In addition, we offer multi-year, post-installation maintenance and support contracts that provide various levels of service support, which enables our customers to select the level of on-going support services, including parts and labor, which they

require. These post-installation contracts are for a period of one to five years and provide services ranging from on-site parts and labor, and preventative maintenance to labor only with a longer response time. We also offer technology upgrades to our MRIdian systems, when and if available, for an additional fee. Service revenue is recognized ratably over the term during which the contracted services are provided.

Distribution Rights Revenue. In December 2014, we entered into a distribution agreement with Itochu Corporation, or Itochu, pursuant to which we appointed Itochu as our exclusive distributor for the promotion, sale and delivery of MRIdian products within Japan. As consideration for the exclusive distribution rights granted, we received $4.0 million, which was recorded as deferred revenue and since August 2016, distribution rights revenue has been recognized ratably over the remaining term of the distribution agreement, which expires in December 2024. A time-elapsed method is used to measure progress because the control is transferred evenly over the contractual period.

Cost of Revenue

Product Cost of Revenue. Product cost of revenue primarily consists of the cost of materials, installation and services associated with the manufacturing and installation of MRIdian systems, and royalty payments to the University of Florida Research Foundation. Product cost of revenue also includes lower of cost or net realizable value inventory, or LCNRV, adjustments if the carrying value of the inventory is greater than its net realizable value. We recorded LCNRV charges of $0.3 million, $0.9 million and $1.9 million for the years ended December 31, 2018, 2017 and 2016, respectively.

We expect our materials, installation and service costs to decrease as we continue to scale our operations, improve product designs and work with our third-party suppliers to lower costs. We expect to continue to lower costs and increase sales prices as we transition to MRIdian Linac.

Service Cost of Revenue. Service cost of revenue is comprised primarily of personnel costs, training and travel expenses to service and perform maintenance on installed MRIdian systems. Service cost of revenue also includes the costs of replacement parts under maintenance and support contracts.

Operating Expenses

Research and Development. Research and development expenses consist primarily of compensation and related costs for personnel, including stock-based compensation, employee benefits and travel expenses. Other significant research and development costs arise from third-party consulting services, laboratory supplies, research materials, medical equipment, computer equipment and licensed technology, and related depreciation and amortization. We expense research and development costs as incurred. As we continue to invest in improving MRIdian and developing new technologies, we expect our research and development expenses to increase.

Selling and Marketing. Selling and marketing expenses consist primarily of compensation and related costs for our direct sales force, sales management, and marketing and customer support personnel, and include stock-based compensation, employee benefits and travel expenses. Selling and marketing expenses also include costs related to trade shows and marketing programs. We expense selling and marketing costs as incurred. We expect selling and marketing expenses to increase in future periods as we expand our sales force and our marketing and customer support organizations and increase our participation in trade shows and marketing programs.

General and Administrative. Our general and administrative expenses consist primarily of compensation and related costs for our operations, finance, human resources, regulatory, and other administrative personnel, and include stock-based compensation, employee benefits and travel expenses. In addition, general and administrative expenses include third-party consulting, legal, audit, accounting services, quality and regulatory functions and facilities costs, and gain or loss on the disposal of property and equipment. We expect our general and administrative expenses to increase as our business grows and as we invest in the development of our MRIdian Linac.

Interest Income

Interest income consists primarily of interest income received on our cash and cash equivalents.

Interest Expense

Interest expense consists primarily of interest and amortization related to our CRG Term Loan. In December 2018, we repaid in full the outstanding obligations under the CRG Term Loan, using the proceeds from the SVB Term Loan and cash on hand.

Other Income (Expense), Net

Other income (expense), net consists primarily of changes in the fair value of the 2017 and 2016 Placement Warrants and foreign currency exchange gains and losses.

The outstanding 2017 and 2016 Placement Warrants are re-measured to fair value at each balance sheet date with the corresponding gain or loss from the adjustment recorded as a component of other expense, net.

Results of Operations

The following tables set forth our results of operations for the periods presented (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Revenue:			
Product	$ 76,626	$ 30,458	$ 20,555
Service	3,861	3,109	1,504
Distribution rights	475	475	178
Total revenue	80,962	34,042	22,237
Cost of revenue:			
Product	66,522	25,488	23,897
Service	7,837	2,222	1,969
Total cost of revenue	74,359	27,710	25,866
Gross margin	6,603	6,332	(3,629)
Operating expenses:			
Research and development	16,520	14,709	11,442
Selling and marketing	15,062	8,412	5,601
General and administrative	50,113	31,375	23,503
Total operating expenses:	81,695	54,496	40,546
Loss from operations	(75,092)	(48,164)	(44,175)
Interest income	8	5	2
Interest expense	(7,701)	(7,247)	(5,951)
Other income (expense), net	6,389	(16,770)	(512)
Loss before provision for income taxes	(76,396)	(72,176)	(50,636)
Provision for income taxes	—	—	—
Net loss	$ (76,396)	$ (72,176)	$ (50,636)

Comparison of the years ended December 31, 2018 and 2017

Revenue

	Year Ended December 31,			
	2018	2017	Change ($)	Change (%)
	(in thousands)			
Product	$ 76,626	$ 30,458	$ 46,168	151.6%
Service	3,861	3,109	752	24.2%
Distribution rights	475	475	—	0.0%
Total revenue	$ 80,962	$ 34,042	$ 46,920	137.8%

Total revenue during the year ended December 31, 2018 increased by $46.9 million or 137.8% compared to the year ended December 31, 2017. The increase was primarily due to revenue recognized from the sale of 13 MRIdian

systems and two systems upgrades during the year ended December 31, 2018, compared to revenue recognized from the sale of six MRIdian systems during the year ended December 31, 2017.

Product Revenue. Product revenue increased by $46.2 million, or 151.6%, in fiscal year 2018 compared to fiscal year 2017. The increase is primarily due to the revenue recognized from the sale of 13 MRIdian systems and two systems upgrades in fiscal year 2018 compared to the revenue recognized from the sale of six MRIdian systems in fiscal year 2017.

Service Revenue. Service revenue increased by $0.8 million, or 24.2%, in fiscal year 2018 compared to fiscal year 2017 due to increased billings to existing customers, as well as the growth in our installed base.

Distribution Rights Revenue. After receipt of Japanese regulatory approval in August 2016, we started recognizing the distribution rights revenue ratably over the remaining term of the distribution agreement with Itochu. Distribution rights revenue remained flat in fiscal year 2018 compared to fiscal year 2017 due to the ratable recognition of revenue over the term of the agreement.

Cost of Revenue

	Year Ended December 31,			
	2018	2017	Change ($)	Change (%)
	(in thousands)			
Product	$ 66,522	$ 25,488	$ 41,034	161.0%
Service	7,837	2,222	5,615	252.7%
Total cost of revenue	$ 74,359	$ 27,710	$ 46,649	168.3%

Product Cost of Revenue. Product cost of revenue increased by $41.0 million, or 161.0%, in fiscal year 2018 compared to fiscal year 2017. The increase was primarily due to costs of two systems upgrades and 13 MRIdian systems sold in fiscal year 2018 compared to costs of six MRIdian systems sold in fiscal year 2017.

Service Cost of Revenue. Service cost of revenue increased by $5.6 million, or 252.7%, in fiscal year 2018 compared to fiscal year 2017. The increase in service cost of revenue was primarily due to the larger installed base in fiscal year 2018 and service personnel being fully utilized for service purposes in the second half of the year. Historically, we allocated a percentage of total service personnel expense to service cost of revenue based on the time service personnel spent on servicing installed units. Unallocated service personnel expense was included in general and administrative expenses. Over time, the allocation percentage has consistently increased as a result of our growing installed base and related utilization of service personnel. Starting in the third quarter of 2018, all service personnel expense is allocated to service cost of revenue.

Operating Expenses

	Year Ended December 31,			
	2018	2017	Change ($)	Change (%)
	(in thousands)			
Research and development	$ 16,520	$ 14,709	$ 1,811	12.3%
Selling and marketing	15,062	8,412	6,650	79.1%
General and administrative	50,113	31,375	18,738	59.7%
Total operating expenses	$ 81,695	$ 54,496	27,199	49.9%

Research and Development. Research and development expenses increased by $1.8 million, or 12.3%, in fiscal year 2018 compared to fiscal year 2017. This increase was primarily attributable to a $2.4 million increase in personnel expense and a $0.9 million increase in facility expense due to higher average headcount. In addition, travel and office expense also increased by $0.5 million. The increase was partially offset by a decrease of $2.1 million in outside services and product development cost due to decreased usage of consultants and contractors.

Selling and Marketing. Selling and marketing expenses increased by $6.7 million, or 79.1%, in fiscal year 2018 compared to fiscal year 2017. This increase was primarily attributable to a $5.2 million increase in personnel expense due to higher average headcount in fiscal 2018, $0.6 million increase in travel expense, $0.5 million increase in outside services and $0.2 million increase in marketing expense.

General and Administrative. General and administrative expenses increased by $18.7 million, or 59.7%, in fiscal year 2018 compared to fiscal year 2017. This increase was primarily attributable to a $10.4 million increase in personnel expense due to higher average headcount, a $5.0 million of severance expense associated with certain terminated executives and $1.2 million of increased depreciation expense. The remaining increase was attributable to an increase in legal expense and office expense.

Interest Expense

	Year Ended December 31,			
	2018	2017	Change ($)	Change (%)
	(in thousands)			
Interest expense	$ (7,701)	$ (7,247)	$ (454)	6.3%

Interest expense increased by $0.5 million in fiscal year 2018 compared to fiscal year 2017, mainly due to the increase in the loan balance under the effective interest rate method, including deferred payment in-kind interest to our CRG Term Loan, although the nominal loan balance remained the same during both periods.

Other Income (Expense), Net

	Year Ended December 31,			
	2018	2017	Change ($)	Change (%)
	(in thousands)			
Other income (expense), net	$ 6,389	$ (16,770)	$ 23,159	-138.1%

Other income (expense), net for fiscal year 2018 consisted primarily of a $9.4 million gain attributable to the change in fair value of warrant liability related to the 2017 and 2016 Placement Warrants and a $2.4 million loss on the CRG Term Loan extinguishment. Other income (expense), net for fiscal year 2017 consisted primarily of a $16.6 million charge attributable to the change in fair value of warrant liability related to the 2017 and 2016 Placement Warrants.

Comparison of the Years Ended December 31, 2017 and 2016

Revenue

	Year Ended December 31,			
	2017	2016	Change ($)	Change (%)
	(in thousands)			
Product	$ 30,458	$ 20,555	$ 9,903	48.2%
Service	3,109	1,504	1,605	106.7%
Distribution rights	475	178	297	166.9%
Total revenue	$ 34,042	$ 22,237	11,805	53.1%

Total revenue during the year ended December 31, 2017 increased by $11.8 million, or 53.1%, compared to the year ended December 31, 2016. The increase was primarily due to revenue recognized from six MRIdian Linac systems during the year ended December 31, 2017, compared to revenue recognized from four MRIdian with Cobalt-60 units during the year ended December 31, 2016.

Product Revenue. Product revenue increased by $9.9 million, or 48.2%, in fiscal year 2017 compared to fiscal year 2016. The increase is primarily due to revenue recognized from six MRIdian Linac systems in fiscal year 2017 compared to revenue recognized from four MRIdian with Cobalt-60 units in fiscal year 2016.

Service Revenue. Service revenue increased by $1.6 million, or 106.7%, in fiscal year 2017 compared to fiscal year 2016 due to increased billings to existing customers, as well as the growth in our installed base.

Distribution Rights Revenue. Distribution rights revenue increased by $0.3 million, or 166.9%, in fiscal year 2017 compared to fiscal year 2016. After receipt of Japanese regulatory approval in August 2016, we started recognizing the distribution rights revenue on a straight-line basis over the remaining term of the distribution agreement with Itochu. The increase was due to recognition of revenue for twelve months in fiscal year 2017 compared to four and a half months in fiscal year 2016.

Cost of Revenue

	Year Ended December 31,			
	2017	2016	Change ($)	Change (%)
	(in thousands)			
Product	$ 25,488	$ 23,897	$ 1,591	6.7%
Service	2,222	1,969	253	12.8%
Total cost of revenue	$ 27,710	$ 25,866	$ 1,844	7.1%

Product Cost of Revenue. Product cost of revenue increased by $1.6 million, or 6.7%, in fiscal year 2017 compared to fiscal year 2016. The increase was primarily due to costs of six MRIdian Linac systems sold in fiscal year 2017 compared to costs of four MRIdian with Cobalt-60 units sold in fiscal year 2016. The increase was partially offset by the lower cost of MRIdian Linac systems.

Service Cost of Revenue. Service cost of revenue increased by $0.3 million, or 12.8%, in fiscal year 2017 compared to fiscal year 2016. The increase in service cost of revenue was primarily due to the larger installed base in fiscal year 2017.

Operating Expenses

	Year Ended December 31,			
	2017	2016	Change ($)	Change (%)
	(in thousands)			
Research and development	$ 14,709	$ 11,442	$ 3,267	28.6%
Selling and marketing	8,412	5,601	2,811	50.2%
General and administrative	31,375	23,503	7,872	33.5%
Total operating expenses	$ 54,496	$ 40,546	$ 13,950	34.4%

Research and Development. Research and development expenses increased by $3.3 million, or 28.6%, in fiscal year 2017 compared to fiscal year 2016. This increase was primarily attributable to a $1.4 million increase in engineering and research expense and expenses for project supplies, a $1.0 million increase in consulting and contract labor expense due to increased usage of consultants and contractors, and a $0.7 million increase in personnel costs due to higher average headcount.

Selling and Marketing. Selling and marketing expenses increased by $2.8 million, or 50.2%, in fiscal year 2017 compared to fiscal year 2016. This increase was primarily attributable to a $1.4 million increase in trade show costs, a $1.1 million increase in personnel expense due to higher average headcount in fiscal year 2017, and a $0.2 million increase in travel expense.

General and Administrative. General and administrative expenses increased by $7.9 million, or 33.5%, in fiscal year 2017 compared to fiscal year 2016. This increase was primarily attributable to a $4.0 million increase in personnel expense due to higher average headcount, a $2.3 million increase in consulting and contract labor expense, a $0.6 million increase in depreciation expense, and a $0.6 million increase in travel and other general expenses.

Interest Expense

	Year Ended December 31,			
	2017	2016	Change ($)	Change (%)
	(in thousands)			
Interest expense	$ (7,247)	$ (5,951)	$ (1,296)	21.8%

Interest expense increased by $1.3 million, or 21.8%, in fiscal year 2017, due primarily to the higher outstanding CRG loan balance in fiscal year 2017.

Other Expense, Net

	Year Ended December 31,			
	2017	2016	Change ($)	Change (%)
	(in thousands)			
Other expense, net	$ (16,770)	$ (512)	$ (16,258)	3175.4%

Other expense, net for fiscal year 2017 consisted primarily of a $16.6 million charge attributable to the change in fair value of warrant liability related to the 2017 and 2016 Placement Warrants. Other expense, net for fiscal year 2016 consisted primarily of a $0.4 million loss on disposal of fixed assets.

Liquidity and Capital Resources

Since our inception in 2004, we have incurred significant net losses and negative cash flows from operations. During the years ended December 31, 2018, 2017 and 2016, we had a net loss of $76.4 million, $72.2 million and $50.6 million, respectively. At December 31, 2018 and 2017, we had an accumulated deficit of $399.0 and $319.9 million, respectively.

At December 31, 2018 and 2017, we had cash and cash equivalents of $167.4 and $57.4 million, respectively. To date, we have financed our operations principally through offerings of our capital stock, issuances of warrants, issuances of convertible promissory notes, use of term loans and receipts of customer deposits for new orders and payments from customers for systems installed and delivered. We may, from time to time, seek to raise capital through a variety of sources, including the public equity market, private equity financing, and public or private debt. In January 2017, we issued common stock and warrants to purchase common stock via the 2017 Private Placement for gross proceeds of $26.1 million. In 2017, we also raised aggregate gross proceeds of $40.1 million through our at-the-market offering program under which we sold approximately 6.6 million shares of our common stock at an average sale price of $6.10 per share. In October 2017, we issued common stock in the October 2017 Direct Registered Offering for gross proceeds of $49.9 million. In March 2018, we issued common stock, Series A convertible preferred stock and warrants to purchase common stock in the March 2018 Direct Registered Offering for gross proceeds of $59.1 million. In May 2018, we raised additional aggregate gross proceeds of $0.3 million through our at-the-market offering program under which we sold 33,097 shares of our common stock at an average sale price of $8.41 per share. In August 2018, we raised aggregate gross proceeds of $172.5 million via a public offering, in which we sold approximately 18.6 million shares of our common stock at a price of $9.25 per share. In December 2018, we entered into SVB Term Loan for a principal amount of $56.0 million. We used the proceeds from SVB Term Loan and cash on hand to repay in full our obligations under the outstanding CRG Term Loan. We expect that our existing cash and cash equivalents, together with proceeds from the sales of MRIdian systems, will enable us to conduct our planned operations for at least the next 12 months.

In January 2019, we filed a registration statement with the SEC which covers the offering, issuance and sale of up to a maximum aggregate offering price of $250.0 million of our common stock, preferred stock, debt securities, warrants, purchase contracts and/or units, including up to $100.0 million of our common shares pursuant to our at-the-market offering program with FBR.

We could potentially use our available financial resources sooner than we currently expect, and we may incur additional indebtedness to meet future operating needs. Adequate additional funding may not be available to us on acceptable terms or at all. In addition, although we anticipate being able to obtain additional financing, we may be unable to do so. Our failure to raise capital as and when needed could have significant negative consequences for our business, financial condition and results of operations. Our future capital requirements and the adequacy of available funds will depend on many factors, including those set forth in the section titled “Risk Factors.”

The following table summarizes our cash flows for the periods presented (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Cash used in operating activities	$ (122,194)	$ (70,053)	$ (28,156)
Cash used in investing activities	(3,685)	(2,163)	(7,043)
Cash provided by financing activities	236,712	115,407	28,930

Operating Activities

We have historically experienced cash outflows as we developed MRIdian with Cobalt-60 and MRIdian Linac and expanded our business. Our primary source of cash flow from operating activities is cash receipts from customers including sales of MRIdian systems and, to a lesser extent, up-front payments from customers. Our primary uses of cash from operating activities are amounts due to vendors for purchased components and employee-related expenditures.

During fiscal year 2018, cash used in operating activities was $122.2 million, resulting from our net loss of $76.4 million, a $60.5 million net change in our operating assets and liabilities and aggregate non-cash charges of $14.7 million. The net change in our operating assets and liabilities was primarily a result of changes in inventory, accounts receivable, accrued expenses and other long-term liabilities, prepaid expenses and other assets, customer deposits and deferred revenue, accounts payable and deposits on purchased inventory, which was partially offset by changes in deferred cost of revenue. Inventory and deposits on purchased inventory increased by $33.3 million, in anticipation of upcoming shipments and installations of MRIdian systems. Accounts receivable increased by $16.5 million resulting from the timing of collections and increase in sales. The decrease of $9.2 million in accrued expense and other long-term liabilities primarily resulted from the payoff of accrued CRG Term Loan interest. Prepaid expenses and other assets increased $2.3 million mainly due to prepayments made for insurance premiums and deferred sales commissions. Customer deposits and deferred revenue decreased by $1.8 million as a result of the recognition of service revenue deferred for units installed prior to fiscal year 2018. Accounts payable decreased by $0.9 million resulting from the timing of payment. The net change in our operating assets and liabilities was partially offset by a $3.5 million decrease in deferred cost of revenue primarily due to the revenue recognized for MRIdian systems for fiscal year 2018, partially offset by the shipment of additional components for MRIdian systems currently being installed. Non-cash charges included $14.2 million of stock-based compensation expense, $3.6 million of amortization of debt discount and interest accrual related to the CRG Term Loan, $3.5 million of depreciation and amortization expense, $2.4 million of loss on debt extinguishment triggered by the payoff of the CRG Term Loan, and $0.3 million of inventory lower of cost and net realizable value adjustment, partially offset by a $9.4 million gain related to the change in fair value of the 2017 and 2016 Placement Warrants.

During fiscal year 2017, cash used in operating activities was $70.1 million as a result of our net loss of $72.2 million and a $26.3 million net change in our operating assets and liabilities, partially offset by aggregated non-cash charges of $28.4 million. The net change in our operating assets and liabilities was primarily a result of an increase in inventory and deposits on purchased inventory, an increase in accounts receivable, an increase in deferred cost of revenue and an increase in prepaid expenses and other assets, partially offset by an increase in customer deposits and deferred revenue, an increase in accounts payable and an increase in accrued expenses and other long-term liabilities. Inventory and deposits on purchased inventory increased by $12.3 million and $4.5 million, respectively, in anticipation of upcoming shipments and installation of MRIdian Linac systems. Deferred cost of revenue increased by $9.8 million due to the shipment of additional components for MRIdian Linac systems currently being installed. Prepaid expenses and other assets increased by $2.0 million, primarily attributable to deferred sales commission on new order contracts and prepaid insurance premium. The $16.2 million increase in accounts receivable resulted primarily from the timing of collection from shipment and installation of four units of MRIdian Linac in the last quarter of fiscal year 2017. The net change in our operating assets and liabilities was partially offset by an $11.4 million increase in customer deposits and deferred revenue mainly due to installation in progress. The $6.3 million increase in accounts payable resulted from the timing of payment. The $0.8 million increase in accrued expenses and other long-term liabilities was primarily due to the timing of invoice receipts for services and inventory purchased. Non-cash charges included a $16.6 million change in the fair value of warrant liability related to the 2017 and 2016 Placement Warrants, $3.3 million of amortization of debt discount and interest accrual related to the CRG Term Loan, $5.3 million of stock-based compensation expense, $2.2 million of depreciation and amortization expense as well as $0.9 million due to lower of cost and net realizable value inventory adjustments.

During fiscal year 2016, cash used in operating activities was $28.2 million primarily as a result of our net loss of $50.6 million, partially offset by a $12.9 million net increase in our operating assets and liabilities and aggregate non-cash charges of $9.5 million. The net change in our operating assets and liabilities was primarily the result of an increase in customer deposits, deferred revenue and accrued expenses, and a decrease in deferred cost of revenue and deposits on purchased inventory components, offset by an increase in accounts receivable, inventory and prepaid expenses and other current assets. The $11.1 million increase in customer deposits and deferred revenue was the result of 13 new order contracts and the receipt of payment from Itochu related to the distribution agreement during the year ended December 31, 2016. The $4.9 million decrease in deferred cost of revenue and the $1.4

million decrease in deposits on purchased inventory components were due to the recognition of revenue on four MRIdian systems sales during the year ended December 31, 2016. The $2.2 million increase in accrued expenses is attributable to the timing of invoice receipts for services and inventory purchased, as well as accrued bonuses. The net increase in our operating assets and liabilities was partially offset by a $3.4 million increase in accounts receivable attributable to our increased sales, a $2.1 million increase in inventories due to upcoming shipments and installations of MRIdian systems, and a $1.7 million increase in prepaid expenses and other current assets due to prepayments made for deferred sales commission on new order contracts. Non-cash charges primarily included $2.9 million of stock-based compensation, $2.6 million due to amortization of debt discount and interest accrual related to the CRG Term Loan, $1.9 million due to LCNRV adjustments related to the reduction of carrying value of inventory to its net realizable value, and $1.7 million depreciation and amortization expense.

Investing Activities

Cash used in investing activities for fiscal year 2018, 2017 and 2016 of $3.7 million, $2.2 million and $7.0 million, respectively, primarily resulted from capital expenditures to purchase property and equipment.

Financing Activities

During fiscal year 2018, financing activities provided $236.7 million in cash, consisting of $172.5 million gross proceeds from the August 2018 Public Offering of Common Stock, $59.1 million gross proceeds from the March 2018 Direct Registered Offering, $56.0 million gross proceeds from the SVB Term Loan, $0.3 million gross proceeds from our at-the-market offering program and $5.3 million proceeds from the exercise of stock options, partially offset by offering costs of $10.6 million for the August 2018 Public Offering of Common Stock and $0.2 million for the March 2018 Direct Registered Offering, the payoff of the CRG Term Loan of $45.0 million and $0.2 million in related debt extinguishment fee, and issuance costs of $0.5 million related to the SVB Term Loan.

Cash provided by financing activities for fiscal year 2017 of $115.4 million primarily resulted from $49.9 million gross proceeds from the October 2017 Direct Registered Offering, $26.1 million gross proceeds from the 2017 Private Placement, $40.1 million gross proceeds from our at-the-market offering program, $0.7 million from the exercise of stock options, and $0.1 million from the exercise of warrants, partially offset by offering costs of $1.2 million for our at-the-market offering program and offering costs of $0.4 million for our October 2017 Direct Registered Offering, the 2017 Private Placement and the 2016 Private Placement

Cash provided by financing activities for fiscal year 2016 of $28.9 million primarily resulted from the net proceeds of $15.0 million related to the additional CRG draw down, net proceeds of $13.4 million related to the 2016 Private Placement and $0.5 million from the exercise of stock options.

Contractual Obligations

The following summarizes our contractual obligations at December 31, 2018, and the effect such obligations are expected to have on our liquidity and cash flow over the next five years (in thousands):

	Payment due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
SVB Term Loan (1)	$ 56,000	$ —	$ 20,222	$ 35,778	$ —
Interest on SVB Term Loan(1)	13,877	3,312	6,517	4,048	—
Operating leases(2)	16,446	2,070	4,777	5,067	4,532
Total	$ 86,323	$ 5,382	$ 31,516	$ 44,893	$ 4,532

(1) Refer to "Note 5. Debt"
(2) Refer to "Note 6. Commitments and Contingencies"

Off-Balance Sheet Arrangements

As of December 31, 2018, we do not have any off-balance sheet arrangements except for our operating leases disclosed in more detail in the section entitled "Notes to Consolidated Financial Statements – Note 6 – Commitments and Contingencies" in the consolidated financial statements included elsewhere in this Form 10-K.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States, or U.S. GAAP, which requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. These estimates and assumptions are based on historical experience and on various other factors that we believe are reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis.

In addition to the accounting policies that are more fully described in the Notes to the Consolidated Financial Statements included in this Annual Report on Form 10-K, we consider the critical accounting policies described below to be affected by critical accounting estimates, and those estimates have the greatest potential impact on our consolidated financial statements. Such accounting policies require us to use judgments, often as a result of the need to make estimates and assumptions regarding matters that are inherently uncertain, and actual results could differ from these estimates.

Revenue Recognition

Our revenues are derived primarily from the sale of MRIdian systems and related services as well as support and maintenance services on sold systems. We recognize the revenue when control of the promised goods or services is transferred to customers, in an amount that reflects the consideration we expect to be entitled to receive in exchange for those goods or services. For sales of MRIdian systems that we are required to install at the customer site, product revenue is recognized upon receipt of customer acceptance. For sales of MRIdian systems for which we are not responsible for installation, product revenue is recognized when the entire system is delivered, which is when the control of the system is transferred to the customer. For sales of the related support and maintenance services, a time-elapsed method is used to measure progress toward complete satisfaction of performance obligations and service revenue is recognized ratably over the service contract term, which is typically 12 months.

We frequently enter into sales arrangements that contain multiple performance obligations including MRIdian system and product support. Judgments as to the standalone selling price and allocation of consideration from an arrangement to the individual performance obligations, and the appropriate timing of revenue recognition are critical with respect to these arrangements. Changes to the performance obligations can impact the arrangement and amounts allocated to each performance obligation could affect the timing and amount of revenue recognition.

Stock-Based Compensation

Stock-based compensation expense is measured and recognized in the consolidated financial statements based on the fair value of the awards granted. The fair value of each option award is estimated on the grant date using the Black-Scholes option-pricing model. The fair value of restricted stock units, or RSUs, is based on the closing market price of the Company's common stock on the grant date. Stock-based compensation expense is recognized, net of estimated forfeitures, over the requisite service periods of the awards, which are generally four years.

Our use of the Black-Scholes option-pricing model requires the input of highly subjective assumptions, including the options' expected term and price volatility of the underlying stock. The assumptions used in our option-pricing model represent management's best estimates. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future.

Common Stock Warrants

We issued the 2017 and 2016 Placement Warrants in connection with the 2017 and 2016 Private Placements. The 2017 and 2016 Placement Warrants were accounted for as a liability with subsequent changes in fair value recorded in other expenses, net at each reporting date until the warrants are exercised or expired.

Inventory Valuation

Inventory consists primarily of purchased components for assembling MRIdian systems and other direct costs associated with MRIdian system installation. Inventory is stated at the lower of cost or net realizable value. When the net realizable value of inventory is lower than related costs, we reduce the carrying value of inventory for the difference while recording a corresponding charge to cost of product revenues. The assumptions we used in

estimating the net realizable value of the inventory primarily include the total cost to complete the applicable MRIdian system.

Income Taxes

We are subject to income taxes in the United States, and we use estimates in determining our provision for income taxes. We use the asset and liability method of accounting for income taxes. Under this method, we calculate deferred tax asset or liability account balances at the balance sheet date using current tax laws and rates in effect for the year in which the differences are expected to affect our taxable income.

We estimate actual current tax exposure together with assessing temporary differences resulting from differences in accounting for reporting purposes and tax purposes for certain items, such as accruals and allowances not currently deductible for tax purposes. These temporary differences result in deferred tax assets and liabilities, which are included in our consolidated balance sheets. In general, deferred tax assets represent future tax benefits to be received when certain expenses previously recognized in our consolidated statements of operations and comprehensive loss become deductible expenses under applicable income tax laws or when net operating loss or credit carryforwards are utilized. Accordingly, realization of our deferred tax assets is dependent on future taxable income against which these deductions, losses and credit carryforwards can be utilized.

We assess the likelihood that our deferred tax assets will be recovered from future taxable income, and to the extent we believe that recovery is not likely, establish a valuation allowance. At December 31, 2018, 2017, and 2016, we have a full valuation allowance set up for our net deferred tax assets.

Under federal and similar state tax statutes, changes in our ownership, including ownership changes resulting from the Merger, may limit our ability to use our available net operating loss and tax credit carryforwards. The annual limitation, as a result of a change of ownership, may result in the expiration of net operating losses and credits before utilization. We performed a Section 382 analysis in February of 2018 and two ownership changes were identified, none of which had a corresponding limitation of tax attributes. Future owner or equity shifts could result in limitations on net operating loss and credit carryforwards.

JOBS Act Accounting Election

We are an "emerging growth company" within the meaning of the JOBS Act. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies that are not emerging growth companies.

Recently Issued and Adopted Accounting Pronouncements

We review new accounting standards to determine the expected financial impact, if any, that the adoption of each such standard will have. For the recently issued accounting standards that we believe may have an impact on our consolidated financial statements, see the section entitled "Notes to Consolidated Financial Statements – Note 2 – Summary of Significant Accounting Policies" in the consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data

VIEWRAY, INC.
Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of ViewRay, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ViewRay, Inc. and its subsidiary (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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 the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. 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/ Deloitte & Touche LLP
San Francisco, California
March 15, 2019

We have served as the Company's auditor since 2012.

VIEWRAY, INC.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31,	
	2018	**2017**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 167,432	$ 57,389
Accounts receivable	36,867	20,326
Inventory	49,462	19,375
Deposits on purchased inventory	8,142	7,043
Deferred cost of revenue	9,736	13,696
Prepaid expenses and other current assets	6,045	4,862
Total current assets	277,684	122,691
Property and equipment, net	13,958	11,564
Restricted cash	1,933	1,143
Intangible assets, net	-	78
Other assets	1,395	235
TOTAL ASSETS	$ 294,970	$ 135,711
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 10,207	$ 11,014
Accrued liabilities	9,983	7,207
Customer deposits	19,968	17,820
Deferred revenue, current portion	13,731	20,151
Total current liabilities	53,889	56,192
Deferred revenue, net of current portion	5,744	3,238
Long-term debt	55,364	44,504
Warrant liability	11,844	22,420
Other long-term liabilities	820	7,370
TOTAL LIABILITIES	127,661	133,724
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Convertible preferred stock, par value $0.01 per share; 10,000,000 shares authorized at December 31, 2018 and 2017; no shares issued and outstanding at December 31, 2018 and 2017	—	—
Common stock, par value of $0.01 per share; 300,000,000 shares authorized at December 31, 2018 and 2017; 96,332,023 and 67,653,974 shares issued and outstanding at December 31, 2018 and 2017	952	666
Additional paid-in capital	565,334	321,174
Accumulated deficit	(398,977)	(319,853)
TOTAL STOCKHOLDERS' EQUITY	167,309	1,987
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 294,970	$ 135,711

The accompanying notes are an integral part of these consolidated financial statements.

VIEWRAY, INC.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Year Ended December 31,		
	2018	**2017**	**2016**
Revenue:			
Product	$ 76,626	$ 30,458	$ 20,555
Service	3,861	3,109	1,504
Distribution rights	475	475	178
Total revenue	80,962	34,042	22,237
Cost of revenue:			
Product	66,522	25,488	23,897
Service	7,837	2,222	1,969
Total cost of revenue	74,359	27,710	25,866
Gross margin	6,603	6,332	(3,629)
Operating expenses:			
Research and development	16,520	14,709	11,442
Selling and marketing	15,062	8,412	5,601
General and administrative	50,113	31,375	23,503
Total operating expenses	81,695	54,496	40,546
Loss from operations	(75,092)	(48,164)	(44,175)
Interest income	8	5	2
Interest expense	(7,701)	(7,247)	(5,951)
Other income (expense), net	6,389	(16,770)	(512)
Loss before provision for income taxes	$ (76,396)	$ (72,176)	$ (50,636)
Provision for income taxes	—	—	—
Net loss and comprehensive loss	$ (76,396)	$ (72,176)	$ (50,636)
Amortization of beneficial conversion feature related to Series A convertible preferred stock	(2,728)	—	—
Net loss attributable to common stockholders, basic and diluted	$ (79,124)	$ (72,176)	$ (50,636)
Net loss per share, basic and diluted	$ (0.98)	$ (1.23)	$ (1.26)
Weighted-average common shares used to compute net loss per share attributable to common stockholders, basic and diluted	81,123,140	58,457,868	40,068,307

The accompanying notes are an integral part of these consolidated financial statements.

VIEWRAY, INC.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share data)

	Convertible Preferred Stock			Common Stock				
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at January 1, 2016	—	$ —	$ —	38,204,960	$ 372	$ 189,712	$ (197,041)	$ (6,957)
Issuance of common stock from option exercises	—	—	—	773,718	8	531	—	539
Stock-based compensation	—	—	—	—	—	2,907	—	2,907
Issuance of common stock upon private placement (net of offering cost of $529)	—	—	—	4,602,506	46	10,448	—	10,494
Net loss	—	—	—	—	—	—	(50,636)	(50,636)
Balance at December 31, 2016	—	$ —	$ —	43,581,184	$ 426	$ 203,598	$ (247,677)	$ (43,653)
Issuance of common stock from option exercises				420,377	4	661	—	665
Issuance of common stock from releases of restricted stock units	—	—	—	57,626	—	—	—	—
Stock-based compensation	—	—	—	—	—	5,319	—	5,319
Issuance of common stock upon private placement (net of offering cost of $111)	—	—	—	8,602,589	86	22,530	—	22,616
Issuance of common stock upon direct registered offering (net of offering cost of $81)	—	—	—	8,382,643	84	49,776	—	49,860
Issuance of common stock from at-the-market offering (net of offering cost of 1,147)	—	—	—	6,575,062	66	38,913	—	38,979
Issuance of common stock from warrant exercises	—	—	—	34,493	—	103	—	103
Reclassification of warrant liability to additional paid-in capital upon warrant exercises	—	—	—	—	—	274	—	274
Net loss	—	—	—	—	—	—	(72,176)	(72,176)
Balance at December 31, 2017	—	$ —	$ —	67,653,974	$ 666	$ 321,174	$ (319,853)	$ 1,987
Issuance of common stock from option exercises	—	—	—	2,608,812	26	5,259	—	5,285
Issuance of common stock from releases of restricted stock units	—	—	—	59,437	—	—	—	—
Stock-based compensation	—	—	—	—	—	14,169	—	14,169
Issuance of common stock upon direct registered offering (net of offering cost of $177)	—	—	—	4,090,000	41	30,052	—	30,093
Issuance of preferred Series A stock upon direct registered offering	3,000,581	30	22,177	—	—	2,728	(2,728)	—
Issuance of common stock warrants in connection with direct registered offering	—	—	—	—	—	6,623	—	6,623
Conversion of Series A preferred stock into common stock	(3,000,581)	(30)	(22,177)	3,000,581	30	22,177	—	22,207
Issuance of common stock upon public offering (net of offering cost of $10,631)	—	—	—	18,648,649	187	161,682	—	161,869
Issuance of common stock from at-the-market offering (net of offering cost of $6)	—	—	—	33,097	—	272	—	272
Issuance of common stock from warrant exercises	—	—	—	237,473	2	1	—	3
Reclassification of warrant liability to additional paid-in capital upon warrant exercises	—	—	—	—	—	1,197	—	1,197
Net loss	—	—	—	—	—	—	(76,396)	(76,396)
Balance at December 31, 2018	—	$ —	$ —	96,332,023	$ 952	$ 565,334	$ (398,977)	$ 167,309

The accompanying notes are an integral part of these consolidated financial statements.

VIEWRAY, INC.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2018	**2017**	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (76,396)	$ (72,176)	$ (50,636)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,499	2,197	1,708
Stock-based compensation	14,169	5,319	2,907
Accretion on asset retirement obligation	33	40	36
Change in fair value of warrant liability	(9,379)	16,598	(3)
Loss on disposal of property and equipment	3	9	358
Inventory lower of cost and net realizable value adjustment	340	911	1,939
Amortization of debt discount and interest accrual	3,628	3,321	2,629
Loss on debt extinguishment	2,416	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(16,541)	(16,126)	(3,370)
Inventory	(32,214)	(12,329)	(2,065)
Deposits on purchased inventory	(1,099)	(4,521)	1,414
Deferred cost of revenue	3,500	(9,787)	4,873
Prepaid expenses and other assets	(2,343)	(2,044)	(1,633)
Accounts payable	(870)	6,309	381
Accrued expenses and other long-term liabilities	(9,174)	850	2,197
Customer deposits and deferred revenue	(1,766)	11,376	11,109
Net cash used in operating activities	(122,194)	(70,053)	(28,156)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(3,685)	(2,163)	(7,031)
Purchase of intangible and other assets	—	—	(12)
Net cash used in investing activities	(3,685)	(2,163)	(7,043)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from draw down of long-term debt, gross	56,000	—	15,000
Payment of debt issuance cost	(468)	—	(18)
Payment of long-term debt	(45,000)	—	—
Payment on debt extinguishment fee	(172)	—	—
Proceeds from common stock public offering, gross	172,500	—	—
Payment of offering costs related to common stock public offering	(10,631)	—	—
Proceeds from direct registered offering, gross	59,100	49,941	—
Payment of offering costs related to direct registered offering	(177)	(81)	—
Proceeds from common stock private placement, gross	—	26,100	13,750
Payment of offering costs related to common stock private placement	—	(300)	(341)
Proceeds from at-the-market offering of common stock, gross	278	40,126	—
Payment of offering costs related to at-the-market offering of common stock	(6)	(1,147)	—
Proceeds from the exercise of stock options	5,285	665	539
Proceeds from the exercise of warrants	3	103	—
Net cash provided by financing activities	236,712	115,407	28,930
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	110,833	43,191	(6,269)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH — BEGINNING OF PERIOD	58,532	15,341	21,610
CASH, CASH EQUIVALENTS AND RESTRICTED CASH — END OF PERIOD	$ 169,365	$ 58,532	$ 15,341
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid for interest	$ 11,161	$ 3,925	$ 3,310
Cash paid for taxes	$ —	$ 1	$ —
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Fair value of common stock warrants reclassed from liability to additional paid-in capital upon exercise	$ 1,197	$ 274	$ —
Transfer of property and equipment from inventory	$ 2,247	$ 125	$ 117
Purchase of property and equipment in accounts payable and accrued expenses	$ 157	$ 96	$ 193
Offering costs included in accounts payable and accrued expenses	$ 168	$ —	$ 189

The accompanying notes are an integral part of these consolidated financial statements.

1. Background and Organization

ViewRay, Inc., or ViewRay or the Company, and its wholly-owned subsidiary ViewRay Technologies, Inc., designs, manufactures and markets MRIdian, an MR Image-Guided radiation therapy system to simultaneously image and treat cancer patients.

Since inception, ViewRay Technologies, Inc. has devoted substantially all of its efforts towards research and development, initial selling and marketing activities, raising capital and the manufacturing, shipment and installation of MRIdian systems. In May 2012, ViewRay Technologies, Inc. was granted clearance from the FDA, to sell MRIdian with Cobalt-60. In November 2013, ViewRay Technologies, Inc. received its first clinical acceptance of a MRIdian with Cobalt-60 at a customer site, and the first patient was treated with that system in January 2014. ViewRay Technologies, Inc. has had the right to affix the CE mark to MRIdian with Cobalt-60 in the European Economic Area since November 2014. In September 2016, the Company received the rights to affix the CE mark to MRIdian Linac, and in February 2017, the Company received 510(k) clearance from the FDA to market MRIdian Linac.

The Company's consolidated financial statements have been prepared on the basis of the Company continuing as a going concern for a reasonable period of time. The Company's principal sources of liquidity are cash flows from public and private shares offerings and available borrowings under its term loan agreement, as well as cash receipts from its sales of MRIdian systems. These have historically been sufficient to meet working capital needs, capital expenditures, and debt service obligations. During the year ended December 31, 2018, the Company incurred a net loss from operations of $76.4 million and used cash in operations of $122.2 million. The Company believes that its existing cash balance of $167.4 million as of December 31, 2018, together with anticipated cash proceeds from sales of MRIdian systems will be sufficient to provide liquidity to fund its operations for at least the next 12 months.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in conformity with U.S. GAAP, and pursuant to the rules and regulations of the Securities and Exchanges Commission, or SEC. The consolidated financial statements include the accounts of ViewRay, Inc. and its wholly-owned subsidiary, ViewRay Technologies, Inc. All inter-company accounts and transactions have been eliminated in consolidation.

Effective January 1, 2018, the Company adopted Accounting Standards Codification Topic 606, or ASC 606, *Revenues from Contracts with Customers,* by using the full retrospective method. The adoption of ASC 606 has no impact on the Company's prior period financial statements. Please see the Company's "Revenue Recognition" policy section below for further information and related disclosures.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported and disclosed in the consolidated financial statements and accompanying notes. Such estimates include, but are not limited to, allocation of revenue to multiple performance obligations within an arrangement, inventory write-downs to reflect net realizable value, assumptions used in the valuation of stock-based awards and warrant liability, and valuation allowances against deferred tax assets. Actual results could differ from these estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The Company deposits its cash primarily in checking and money market accounts.

Restricted Cash

At December 31, 2018 and 2017, the Company had an aggregate of $0.9 million of outstanding letters of credit related to its operating leases and its contractual obligations with distributors and customers. The letters of credit are collateralized by a restricted cash deposit account, which is presented as part of noncurrent assets on the balance sheets because the Company is not certain when the restriction will be lifted on the collateralized letters of credit. At December 31, 2018, and 2017, no amounts were drawn on the letters of credit.

The restricted cash balance as of December 31, 2018 and 2017 also includes collateral of $1.0 million and $0.2 million, respectively, for credit card accounts.

Concentration of Credit Risk, Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. Cash and cash equivalents are deposited in checking and money market accounts with various financial institutions. At times, cash balances may be in excess of the amounts insured by the Federal Deposit Insurance Corporation. Management believes the financial risk associated with these balances is minimal and has not experienced any losses to date. The Company performs periodic credit evaluations of its customers' financial condition and generally requires deposits from its customers. The Company's accounts receivable were derived from billings to customers. The Company's customers representing greater than 10% of accounts receivable or revenue for the periods presented were as follows:

	Revenue			Accounts Receivables	
	Year Ended December 31,			December 31,	
Customers	2018	2017	2016	2018	2017
Customer A				23%	
Customer B				22%	
Customer C				19%	
Customer D			23%	16%	
Customer E				15%	
Customer F		16%			24%
Customer G			25%		
Customer H		17%			
Customer I		17%			
Customer J		16%			
Customer K		14%			16%
Customer L		10%			
Customer M					36%
Customer N			47%		

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, rapid technological change, continued acceptance of MRIdian, competition from substitute products and larger companies, protection of proprietary technology, ability to maintain distributor relationships and dependence on key individuals. Furthermore, new products to be developed by the Company require approval from the FDA or other international regulatory agencies prior to commercial sales. There can be no assurance that the Company's future products will receive the necessary clearances.

The Company relies on a concentrated number of suppliers to manufacture essentially all of the components used in MRIdian. The Company's suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to comply with applicable regulations, including the FDA's Quality System Regulation, equipment malfunction and environmental factors, any of which could delay or impede our ability to meet demand.

Accounts Receivables and Allowance for Doubtful Accounts

Accounts receivable are recorded at the invoiced amount, net of any allowance for doubtful accounts, and do not bear interest. The allowance for doubtful accounts, if any, is based on the assessment of the collectability of customer accounts.

There was no allowance for doubtful accounts recorded at December 31, 2018 and 2017.

Fair Value of Financial Instruments

Financial instruments consist of cash and cash equivalents, accounts receivable, restricted cash, prepaid expenses and other current assets, accounts payable, accrued liabilities, warrant liability and long-term debt. Cash equivalents are stated at amortized cost, which approximates fair value at the balance sheet dates, due to the short period of time to maturity. Accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities are stated at their carrying value, which approximates fair value due to the short time to the expected receipt or payment date. The warrant liability is carried at fair value. The carrying amount of the Company's long-term debt approximates its fair value as the stated interest rate approximates market rates currently available to the Company.

Inventory and Deposits on Purchased Inventory

Inventory consists of purchased components for assembling MRIdian systems and other direct and indirect costs associated with MRIdian system installation. Inventory is stated at the lower of cost or net realizable value. All inventories expected to be placed in service during the normal operating cycle of the Company for the delivery and assembly of MRIdian systems, including items expected to be on hand for more than one year, are classified as current assets.

The Company reduces the carrying value of its inventory for the difference between cost and net realizable value and records a charge to cost of product revenues. The Company recorded an inventory lower of cost and net realizable value adjustment of $0.3 million, $0.9 million and $1.9 million during the years ended December 31, 2018, 2017 and 2016, respectively.

The Company records inventory items which have been paid for but not yet received and for which title has not yet transferred to the Company as deposits on purchased inventory. Deposits on purchased inventory are included within current assets as the related inventory items are expected to be received and used in MRIdian systems within the Company's normal operating cycle. The Company assesses the recoverability of deposits on purchased inventory based on credit assessments of the vendors and their history supplying these assets. At December 31, 2018, the Company did not have any instances whereby deposits for purchased inventory were written off or the purchased inventory was not delivered.

Shipping and Handling Costs

Shipping and handling costs for product shipments to customers are included in cost of product revenue. Shipping and handling costs incurred for inventory purchases are capitalized in inventory and expensed in cost of product revenue.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is computed over the estimated useful lives, ranging from two to 15 years, of the related assets using the straight-line method. Acquired software is recorded at cost. Amortization of acquired software generally occurs over three years using the straight-line method. Leasehold improvements are amortized on a straight-line basis over the shorter of the useful life or term of the lease. Demonstration units, which are the Company products used for demonstration purpose for customers and/or potential customers, and generally not intended to be sold, are amortized using the straight-line method.

Depreciation and amortization periods for property and equipment are as follows:

Property and Equipment	Estimated Useful Life
Prototype	2 years
Machinery and equipment	3 – 15 years
Furniture and fixture	5 – 10 years
Software	3 years
Leasehold improvements	Lesser of estimated useful life or remaining lease term

Asset Retirement Obligation

In connection with a lease agreement entered into in October 2015, the Company has a legal obligation to remove long-lived assets constructed on the leased property and to restore the leased property to its original condition. The Company records the fair value of the asset retirement obligation in the period in which it is incurred. The fair value is measured based upon the present value of the expected future payments at inception and remeasured upon the extension of the lease agreement. The liability is accreted to its present value each period and the capitalized cost is depreciated over the remaining lease term. Accretion expense is calculated by applying the effective interest rate to the carrying amount of the liability at the beginning of each period. The effective interest rate is the credit-adjusted risk-free rate applied when the liability was initially measured at inception and remeasured upon the lease extension.

At December 31, 2018, the Company had outstanding asset retirement obligations of $192,000, which was included in other long-term liabilities in the accompanying consolidated balance sheets. For the years ended December 31, 2018, 2017 and 2016, the Company recognized accretion expenses of $33,000, $40,000 and $36,000 in the accompanying statements of operations and comprehensive loss.

Impairment of Long-Lived Assets

The Company reviews the recoverability of long-lived assets, including equipment, leasehold improvements, software and intangible assets when events or changes in circumstances occur that indicate that the carrying value of the asset may not be recoverable. The assessment of possible impairment is based on the ability to recover the carrying value of the assets from the expected future cash flows (undiscounted and without interest charge) of the related operations. If these cash flows are less than the carrying value of such assets, an impairment loss for the difference between the estimated fair value and carrying value is recorded. There was no impairment loss recognized during the years ended December 31, 2018, 2017 and 2016.

Revenue Recognition

The Company derives revenues primarily from the sale of MRIdian systems and related services as well as support and maintenance services on sold systems. The Company accounts for revenue contracts with customers by applying the requirements of ASC 606, which includes the following steps:

- Identification of the contract, or contracts, with a customer;
- Identification of the performance obligations in the contract
- Determination of the transaction price;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when, or as, the Company satisfies a performance obligation.

In all sales arrangements, revenues are recognized when control of the promised goods or services are transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to receive in exchange for those goods or services. For sales of MRIdian systems that the Company is required to install at the customer site, product revenue is recognized upon receipt of customer acceptance. For sales of MRIdian systems for which the Company is not responsible for installation; product revenue is recognized when the entire system is delivered and control of the system is transferred to the customer. For sales of the related support and maintenance services, a time-elapsed method is used to measure progress toward complete satisfaction of performance obligations and service revenue is recognized ratably over the service contract term, which is typically 12 months.

Arrangements with Multiple Performance Obligation

The Company frequently enters into sales arrangements that include multiple performance obligations. Such performance obligations mainly consist of (i) sale of MRIdian systems, which generally includes installation and

embedded software, and (ii) product support, which includes extended service and maintenance. For such arrangements, the Company allocates revenue to each performance obligation based on its relative standalone selling price. The standalone selling price, or SSP, is determined based on observable prices at which the Company separately sells the products and services. If an SSP is not directly observable, the Company will estimate the SSP considering market conditions or internally approved pricing guidelines related to the performance obligations.

Product Revenue

Product revenue is derived primarily from the sales of MRIdian system. The system contains both software and non-software components that together deliver essential functionality.

The Company's customer contracts generally call for on-site assembly of the system components and system integration. Once the system installation is completed, the Company performs a detailed demonstration with the customer showing that the MRIdian system meets the standard product specifications. After successful demonstration, the customer signs a document indicating customer's acceptance. For sales of MRIdian systems that the Company is required to install at the customer site, revenue recognition occurs when the customer acknowledges that the system operates in accordance with standard product specifications, the customer accepts the installed unit by signing the acceptance document and the control of the system is transferred to the customer.

Certain customer contracts with distributors do not require ViewRay installation at the ultimate user site, and the distributors typically perform the installation. For sales of MRIdian systems for which the Company is not responsible for installation, revenue recognition occurs when the entire system is delivered, which is when the control of the system is transferred to the customer.

Service Revenue

Service revenue is derived primarily from maintenance services. The maintenance and support service is a stand-ready obligation which is performed over the term of the arrangement and, as a result, service revenue is recognized ratably over the service period as the customers benefit from the service throughout the service period.

Distribution Rights Revenue

In December 2014, the Company entered into a distribution agreement with Itochu Corporation pursuant to which it appointed Itochu as its exclusive distributor for the promotion, sale and delivery of MRIdian products within Japan. In consideration of the exclusive distribution rights granted, the Company received $4.0 million, which was recorded as deferred revenue. Starting in August 2016, distribution rights revenue is recognized ratably over the remaining term of the distribution agreement of approximately 8.5 years. A time-elapsed method is used to measure progress because the control is transferred evenly over the remaining contractual period.

The following table presents revenue disaggregated by type and geography (in thousands):

	Years Ended December 31,		
U.S.	**2018**	**2017**	**2016**
Product	$ 32,265	$ 9,529	$ —
Service	1,966	1,977	1,066
Distribution rights	—	—	40
Total U.S. revenue	$ 34,231	$ 11,506	$ 1,106
Outside of U.S. ("OUS")			
Product	$ 44,361	$ 20,929	$ 20,555
Service	1,895	1,132	438
Distribution rights	475	475	138
Total OUS revenue	$ 46,731	$ 22,536	$ 21,131
Total			
Product	$ 76,626	$ 30,458	$ 20,555
Service	3,861	3,109	1,504
Distribution rights	475	475	178
Total revenue	$ 80,962	$ 34,042	$ 22,237

Contract Balances

The timing of revenue recognition, billings and cash collections results in short-term and long-term trade receivables, customer deposits, deferred revenues and deferred cost of revenue on the consolidated balance sheets.

Trade receivables are recorded at the original invoiced amount, net of an estimated allowance for doubtful accounts. Trade credit is generally extended on a short-term basis. The Company occasionally provides for long-term trade credit for its maintenance services so that the period between when the services are rendered to its customers and when the customers pay for that service is within one year. Thus, the Company's trade receivables do not bear interest or contain a significant financing component. Long-term trade receivables of $0.4 million were reported within other assets in the consolidated balance sheets at December 31, 2018. These amounts are billed in accordance with the terms of the customer contracts to which they relate and are expected to be collected three to four years from the date of invoice as the underlying maintenance services are rendered. At times, billing occurs subsequent to revenue recognition, resulting in an unbilled receivable which represents a contract asset. This contract asset is recorded as an unbilled receivable and reported as part of accounts receivable on the consolidated balance sheets. The Company had no long-term trade receivables at December 31, 2017.

Trade receivables are periodically evaluated for collectability based on past credit history of the respective customers and their current financial condition. Changes in the estimated collectability of trade receivables are included in the results of operations for the period in which the estimate is revised. Trade receivables that are deemed uncollectible are offset against the allowance for doubtful accounts. The Company generally does not require collateral for trade receivables. There was no allowance for doubtful accounts recorded at December 31, 2018 and 2017.

Customer deposits represent payments received in advance of system installation. For domestic and international sales, advance payments received prior to inventory shipments and customer acceptance are recorded as customer deposits. Advance payments are subsequently reclassified to deferred revenue upon inventory shipment when the title and risk of loss of inventory items transfer to customers. All customer deposits, including those that are expected to be a deposit for more than one year, are classified as current liabilities based on consideration of the Company's normal operating cycle (the time between acquisition of the inventory components and the final cash collection from customers on these inventory components) which is in excess of one year.

Deferred revenue consists of deferred product revenue and deferred service revenue. Deferred product revenue arises from timing differences between the fulfillment of contract obligations and satisfaction of all revenue recognition criteria consistent with the Company's revenue recognition policy. Deferred service revenue results from the advance billing for services to be delivered over a period of time. Deferred revenues expected to be realized within one year or the Company's normal operating cycle are classified as current liabilities.

Deferred cost of revenue consists of cost for inventory items that have been shipped with title and risk of loss transferred to the customer, but the customer acceptance has not yet been received. Deferred cost of revenue is included as part of current assets as the corresponding deferred product revenue is expected to be realized within one year or the Company's normal operating cycle.

During the years ended December 31, 2018, 2017 and 2016, the Company recognized $19.9 million, $6.6 million and $0.6 million, respectively, in revenue that was included in the deferred revenue balance at the beginning of each reporting period.

Variable Consideration

The Company records revenue from customers in an amount that reflects the transaction price it expects to be entitled to after transferring control of those goods or services. The Company estimates the transaction price at contract inception, including any variable consideration, and updates the estimate each reporting period for any changes. During the year ended December 31, 2018, one of the contracts contained variable consideration, which is attributed to an asserted penalty that the Company is disputing related to a system installation for one customer. The Company estimated the variable consideration based on the best information available to management and applied the most likely amount method to estimate the transaction price. The transaction price, which includes variable consideration reflecting the impact of the asserted penalty dispute, may be subject to constraint and is included in the net revenues only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period when the uncertainty is subsequently resolved. The net transaction price after reducing the variable consideration was then proportionally allocated to all the distinct performance obligations

in the transaction. The Company will update the estimate of the variable consideration at each reporting period until the uncertainty is resolved.

Practical Expedients Election

As part of the Company's adoption of ASC 606, the Company elected to use the practical expedient to expense costs to obtain a contract as incurred when the amortization period would have been one year or less. Such costs include the Company's internal sales force compensation program.

Research and Development Costs

Expenditures, including payroll, contractor expenses and supplies, for research and development of products and manufacturing processes are expensed as incurred.

Software development costs incurred subsequent to establishing technological feasibility are capitalized through the general release of MRIdian systems that contain the embedded software elements. Technological feasibility is demonstrated by the completion of a working model. The Company has not capitalized any software development costs at December 31, 2018 or 2017, since the costs incurred subsequent to achieving technological feasibility and completing the research and development for the software components were immaterial.

Stock-Based Compensation

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options. The Black-Scholes option-pricing model requires the use of highly subjective assumptions, including the options' expected term and the price volatility of the underlying stock. The fair value of restricted stock units, or RSUs, is based on the closing market price of the Company's common stock on the grant date. The fair value of the portion of the award that is ultimately expected to vest is recognized as compensation expense over the awards' requisite service periods in the consolidated statements of operations and comprehensive loss. The Company attributes the value of stock-based compensation to expense using the straight-line method.

Deferred Commissions

Deferred commissions are the direct and incremental costs directly associated with the MRIdian system contracts with customers, which primarily consist of sales commissions to our direct sales force. The commissions are deferred and expensed in proportion to the revenue recognized upon the acceptance of the MRIdian system. At December 31, 2018 and 2017, the Company had $3.9 million and $3.5 million deferred commissions recorded as part of prepaid expenses and other current assets on the consolidated balance sheets.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax expense or benefit is the result of changes in the deferred tax assets and liabilities. Valuation allowances are established when necessary to reduce deferred tax assets where, based upon the available evidence, management concludes that it is more-likely-than not that the deferred tax assets will not be realized. Because of the uncertainty of the realization of the deferred tax assets, the Company has recorded a full valuation allowance against its net deferred tax assets.

In evaluating the ability to recover its deferred income tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. In the event the Company was to determine that it would be able to realize its deferred income tax assets in the future in excess of their net recorded amount, it would make an adjustment to the valuation allowance which would reduce the provision for income taxes.

Reserves are provided for tax benefits for which realization is uncertain. Such benefits are only recognized when the underlying tax position is considered more likely than not to be sustained on examination by a taxing authority, assuming they possess full knowledge of the position and facts. It is the Company's policy to include any penalties and interest related to income taxes in its income tax provision; however, the Company currently has no penalties or

interest related to income taxes. The earliest year that the Company is subject to examination is the year ended December 31, 2004.

Warrant Liability

Certain warrants to purchase common stock provide for cash settlement in the event of a change in control, and are recorded as liabilities on the balance sheets at fair value upon issuance (see Note 12). These warrants are subject to re-measurement to fair value at each balance sheet date. Any changes in fair value are recognized in the consolidated statements of operations and comprehensive loss as other expense, net. Upon exercise or expiration of the warrants, the related warrant liability will be reclassified to additional paid-in capital.

Net Loss per Share

The Company's basic net loss per share is calculated by dividing net loss by the weighted-average number of shares of common stock outstanding for the period. Contingently issuable shares are included in the computation of basic net loss per share as of the date that all necessary conditions have been satisfied and issuance of the shares is no longer contingent. The diluted net loss per share is computed by giving effect to all potential common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, stock options, restricted stock units and warrants to purchase common stock are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share as their effect is anti-dilutive.

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update, or ASU, No. 2016-02, *Leases* and issued subsequent amendments to the initial guidance in September 2017 within ASU 2017-13, in January 2018 within ASU 2018-01 and in July 2018 within ASU 2018-11 (collectively, Topic 842). Topic 842 supersedes Topic 840, Leases, and requires lessees to recognize on their balance sheets all leases, with the exception of short-term leases, as a right-of-use asset and a corresponding lease liability measured at the present value of the lease payments. The new standard also requires expanded disclosures regarding leasing arrangements. Topic 842 is effective for fiscal years beginning after December 15, 2018, and interim periods therein. Early adoption is permitted. The Company is substantially complete with its evaluation of the effect that the adoption of Topic 842 will have on its consolidated financial statements. Upon adoption on January 1, 2019, the Company expects to recognize the right-of-use assets and lease liabilities totaling approximately $11.9 million and $12.6 million, respectively, to reflect the present value of remaining lease payments under existing lease arrangements. The difference between the leased assets and lease liabilities represents the existing deferred rent liabilities balance, resulting from historical straight-lining of operating leases, which will be effectively reclassified upon adoption to reduce the measurement of the leased assets. While the recognition of such assets and liabilities will impact the consolidated balance sheets, the Company does not expect a material impact on its consolidated statements of operations and comprehensive loss or cash flows. The Company will apply the modified retrospective transition approach and recognize a cumulative effect adjustment to the opening balance of retained earnings on the effective date and will not recast prior periods. As permitted by the standard, the Company will elect the transition practical expedient package, which among other things, allows the carryforward of historical lease classifications.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, and interim periods therein. Early adoption is permitted. The Company does not expect the adoption will have a material impact on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework- Changes to the Disclosure Requirements for Fair Value Measurement,* to modify the disclosure requirements on fair value measurements in Topic 820. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019, and interim periods therein. The Company is allowed to early adopt either the entire standard or only the provisions that eliminate or modify the requirements of Topic 820. The Company is evaluating the impact of this update on its consolidated financial statements.

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued ASC 606. Under the standard, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. Effective January 1, 2018, the Company adopted the requirements of ASC 606 using the full retrospective method. The adoption had no impact on the prior period financial statements, and the related disclosures required by the new standard have been updated in the "Significant Accounting Policies" section above.

On January 1, 2018, the Company adopted ASU No. 2016-15*, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* and ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* on a retrospective basis. The adoption of ASU 2016-15 did not have a material impact on the Company's consolidated statements of cash flows and related disclosures. Under ASU 2016-18, restricted cash and restricted cash equivalent amounts are presented along with cash and cash equivalents when reconciling the total beginning and ending amounts shown on the statements of cash flows. The Company reflected the impact of ASU 2016-18 to the comparative prior periods which resulted in an increase of $1.1 million in the beginning and ending cash, cash equivalents and restricted cash balances for the prior periods presented, except for the beginning cash, cash equivalents and restricted cash for the fiscal year 2016 with an increase of $0.9 million.

In May 2017, the FASB issued ASU No. 2017-09*, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*, which provides clarified guidance on applying modification accounting to changes in the terms or conditions of a share-based payment award. The Company adopted ASU 2017-09 on January 1, 2018, and the adoption did not have a material impact on its consolidated financial statements and related disclosures.

In the first quarter of 2018, the Company adopted ASU No. 2018-05, *Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118,* which included amendments to expand income tax accounting and disclosure guidance pursuant to SEC Staff Accounting Bulletin No. 118, or SAB 118, issued by the SEC in December 2017. SAB 118 provides guidance on accounting for the income tax effects of the Tax Reform Act. Refer to Note 14, Income Taxes, for more information and disclosures related to this amended guidance.

3. Balance Sheet Components

Property and Equipment, Net

Property and equipment consisted of the following (in thousands):

	December 31,	
	2018	2017
Prototype	$ 12,425	$ 11,929
Machine and equipment	12,654	7,831
Leasehold improvements	4,600	4,438
Furniture and fixtures	636	558
Software	1,250	1,142
Construction in progress	148	—
Property and equipment, gross	31,713	25,898
Less: accumulated depreciation and amortization	(17,755)	(14,334)
Property and equipment, net	$ 13,958	$ 11,564

Depreciation and amortization expense related to property and equipment was $3.4 million, $2.2 million and $1.6 million during the years ended December 31, 2018, 2017 and 2016, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2018	2017
Accrued payroll and related benefits	$ 5,047	$ 3,944
Accrued accounts payable	3,626	2,671
Payroll withholding tax, sales and other tax payable	782	149
Accrued legal and accounting	360	322
Other	168	121
Total accrued liabilities	$ 9,983	$ 7,207

Deferred Revenue

Deferred revenue consisted of the following (in thousands):

	December 31,	
	2018	2017
Deferred revenue:		
Product	$ 9,623	$ 18,861
Services	6,981	1,182
Distribution rights	2,871	3,346
Total deferred revenue	19,475	23,389
Less: current portion of deferred revenue	(13,731)	(20,151)
Noncurrent portion of deferred revenue	$ 5,744	$ 3,238

Other Long-Term Liabilities

Other long-term liabilities consisted of the following (in thousands):

	December 31,	
	2018	2017
Accrued interest, noncurrent portion	$ —	$ 6,218
Deferred rent, noncurrent portion	628	167
Other	192	985
Total other-long term liabilities	$ 820	$ 7,370

4. Fair Value of Financial Instruments

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The assets' or liabilities' fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company's financial instruments that are carried at fair value mainly consist of Level 1 assets and Level 3 liabilities. Level 1 assets include highly liquid bank deposits and money market funds, which were not material at December 31, 2018 and 2017. Level 3 liabilities that are measured on a recurring basis relate to the 2017 and 2016 Placement Warrants, as described in Note 12. Placement warrant liabilities are valued using the Black-Scholes option-pricing model. Generally, increases (decreases) in the fair value of the underlying stock, estimated term and volatility would result in a directionally similar impact to the fair value of the warrant (see Note 12). During the year ended December 31, 2018 and 2017, warrants to purchase 385,627 shares and 34,493 shares of common stock were exercised and the aggregate fair value upon exercise of $1.2 million and $0.3 million, respectively, was reclassified from liabilities to additional paid-in-capital. There were no warrants exercised during the year ended December 31, 2016.

The gains and losses from re-measurement of Level 3 financial liabilities are recorded as part of other income (expense), net in the consolidated statements of operations and comprehensive loss. During the year ended December 31, 2018 and 2017, the Company recorded a gain of $9.4 million and a loss of $16.6 million, respectively, related to the change in fair value of the 2017 and 2016 Placement Warrants. There have been no transfers between Level 1, Level 2 and Level 3 in any periods presented.

The following table sets forth the fair value of the Company's financial liabilities by level within the fair value hierarchy (in thousands):

	At December 31, 2018			
	Level 1	Level 2	Level 3	Total
2017 Placement Warrants Liability	$ —	$ —	$ 7,115	$ 7,115
2016 Placement Warrants Liability	$ —	$ —	$ 4,729	$ 4,729
Total Warrant Liability	$ —	$ —	$ 11,844	$ 11,844

	At December 31, 2017			
	Level 1	Level 2	Level 3	Total
2017 Placement Warrants Liability	$ —	$ —	$ 12,487	$ 12,487
2016 Placement Warrants Liability	$ —	$ —	$ 9,933	$ 9,933
Total Warrant Liability	$ —	$ —	$ 22,420	$ 22,420

The following table summarizes the changes in the fair value of the Company's Level 3 financial liabilities (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Fair value, beginning of period	$ 22,420	$ 2,723	$ —
Issuance of 2016 Placement Warrants	—	—	2,726
Issuance of 2017 Placement Warrants	—	3,373	—
Change in fair value of Level 3 financial liabilities	(9,379)	16,598	(3)
Fair value of 2016 Placement Warrants at exercise	(1,187)	(200)	—
Fair value of 2017 Placement Warrants at exercise	(10)	(74)	—
Fair value, end of period	$ 11,844	$ 22,420	$ 2,723

5. Debt

CRG Term Loan

In June 2015, ViewRay Technologies, Inc. entered into a term loan agreement, or the CRG Term Loan, with Capital Royalty Partners II L.P., Capital Royalty Partners II – Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P. or together with their successors by assignment, CRG, for up to $50.0 million of which $30.0 million was made available to the Company upon closing with the remaining $20.0 million to be available on or before June 30, 2016 upon the achievement of certain milestones. The Company drew down the first $30.0 million on the closing date. The CRG Term Loan had a maturity date of June 30, 2020

and bears cash interest at a rate of 12.5% per annum to be paid quarterly during the interest-payment-only period of three years. In April 2017, the CRG Term Loan was amended to allow for interest-payment-only until March 31, 2020. During the interest-payment-only period, the Company had the option to elect to pay only 8% of the 12.5% per annum interest in cash, and the remaining 4.5% of the 12.5% per annum interest as compounded interest, or deferred payment in-kind interest, added to the aggregate principal amount of the CRG Term Loan. Principal payment and any deferred payment in-kind interest would be paid on maturity date.

The CRG Term Loan was subject to a prepayment penalty of: 3% on the outstanding balance during the first 12 months following the funding of the Term Loan; 2% on the outstanding balance after year 1 but on or before year 2; 1% on the outstanding balance after year 2 but on or before year 3; and 0% on the outstanding loan if prepaid after year 3 thereafter until maturity. The CRG Term Loan was also subject to a facility fee of 7% based on the total outstanding principal and payment in-kind interest, which was payable on the maturity date. All direct financing costs were accounted for as a discount on the CRG Term Loan and were amortized to interest expense during the term of the loan using the effective interest method. The CRG Term Loan was subject to financial covenants and was collateralized by essentially all assets of the Company and limits the Company's ability with respect to additional indebtedness, investments or dividends, among other things, subject to customary exceptions.

In March 2016, the Company amended the agreement with regard to the conditions for borrowing the remaining $20.0 million under the CRG Term Loan if certain product and service revenue amounts were achieved. In May 2016, the Company drew down an additional $15.0 million under the CRG Term Loan.

In April and October 2017, and in February 2018, the Company executed three amendments, which allowed the Company to borrow the remaining $5.0 million through June 30, 2017, included an additional $15.0 million borrowing capacity available through December 31, 2017, extended the interest only and payment in-kind period, decreased the combined 2016 and 2017 revenue covenant, and increased the facility fee by 1.75%. The Company did not draw down any amounts under these amendments and they have since expired.

In December 2018, the Company paid off its outstanding obligations under the CRG Term Loan using the proceeds from the SVB Term Loan.

SVB Term Loan

In December 2018, the Company entered into a term loan agreement, or the SVB Term Loan, with Silicon Valley Bank, for a principal amount of $56.0 million. The SVB Term Loan has a maturity date of December 1, 2023 and bears interest at a rate of 6.30% per annum to be paid monthly over the term of the loan. Beginning on December 1, 2020 (or June 1, 2021, if the Company achieves a trailing twelve-month revenue of at least a specified amount and elects to apply such later date), the Company will make thirty-six equal monthly payments of principal (or thirty equal payments, if the Company so elects). In addition, upon repayment of the SVB Term Loan in full, the Company will make a final payment equal to 3.15% of the original aggregate principal amount of the SVB Term Loan.

The Company used the proceeds of the SVB Term Loan and cash on hand to repay in full its outstanding obligations under the then outstanding CRG Term Loan and to pay fees and expenses related thereto. The Company accounted for the termination of the CRG Term Loan as a debt extinguishment and recorded a debt extinguishment loss of $2.4 million from the difference between the net carrying amount of debt and the amount paid. The debt extinguishment loss includes $0.3 million in write-off of unamortized debt discount and debt issuance costs associated with the CRG Term Loan.

The Company received net proceeds of $55.4 million after related legal and consulting fees totaling $0.6 million. Such fees are accounted for as debt discount and issuance costs and presented as a direct deduction from the carrying amount of debt on the Company's consolidated balance sheets. Debt discount, issuance costs and the final payment are amortized or accreted as interest expense over the term of the loan using the effective interest method.

The SVB Term Loan is secured by substantially all assets of the Company, except that the collateral does not include any intellectual property held by the Company, provided, however, the collateral shall include all accounts and proceeds of such intellectual property.

The SVB Term Loan contains customary representations and warranties and customary affirmative and negative covenants applicable to the Company and its subsidiaries, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness, dividends and other distributions and transactions with affiliates. The SVB Term Loan also contains financial covenants that require the

Company to maintain a minimum cash balance in accounts maintained at Silicon Valley Bank or one of its affiliates or else comply with a liquidity ratio and/or a minimum revenue target.

The SVB Term Loan includes standard events of default, including, among other things, subject in certain cases to customary grace periods, thresholds and notice requirements, the Company's failure to fulfill its obligations under the SVB Term Loan or the occurrence of a material adverse change in the Company's business, operations, or condition (financial or otherwise). In the event of default by the Company under the SVB Term Loan, Silicon Valley Bank would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which the Company may be required to repay all amounts then outstanding under the SVB Loan, which could harm the Company's financial condition.

The Company's scheduled future payments on the SVB Term Loan at December 31, 2018 are as follows (in thousands):

Year Ended December 31,	
2019	$ -
2020	1,555
2021	18,667
2022	18,667
2023	17,111
Total future principal payments	56,000
Less: unamortized debt discount	(636)
Carrying value of long-term debt	55,364
Less: current portion	—
Long-term portion	$ 55,364

6. Commitments and Contingencies

Operating Leases

The Company leases office space in Oakwood Village, Ohio and Mountain View, California under noncancelable operating lease agreements. The Company leases and occupies approximately 19,800 square feet of office space in Oakwood Village, Ohio, which expires on October 31, 2019, with an option to extend the term through October 31, 2021.

In June 2014, the Company entered into an office lease agreement to lease approximately 25,500 square feet of office space located in Mountain View, California, which expires on November 30, 2019. In June 2018, the Company entered into an amendment to extend the term of the lease agreement through July 31, 2025.

In April 2018, the Company entered into a lease agreement to lease approximately 24,600 square feet of additional office space located in Mountain View, California. The lease commenced in December 2018, and will expire on the seventh anniversary of the commencement date, and the Company has the option to extend the term of the lease for a period of up to five years.

At December 31, 2018, the future minimum payments for the operating leases are as follows (in thousands):

Year Ended December 31,	
2019	$ 2,070
2020	2,353
2021	2,424
2022	2,496
2023	2,571
Thereafter	4,532
Total future minimum payments	$ 16,446

Rent expense incurred under operating leases was $1.4 million, $1.3 million and $1.3 million in each of the years ended December 31, 2018, 2017 and 2016, respectively.

Legal Proceedings

In the normal course of business, the Company may become involved in legal proceedings. The Company will accrue a liability for such matters when it is probable that a loss has been incurred and the amount can be reasonably estimated. When only a range of possible losses can be established, the most probable amount in the range is accrued. If no amount within this range is a better estimate than any other amount within the range, the minimum amount in the range is accrued. At December 31, 2018, and 2017, the Company was not involved in any material legal proceedings.

Purchase Commitments

At December 31, 2018 and 2017, the Company had no outstanding firm purchase commitments.

7. Licensing Agreement

In December 2004, ViewRay Technologies, Inc. entered into a licensing agreement with the University of Florida Research Foundation, Inc., or UFRF, whereby UFRF granted the Company a worldwide exclusive license to certain of UFRF's patents in exchange for 33,652 shares of common stock and a royalty from sales of products developed and sold by the Company utilizing the licensed patents. ViewRay Technologies, Inc. met all of the product development and commercialization milestones at December 31, 2013, and started to make quarterly royalty payments in 2014. Royalty payments are based on 1% of net sales, defined as the amount collected on sales of licensed products and/or licensed processes after deducting trade and/or quantity discounts, credits on returns and allowances, outbound transportation costs paid and sales tax. Minimum quarterly royalty payments of $50 thousand commenced with the quarter ended March 31, 2014, and are payable in advance. Minimum royalties paid in any calendar year are credited against earned royalties for such calendar year. The royalty payments continue until the earlier of (i) the date that no licensed patents remain enforceable or (ii) once the payment of earned royalties cease for more than four consecutive calendar quarters. Royalty expenses based on 1% of net sales were $0.6 million, $0.3 million and $0.2 million during the years ended December 31, 2018, 2017 and 2016, respectively, and were recorded as product cost of revenue in the consolidated statements of operations and comprehensive loss. The minimum royalty payments in excess of 1% of net sales were $30 thousand, $25 thousand and $57 thousand during the years ended December 31, 2018, 2017 and 2016, respectively, and were recorded as general and administrative expenses in the consolidated statements of operations and comprehensive loss.

8. Distribution Agreement

In December 2014, the Company entered into a distribution agreement with Itochu Corporation, or Itochu, a Japanese entity, pursuant to which the Company appointed Itochu as its exclusive distributor for the sale and delivery of its MRIdian products within Japan. The exclusive distribution agreement has an initial term of 10 years from December 2014, and contains features customary in such distribution agreements. Under this distribution agreement, the Company will supply its products and services to Itochu based upon the Company's then-current pricing. In consideration of the exclusive distribution rights granted, ltochu agreed to pay a distribution fee of $4.0 million in three installments: (i) the first installment of $1.0 million was due upon execution of the distribution agreement; (ii) the second installment of $1.0 million was due within 10 business days following submission of the application for regulatory approval of the Company's product to the Japan regulatory authority; and (iii) the final installment of $2.0 million was due within 10 business days following receipt of approval for the Company's product from the Japanese Ministry of Health, Labor and Welfare. The first and second installments of $2.0 million in aggregate were received in December 2014 and December 2015, respectively. In August 2016, the Company received the third and final $2.0 million installment upon the receipt of regulatory approval to market MRIdian in Japan. The entire $4.0 million distribution fee received was reclassified to deferred revenue as it was no longer refundable. In August 2016, the Company started recognizing distribution rights revenue ratably over the remaining term of the exclusive distribution agreement of approximately 8.5 years. The distribution rights revenue was $0.5 million, $0.5 million and $0.2 million during the years ended December 31, 2018, 2017 and 2016, respectively.

9. Equity Financing

Public Offering of Common Stock

On August 14, 2018, the Company entered into an underwriting agreement with Morgan Stanley & Co. LLC and Jefferies LLC, as representatives of several underwriters, or the "Underwriters", in connection with the issuance and sale of 16,216,217 shares of the Company's common stock at a public offering price of $9.25 per share. In addition, the Company granted the Underwriters a 30-day option to purchase up to 2,432,432 additional shares of common stock on the same terms, which the Underwriters exercised in full. The Company completed the offering on August 17, 2018 and received aggregate net proceeds of approximately $161.9 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

Direct Registered Offerings

In October 2017, the Company entered into securities purchase agreements pursuant to which it sold 8,382,643 shares of its common stock for total gross proceeds of $49.9 million, or the October 2017 Direct Registered Offering. The October 2017 Direct Registered Offering was closed on October 25, 2017.

In February 2018, the Company entered into a securities purchase agreement pursuant to which it sold (i) 4,090,000 shares of its common stock; (ii) 3,000,581 shares of its Series A convertible preferred stock and (iii) warrants to purchase 1,418,116 shares of its common stock, or the 2018 Offering Warrants, for total gross proceeds of $59.1 million, or the March 2018 Direct Registered Offering. The March 2018 Direct Registered Offering was closed on March 5, 2018. The 2018 Offering Warrants have an exercise price of $8.31 per share, became exercisable upon issuance and expire in March 2025. All outstanding shares of Series A convertible preferred stock were converted into common stock at a conversion ratio of 1:1 on April 19, 2018 (see Note 11).

Private Placements

In September 2016, the Company completed the final closing of a private placement offering, or the 2016 Private Placement, through which it sold (i) 4,602,506 shares of its common stock and (ii) warrants that provide the warrant holders the right to purchase 1,380,745 shares of common stock, or the 2016 Placement Warrants, and raised total gross proceeds of $13.8 million. The 2016 Placement Warrants have an exercise price of $2.95 per share, are exercisable at any time at the option of the holder and expire seven years from the date of issuance.

In January 2017, the Company completed the final closing of a private placement offering, or the 2017 Private Placement, through which it sold (i) 8,602,589 shares of its common stock and (ii) warrants that provide the warrant holders the right to purchase 1,720,512 shares of common stock, or the 2017 Placement Warrants, and raised total gross proceeds of $26.1 million. The 2017 Placement Warrants have an exercise price of $3.17 per share, became exercisable in July 2017 and expire in January 2024.

At-The-Market Offering of Common Stock

In January 2017, the Company filed a shelf registration statement on Form S-3 with the SEC, which included a base prospectus covering the offering, issuance and sale of up to a maximum aggregate offering of $75.0 million of the Company's common stock, preferred stock, debt securities, warrants, purchase contracts and/or units. In January and April 2017, the Company agreed to sell up to a cumulative $50.0 million of its common stock in accordance with the terms of a sales agreement with FBR Capital Markets & Co., or FBR, pursuant to an at-the-market offering program in accordance with Rule 415(a)(4) under the Securities Act.

Under the at-the-market offering program, the Company sold an aggregate of 33,097 shares of its common stock at an average market price of $8.41 per share, resulting in aggregate gross proceeds of approximately $0.3 million for the year ended December 31, 2018; and sold an aggregate of 6,575,062 shares of its common stock at an average market price of $6.10 per share, resulting in aggregate gross proceeds of approximately $40.1 million for the year ended December 31, 2017.

In January 2019, the Company filed a registration statement with the SEC which covers the offering, issuance and sale of up to a maximum aggregate offering price of $250.0 million of our common stock, preferred stock, debt securities, warrants, purchase contracts and/or units, including up to $100.0 million of the Company's common shares pursuant to the Company's at-the-market offering program with FBR.

10. Common Stock Reserved for Issuance

The common stock reserved for future issuance at December 31, 2018 and 2017 was as follows:

	December 31,	
	2018	2017
Shares underlying outstanding stock options	11,603,708	8,592,747
Shares available for future stock option grants	1,908,626	969,783
Shares issuable upon settlement of restricted stock units outstanding	1,857,741	149,636
ESPP shares available for issuance	1,780,020	1,103,481
Warrants to purchase common stock	4,426,244	3,393,755
Total shares of common stock reserved	21,576,339	14,209,402

11. Convertible Preferred Stock

In March 2018, the Company issued 3,000,581 shares of Series A convertible preferred stock to an existing investor through the March 2018 Direct Registered Offering at a price of $8.31 per share (see Note 9). At the date of the financing, because the effective conversion rate of the preferred stock was less than the market value of the Company's common stock, a beneficial conversion feature of $2.7 million was recorded as a discount to the convertible preferred stock and an increase to additional paid in capital. Because the preferred stock was perpetual and convertible at the option of the holder at any time, the Company fully amortized the discount related to the beneficial conversion feature as a deemed dividend which was recognized as an increase to accumulated deficit and net loss attributable to common stockholders. Effective on April 19, 2018, all outstanding shares of Series A convertible preferred stock were converted into shares of common stock at a conversion ratio of 1:1. Further, in May 2018, the Company filed a Certificate of Elimination of the Series A Convertible Preferred Stock de-authorizing the 3,000,581 shares of Series A convertible preferred stock. The Company had no outstanding preferred stock as of December 31, 2018.

12. Warrants

Equity Classified Common Stock Warrants

In connection with a debt financing in December 2013, the Company issued warrants to purchase 128,231 shares of its common stock with an exercise price of $5.84 per share. These warrants are exercisable any time at the option of the holder until December 16, 2023. None of these warrants have been exercised to date and they all remained outstanding at December 31, 2018.

In connection with the merger of ViewRay, Inc. and ViewRay Technologies, Inc. in July 2015, or the Merger, in July and August 2015, the Company conducted a private placement offering as part of which the Company issued warrants, or the 2015 Placement Warrants, that provide the warrant holder the right to purchase 198,760 shares of common stock at an exercise price of $5.00 per share. The 2015 Placement Warrants are exercisable at any time at the option of the holder until the five-year anniversary of their date of issuance. During the year ended December 31, 2018, the Company issued 92,487 shares of its common stock upon the net exercise of 159,010 shares of the 2015 Placement Warrants. The remaining 39,750 shares of the 2015 Placement Warrants have not been exercised and remained outstanding at December 31, 2018.

In connection with the March 2018 Direct Registered Offering, the Company issued warrants to purchase 1,418,116 shares of common stock at an exercise price of $8.31 per share. The 2018 Offering Warrants became exercisable upon issuance and expire in March 2025. None of the 2018 Offering Warrants have been exercised to date and they all remained outstanding at December 31, 2018.

As separate classes of securities were issued in a bundled transaction, the gross proceeds from the March 2018 Direct Registered Offering of $59.1 million were allocated to common stock, Series A convertible preferred stock and the 2018 Offering Warrants based on their respective relative fair value upon issuance. The aggregate fair value

of the 2018 Offering Warrants of $7.4 million was estimated using the Black-Scholes option-pricing model with the following assumptions:

	Upon Issuance
Common Stock Warrants:	
Expected term (in years)	7.0
Expected volatility (%)	62.5%
Risk-free interest rate (%)	2.8%
Expected dividend yield (%)	0%

Liability Classified Common Stock Warrants

In connection with the 2017 and 2016 Private Placements, the Company issued the 2017 and 2016 Placement Warrants, that provide the warrant holder the right to purchase 1,720,512 and 1,380,745 shares of common stock. The 2017 and 2016 Placement Warrants contain protection whereby the warrant holders will have the right to receive cash in the amount equal to the Black-Scholes value of the warrants upon the occurrence of a change in control, as defined in the agreement. The 2017 and 2016 Placement Warrants were accounted for as a liability at the date of issuance and are adjusted to fair value at each balance sheet date, with the change in fair value recorded as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. The key terms and activity of the 2017 and 2016 Placement Warrants are summarized as follows:

	Issuance Date	Term	Exercise Price Per Share	Warrants Exercised during the Year Ended December 31, 2017	Warrants Outstanding at December 31, 2017	Warrants Exercised during the Year Ended December 31, 2018	Warrants Outstanding at December 31, 2018
2017 Placement Warrants	January 2017	7 years	$ 3.17	9,389	1,711,123	1,591	1,709,532
2016 Placement Warrants	August and September 2016	7 years	$ 2.95	25,104	1,355,641	225,026	1,130,615
Total				34,493	3,066,764	226,617	2,840,147

As separate classes of securities were issued in a bundled transaction, the gross proceeds of $26.1 million and $13.8 million from the 2017 and 2016 Private Placement were allocated first to the 2017 and 2016 Placement Warrants based on their fair value upon issuance, and the residuals were allocated to common stock. The fair value upon issuance of $3.4 million and $2.7 million were estimated using the Black-Scholes option-pricing model using the following assumptions:

	Upon Issuance	
	2017 Placement Warrants	2016 Placement Warrants
Expected term (in years)	7.0	7.0
Expected volatility (%)	62.9%	61.6%
Risk-free interest rate (%)	2.2%	1.4%
Expected dividend yield (%)	0%	0%

During the year ended December 31, 2018, the Company recorded a gain of $5.4 million and $4.0 million, respectively, related to the change in fair value of the 2017 and 2016 Placement Warrants. During the year ended December 31, 2017, the Company recorded a loss of $9.2 million and $7.4 million, respectively, related to the change in fair value of the 2017 and 2016 Placement Warrants. The fair value of the 2017 and 2016 Placement

Warrants at December 31, 2018 and 2017 was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions:

	2017 Placement Warrants		2016 Placement Warrants	
	December 31, 2018	December 31, 2017	December 31, 2018	December 31, 2017
Expected term (in years)	5.1	6.1	4.7	5.7
Expected volatility	60.8%	62.3%	60.9%	62.1%
Risk-free interest rate	2.5%	2.3%	2.5%	2.2%
Expected dividend yield	0%	0%	0%	0%

13. Stock-Based Compensation

The Company adopted the 2008 Stock Option and Incentive Plan, or the 2008 Plan, and the 2015 Equity Incentive Award Plan, or the 2015 Plan, providing for the issuance of stock-based compensation awards to its employees, officers, directors, advisors and consultants. With the establishment of the 2015 Plan, the Company no longer grants stock options under the 2008 Plan, and the shares available for future grants under the 2008 Plan were transferred to the 2015 Plan. In July 2018, the Company adopted the 2018 Equity Inducement Award Program, or the 2018 Plan. The operative terms of the 2018 Plan adhere to the terms and conditions of the 2015 Plan.

Only stock options were granted under the 2008 Plan. The 2015 Plan and the 2018 Plan provide for the grant of stock and stock-based awards including stock options, restricted stock awards, restricted stock units and stock appreciation rights.

Options granted pursuant to the 2008 Plan and the 2015 Plan may be either incentive stock options or non-statutory stock options. Options granted pursuant to the 2018 Plan are non-statutory stock options. Under the 2008 Plan, incentive stock options could only be granted to employees at an exercise price of no less than the fair value of the common stock on the grant date and non-statutory options may be granted to employees or consultants at an exercise price of no less than 85% of the fair value of the common stock on the grant date, as determined by the board of directors. Under the 2015 Plan and the 2018 Plan, for both incentive stock options and non-statutory options, the exercise price should not be less than the fair value of the common stock on the date of grant. Under the 2008 Plan, the 2015 Plan and the 2018 Plan, if, at the time of grant, the optionee is a 10% shareholder, owning stock representing more than 10% of the voting power of all classes of stock of the Company, the exercise price must be at least 110% of the fair value of the common stock on the grant date as determined by the board of directors. Options generally vest ratably over four years, and expire in 10 years from the date of grant, or five years from the date of grant for 10% shareholders.

In July 2015, the Company adopted the 2015 Employee Stock Purchase Plan, or the 2015 ESPP. At December 31, 2018 and 2017, 1,780,020 shares and 1,103,481 shares were reserved for issuance and no shares have been issued under the 2015 ESPP.

A summary of the Company's stock option activity and related information is as follows:

	Shares Available for Grant	Options Outstanding			
		Number of Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
					(In thousands)
Balance at December 31, 2017	969,783	8,592,747	$ 3.69	7.4	$ 47,864
Additional authorized	8,326,158	—			
Granted	(6,997,114)	6,997,114	8.44		
Exercised	—	(2,608,812)	2.03		
Cancelled	1,377,341	(1,377,341)	6.12		
RSUs granted	(1,767,542)	—			
Balance at December 31, 2018	1,908,626	11,603,708	$ 6.64	7.6	$ 10,151
Vested and exercisable at December 31, 2018		4,299,323	$ 4.28	5.7	$ 8,581
Vested and expected to vest at December 31, 2018		11,124,469	$ 6.58	7.6	$ 10,092

The weighted-average grant date fair value of options granted to employees was $4.89, $3.38 and $2.72 per share for the years ended December 31, 2018, 2017 and 2016. The grant date fair value of options vested was $6.3 million, $4.8 million and $2.4 million, respectively, for the years ended December 31, 2018, 2017 and 2016, respectively.

Aggregate intrinsic value represents the difference between the estimated fair value of the underlying common stock and the exercise price of outstanding, in-the-money options. The aggregate intrinsic value of options exercised was $17.7 million, $2.6 million and $2.3 million for the years ended December 31, 2018, 2017 and 2016, respectively.

At December 31, 2018, total unrecognized compensation cost related to stock-based awards granted to employees, net of estimated forfeitures, was $29.0 million which is expected to be recognized over a weighted-average period of 3.2 years.

Determination of Fair Value

The determination of the fair value of stock options on the date of grant using an option-pricing model is affected by the estimated fair value of the Company's common stock, as well as assumptions regarding a number of complex and subjective variables. The variables used to calculate the fair value of stock options using the Black-Scholes option-pricing model include actual and projected employee stock option exercise behaviors, expected price volatility of the Company's common stock, the risk-free interest rate and expected dividends. Each of these inputs is subjective and generally requires significant judgment to determine.

Fair Value of Common Stock

Beginning March 31, 2016, the Company's common stock shares were listed on The Nasdaq Global Market. Fair value of the common stock is the adjusted closing price of the Company's common stock on the trading date.

Expected Term

The expected term represents the period that the Company's option awards are expected to be outstanding. The Company considers several factors in estimating the expected term of options granted, including the expected lives used by a peer group of companies within the Company's industry that the Company considers to be comparable to its business and the historical option exercise behavior of its employees, which the Company believes is representative of future behavior.

Expected Volatility

As the Company does not have a sufficient trading history for its common stock, the expected stock price volatility for the Company's common stock was estimated by taking the average historic price volatility of industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. The

Company intends to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-Free Interest Rate

The risk-free interest rate is based on the zero-coupon U.S. Treasury notes, with maturities similar to the expected term of the options.

Expected Dividend Yield

The Company does not anticipate paying any dividends in the foreseeable future and, therefore, uses an expected dividend yield of zero in the Black-Scholes option-pricing model.

In addition to the Black-Scholes assumptions discussed above, the estimated forfeiture rate also has a significant impact on stock-based compensation. The forfeiture rate of stock options is estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting option forfeitures and records stock-based compensation expense only for those awards that are expected to vest.

The fair value of employee stock options was estimated at the date of grant using a Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,		
	2018	2017	2016
Expected term (in years)	6.0	5.9	6.0
Expected volatility (%)	60.4%	66.0%	67.1%
Risk-free interest rate (%)	2.8%	2.1%	1.3%
Expected dividend yield (%)	0%	0%	0%

Restricted Stock Units

From time to time, the Company grants RSUs to its board of directors for their services. These RSUs are either fully vested upon issuance or vest over a period of time from the grant date and will be released and settled upon termination of the board member's services or the occurrence of a change in control event. In December 2016, the Company granted RSUs to certain executive officers and one consultant for services rendered, and these RSUs were fully vested upon issuance. In November 2017, the Company granted RSUs to one executive officer upon his termination, and these RSUs were fully vested upon issuance. In July 2018, the Company granted RSUs to two new executive officers, and these RSUs vest in equal annual installments over three years from the grant date. The fair value of RSUs is based on the closing market price of the Company's common stock on the grant date. The weighted -average grant date fair value of RSUs granted in fiscal year 2017 and 2016 was $8.02 per share and $3.52 per share, respectively.

A summary of the Company's RSU activity and related information is as follows:

	RSUs	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2017	—	$ —
RSUs granted	1,767,542	$ 9.65
RSUs vested	(31,308)	$ 9.17
Unvested at December 31, 2018	1,736,234	$ 9.65
Vested and unreleased	121,507	
Outstanding at December 31 2018	1,857,741	

The total grant date fair value of RSUs awarded was $17.0 million, $0.4 million and $0.5 million for the years ended December 31, 2018, 2017 and 2016, respectively. The total fair value of RSUs vested was $0.3 million, $0.4 million and $0.5 million for the years ended December 31, 2018, 2017 and 2016, respectively.

As of December 31, 2018, total unrecognized stock-based compensation cost related to RSUs was $13.3 million, which is expected to be recognized over a weighted-average period of 2.6 years. As of December 31, 2018, 1,616,819 shares of RSUs are expected to vest.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized in the Company's consolidated statements of operations and comprehensive loss is classified as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Research and development	$ 1,411	$ 952	$ 593
Selling and marketing	700	303	120
General and administrative	12,058	4,064	2,194
Total stock-based compensation expense	$ 14,169	$ 5,319	$ 2,907

During the years ended December 31, 2018, 2017 and 2016, there were no stock-based compensation expenses capitalized as a component of inventory or recognized in cost of revenue. Stock-based compensation relating to stock-based awards granted to consultants was insignificant for the years ended December 31, 2018, 2017 and 2016.

14. Income Taxes

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act ("TCJA"). The TCJA reduced the U.S. statutory corporate tax rate to 21%, effective January 1, 2018. Consequently, we recorded a decrease to the Company's federal deferred tax assets of $38.7 million, which was fully offset by a reduction in the Company's valuation allowance for the year ended December 31, 2017. The other provisions of the TCJA did not have an impact on the Company's financial statements as of December 31, 2017 or December 31, 2018.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the TCJA ("SAB 118"), which allowed companies to record provisional amounts during a measurement period not to extend beyond one year of the TCJA enactment date. In the fourth quarter of 2018, we completed our accounting for the TCJA and we did not have any adjustments to provisional amounts recorded as of December 31, 2017.

Income Tax Expense

The following reconciles the differences between income taxes computed at the federal income tax rate and the provision for income taxes:

	Year Ended December 31,		
	2018	2017	2016
Expected income tax benefit at the federal statutory rate	21.0 %	34.0 %	34.0 %
State taxes, net of federal benefit	0.0	0.0	0.0
Change in federal statutory rate	0.0	(54.1)	0.0
Non-deductible items and other	(0.2)	0.5	(0.7)
Federal and state credits	0.7	0.5	0.6
Change in valuation allowance	(21.5)	19.1	(33.9)
Total	0.0 %	0.0 %	0.0 %

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The principal components of the Company's net deferred tax assets consisted of the following at December 31, 2018 and 2017 (in thousands):

	Year Ended December 31,	
	2018	2017
Net operating loss carryforwards	$ 76,753	$ 61,049
Research and development tax credits	4,699	3,731
Reserves and accruals	1,444	1,168
Other	9,109	6,611
Total deferred tax assets	92,005	72,559
Valuation allowance	(92,005)	(72,559)
Net deferred tax assets	$ —	$ —

The Company maintains a valuation allowance related to its deferred tax asset position when management believes it is more likely than not that the net deferred tax assets will not be realized in the future. The Company's valuation allowance increased by $19.4 million and decreased by $11.0 million during the year ended December 31, 2018 and 2017, respectively.

At December 31, 2018, the Company had federal net operating loss carryforwards of $330.8 million, which begin to expire in the year ending December 31, 2024, and $198.1 million related to state net operating loss carryforwards, which begin to expire in the year ending December 31, 2019. The Company had federal research and development tax credit carryforwards of $4.6 million, and state carryforwards of $2.0 million at the year ended December 31, 2018. These credits expire at various dates through the year ending December 31, 2024.

Under the provisions of the Internal Revenue Code, or IRC, net operating loss and credit carryforwards and other tax attributes may be subject to limitation if there has been a significant change in ownership of the Company, as defined by the IRC. The Company performed a Section 382 analysis in February of 2018 and two ownership changes were identified, none of which had a corresponding limitation of tax attributes. Future owner or equity shifts could result in limitations on net operating loss and credit carryforwards.

Because of the net operating loss and credit carryforwards, all of the Company's federal tax returns and state returns since the year ended December 31, 2004 remain subject to federal and California examination.

The Company accounts for uncertain tax positions using a "more-likely-than-not" threshold. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. The Company evaluates these tax positions on an annual basis. In addition, the Company also accrues for potential interest and penalties related to unrecognized tax benefits in income tax expense.

At December 31, 2018 and 2017, the Company's unrecognized tax benefits consist of the following:

	Year Ended December 31,	
	2018	2017
Unrecognized tax benefit, beginning of period	$ 1,135	$ 940
Gross increases — current year tax positions	422	327
Gross increases — prior year tax positions	38	73
Gross decreases — prior year tax positions	—	(205)
Unrecognized tax benefit, end of period	$ 1,595	$ 1,135

15. Employee Benefits

The Company has a 401(k) Plan which covers its eligible employees. The 401(k) Plan permits the participants to defer a portion of their compensation in accordance with the provisions of Section 401(k) of the IRC. Participant contributions are limited to a maximum annual amount as set periodically by the IRC. The Company started to match 50% of eligible participant contributions up to 6% annual contribution during the year ended December 31,

2018. The Company's matching contribution to the 401(k) Plan was $0.5 million for the year ended December 31, 2018. There were no matching or profit-sharing contributions during the years ended December 31, 2017 or 2016.

16. Net Loss per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share for the periods presented (in thousands, except share and per share data):

	Year Ended December 31,		
	2018	2017	2016
Net loss attributable to common stockholders, basic and diluted	$ (79,124)	$ (72,176)	$ (50,636)
Weighted-average common shares used in computing net loss per share, basic and diluted	81,123,140	58,457,868	40,068,307
Net loss per share, basic and diluted	$ (0.98)	$ (1.23)	$ (1.26)

Since the Company was in a loss position for all periods presented, diluted net loss per common share is the same as basic net loss per common share for all periods presented, because the inclusion of any potential common shares outstanding would have an anti-dilutive effect. The following weighted-average common stock equivalents were excluded from the calculation of diluted net loss per share for the periods presented, because including them would have had an anti-dilutive effect:

	Year Ended December 31,		
	2018	2017	2016
Convertible preferred stock (if converted)	369,934	—	—
Options to purchase common stock	10,486,468	7,914,067	6,181,015
Common stock warrant	4,464,965	3,345,674	804,248
Restricted stock units	903,163	108,107	33,835

17. Segment and Geographic Information

The Company has one business activity, which is radiation therapy technology combined with magnetic resonance imaging, and operates in one reportable segment. The Company's chief operating decision-maker, its chief executive officer, reviews its operating results on an aggregate basis for purposes of allocating resources and evaluating financial performance. Also, the Company does not have segment managers as the Company manages its operations as a single operating segment.

The following table sets forth revenue by geographic area based on the customers' location (in thousands):

	Year Ended December 31,		
	2018	2017	2016
United States	$ 34,231	$ 11,506	$ 1,106
Germany	13,727	—	—
Rest of world	33,004	22,536	21,131
Total revenue	$ 80,962	$ 34,042	$ 22,237

At December 31, 2018 and 2017, all long-lived assets are located in the United States.

18. Related Party Transactions

As discussed in Note 7, the Company pays a royalty to UFRF, a stockholder in the Company, related to a licensing agreement.

In January 2017, the Company entered into a sales consulting agreement with Puissance Capital Management, or PCM, to assist with business development activities in a key market in Asia. PCM is the investment manager of Puissance Cross Board Opportunities LLP, a stockholder in the Company. Theodore T. Wang, Ph.D., a member of the Company's board of directors, is the managing member of the general partners of PCM for the year ended December 31, 2018. The sales consulting agreement has a term of one year with a total consideration of $1.3 million. This amount has been fully expensed in the first quarter of 2018.

Item 9. Changes in and Disagreements with Accountants and Financial Disclosure and Supplementary Data

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at December 31, 2018 at the reasonable assurance level.

Changes in Internal Control

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the fourth quarter of 2018 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018 based on the framework established in "Internal Control – Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our management concluded that our internal control over financial reporting was effective as of that date.

As an emerging growth company, pursuant to the rules of the SEC, this Annual Report on Form 10-K does not include an attestation report of the Company's independent registered public accounting firm regarding our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors, Executive Officers and Corporate Governance

The information in our Proxy Statement for the 2019 Annual Meeting of stockholders regarding directors and executive officers appearing under the headings "Proposal No. 1—Election of Directors," "Executive Officers" and "Information About Stock Ownership -Section 16(a) Beneficial Ownership Reporting Compliance" is incorporated herein by reference.

In addition, the information in our Proxy Statement for the 2019 Annual Meeting of stockholders regarding the director nomination process, the Audit Committee financial expert and the identification of the Audit Committee members appearing under the heading "Corporate Governance and Board of Directors Matters" is incorporated herein by reference.

Code of Conduct and Ethics

We have adopted a Code of Conduct and Ethics that applies to all employees, including our principal executive officer and principal financial officer. The full text of our Code of Business Conduct and Ethics is posted on our website at http://investors.viewray.com/corporate-governance/highlights. We intend to disclose future amendments to certain provisions of our code, or waivers of such provisions granted to executive officers and directors, on our website within four business days following the date of such amendment or waiver. Any information on ViewRay's website or which can be accessed through it is not a part of this Annual Report on Form 10-K.

Item 11. Executive Compensation

We maintain employee compensation programs and benefit plans in which our executive officers are participants. Copies of these plans and programs are set forth or incorporated by reference as Exhibits to this Annual Report. The information in our Proxy Statement for the 2019 Annual Meeting of stockholders appearing under the heading "Executive Compensation" is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management Related Stockholder Matters

The information in our Proxy Statement for the 2019 Annual Meeting of stockholders appearing under the heading "Information About Stock Ownership - Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation - Equity Compensation Plan Information" is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information in our Proxy Statement for the 2019 Annual Meeting of stockholders appearing under the headings Certain Relationships and Related Party Transactions" and "Corporate Governance and Board of Directors Matters—Director Independence" is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information in our Proxy Statement for the 2019 Annual Meeting of stockholders appearing under the headings "Proposal No. 2—Ratification of Appointment of Independent Registered Public Accounting Firm—Audit and Non-Audit Services" and "Proposal No. 2—Ratification of Appointment of Independent Registered Public Accounting Firm—Audit Committee Pre-Approval Policies and Procedures" is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) (1) The financial statements required by Item 15(a) are filed in Item 8 of this Report.

(2) The financial statement schedules required by Item 15(a) are omitted because they are not applicable, not required or the required information is included in the financial statements or notes thereto as filed in Item 8 of this Report.

(3) We have filed, or incorporated into this report by reference, the exhibits listed below.

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Date Filed	
2.1	Agreement and Plan of Merger and Reorganization, dated as of July 23, 2015, by and among ViewRay Inc., Acquisition Sub and ViewRay Technologies, Inc.	S-1/A	2.1	12/16/15	
3.1	Amended and Restated Certificate of Incorporation.	S-1/A	3.1	12/16/15	
3.2	Amended and Restated Bylaws of ViewRay, Inc.	8-K	3.2	5/10/18	
3.3	Certificate of Merger of Acquisition Sub with and into ViewRay Technologies, Inc.	S-1/A	3.3	12/16/15	
3.4	Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock of ViewRay, Inc.	10-K	3.4	3/12/18	
3.5	Form of Series A Convertible Preferred Stock Certificate.	8-K/A	3.2	3/7/18	
3.6	Certificate of Elimination of the Series A Convertible Preferred Stock of ViewRay, Inc.	8-K	3.1	5/10/18	
4.1	Form of Common Stock Certificate.	S-1/A	4.1	12/16/15	
4.2	Form of Placement Agent Warrant for Common Stock of ViewRay, Inc.	S-1/A	10.6	12/16/15	
4.3	Form of Warrants issued pursuant to that certain Securities Purchase Agreement, dated as of August 19, 2016, by and among ViewRay, Inc. and the Purchasers named therein.	S-1	10.3	9/26/16	
4.4	Form of Warrants issued pursuant to that certain Securities Purchase Agreement, dated as of January 13, 2017, by and among ViewRay, Inc. and the Purchasers named therein.	10-K	4.4	3/17/17	
10.1	Split-Off Agreement, dated as of July 23, 2015, by and among ViewRay, Inc., Mirax Enterprise Corp. and Dinara Akzhigitova.	S-1/A	10.1	12/16/15	
10.2	General Release Agreement, dated as of July 23, 2015, by and among ViewRay, Inc., Mirax Enterprise Corp. and Dinara Akzhigitova.	S-1/A	10.2	12/16/15	
10.3	Form of Lock-Up and No Short Selling Agreement between ViewRay, Inc., and the officers, directors and shareholders party thereto.	S-1/A	10.3	12/16/15	
10.4	Form of Securities Purchase Agreement between ViewRay, Inc., and the investors party thereto.	S-1/A	10.4	12/16/15	
10.5	Engagement Letter, dated June 9, 2015, among ViewRay, Inc. and the Placement Agents as defined therein.	S-1/A	10.5	12/16/15	

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Date Filed	
10.6	Form of Registration Rights Agreement, by and among ViewRay, Inc. and certain investors named therein.	S-1/A	4.2	12/16/15	
10.7(a)	Office Lease, effective April 17, 2008, by and between Cleveland Industrial Portfolio, LLC and ViewRay Incorporated.	S-1/A	10.7(a)	12/16/15	
10.7(b)	First Amendment to the Office Lease, effective April 16, 2013 by and between Cleveland Industrial Portfolio, LLC and ViewRay Incorporated.	S-1/A	10.7(b)	12/16/15	
10.7(c)	Second Amendment to the Office Lease, effective August 15, 2014 by and between Cleveland Industrial Portfolio, LLC and ViewRay Incorporated.	S-1/A	10.7(c)	12/16/15	
10.8	Office Lease, effective June 19, 2014, by and between BXP Research Park LP and ViewRay Incorporated.	S-1/A	10.8	12/16/15	
10.9†	Employment Agreement, effective January 18, 2013, by and between ViewRay Incorporated and Chris A. Raanes.	S-1/A	10.9	12/16/15	
10.10†	Offer Letter, effective November 11, 2010, by and between ViewRay Incorporated and D. David Chandler.	S-1/A	10.10	12/16/15	
10.11†	First Amended and Restated Offer Letter, dated October 6, 2010, by and between ViewRay Incorporated and James F. Dempsey, Ph.D.	S-1/A	10.11	12/16/15	
10.12†	Offer Letter, dated December 9, 2011, by and between ViewRay Incorporated and Michael Brandt.	S-1/A	10.12	12/16/15	
10.13#	Manufacturing and Supply Agreement, effective September 18, 2013, by and between ViewRay Incorporated and Japan Superconductor Technology, Inc.	S-1/A	10.13	12/16/15	
10.14(a)#	Development and Supply Agreement, effective May 29, 2008, by and between ViewRay Incorporated and Siemens Aktiengesellschaft, Healthcare Sector.	S-1/A	10.14(a)	12/16/15	
10.14(b)#	Amendment No. 1 to the Development and Supply Agreement, effective December 1, 2009, by and between ViewRay Incorporated and Siemens Aktiengesellschaft, Healthcare Sector.	S-1/A	10.14(b)	12/16/15	
10.14(c)#	Amendment No. 2 to the Development and Supply Agreement, effective May 4, 2010, by and between ViewRay Incorporated and Siemens Aktiengesellschaft, Healthcare Sector.	S-1/A	10.14(c)	12/16/15	
10.14(d)#	Amendment No. 3 to the Development and Supply Agreement, effective February 9, 2011, by and between ViewRay Incorporated and Siemens Aktiengesellschaft, Healthcare Sector.	S-1/A	10.14(d)	12/16/15	
10.14(e)#	Amendment No. 4 to the Development and Supply Agreement, effective May 11, 2012, by and between ViewRay Incorporated and Siemens Aktiengesellschaft, Healthcare Sector.	S-1/A	10.14(e)	12/16/15	

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Date Filed	
10.14(f)#	Amendment No. 5 to the Development and Supply Agreement, effective May 30, 2012, by and between ViewRay Incorporated and Siemens Aktiengesellschaft, Healthcare Sector.	S-1/A	10.14(f)	12/16/15	
10.14(g)#	Amendment No. 6 to the Development and Supply Agreement, effective February 21, 2014, by and between ViewRay Incorporated and Siemens Aktiengesellschaft, Healthcare Sector.	S-1/A	10.14(g)	12/16/15	
10.15#	Cobalt-60 Source Supply and Removal Agreement, effective December 19, 2013, by and between ViewRay Incorporated and Best Theratronics, Ltd.	S-1/A	10.15#	12/16/15	
10.16#	Development and Supply Agreement, effective June 24, 2009, by and between ViewRay Incorporated and Manufacturing Sciences Corporation.	S-1/A	10.16#	12/16/15	
10.17(a)#	Development and Supply Agreement, effective July 9, 2009, by and between ViewRay Incorporated and Tesla Engineering Limited.	S-1/A	10.17(a)	12/16/15	
10.17(b)#	Amendment No. 1 to the Development and Supply Agreement, effective January 20, 2015, by and between ViewRay Incorporated and Tesla Engineering Limited.	S-1/A	10.17(b)	12/16/15	
10.18#	Development and Supply Agreement, effective July 2, 2010, by and between ViewRay Incorporated and PEKO Precision Products, Inc.	S-1/A	10.18	12/16/15	
10.19(a)#	Amended and Restated Joint Development and Supply Agreement, effective May 15, 2008, by and between ViewRay Incorporated and 3D Line GmbH.	S-1/A	10.19(a)	12/16/15	
10.19(b)#	Amendment No. 1 to the Amended and Restated Joint Development and Supply Agreement, effective August 13, 2008, by and between ViewRay Incorporated and Euromechanics Medical GmbH.	S-1/A	10.19(b)	12/16/15	
10.19(c)#	Amendment No. 2 to the Amended and Restated Joint Development and Supply Agreement, effective November 27, 2009, by and between ViewRay Incorporated and Euromechanics Medical GmbH.	S-1/A	10.19(c)	12/16/15	
10.20#	Development and Supply Agreement, effective June 1, 2010, by and between ViewRay Incorporated and Quality Electrodynamics, LLC.	S-1/A	10.20	12/16/15	
10.21(a)#	Standard Exclusive License Agreement with Sublicensing Terms, effective December 15, 2004, by and between ViewRay Incorporated and the University of Florida Research Foundation, Inc.	S-1/A	10.21(a)	12/16/15	
10.21(b)#	Amendment No. 1 to the Standard Exclusive License Agreement with Sublicensing Terms, effective December 6, 2007, by and between ViewRay Incorporated and the University of Florida Research Foundation, Inc.	S-1/A	10.21(b)	12/16/15	

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Date Filed	
10.22	Warrant Agreement, effective December 16, 2013, by and between ViewRay Incorporated and Hercules Technology III, L.P.	S-1/A	10.23	12/16/15	
10.23(a)#	Term Loan Agreement, effective June 26, 2015, by and among ViewRay Incorporated, the Subsidiary Guarantors (as defined therein), Capital Royalty Partners II L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P.	S-1/A	10.22	12/16/15	
10.23(b)	Amendment No. 1 to Term Loan Agreement effective March 24, 2016, by and among ViewRay Technologies, Inc. (formerly known as ViewRay Incorporated), the Subsidiary Guarantors (as defined therein), Capital Royalty Partners II L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P.	10-K	10.23(b)	3/28/16	
10.23(c)	Amendment No. 2 to Term Loan Agreement dated April 12, 2017, by and among ViewRay Technologies, Inc. (formerly known as ViewRay Incorporated), the Subsidiary Guarantors (as defined therein), Capital Royalty Partners II L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P.	10-Q	10.1	8/7/17	
10.23(d)	Amendment No. 3 to Term Loan Agreement effective September 30, 2017, by and among ViewRay Technologies, Inc. (formerly known as ViewRay Incorporated), the Subsidiary Guarantors (as defined therein), Capital Royalty Partners II L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P.	10-Q	10.1	11/13/17	
10.23(e)	Amendment No. 4 to Term Loan Agreement effective December 31, 2017, by and among ViewRay Technologies, Inc. (formerly known as ViewRay Incorporated), the Subsidiary Guarantors (as defined therein), Capital Royalty Partners II L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P	10-K	10.23(e)	3/12/18	
10.24(a)†	ViewRay Incorporated 2008 Stock Incentive Plan.	S-1/A	10.24(a)	12/16/15	
10.24(b)†	Form of Incentive Stock Option and Reverse Vesting Agreement (Change of Control) under the 2008 Plan.	S-1/A	10.24(b)	12/16/15	
10.24(c)†	Form of Incentive Stock Option and Reverse Vesting Agreement under the 2008 Plan.	S-1/A	10.24(c)	12/16/15	

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Date Filed	
10.24(d)†	Form of Nonstatutory Stock Option and Reverse Vesting Agreement under the 2008 Plan.	S-1/A	10.24(d)	12/16/15	
10.25†	Contingent Equity Agreement, effective January 8, 2008, by and among ViewRay Incorporated, James F. Dempsey, Ph.D., Russell S. Donda, Jim Carnall and William Wells.	S-1/A	10.25	12/16/15	
10.26(a)†	ViewRay, Inc. 2015 Equity Incentive Award Plan.	S-1/A	10.26(a)	12/16/15	
10.26(b)†	Form of Option Agreement under the 2015 Plan.	S-1/A	10.26(b)	12/16/15	
10.26(c)†	Form of Restricted Stock Agreement under the 2015 Plan.	S-1/A	10.26(c)	12/16/15	
10.26(d)†	Form of Restricted Stock Unit Agreement under the 2015 Plan.	S-1/A	10.26(d)	12/16/15	
10.27†	Form of Indemnification Agreement for directors and executive officers.	S-1/A	10.27	12/16/15	
10.28†	Agreement, effective June 11, 2008, by and among ViewRay Incorporated, James F. Dempsey, Ph.D., William W. Wells, James D. Carnall and Russell S. Donda.	S-1/A	10.28	12/16/15	
10.29†	ViewRay, Inc. 2015 Employee Stock Purchase Plan.	S-1/A	10.29	12/16/15	
10.30†	Offer Letter, dated April 30, 2015, between ViewRay, Inc. and Doug Keare.	S-1/A	10.30	12/16/15	
10.31	Securities Purchase Agreement, dated as of August 19, 2016, by and among ViewRay, Inc. and the Purchasers named therein.	S-1	10.1	9/26/16	
10.32	Registration Rights Agreement, dated as of August 22, 2016, by and among ViewRay, Inc. and the Purchasers named therein.	S-1	4.3	9/29/16	
10.33	Securities Purchase Agreement, dated as of January 13, 2017, by and among ViewRay, Inc. and the Purchasers named therein.	10-K	10.33	3/17/17	
10.34	Stockholders' Agreement, dated as of January 13, 2017, by and among ViewRay, Inc. and the Purchasers named therein.	10-K	10.34	3/17/17	
10.35	Agreement for Consulting Services by and among ViewRay, Inc. and Puissance Capital Management dated January 13, 2017.	10-Q	10.3	5/15/17	
10.36	Securities Purchase Agreement, dated as of October 23, 2017, by and among ViewRay, Inc. and Fosun International Limited named therein.	8-K	10.1	10/25/17	
10.37	Securities Purchase Agreement, dated as of October 23, 2017, by and among ViewRay, Inc. and the Purchasers named therein.	8-K	10.2	10/25/17	
10.38	Registration Rights Agreement, dated as of October 23, 2017, by and among ViewRay, Inc. and Strong Influence Limited.	8-K	10.3	10/25/17	

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Date Filed	
10.39	Registration Rights Agreement, dated as of October 23, 2017, by and among ViewRay, Inc. and KVP Capital, LP.	8-K	10.4	10/25/17	
10.40	Amended and Restated Securities Purchase Agreement, dated as of March 5, 2018, by and among ViewRay, Inc. and Fosun International Limited named therein	10-K	10.40	3/12/18	
10.41	Amended and Restated Registration Rights Agreement, dated as of March 5, 2018, by and among ViewRay, Inc. and Strong Influence Limited.	10-K	10.41	3/12/18	
10.42	Warrant Agreement, effective February 25, 2018, by and between ViewRay Inc. and Strong Influence Limited.	10-K	10.42	3/12/18	
10.43	Vanni Business Park Industrial Lease by and between Vanni Business Park, LLC and ViewRay, Inc. dated April 11, 2018.	10-Q	10.1	8/7/18	
10.44	Second Amendment to Office Lease by and between BXP Research Park LP and ViewRay, Inc. dated September 1, 2018.	10-Q	10.2	8/7/18	
10.45†	Separation Agreement, dated July 22, 2018, by and between ViewRay Inc. and Chris A. Raanes	10-Q	10.3	8/7/18	
10.46†	Separation Agreement, dated July 22, 2018, by and between ViewRay Inc. and Doug Keare	10-Q	10.4	8/7/18	
10.47†	Employment Agreement, dated July 22, 2018, by and between ViewRay Inc. and Scott Drake	10-Q	10.5	8/7/18	
10.48†	Employment Agreement, dated July 22, 2018, by and between ViewRay Inc. and Shahriar Matin	10-Q	10.6	8/7/18	
10.49†	ViewRay, Inc. 2018 Equity Inducement Award Program	S-8	99.1	8/10/18	
10.50	Loan and Security Agreement by and between Silicon Valley Bank, ViewRay, Inc. and ViewRay Technologies, Inc. dated December 28, 2018.	8-K	10.1	12/31/18	
10.51†	Amendment to Employment Agreement, dated December 20, 2018 by and between ViewRay Inc. and Scott Drake				X
10.52†	Amendment to Employment Agreement, dated December 20, 2018 by and between ViewRay Inc. and Shar Matin				X
10.53	At Market Issuance Sales Agreement, dated as of May 10, 2018, by and between ViewRay, Inc. and B. Riley FBR, Inc.	S-3	1.2	5/10/18	
21	List of Subsidiaries.				X
23.1	Consent of Deloitte & Touche LLP				X
24	Power of Attorney (contained on the signature page hereto).				X
31.1	Certification of Principal Executive Officer Required under Securities Exchange Act Rule 13a-14(a) and 15d-14(a).				X

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Date Filed	
31.2	Certification of Principal Financial Officer under Securities Exchange Act Rule 13a-14(a) and 15d-14(a).				X
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350 and Securities Exchange Act Rule 13a-14(b).				X
101	Interactive Data Files of Financial Statements and Notes.				X
101.INS	Instant Document.				X
101.SCH	XBRL Taxonomy Schema Document.				X
101.CAL	XBRL Taxonomy Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Label Linkbase Document.				X
101.PRE	XBRL Taxonomy Presentation Linkbase Document.				X

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.

† Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary

None.

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, on March 15, 2019.

VIEWRAY, INC.

By: /s/ Scott Drake
Scott Drake
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Scott Drake and Ajay Bansal, and each of them, with full power of substitution and full power to act without the other, his or her true and lawful attorney-in-fact and agent to act for him or her in his or her name, place and stead, in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or his substitute, may do or cause to be done by virtue thereof.

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

Signature	Title	Date
/s/ Scott Drake Scott Drake	Director, President and Chief Executive Officer (Principal Executive Officer)	March 15, 2019
/s/ Ajay Bansal Ajay Bansal	Chief Financial Officer (Principal Financial and Accounting Officer)	March 15, 2019
/s/ Daniel Moore Daniel Moore	Director	March 15, 2019
/s/ Caley Castelein, M.D. Caley Castelein, M.D.	Director	March 15, 2019
/s/ James F. Dempsey, Ph.D. James F. Dempsey, Ph.D.	Director and Chief Scientific Officer	March 15, 2019
/s/ Keith Grossman Keith Grossman	Director	March 15, 2019
/s/ Aditya Puri Aditya Puri	Director	March 15, 2019
/s/ Henry A. McKinnell, Jr., Ph.D. Henry A. McKinnell, Jr., Ph.D	Director	March 15, 2019
/s/ Brian K. Roberts Brian K. Roberts	Director	March 15, 2019
/s/ Theodore T. Wang, Ph.D. Theodore T. Wang, Ph.D.	Director	March 15, 2019
/s/ Scott Huennekens Scott Huennekens	Director	March 15, 2019

Exhibit 10.51

Amendment

Amendment Date:	December 20, 2018
Parties:	ViewRay, Inc. Scott Drake
Original Agreement:	Employment Agreement dated July 22, 2018

The below signatories are parties to the Original Agreement. The parties hereby agree to amend the Original Agreement as follows:

1. Section 4 of the Original Agreement is amended with the addition of the following clause:

> *Notwithstanding anything to the contrary in the Original Agreement, as of October 22, 2018, Executive's office location shall be Denver, Colorado or a Colorado-based home office, and the "stipend" provided under the Original Agreement shall be deemed terminated of even date therewith.*

2. This Amendment is effective as of the date set forth above. This Amendment may be executed in multiple counterparts all of which together will constitute one instrument. This Amendment is made a part of the Original Agreement. Except as specifically amended by this Amendment, the Original Agreement will remain in full force and effect without addition, deletion or change.

ViewRay, Inc.	**Executive**
By: (signature)	By: (signature)
Printed Name:	Printed Name:Scott Drake
Title:	Title:President, CEO

Exhibit 10.52

Amendment

Amendment Date:	December 20, 2018
Parties:	ViewRay, Inc. Shahriar Matin
Original Agreement:	Employment Agreement dated July 22, 2018

The below signatories are parties to the Original Agreement. The parties hereby agree to amend the Original Agreement as follows:

1. Section 4 of the Original Agreement is amended with the addition of the following clause:

> *Notwithstanding anything to the contrary in the Original Agreement, as of January 23, 2019, Executive's office location shall be Denver, Colorado or a Colorado-based home office, and the "stipend" provided under the Original Agreement shall be deemed terminated of even date therewith.*

2. This Amendment is effective as of the date set forth above. This Amendment may be executed in multiple counterparts all of which together will constitute one instrument. This Amendment is made a part of the Original Agreement. Except as specifically amended by this Amendment, the Original Agreement will remain in full force and effect without addition, deletion or change.

ViewRay, Inc.	**Executive**
By: (signature)	By: (signature)
Printed Name:	Printed Name:Shahriar Matin
Title:	Title:Chief Operating Officer

Exhibit 21

Subsidiaries

Entity	**Jurisdiction of Organization**
ViewRay Technologies, Inc. (formerly known as ViewRay Incorporated)	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements No. 333-216797, No. 333-222264, and No. 333-229145 on Form S-3, Registration Statements No. 333-224013, No. 333-226797, No. 333-227383, No. 333-210472 and No. 333-216794 on Form S-8, of our report dated March 15, 2019, relating to the consolidated financial statements of ViewRay, Inc. and its subsidiary (the "Company") appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2018.

/s/ Deloitte & Touche LLP
San Francisco, CA
March 15, 2019

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
EXCHANGE ACT RULE 13a-14(a)/15d-14(a)
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott Drake, certify that:

1. I have reviewed this Annual Report on Form 10-K of ViewRay, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 15, 2019

/s/ Scott Drake
Scott Drake
Title: Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
EXCHANGE ACT RULE 13a-14(a)/15d-14(a)
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ajay Bansal, certify that:

1. I have reviewed this Annual Report on Form 10-K of ViewRay, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 15, 2019

/s/ Ajay Bansal
Ajay Bansal
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officers of ViewRay, Inc., a Delaware corporation (the "Company"), hereby does certify that:

(i) the Annual Report on Form 10-K of the Company for the year ended December 31, 2018 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

The foregoing certification (i) is given to such officers' knowledge, based upon such officers' investigation as such officers reasonably deem appropriate; and (ii) is being furnished solely pursuant to 18 U.S.C. § 1350 (section 906 of the Sarbanes-Oxley Act of 2002) and is not being filed as part of the Report or as a separate disclosure document and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

VIEWRAY, INC.

Dated: March 15, 2019

By: /s/ Scott Drake
Name: Scott Drake
Title: Chief Executive Officer
(Principal Executive Officer)

Dated: March 15, 2019

By: /s/ Ajay Bansal
Name: Ajay Bansal
Title: Chief Financial Officer
(Principal Financial Officer)