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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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, 2021

OR

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

Commission File Number 001-37725

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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01	**VRAY**	**The Nasdaq Global Market**

Securities registered pursuant to Section 12(g) of the Act: **None**

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

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the 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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☐
Smaller reporting company	☒	Emerging growth company	☐		

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The NASDAQ Stock Market on June 30, 2021, was $1,058,915,946.

The number of shares of Registrant's Common Stock outstanding as of February 15, 2022 was 179,404,696.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement to be delivered to stockholders in connection with the Annual Meeting of Shareholders to be held in 2022 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 (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 (“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:

- the effect of the coronavirus and its variants ("COVID-19") and associated disruption to the global economy and our business operations and financial condition;
- our ability to procure materials and components in connection with the manufacture and installation of MRIdian;
- the effect or impact of market consolidation;
- market acceptance of magnetic resonance imaging (“MRI”) guided radiation therapy;
- the benefits of MR Image-Guided radiation therapy;
- our ability to obtain and maintain regulatory approval in targeted markets for MRIdian;
- 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;
- 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 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 Part I, 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

ViewRay, Inc. designs, manufactures, and markets the MRIdian® MRI-Guided Radiation Therapy System. MRIdian is built upon a proprietary high-definition magnetic resonance (“MR”) imaging system designed from the ground up to address the unique challenges and clinical workflow for advanced radiation oncology. Unlike MR systems used in diagnostic radiology, MRIdian's high-definition MR was purpose-built to address specific challenges, including beam distortion, skin toxicity, and other concerns that may arise when high magnetic fields interact with radiation beams. The MRIdian MR-Guided Radiation Therapy System integrates diagnostic-quality MR imaging with radiation therapy delivery to enable on-table adaptive treatments with real-time tissue tracking and automatic beam gating. MRIdian supports the delivery of ablative radiation doses in five or fewer fractions, without implantable markers resulting in lower toxicities in hard-to-treat cancers. 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. MRIdian with Cobalt-60 is no longer commercially available.

MRIdian was designed 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 anatomical visualization and accurate dose calculation and delivery will improve the safety and efficacy of radiation therapy, leading to better outcomes for patients suffering from cancer.

Both generations of the MRIdian have received 510(k) marketing clearance from the U.S. Food and Drug Administration, (“FDA”) and permission to affix the Conformité Européene, (“CE”) mark. Additionally, the newest version of MRIdian, MRIdian A3i™, received 510(k) marketing clearance from the FDA in December 2021.

- We received initial 510(k) marketing clearance from the 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.
- In August 2016, we received regulatory approval from the Japanese Ministry of Health, Labor and Welfare to market MRIdian with Cobalt-60 in Japan as well as from the China Food and Drug Administration to market MRIdian with Cobalt-60 in China.
- In September 2016, we received the CE mark for the MRIdian Linac (with a linear accelerator as the radiation source) in the European Economic Area ("EEA").
- In February 2017, we received 510(k) marketing clearance from the FDA to market MRIdian Linac in the United States (“U.S.”).
- In June 2017, we received 510(k) marketing 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) marketing clearance for advancements in MRI, 8 frames per second cine, Functional imaging (T1/T2/DWI) and High-Speed MLC. In December 2019, we received the CE mark for these advancements in the EEA.
- In December 2021, we received 510(k) marketing clearance for new MRIdian features focused on enhancing on-table adaptive workflow efficiency and expanding clinical utility.
- We are also seeking required regulatory approvals for MRIdian in other countries, including CE mark for the EEA.

Nearly 18,000 patients have been treated with MRIdian. As of December 31, 2021, 48 MRIdian systems are installed at hospitals around the world where they are used to treat a wide variety of solid tumors and are the focus of numerous ongoing research efforts. MRIdian has been the subject of hundreds of peer-reviewed publications, scientific meeting abstracts, and presentations.

We currently market MRIdian through a direct sales force in the U.S. In the rest of the world, we market MRIdian through a hybrid model of both a direct sales force and distribution network. 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 conventional 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 45 to 60 days for us to install MRIdian and perform on-site testing of the system, including the completion of acceptance test procedures.

As of December 31, 2021, we had installed or delivered 57 MRIdian systems worldwide and had a backlog with total value of $313.4 million. We generated revenue of $70.1 million, $57.0 million, and $87.8 million for the years ended December 31, 2021, 2020, and 2019, respectively. We had net losses of $110.0 million, $107.9 million and $120.2 million for the years ended December 31, 2021, 2020, and 2019, respectively.

We expect to continue to incur significant expenses and operating losses for the foreseeable future, as we:

- navigate our business activities through the impacts of the COVID-19 pandemic;
- 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.

Impact of the COVID-19 Pandemic

The COVID-19 pandemic, the resulting global recession and its follow-on effects have impacted and will continue to impact business activity across industries worldwide, including ViewRay.

Due to pandemic-related factors like the delays in service from our global supply chain partners and travel and quarantine restrictions imposed by government agencies and our customers in response to the spread of COVID-19, we have experienced delays in installation of systems in the United States, Asia and Europe. Similarly, our ability to conduct commercial efforts with our customers has been and is likely to continue to be disrupted as customers have in most cases suspended in-person sales calls and turned their focus to dealing with the impact of the COVID-19 on their operations. Lastly, many customers have reduced spending on capital equipment and redirected financial resources to pandemic-related spending and otherwise preserve capital in anticipation of a prolonged pandemic. If the economic effects and travel restrictions of the COVID-19 pandemic persist, our ability to conduct our business and access capital markets will be negatively impacted; and capital equipment sales, which make up the majority of our revenue, may take longer than other areas of the economy in a recovery, which may have a material impact on our business. The COVID-19 pandemic continues to evolve and shift rapidly, and its continued global economic impact may negatively impact our operations in areas that we are not aware of currently.

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, over 1.9 million people are expected to be newly diagnosed with cancer in the United States during 2022 and more than 600,000 are expected to die from cancer, which translates to over 1,600 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 rose to 19.3 million new cases and 10.0 million cancer deaths estimated in 2020.

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 U.S. 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.

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 2019 IMV report, patients made an estimated 18.5 million radiation therapy treatment visits in the U.S. in 2019.

Radiation Therapy Equipment Market

According to Markets and Markets 2019 Radiotherapy Market Global Forecasts 2023 report, the global radiotherapy market is estimated to grow to approximately $6.8 billion by 2023. According to IAEA Human Health Campus, there are nearly 12,200 linacs installed at nearly 7,500 centers worldwide. In North America, there are over nearly 4,000 linacs installed at over 2,200 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 ("IMRT"), grew from 30% in 2002 to 96% in 2012. The percentage of sites utilizing image-guided radiation therapy ("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.

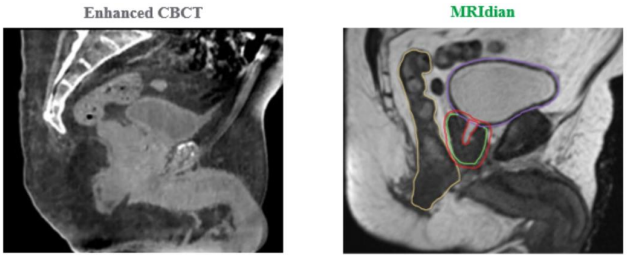
Limitations of Conventional Radiation Therapy

Limitations with conventional 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 conventional 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.

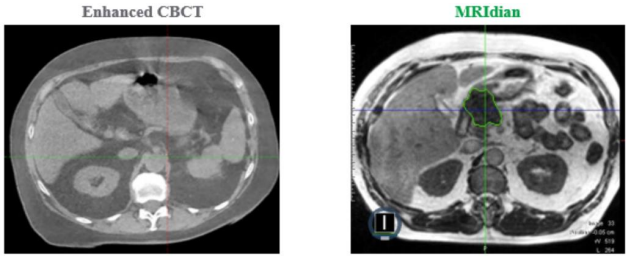
- ***Inability to accurately visualize a tumor for treatment alignment.*** To locate a tumor, current radiation therapy systems rely on CT scans taken while the patient is on the delivery unit treatment table, or “on-table.” Because it is difficult to differentiate between the tumor and nearby soft tissues 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

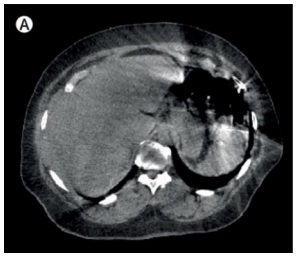
Prostate cancer



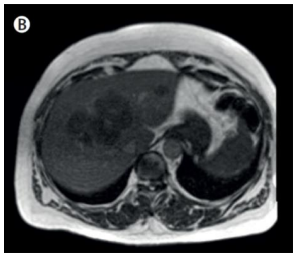
Abdominal Cancer



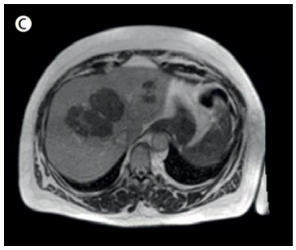
Cone beam CT breath hold



MRIdian no contrast



MRIdian with contrast



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 and bleeding; and fiducials may change location and even migrate inside the body. Fiducial placement also may

add extra costs for payers, providers and patients. 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 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 a course of 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 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 increase in the irradiated region exposes additional healthy tissues to unnecessary radiation and limits the dose that is delivered to the tumor.

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. Many of these side effects can be costly for patients and the healthcare system.

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 MR 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 additional 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 is the world's first device to integrate a diagnostic-quality MRI with an advanced linear accelerator. MRIdian is the first and only MR-guided, on-table adaptive radiotherapy system with real-time, tissue tracking-based automated beam gating with an advanced linear accelerator. MRIdian offers:

- MR-guided imaging that provides advanced tissue visualization compared to cone-beam computed tomography ("CBCT"), to enable precise contouring and reduced margins.
- Fully integrated, on-table adaptive workflow that allows complete re-optimization of the daily treatment plan.
- Real-time tissue tracking that controls the automated beam gating without the need for implanted markers.

MRIdian A3i is the Company's next version of MRIdian. MRIdian A3i streamlines the on-table adaptive workflow by allowing clinicians to intelligently auto-contour, auto-adapt, and auto-gate. Enabling clinicians to collaborate simultaneously and connect remotely during patient treatment. The automated workflow steps and contouring tools are designed to minimize clinician time and increase patient throughput.

MRIdian A3i expands existing real-time tissue tracking and automated beam gating functionalities to include multiplanar tracking and gating in up to three planes. Our customers have the flexibility to select up to three different tracking targets in any combination of coronal, sagittal, or axial planes to automatically stop the beam when any single target exceeds the clinician-defined treatment boundaries.

Brain treatment package consists of a dedicated brain coil with an integrated stereotactic brain immobilization system. New, high-resolution volumetric and real-time imaging features are designed to enable customers to treat brain metastases, resection cavities, gliomas, and other cranial lesions.

MRIdian represents a new paradigm in the treatment of cancer, providing clinicians with the ability to improve targeting precision and thus deliver higher —and potentially more effective—radiation doses.

This approach to radiation therapy is called MRIdian SMART (Stereotactic MRI-guided, adaptive radiotherapy). The benefits of MRIdian SMART include:

- safe delivery of ablative doses;
- tight margins;
- ability to treat patients, often with five or fewer fractions;
- elimination of the need for invasive fiducials; and
- demonstrated clinical outcomes with no to low grade three toxicities

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 MRIdian’s SmartVISION was designed specifically to not interfere with high-fidelity beam delivery. Most importantly, SmartVISION provides diagnostic-quality, multi-sequence MR imaging while coexisting in close proximity with the integrated linear accelerator. MRIdian’s proprietary magnetic and radiofrequency shielding design ensures minimal interaction between the linear accelerator and magnetic field. SmartVISION virtually eliminates the risk of skin toxicities and trapped or distorted doses. With a proprietary split-magnet design exclusive to SmartVISION, MRIdian provides an unobstructed radiation beam path and optimal source-axis distance (“SAD”) enabling sophisticated beam dosimetry, exceptionally sharp penumbra tailored for SRS and SBRT, and high-dose rate beam delivery.
- The ability to SHAPE: SmartADAPT™

  Patient anatomy changes from day to day resulting in significant changes to the position, shape, and size of the tumor and surrounding healthy tissue between treatment sessions. Using MRIdian's SmartADAPT adaptive radiotherapy software, clinicians can now acquire daily on-table MR setup scans in seconds and leverage high-contrast, high-definition imaging to rapidly reshape dose delivery to accommodate the anatomical changes that occur 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 anatomy at that time—all while the patient is in the treatment position.
- The ability to STRIKE: SmartTARGET™

  While the patient is on the table during beam delivery, transient gas bubbles, filling bladders and respiratory motion may cause tumors and surrounding organs at risk (OARs) to rapidly change position and shape. MRIdian’s SmartTARGET continuously acquires MR images and tracks target tissue and OARs faster than human reaction time. SmartTARGET’s real-time tissue tracking controls the automated beam gating by delivering the radiation dose only when the tumor is located in the pre-defined treatment boundary. If the tumor moves outside the pre-defined treatment boundary and OARs move into the treatment boundary, the beam automatically stops. When the tumor moves back into the boundary, the beam is turned on and the treatment resumes. SmartTARGET provides confidence that 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. MRIdian’s SmartSITE design allows MRIdian to fit within almost any existing standard linear-accelerator vault and shielding configuration, helping reduce prolonged installation schedules and additional costs necessary to build custom, large-scale vaults. MRIdian components are also able to fit through conventional vault doorways, so there is no need to remove walls, raise ceilings, or dig trenches, eliminating interruptions and delays.

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-conformal radiation therapy (“CRT”), IMRT, IGRT, SBRT/SABR and SRS. MRIdian treatments are supported by existing radiation therapy payment codes in almost all countries in which we offer MRIdian. 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.

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 by focusing on the clinical, strategic, and economic value of MRIdian.

MRIdian's value propositions set us apart in the market and resonate with our customers by enabling them, in a financially responsible manner, to:

- treat patients with excellent care;
- attract new patients into their health system; and
- retain patients already in-network.

MRIdian's capabilities help our customers add net new patients. These patients generally come in three forms: (1) those that they would not or could not treat prior to MRIdian, (2) those who travel from outside traditional catchment areas, and (3) an increase in those in-network referrals.

Clinical Value - MRIdian opens new treatment possibilities for patients by:

- allowing margins to shrink and spare healthy tissue;
- reoptimizing to escalate dose; and
- reducing fractionation schemes with confidence, thus accelerating ablative therapy with improved outcomes.

Strategic Value - MRIdian truly differentiates cancer programs by:

- expanding hypofractionation and SBRT radiation therapy service lines to patients that otherwise may not have been able to be treated with conventional linacs;
- allowing programs to garner patients from outside traditional referral networks and catchment areas; and
- optimizing vault efficiencies. As the cornerstone to the SBRT program, MRIdian allows our customers to free up time on existing linacs as patients shift to hypofractionated treatment plans.

Economic Value - By expanding our customers SBRT service line and optimizing vault efficiencies, MRIdian helps to deliver positive financial results by:

- capturing patients that otherwise may not have been treated;
- expanding the referral base and geographic catchment area; and
- optimizing vaults and tapping into the potential for incremental adaptive reimbursement.

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 continue to fortify our United States sales force, while enhancing the international direct sales force to assist distributors in EMEA and Asia. We also have maintained our efforts to develop a focused commercial presence that is highly competitive, resulting in the continued adoption of MRIdian through pipeline development activities in targeted markets worldwide.
- ***Operational excellence.*** In tandem with our focus on building our customer pipeline, we are also committed to achieving internal operational excellence in parallel. We continually seek to create efficiencies across the organization to reduce the purchase order to revenue recognition cycle time. Achievement of this goal is to be driven by 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 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 continue to work to improve and refine the capabilities and resulting benefits of MRIdian. Current priorities are focused on addressing service and technical support, clinical workflow enhancements, reducing treatment times, the development of clinical data and maintaining our technology lead in MR Image-Guided radiation therapy through continued innovation.
- ***Customer program success.*** The success of our customers is paramount. This past year we have invested in developing the Customer Success Team. This critical and strategic team for ViewRay will explore, understand, co-define and execute on our customer’s vision to increase utilization of the MRIdian system and help enable the success of their MR Linac program. We are not only committed to providing industry-leading technology, we also focus on optimizing our customers' investment. Rapid Adapt® is a comprehensive customer care program designed to move customers from contract execution into adaptive treatments as efficiently as possible, giving our customers the ability to:

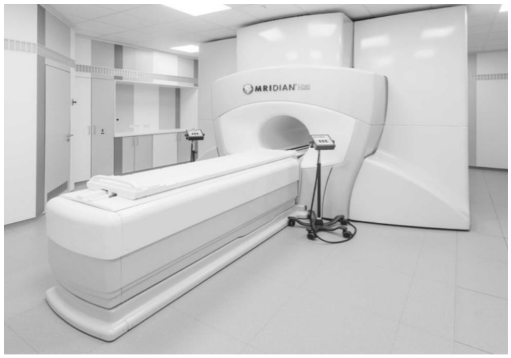
- Deliver personalized care to each patient;
- Expand our customers' patient population by allowing them to treat additional cancer types; and
- Drive utilization, patient throughput, and return on investment (“ROI”).

- ***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. We continue to invest in our technology to maintain our leadership position in the emerging MR Image-Guided radiation therapy market. In December 2021, we received 510(k) clearance from the FDA on MRIdian A3i, with new features focused on enhancing on-table adaptive workflow efficiency and expanding clinical utility, and includes new MRI imaging sequences, automated workflow steps, on-table auto-contouring tools, multi-planar tissue tracking and automated beam gating, and the ability for clinicians to work collaboratively during patient treatments. MRIdian A3i also includes a new brain treatment package and the integration of a real-time patient feedback display. As we advance our strong intellectual property portfolio, our innovation pipeline includes projects to address treatment delivery speed, machine vision and biological imaging. We continue to work 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 are developing an impressive compendium of clinical data. Over the last seven years, more than 65 different types of cancer have been treated on MRIdian systems. MRIdian users have generated hundreds of peer reviewed articles and abstracts highlighting thousands of patients with clinically reported outcomes. There are over 60 investigator lead clinical trials ongoing on MRIdian. Radiation oncologists and medical physicists have expanded treatment to areas such as abdominal oligometastatic cancer, tumors in the central lung, and non-invasive heart ablations.
  - ***Training.*** Training remains paramount to adoption. We invest in peer-to-peer symposia and training courses to facilitate sharing of 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.

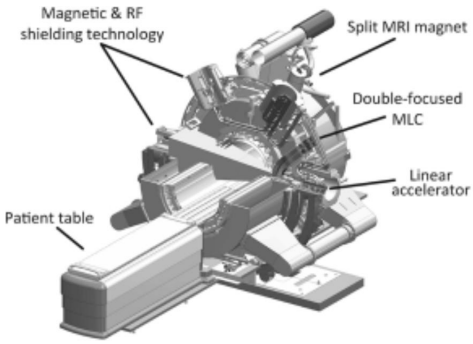
The MRIdian System

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 heart of the MRIdian is the MRI system which 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 allows radiation doses to be delivered through a central gap, which places the MRI components away from the path of the beam. Our MRI system captures and displays live, high-quality images in one plane, eight or 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. Features in MRIdian A3i include multi-planar tissue tracking and automated beam gating on multiple planes simultaneously. The Company received FDA 510(k) clearance for MRIdian A3i in December 2021.

We have engineered our MRI system to be able to produce clear images using a low-field strength 0.35 Tesla magnet, which helps enable us to minimize image and radiation dose distortions.

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.

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 addressed 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. 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 adaptive treatment software works with the integrated patented split-magnet MRI System, 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. MRIdian A3i includes enhanced on-table adaptive workflow efficiency through, workflow automation, auto-contouring tools, intrafraction “scan and adapt” option and a collaborative on-table adaptation integrated remote access platform.

Installed Base and Clinical Use

At December 31, 2021, a total of 48 MRIdian systems, 2 MRIdian with Cobalt-60 systems and 46 MRIdian Linac systems, are in operation worldwide (21 in the United States and 27 outside the United States). In addition, 9 MRIdian Linacs have been delivered to customers that are in varying stages of deployment.

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 $158.9 million, $94.6 million and $118.5 million in fiscal years 2021, 2020 and 2019, respectively. Based on our assessment, we removed $30.4 million, $36.1 million and $21.9 million from the backlog for fiscal years 2021, 2020 and 2019, respectively. At December 31, 2021, we had a backlog with a total value of $313.4 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 customize 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 45 to 60 days for us to install MRIdian and perform 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 ("ESTRO"), to raise awareness of MR Image-Guided radiation therapy and to market MRIdian to leading cancer centers. Additionally, centers have published hundreds of peer-reviewed articles on the technical and clinical benefits of MRIdian.

In order to promote broader adoption rates at other cancer centers and hospitals, we plan to work with our customers to continue to collect and publish data on clinical efficacy, treatment times and clinical results for patients who have been treated on a MRIdian. Multicenter retrospective outcomes data presented at the 2021 Annual Meeting of ASTRO highlighted compelling results using the Company's MRIdian system for the treatment of inoperable, locally advanced pancreatic cancer. The data from 148 pancreatic cancer patients reported 52.7% two-year overall survival with only 4.1% acute Grade 3 toxicity. These results will be explored further in a multi-center, prospective, single-arm clinical trial for inoperable, locally advanced or borderline resectable pancreatic cancer. The ViewRay sponsored trial, Stereotactic MRI-guided On-table Adaptive Radiation Therapy ("SMART") for Locally Advanced Pancreatic Cancer has completed enrollment of the target 133 patients as of December 31, 2021.

Additionally, in 2016, Washington University published a prospective study on Magnetic Resonance Image Guided Radiation Therapy for External Beam Accelerated Partial-Breast Irradiation ("APBI") 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. This work has been extended with a 2020 publication from Washington University demonstrating the feasibility of single-fraction APBI for breast cancer.

Finally, we have recently seen centers publishing data on the impact of MRIdian's ability to safely deliver ablative doses in difficult to treat patients/tumors across areas such as high-risk prostate cancer and high-risk lung cancer. In 2020, Amsterdam University Medical Center published two papers in the Red Journal demonstrating low to no severe toxicity, improved patient quality of life and robust tumor control/survival after treatment with MRIdian for prostate and lung cancer.

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 our sponsorship and support for 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, potential improvements in reimbursement and delivery system reforms.

Selling and Marketing

We currently market MRIdian through a direct sales force in the United States. In the rest of the world, we market MRIdian through a hybrid model of both a direct sales force and distribution network. 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 conventional 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 sales directors are responsible for selling MRIdian within the United States. 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 program development managers who provide post-sales support.

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

Competition

We compete 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, among 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 U.S. or globally include Accuray Incorporated (“Accuray”), Elekta AB (“Elekta”), and Varian Medical Systems, Inc. ("Varian"). During 2021, Siemens Healthineers AG completed the acquisition of 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. Elekta is currently the only competitor which also markets an MRI-guided device combined with a linear accelerator. ***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 an MRI-linac and Reflexion Medical, Inc is working on a device that will use PET imaging to guide radiation therapy in real time. Although these academic research centers and very early stage companies may not present significant competition, if they were to progress commercially, 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 may consider more 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, ("OEM"), suppliers and contract manufacturers. These major components include the magnet, MRI electronics, ring gantry, radiation therapy heads, 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, 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; however, the ongoing COVID-19 pandemic and its follow-on effects could potentially have negative effects on our supply chain which could negatively impact our costs and gross margin.

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 an exclusive license to four issued U.S. patents, four issued foreign patents, and one pending U.S. application as of February 9, 2022. We own an additional 42 issued U.S. patents, 100 issued foreign patents (60 of which were issued in Great Britain, Germany, France, Italy, and the Netherlands as a result of twelve patent applications filed and allowed through the European Patent Office), 18 pending U.S. applications and 48 pending foreign applications as of February 9, 2022. Assuming all required fees are paid, individual patents or patent applications owned or licensed by us will expire between 2022 and 2042. We also have a joint ownership interest with Case Western Reserve University in two U.S. issued patents.

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 and we have issued U.S. and foreign patents and pending continuation applications 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 methods for integrating MRI with the radiation delivery system, and the design of our disassemble, or “pop apart,” magnet which enables the MRI sub-system to fit into most standard radiation therapy vaults. In addition, we have U.S., and foreign patents and patent applications that cover technologies enabling the use of MR-imaging at a frequency sufficient to account for real-time organ motion to provide video-rate tissue tracking in disciplines in and outside of radiation therapy. Furthermore, we have patents issued in the U.S., Canada, Europe, 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. ("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. 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. Standard radiation therapy treatments using MRIdian, including 3D-CRT, IMRT and SBRT, are generally reported under existing Current Procedural Terminology ("CPT") codes. Most payers, including Medicare, generally cover standard radiation therapy treatments furnished in outpatient hospital and free-standing centers.

Third-party payors, including public programs such as Medicare and Medicaid, establish coverage policies and reimbursement rates for procedures performed by physicians in hospitals and free-standing clinics. For example, the Centers for Medicare & Medicaid Services (“CMS”) publishes annual updates to the hospital outpatient prospective payment system (“HOPPS”) which is used to pay for services performed in hospital outpatient departments. CMS also publishes annual updates to the Medicare physician fee schedule (“MPFS”) which is used to pay for services performed by physicians in all sites of service. The MPFS is also used by Medicare to pay for services furnished in free-standing radiation therapy centers. 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. Private insurers often model their payment rates and coverage policies based on those established by Medicare. These 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.

In 2019, CMS proposed an alternative payment model, the Radiation Oncology Model ("RO Model"), for a majority of cancers that are typically treated with radiation therapy ("RT"). On September 18, 2020, CMS issued a final rule for the RO Model with implementation on January 1, 2021. Under the final rule, many parts of the country will be paid using a bundled payment amount based on historical Medicare payment for RT services included in the model. Other parts of the country will continue to be paid under the traditional fee-for-service system. CMS will test whether a bundled payment approach would incentivize the use of shorter courses of RT, such as those that can be delivered using MRIdian, which could potentially reduce costs for Medicare and Medicare beneficiaries. On October 21, 2020, CMS announced that it would begin rulemaking to delay implementation until July 2021. However, in December 2020, Congress delayed implementation of the RO Model to January 1, 2022. Then in December 2021, Congress further delayed implementation of the RO Model to January 1, 2023. We expect implementation to occur sometime in 2023.

Foreign Reimbursement Regulations

Healthcare delivery, financing and payment systems vary from country to country and include single-payor and multiple public and private payors as well as public and private ownership of hospitals and centers. 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, demonstrating the value of MRIdian for payers and purchasers, and in some countries, funding for capital equipment purchases.

Research and Development

Continued innovation and development of advanced technologies is critical to our goal of making MR Image-Guided radiation therapy a 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 customer adoption of new features and capabilities. In addition, we believe our IP portfolio will enable us to continuously develop innovative technologies to further differentiate MRIdian.

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, (“NRC”), other federal, state, and local authorities in the U.S. and foreign regulatory authorities. The U.S. Food, Drug, and Cosmetic Act (“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 ("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 ("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 further 510(k) clearance.

In February 2017, we received 510(k) clearance from the FDA to market the MRIdian Linac system in the U.S. We received 510(k) clearance from the FDA for modifications of the MRIdian Linac system in June 2017 and February 2019.

In December 2021, we received 510(k) clearance for new MRIdian features focused on enhancing on-table adaptive workflow efficiency and expanding clinical utility.

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 ("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 ("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. For example, we received a Voluntary Action Indicated ("VAI") FDA Form 483 in December 2021, which included seven (7) inspectional observations. We promptly responded to the FDA with completed corrective actions for four of the inspectional observations and detailed our plan to address the remaining three inspectional observations in a timely manner. 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 ("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 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 other therapies 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. In this regard, we believe that the MRIdian Linac complies with applicable 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 ("HIPAA") as amended by the Health Information Technology and Clinical Health Act ("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 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 (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 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 ("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.

Congress may seek changes in the Affordable Care Act, Medicare, RO Model and other federal health care programs that impact our business. Any changes in the Affordable Care Act, Medicare, RO Model or other federal health care programs may affect how state and federal governments and employers pay for health care products and services. Such changes could result in reduced demand for MRIdian or additional pricing pressure.

Similarly, we expect governments in other countries to continue introducing changes in their delivery, financing, and payment systems to reduce costs and improve outcomes. Some of these changes could result in reduced demand for MRIdian and bring additional price 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 (the "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 27 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.

In September 2016, we received approval for CE mark for our MRIdian Linac (with a linear accelerator as the radiation source) in the EEA. In December 2019, we received approval for CE mark for modifications of the MRIdian Linac system.

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 applied to ViewRay starting on May 26, 2020. The new regulation among other things:

- strengthens the rules on placing devices on the market and reinforce surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improves the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number; and
- sets 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 15 countries and MRIdian A3i into 1 country. We will seek approvals in other countries as may be required in the future.

The International Standards Organization ("ISO") 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 February 2021.

Teammates and Human Capital

At ViewRay, we believe our shared values and a culture where we truly care for and about one another is instrumental to our growth and success. We are passionate about attracting, retaining, and developing the best talent on the planet – it is essential to our success. At December 31, 2021,we had 267 full-time teammates, including our international teammates; 64 of our teammates were engaged in research and development, and 203 in sales and marketing, business development, finance, human resources, facilities and general management and administration. None of our teammates are covered by a collective bargaining agreement, and we have not experienced any work stoppages. We consider our relations with our teammates to be good.

We are engaged in an ongoing effort to attract, retain, and develop a diverse team ready for the challenge a growth company presents. We believe diversity and inclusion are more than just words – they are fundamental to ViewRay's shared values, which put Teammates at the center of all we do. We believe that we successfully attract and retain a qualified team in a highly competitive market due, in large part, to our strong culture, rewarding work environment, competitive compensation and benefits, and by encouraging continuous professional development.

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, 2021, 2020 and 2019 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.

Risk Factors Summary

The following is a summary of the principal risks that could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Our Business and Strategy

- The effects of the COVID-19 disease outbreak.
- Our incurrence of significant losses since our inception and anticipation that we will continue to incur significant losses.
- The ability of MRIdian to achieve and sustain sufficient market acceptance.
- Our ability to commercialize our MRIdian systems to achieve and maintain profitability.
- Our limited history commercializing MRIdian which may make it difficult to evaluate our current business and predict future performance.
- MRIdian systems may not perform as expected or may be less safe and effective than initially anticipated.
- Our ability to educate clinicians and patients about the benefits of MRIdian.
- Our ability to establish MRIdian as a standard of care and achieve market acceptance.
- Our limited experience in marketing and selling MRIdian.
- The long sales cycle, low unit volume sales and payment structure of MRIdian may contribute to substantial fluctuations in our operating results and stock price.
- Amounts included in backlog may not result in actual revenue.
- Our ability to increase gross margins by standardizing the selling price, reducing costs of MRIdian and improving our economies of scale.
- Our ability to develop new products or enhance the capabilities of MRIdian.
- The effects of competition.
- Negative press regarding MR Image-Guided radiation therapy for the treatment of cancer.
- Future acquisitions, joint ventures or investments could negatively affect our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

Risks Related to Our Reliance on Third Parties

- Our reliance on third-party, and in some cases sole suppliers.
- Our dependence on third-party distributors to market, distribute, deliver and install MRIdian.
- Our reliance on third parties to perform logistics functions on our behalf.
- The provision of coverage and adequate payment to our customers by third party-payors.
- Compliance of our employees, consultants and commercial partners with regulatory standards and requirements.

Risks Related to Our Financial Condition and Capital Requirements

- We may need to raise additional capital.
- Costs of operating as a public company.
- Covenants and restrictions in our loan and security agreement with Silicon Valley Bank ("SVB").
- Our ability to use our net operating losses to offset future taxable income.
- The current global economic environment.

Risks Related to Administrative, Organizational and Commercial Operations and Growth

- Our ability to manage our future growth effectively.
- Our ability to support demand for MRIdian and our future products.
- The loss of or our inability to attract and retain key personnel.
- Our limited history of manufacturing, assembling and installing MRIdian in commercial quantities.
- Potential product liability or professional liability related lawsuits.
- International tariffs, including tariffs applied to our MRIdian systems sold into China.
- The results of the United Kingdom's withdrawal from the EU.

- Risks associated with our international business.
- Changes in foreign currency exchange rates.
- Compliance with anti-corruption laws and our internal policies designed to ensure ethical business practices.
- Export restrictions and laws affecting trade and investments.
- Dependence on our information technology systems.
- The effects of natural or other disasters, power loss, strikes and other events beyond our control.
- The effects of enacted tax reforms.

Risks Related to Intellectual Property

- Litigation or other proceedings or third-party claims of intellectual property infringement.
- Our ability to adequately protect our proprietary technology or maintain issued patents.
- Compliance with our license agreement with the University of Florida Research Foundation, Inc.
- Changes in U.S. patent laws and their effect on our ability to obtain, defend or enforce our patents.
- Our ability to protect the confidentiality of our trade secrets.
- Our ability to enforce our intellectual property rights throughout the world.
- Third parties may assert ownership or commercial rights to inventions we develop.
- Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.
- Network or data security incidents.

Risks Related to Regulatory Matters

- We are subject to extensive government regulation and oversight.
- Modifications to our products may require new 510(k) clearances or PMA approvals.
- Changes in treatment guidelines for cancer radiation therapies and related regulatory requirements.
- The misuse or off-label use of MRIdian Linac.
- Our MRIdian systems may cause or contribute to adverse medical events.
- Compliance with legal or regulatory requirements related to privacy or data security.
- International regulatory registrations or approvals required to be able to market and sell MRIdian.
- Compliance with regulations regarding the manufacture of MRIdian.
- Legislative or regulatory reforms in the United States or the EU.
- Compliance with fraud and abuse laws and health information privacy and security laws.
- Healthcare policy changes, including legislation reforming the U.S. healthcare system.

Risks Related to Ownership of Our Common Stock

- The price of our common stock may be volatile.
- The impact of future sales of our common stock or securities convertible or exchangeable for our common stock.
- Future issuance of additional shares of our common or preferred stock or securities that are convertible into or exercisable for our common or preferred stock may cause dilution.
- Our operating results may fluctuate significantly or fall below the expectations of investors or analysts.
- 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.
- Provisions of our charter documents or Delaware law could delay or prevent an acquisition of the Company.
- We do not anticipate paying any cash dividends on our common stock in 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.

Risks Related to Environmental and Climate Concerns

- Our manufacturing operations are subject to a number of federal, state and local environmental laws, rules and regulations.
- 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.
- Regulations related to “conflict minerals”.

For a more complete discussion of the material risks facing our business, see below.

Risks Related to Our Business and Strategy

The COVID-19 pandemic has and will continue to adversely affect our business operations and financial condition.

COVID-19 has been declared a pandemic by the World Health Organization ("WHO") and has and will continue to adversely affect our business operations and financial condition. The outbreak continues globally, and government and private sector responsive actions have and will continue to adversely affect our business operations. Many countries are in the process of vaccinating their residents against COVID-19. However, the large scale and challenging logistics of distributing the vaccines, as well as uncertainty over the efficacy of the vaccines against new variants of the virus, may impact the economy as well as our operations in the future. It is impossible to predict the effect and potential spread of the COVID-19 globally.

As COVID-19 persists, our business plans will be further materially delayed or interrupted. Our sales and revenue cycles, including MRIdian orders, deliveries and installations, as well as our other business operations, are likely to be significantly delayed as we experience adverse impacts, including but not limited to adverse impacts affecting our teammates, global supply chain partners, transportation service providers, and customers. For example, along with delays in service from our global supply chain partners, we have experienced delays in installation of systems in the United States, Asia and Europe due to the travel and quarantine restrictions imposed by government agencies and our customers in response to the spread of COVID-19.

Similarly, our ability to conduct commercial efforts with our customers has been and is likely to continue to be disrupted as customers have suspended in-person meetings and turned their focus toward the impact of COVID-19 on their operations. Lastly, many customers have reduced spending on capital equipment, redirected financial resources to pandemic-related expenses, or sought to preserve capital in anticipation of a prolonged pandemic. If our business operations continue to be adversely impacted by the spread of COVID-19, our costs associated with operating our business could be significantly higher than planned, which may have a material impact on our business. COVID-19 could also further adversely impact our teammate population, as well as our near-term and long-term revenues, earnings and cash flow and may require significant additional expenditures to mitigate such impacts.

Should COVID-19 persist, our ability to conduct our business and to access capital markets may be negatively impacted; and delays in capital equipment sales, which make up the majority of our revenue, may have a material impact on our business. The COVID-19 pandemic continues to evolve and shift rapidly, and its continued global economic impact may heighten the other risk factors described herein and negatively impact our operations in areas that we are not aware of currently.

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 $110.0 million, $107.9 million, and $120.2 million during the years ended December 31, 2021, 2020, and 2019, respectively. At December 31, 2021, we had an accumulated deficit of $737.1 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 clearance, 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 appropriate 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, 2021, we recognized revenue of $51.9 million from installation or delivery of ten MRIdian Linac systems and $17.8 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 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, 2021, there were two MRIdian with Cobalt-60 and 46 MRIdian Linacs installed. In addition, 9 MRIdian Linacs have been delivered to customers that are in varying stages of deployment. Consequently, we have limited data 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 not 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 intended 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 intended.

To date, we have not been required to complete long-term clinical studies in connection with the sale of MRIdian Linac. If future patient studies or clinical testing do not support our belief that 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 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 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 in treatment with radiation therapy, including operator error, misuse, radiation therapy product or customer system malfunctions, and other factors. Although we have not experienced such instances, 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, a MRIdian system 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 our devices have only been used to treat patients since early 2014. We have two MRIdian with Cobalt-60 and 46 MRIdian Linac installed at December 31, 2021. In addition, 9 MRIdian Linacs have been delivered to customers that are in varying stages of deployment. 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 recognize installation revenue over the period of installation as the installation services are performed and control is transferred to the customer. When a qualified third party is responsible for the installation, revenue recognition occurs when the title and risk of loss is transferred in accordance with the customer contract. If we don't install or transfer title when anticipated, our operating results may 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, we have experienced delays in our installations due to concerns regarding the COVID-19 pandemic. 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:

- delays in business operations and installation caused by the concerns in connection with the COVID-19 pandemic;
- disruptions in the supply or changes in the costs of raw materials, labor, product components, or transportation services as a result of inflation;
- 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; 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 three to six 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 45 to 60 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 based on the terms of the executed contract. 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. 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 payment 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, delays in obtaining financing and delays associated with the ongoing COVID-19 pandemic. 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, cost-effectiveness and efficiency 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., which was acquired by Siemens Healthineers AG in 2021, 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 ("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. 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 Jastec, Siemens AG, Norman Noble, Inc. and Tesla Engineering Limited, 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, including as a result of concerns regarding the COVID-19 pandemic, which could impede our ability to manufacture, assemble and install MRIdian on our expected timeline, which could result in order cancellations or contractual penalties.

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, including as a result of concerns regarding the COVID-19 pandemic, 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 shortages and/or strikes, third-party error, concerns regarding the COVID-19 pandemic 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 payment 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 payment for radiation oncology services are available to our customers from third-party payors, such as government healthcare insurance programs, including the Medicare and Medicaid programs, and private insurance plans. In general, third-party payors in the United States have become increasingly cost-conscious, which has limited coverage and payment for certain procedures including 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 are no uniform coverage and payment policies 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 used as a model by many private payors and other governmental payors to develop their coverage and payment 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 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 ("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 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, because the coverage policies may limit coverage to only certain types of cancer.

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

Third-party payors regularly update payment amounts and, from time to time, revise the methodologies used to determine payment amounts. This includes annual updates to payments to physicians, hospitals and free-standing radiation centers for 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 paid, these updates could directly affect 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 prescribed statutory formulas.

Third-party payors are incentivizing value-based health care by moving away from fee-for-service payment systems to alternative payment models that pay providers based on an episode of care. Under such models, providers are paid a prospectively determined payment amount per episode and must furnish all medically necessary services to treat the patient. Providers may enter into risk-share arrangements with payors under such models. An example of such a model is Medicare's Radiation Oncology Model ("RO APM"). The expected implementation of the RO APM on January 1, 2023 could affect the demand for MRIdian. Demand can also change as CMS makes changes to the RO APM model in later years as well as if other third-party payors adopt similar models.

Any significant changes, or proposed changes, in payment rates or payment methodologies for radiation therapy or MR Image-Guided therapy specifically, could further increase uncertainty, influence our customers' decisions, reduce demand for MRIdian, cause customers to cancel orders and affect our revenue and harm our business.

Foreign countries also have their own healthcare financing, delivery, and payment systems, which vary significantly by country and region, and we cannot be sure that adequate payments will be made available to customers in those countries with respect to MRIdian under any such foreign health care financing and delivery systems.

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 and debt covenants, 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 address delays impacting our business operations caused by concerns in connection with the COVID-19 pandemic;
- 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 (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 further regulations and disclosure obligations expected in the future. 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 have developed and refined 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 (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 are 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 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, 2021, we had $58 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 does 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, 2021, we had federal net operating loss carryforwards ("NOLs") of $605.5 million, which begin to expire in the year ending December 31, 2024, and $258.6 million related to state net operating loss carryforwards, which begin to expire in the year ending December 31, 2021. We also had federal research and development tax credit carryforwards of $7.5 million which begin to expire in the year ending December 31, 2027 and state research and development tax credit carryforwards of $5.0 million which carry forward indefinitely. Under Section 382 of the Internal Revenue Code of 1986, as amended (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 three ownership changes which had a corresponding limitation of tax attributes. Future owner or equity changes, including changes that may be outside of our control, could result in additional 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, including risks arising in connection with the COVID-19 pandemic, 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, including as a result of concerns regarding the COVID-19 pandemic, 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, Colorado 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.

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

Recent U.S. government actions are imposing greater restrictions and economic disincentives on international trade impacting imports and exports. The U.S. government has adopted changes, and intends to adopt further changes, to trade policy and in some cases, to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements. It has initiated the imposition of additional tariffs on certain foreign goods, including radiation therapy equipment. Additionally, the government may also propose export rule changes that lower the percentage of permissible U.S. content for certain non-U.S. manufactured goods being sold to certain specified companies, further restrict the sale of foreign-made goods that are based on U.S. technology, and regulate the use of any U.S. origin content in certain manufacturing equipment used to produce goods for certain companies.

Changes in U.S. trade policy could result in one or more U.S. trading partners adopting responsive trade policy making it more difficult or costly for us to export our products to those countries. As indicated above, these measures could also result in increased costs for goods imported into the U.S. This in turn could require us to increase prices to our customers, which may reduce demand, or, if we are unable to increase prices, result in lowering our margin on goods and services sold. To the extent that trade tariffs and other restrictions imposed by the U.S. increase the price of radiation therapy equipment and related parts imported into the U.S., the cost of our materials may be adversely affected and the demand from customers for products and services may be diminished, which could adversely affect our revenues.

We cannot predict future trade policy, the terms of any renegotiated trade agreements or additional imposed tariffs and their impact on our business. The adoption and expansion of trade restrictions, the occurrence of a trade war, or other governmental action related to tariffs or trade agreements or policies have the potential to adversely impact demand for our products, our costs, our customers, our suppliers, and the U.S. economy, which in turn could adversely impact our business, financial condition and results of operations.

Changes in U.S. social, political, regulatory and economic conditions or in laws and policies governing foreign trade, manufacturing, development and investment in the territories and countries where we currently develop and sell products, and any negative sentiments towards the United States as a result of such changes, could adversely affect our business. In addition, negative sentiments towards the United States among non-U.S. customers and among non-U.S. employees or prospective employees could adversely affect sales or hiring and retention, respectively.

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

The U.K. held a referendum on June 23, 2016 in which a majority voted for the U.K.'s withdrawal from the European Union, which is commonly referred to as Brexit. On January 29, 2020, the U.K. Parliament approved a withdrawal agreement submitted on January 22, 2020, and the U.K. officially withdrew from the EU on January 31, 2020, although it continued to participate in the European Union during a transition period through December 31, 2020. The effects of Brexit and the perceptions as to the impact of the withdrawal of the U.K. from the European Union may adversely affect business activity and economic and market conditions in the U.K., the Eurozone, and globally and could contribute to instability in global financial and foreign exchange markets, including volatility in the value of the pound sterling and the euro. In addition, Brexit could lead to additional political, legal and economic instability in the European Union. Any of these effects of Brexit could adversely affect the value of our assets in the U.K., as well as our business, financial condition, results of operations and cash flows.

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:

- delays impacting our business operations caused by concerns in connection with the COVID-19 pandemic;
- 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 (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;
- economic, political or social instability in foreign countries and regions, including the possible political unrest involving Russia and Ukraine that may impact our business operations in Russia;
- 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;
- 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.

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 (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. 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, Colorado, Ohio and other areas that have experienced major earthquakes, tornadoes and other natural disasters.

A major earthquake, tornado or other disaster (such as pandemic outbreaks, 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.

Risks Related to Intellectual Property

Litigation or other proceedings or third-party claims of intellectual property infringement can and are requiring 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 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 additional 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 partes 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.

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 partes 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 (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 ("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. Even if we 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 still 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.

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, and seek to ensure that our third-party providers have required capabilities and controls, to address this risk.

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.

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.

We maintain cybersecurity insurance in the event of an information security or cyber incident; however, the coverage may not be sufficient to cover all financial, legal, business, or reputational losses.

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 ("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. In February 2019, we received 510(k) clearance for modifications to the MRIdian Linac system, including image pulse sequencing, changing from four to eight frames per second for imaging during radiation therapy delivery and modifications to the multi-channel radiofrequency system. In December 2021, we received 510(k) clearance for MRIdian A3i, which includes new features focused on enhancing on-table adaptive workflow efficiency and expanding clinical utility.

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. Certain policies of the Biden administration may impact our business and industry. For example, if the Biden administration were to impose constraints on the 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 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 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 Linac, which would prevent us from selling 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 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 December 2021, we received a 510(k) clearance from the FDA to market the MRIdian A3i. 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 premarket 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 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 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 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 Linac has been cleared by the FDA for specific treatments. We train our marketing and direct sales force to not promote MRIdian Linac for uses outside of the FDA-cleared indications for use, known as "off-label uses." For example, MRIdian Linac has not been indicated for diagnostic use. We cannot, however, prevent a physician from using 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 Linac off-label. Furthermore, the use of 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 continually work 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.

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.

Any changes in federal health care programs, including the Affordable Care Act, Medicare, and others, may affect how state and federal governments and employers pay for health care products and services. Such changes could result in reduced demand for MRIdian or additional pricing pressure. Other changes, such as the RO Model, could also affect demand for MRIdian systems.

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:

- impacts to our business operations caused by concerns in connection with the COVID-19 pandemic;
- 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, such as the class action litigation described in Item 3. Legal Proceedings in this Report. We have incurred substantial costs in defending the class action litigation, and any future lawsuits of this type could cause us to incur substantial defense costs and could divert our management's attention from the operation of our business.

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, 2021, we have outstanding a total of 179,206,456 shares of common stock.

In addition, at December 31, 2021, 12.4 million shares of our common stock were issuable upon exercise of options or vesting of restricted stock units and deferred stock units issued under our stock incentive plans and there were 9.0 million shares of our common stock available for issuance under our stock incentive plans and employee stock purchase plan. 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 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. From time to time, we may request additional shares if we anticipate that equity-based compensation needs may exceed the remaining shares available under the 2015 Equity Incentive Award Plan (as amended and restated, the "2015 Plan"). If the shares we may issue from time to time under the 2015 Plan, the 2018 Inducement Plan (the "2018 Plan") or the 2015 Employee Stock Purchase Plan (as amended and restated, the "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:

- impacts to our business operations caused by concerns in connection with the coronavirus pandemic;
- 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 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, 2021, our officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially own approximately 54% 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, Fosun International Limited (Fosun) has the right pursuant to certain securities purchase agreements to request appointment of a representative of Fosun as a non-voting observer to our board of directors, subject to meeting certain continuing stock ownership thresholds. Currently, no such non-voting observer has been appointed by Fosun. 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 SVB 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 Environmental and Climate Concerns

Our manufacturing operations are subject to a number of federal, state and local environmental laws, rules and regulations.

Although our manufacturing and other activities do not presently produce meaningful levels of greenhouse gas emissions, our operating expenses could be adversely affected if legal and regulatory developments related to climate change or other initiatives result in increased energy or other costs. We could also be affected by climate change and other environmental issues to the extent such issues adversely affect the general economy or result in severe weather affecting the communities in which our facilities are located. At this time, based on current climate conditions and our assessment of existing and pending environmental rules and regulations, as well as treaties and international accords relating to climate change, we do not believe that the costs of complying with environmental laws, including regulations relating to climate change issues, will have a material adverse effect on our future capital expenditures, results of operations or cash flows. There were no material capital expenditures for environmental matters in the year ended December 31, 2021.

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.

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.

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, 2026. 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, 2021. 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. The second office lease in Mountain View, California commenced in December 2018 and will expire in December 2025. The Company has the option to extend the term of the lease for a period of up to five years. In March 2021, we entered into a lease agreement to lease approximately 12,800 square feet of office space in Denver, Colorado. The lease commenced on September 1, 2021 and will expire October 31, 2024.

Item 3. LEGAL PROCEEDINGS

Class Action Litigation

On September 13, 2019, a class action complaint for violation of federal securities laws was filed in U.S. District Court for the Northern District of Ohio against the Company, our chief executive officer, chief scientific officer, and former chief financial officer. On December 19, 2019, the court appointed Plymouth County Retirement Association as the lead plaintiff, and on February 28, 2020 the lead plaintiff filed an amended complaint asserting securities fraud claims against the Company, our chief executive officer, chief operating officer, chief scientific officer, and former chief executive officer and former chief financial officer. Now captioned Plymouth County Retirement Association v. ViewRay, Inc., et al., the

amended complaint alleges that we violated federal securities laws by issuing materially false and misleading statements that failed to disclose adverse facts concerning our business, operations, and financial results, and seeks damages, interest, and other relief. On August 25, 2021, the District Court dismissed the lead plaintiff's second amended complaint, with prejudice. On September 17, 2021, the lead plaintiff filed notice of its intent to appeal the District Court's opinion and order dismissing the complaint to the Sixth Circuit Court of Appeals. The lead plaintiff filed its opening appellate brief on January 14, 2022, and the defendants' response is due March 15, 2022. We believe the appeal is without merit and intend to vigorously defend the litigation.

Stockholder Derivative Lawsuit

On July 22, 2020, a stockholder derivative lawsuit, captioned Gile derivatively on behalf of ViewRay, Inc. v. ViewRay Inc., et al., was filed against ViewRay (as a nominal defendant) and certain of its current and former officers and directors in the U.S. District Court for the Northern District of Ohio. This action alleges, purportedly on behalf of ViewRay, that the officers and directors violated Section 14(a) of the Securities Exchange Act of 1934, breached their fiduciary duties, wasted corporate assets, and were unjustly enriched based on factual assertions substantially similar to those in the class action complaint described above. The complaint seeks, among other things, damages awarded to ViewRay, restitution and disgorgement of profits in an unspecified amount, and corporate reforms. Due to the overlap between the allegations in the derivative complaint and those in the putative securities class action complaint, this lawsuit is presently stayed, pending a decision on the appeal by the Sixth Circuit Court of Appeal.

Given the early stage of each of the litigation matters described above, at this time we are unable to reasonably estimate possible losses or form a judgment that an unfavorable outcome is either probable or remote. 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 in 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 February 15, 2022, there were 72 registered stockholders of record of our common stock. Because many of our shares of common stock are held by brokers or other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial stockholders and believe the number of registered stockholders of record underestimates our total number of stockholders.

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, 2021, 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, 2021.

Item 6. RESERVED

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.

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.

A comparison of the results for the year ended December 31, 2021 and 2020 is provided below. Our Annual Report on Form 10-K for the year ended December 31, 2020 includes a discussion and analysis of our financial condition and results of operations for the year ended December 31, 2019 in Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

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 FDA and permission to affix the CE mark. Additionally, the newest version of MRIdian, MRIdian A3i, received 510(k) marketing clearance from the FDA in December 2021.

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.

MRIdian A3i streamlines the on-table adaptive workflow by allowing clinicians to intelligently auto-contour, auto-adapt, and auto-gate. Enabling clinicians to collaborate simultaneously and connect remotely during patient treatment. The automated workflow steps and contouring tools are designed to minimize clinician time and increase patient throughput.

MRIdian A3i expands existing real-time tissue tracking and automated beam gating functionalities to include multiplanar tracking and gating in up to three planes. Our customers have the flexibility to select up to three different tracking targets in any combination of coronal, sagittal, or axial planes to automatically stop the beam when any single target exceeds the clinician-defined treatment boundaries.

At December 31, 2021, a total of 48 MRIdian systems, 2 MRIdian with Cobalt-60 systems and 46 MRIdian Linac systems, are in operation worldwide (21 in the United States and 27 outside the United States). In addition, 9 MRIdian Linac systems have been delivered to customers that are in varying stages of deployment.

We currently market MRIdian through a direct sales force in the United States. In the rest of the world, we market MRIdian through a hybrid model of both a direct sales force and distribution network. 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 45 to 60 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 $70.1 million, $57.0 million and $87.8 million, and had net losses of $110.0 million, $107.9 million and $120.2 million during the years ended December 31, 2021, 2020, and 2019, 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.

November 2021 Public Offering of Common Stock

On November 16, 2021, the Company entered into an underwriting agreement with Piper Sandler & Co. and Stifel, Nicolaus & Company, Incorporated, as representatives of the several underwriters named therein (the "November 2021 Underwriters"), with respect to the issuance and sale by the Company of 14,375,000 shares of our common stock, which

included the full exercise of the November 2021 Underwriters' option to purchase additional shares, at a price to the public of $5.60 per share. The Company completed the offering on November 18, 2021, and received net proceeds of approximately $75.1 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company.

January 2021 Public Offering of Common Stock

On January 4, 2021, we entered into an underwriting agreement with Piper Sandler & Co., as representative of the several underwriters named therein, with respect to the issuance and sale of 11,856,500 shares of our common stock, which included the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $4.85 per share. We completed the offering on January 7, 2021 and received net proceeds of approximately $53.5 million, after deducting the underwriting discounts and commissions and offering expenses payable by us.

December 2019 Public Offering of Common Stock

On December 3, 2019, we entered into an underwriting agreement with Piper Jaffray & Co., as representatives of several underwriters (the "December 2019 Underwriters"), in connection with the issuance and sale of 47,782,500 shares of our common stock, which included the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $3.13 per share. We completed the offering on December 6, 2019 and received aggregate net proceeds of approximately $138.4 million, after deducting the underwriting discounts and commissions and offering expenses payable by us.

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 a specified amount and elects to apply such later date), the Company would have made 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.

On December 31, 2019, we entered into the First Amendment (the “First Amendment”) to Loan and Security Agreement by and among the Company, ViewRay Technologies, Inc. and SVB dated as of December 28, 2018. The First Amendment, among other things, amended the Loan Agreement to (i) suspend testing of the minimum revenue financial covenant for the fiscal quarter ending December 31, 2019, (ii) provide for the minimum trailing twelve-month revenue thresholds under the minimum revenue financial covenant for periods ending on the last day of fiscal quarters in fiscal years subsequent to 2020 to be determined annually at the greater of (a) a 25% cushion to revenue forecasts provided by the Company to SVB and (b) 10% year-over-year annual growth, unless otherwise agreed, (iii) increase the minimum liquidity ratio financial covenant from 1.50:1.00 to 1.75:1.00 and (iv) increase the prepayment premium from 1.00% to 2.00% for amounts prepaid under the SVB Term Loan for prior to the maturity date thereof, subject to certain exceptions.

On October 30, 2020, we entered into the Second Amendment (the “Second Amendment”) to the SVB Term Loan. The Second Amendment, among other things, amended the SVB Term Loan to (i) increase the term loan agreement principal amount from $56.0 million to $58.0 million, (ii) revise the thirty-six equal monthly payments of principal to begin on November 1, 2022, (iii) revise the maturity date to October 1, 2025, (iv) decrease the interest rate from a fixed rate of 6.3% to a floating rate of 2.4% above the Prime Rate, (v) increase the final payment from 3.15% of the original aggregate principal amount to 3.7% of the revised aggregate principal amount, (vi) revise the minimum trailing twelve-month revenue thresholds under the minimum revenue financial covenant for periods ending on the last day of fiscal quarters in fiscal years subsequent to 2020, (vii) decrease the minimum liquidity ratio financial covenant from 1.75:1.00 to 1.70:1.00, (viii) remove the minimum cash balance as a condition of the minimum revenue financial covenant and the minimum liquidity ratio financial covenant, and (ix) increase the prepayment premium from 2.00% to 3.00% for the first 30 months of the term for amounts prepaid under the SVB Term Loan prior to the maturity date thereof, subject to certain exceptions. In connection with the execution of the Second Amendment, we agreed to pay the earned portion of the final payment, which equated to $0.8 million.

On October 29, 2021, the Company entered into the Third Amendment (the “Third Amendment”) to the SVB Term Loan. The Third Amendment amended the SVB Term Loan to (i) decrease the minimum liquidity ratio financial covenant from 1.70:1.00 to 1.35:1.00, and (ii) increase the prepayment premium from 3.00% to 3.5% for the first 30 months of the term and from 2.00% to 2.50% thereafter for the remaining term, for amounts prepaid under the SVB Term Loan prior to the maturity date thereof, subject to certain exceptions.

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 does 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.

At-The-Market Offering of Common Stock

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 an at-the-market offering program with FBR Capital Markets & Co., now known as B. Riley Securities. There were no sales of our common stock pursuant to our at-the-market offering program during fiscal year 2019 or fiscal year 2020. This shelf registration statement expired in February 2022.

Impact of the COVID-19 Pandemic

We continue to see an impact of COVID-19 on our operations which has affected both our own commercial efforts with our customers and our global supply chain. This situation remains dynamic and may continue to affect our operations. See Item 1A "Risk Factors" for a discussion of certain risks related to COVID-19.

Impact of Inflation

In recent years, inflation has not had a significant impact on our operations. However, we continuously monitor the current economic environment including product cost increases, particularly in connection with the parts used in our manufacturing process. Inflation may generally reduce the real value of the purchase price payable which could cause our gross margins to decline or cause us to lose money on the sale of a MRIdian. See Item 1A "Risk Factors" for a discussion of certain risks related to inflation.

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, 2021, 2020 and 2019, our new orders were $158.9 million, $94.6 million and $118.5 million, respectively. Based on our assessment, we removed $30.4 million, $36.1 million and $21.9 million from the backlog for fiscal years 2021, 2020 and 2019, respectively. At December 31, 2021, we had a backlog with a total value of $313.4 million.

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 45 to 60 days to complete the installation and on-site testing of the system, including the completion of customer test procedures. On-site training can take up to multiple weeks 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.

Beginning in the second quarter of 2019, for new contracts in which control of the system transfers upon delivery and inspection, the Company recognizes revenue for the system at the point in time when delivery and inspection has occurred. For these same contracts, the Company recognizes installation revenue over a period of time as control of the installation services is transferred. For all contracts in which control continues to transfer upon post-installation customer acceptance, revenue for the system and installation will continue to be recognized upon customer acceptance. 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 a twelve-month warranty. 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 beginning in 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 $0.9 million and $0.2 million for the years ended December 31, 2021 and 2020, respectively. We did not record LCNRV charges for the year ended December 31, 2019.

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 SVB Term Loan.

Other Income (Expense), Net

Other income (expense), net consists primarily of changes in the fair value of the warrants to purchase 1,720,512 shares of common stock that we issued in a private placement in January 2017 (the "2017 Placement Warrants") and the warrants to purchase 1,380,745 shares of common stock that we issued in a private placement in August 1026 (the "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 income (expense), net.

Results of Operations

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

	Year Ended December 31,		
	2021	2020	2019
Revenue:			
Product	$ 51,865	$ 42,742	$ 79,504
Service	17,779	13,800	7,803
Distribution rights	475	475	475
Total revenue	70,119	57,017	87,782
Cost of revenue:			
Product	51,780	49,347	80,446
Service	18,004	11,729	12,814
Total cost of revenue	69,784	61,076	93,260
Gross profit (loss)	335	(4,059)	(5,478)
Operating expenses:			
Research and development	31,849	25,008	23,794
Selling and marketing	16,044	15,181	25,806
General and administrative	56,091	61,729	65,717
Total operating expenses	103,984	101,918	115,317
Loss from operations	(103,649)	(105,977)	(120,795)
Interest income	13	791	1,721
Interest expense	(4,241)	(3,307)	(4,327)
Other income (expense), net	(2,171)	585	3,202
Loss before provision for income taxes	(110,048)	(107,908)	(120,199)
Provision for income taxes	—	—	—
Net loss	$ (110,048)	$ (107,908)	$ (120,199)

Comparison of the years ended December 31, 2021 and 2020

Revenue

	Year Ended December 31,			
	2021	2020	Change ($)	Change (%)
	(in thousands)			
Product	$ 51,865	$ 42,742	$ 9,123	21.3 %
Service	17,779	13,800	3,979	28.8 %
Distribution rights	475	475	—	— %
Total revenue	70,119	57,017	13,102	23.0 %

Total revenue during the year ended December 31, 2021 increased by $13.1 million, or 23.0% compared to the year ended December 31, 2020. The increase was due to an increase in product revenue of $9.1 million as well as an increase in service revenue of $4.0 million during the year ended December 31, 2021 as compared to December 31, 2020.

Product Revenue. Product revenue increased by $9.1 million, or 21.3%, in fiscal year 2021 compared to fiscal year 2020. The increase was primarily attributable to additional MRIdian Linac systems recognized as revenue in fiscal year 2021 as compared to fiscal year 2020. The Company recognized revenue for ten MRIdian Linac systems during the fiscal year 2021, as compared to seven MRIdian Linac systems and two upgrades during the fiscal year 2020.

Service Revenue. Service revenue increased by $4.0 million, or 28.8%, in fiscal year 2021 compared to fiscal year 2020 primarily due to the increase in installed base.

Cost of Revenue

	Year Ended December 31,			
	2021	2020	Change ($)	Change (%)
	(in thousands)			
Product	$ 51,780	$ 49,347	$ 2,433	4.9 %
Service	18,004	11,729	6,275	53.5 %
Total cost of revenue	69,784	61,076	8,708	14.3 %

Product Cost of Revenue. Product cost of revenue increased by $2.4 million, or 4.9%, in fiscal year 2021 compared to fiscal year 2020. The increase was primarily attributable to the additional MRIdian Linac systems recognized in fiscal year 2021 as compared to fiscal year 2020.

Service Cost of Revenue. Service cost of revenue increased by $6.3 million, or 53.5%, in fiscal year 2021 compared to fiscal year 2020. The increase in service cost of revenue was primarily due to the increase in installed base and freight expenses. Additionally, in the fiscal year 2020 there was a decrease in cost of service-related inventory parts, travel, and payroll reductions for our service personnel as a result of COVID-19.

Operating Expenses

	Year Ended December 31,			
	2021	2020	Change ($)	Change (%)
	(in thousands)			
Research and development	$ 31,849	$ 25,008	$ 6,841	27.4 %
Selling and marketing	16,044	15,181	863	5.7 %
General and administrative	56,091	61,729	(5,638)	(9.1)%
Total operating expenses	103,984	101,918	2,066	2.0 %

Research and Development. Research and development expenses increased by $6.8 million, or 27.4%, in fiscal year 2021 compared to fiscal year 2020. This increase was a result of increased personnel and consulting expenses related to clinical studies and development of MRIdian A3i.

Selling and Marketing. Selling and marketing expenses increased by $0.9 million, or 5.7%, in fiscal year 2021 compared to fiscal year 2020. This slight increase was primarily attributable to an increase in travel and marketing expenses for in-person events of $1.8 million, offset by a decrease in personnel and other expenses of $0.8 million.

General and Administrative. General and administrative expenses decreased by $5.6 million, or 9.1%, in fiscal year 2021 compared to fiscal year 2020. This decrease was primarily attributable to a $3.5 million and $4.8 million decrease in personnel and legal expenses, respectively, partially offset by an increase in office and other related expenses as our office spaces began to reopen after the COVID-19 shutdowns.

Interest Income

	Year Ended December 31,			
	2021	2020	Change ($)	Change (%)
	(in thousands)			
Interest income	$ 13	$ 791	$ (778)	(98.4)%

Interest income decreased by $0.8 million in fiscal year 2021 compared to fiscal year 2020 due to an overall decrease in interest rates during 2020.

Interest Expense

	Year Ended December 31,			
	2021	2020	Change ($)	Change (%)
	(in thousands)			
Interest expense	$ (4,241)	$ (3,307)	$ (934)	28.2 %

Interest expense increased by $0.9 million in fiscal year 2021 compared to fiscal year 2020. In October 2020, the Company modified the SVB Term Loan. Based on the terms of modification, the Company wrote off the applicable debt issuance costs and discounts. Then in October 2021, the Company further modified the SVB Term Loan. Based on the terms of the modification, there was minimal impact on interest expense.

Other Income (Expense), Net

	Year Ended December 31,			
	2021	2020	Change ($)	Change (%)
	(in thousands)			
Other income (expense), net	$ (2,171)	$ 585	$ (2,756)	(471.1)%

Other income (expense), net for fiscal year 2021 consisted primarily of a $2.3 million increase in the fair value of warrant liabilities related to the 2017 and 2016 Placement Warrants. Other income (expense), net for fiscal year 2020 consisted primarily of a $0.5 million decrease in the fair value of warrant liabilities related to the 2017 and 2016 Placement Warrants.

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, 2021, 2020 and 2019, we had a net loss of $110.0 million, $107.9 million and $120.2 million, respectively. At December 31, 2021 we had an accumulated deficit of 737.1 million.

At December 31, 2021 and 2020, we had cash and cash equivalents of $218.3 million and $156.7 million, respectively. To date, we have financed our operations principally through offerings of our capital stock, issuances of warrants, use of term loans, 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.

We expect that our existing cash and cash equivalents, together with proceeds from the sales of MRIdian systems, will be adequate to meet anticipated working capital needs, anticipated levels of capital expenditures, and contractual obligations for the next twelve months. However, we continue to critically review our liquidity and anticipated capital requirements in light of the significant uncertainty created by the COVID-19 pandemic.

We could potentially use our available financial resources sooner than we currently expect, and we may incur additional indebtedness to meet long-term 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,		
	2021	2020	2019
Cash used in operating activities	$ (62,091)	$ (63,474)	$ (79,567)
Cash used in investing activities	(1,559)	(6,183)	(7,817)
Cash provided by (used in) financing activities	125,278	(350)	146,206

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 in operating activities are amounts due to vendors for purchased components and employee-related expenditures.

During fiscal year 2021, cash used in operating activities was $62.1 million, resulting from our net loss of $110.0 million, offset by a net change of $12.9 million in our working capital, and the aggregate non-cash charges of $35.0 million.

During fiscal year 2020, cash used in operating activities was $63.5 million, resulting from our net loss of $107.9 million, offset by a net change $16.9 million of in our working capital, and the aggregate non-cash charges of $27.5 million.

Investing Activities

Cash used in investing activities during the year ended December 31, 2021 and 2020 of $1.6 million and $6.2 million, respectively, primarily resulted from capital expenditures to purchase property and equipment.

Financing Activities

During the year ended December 31, 2021, net cash provided by financing activities was $125.3 million, which consisted of net proceeds from the January and November common stock public offerings of $128.6 million, proceeds from the exercise of stock options of $0.8 million, and proceeds from the employee stock purchase plan of $0.6 million, partially offset by the cash used to pay taxes related to net share settlement of equity awards of $4.6 million.

Contractual Obligations

Per Rule 12b-2 of the Exchange Act, we are not required to provide the information required under this item.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States ("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. Beginning in the second quarter of 2019, the Company determined that the MRIdian system and installation of the MRIdian system, which had previously been one performance obligation, are now two performance obligations as they are capable of being distinct and are distinct within the context of the system contracts. This change occurred due primarily to changes in facts and circumstances, whereby there are now readily available resources outside the Company that can perform the system installations.

Additionally, certain revenue contracts have terms that result in the control of the system transferring to the customer upon delivery and inspection, as opposed to historically upon customer acceptance. For contracts in which control of the system

transfers upon delivery and inspection, the Company recognizes revenue for the systems at the point in time when delivery and inspection by the customer has occurred. For these same contracts, the Company recognizes installation revenue over the period of installation as the installation services are performed and control is transferred to the customer. For all contracts in which control continues to transfer upon post-implementation customer acceptance, revenue for the system and installation will continue to be recognized upon customer acceptance.

Certain customer contracts with distributors do not require ViewRay installation at the ultimate user site, and the distributors may either perform the installation themselves or hire another party to 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 shipped, 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. We use the Black-Scholes option-pricing model to estimate the fair value of our stock-based awards including: restricted stock units ("RSUs"), deferred stock units ("DSUs"), performance share units (“PSUs”), employee stock purchase plan ("ESPP"), and stock options. This valuation model requires the input of highly subjective assumptions, the most significant of which is our estimates of expected volatility and the forfeiture rate of the award. During the fourth quarter of 2020, the Company began to determine volatility by solely using the Company’s own historical volatility measurements, since more than four years of historical data became available in the public market. Prior to the fourth quarter of 2020, the Company determined the volatility for stock awards granted based on the average historical price volatility for the Company and industry peers over a period equivalent to the expected term of the stock options grants. The forfeiture rate of stock awards is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures have been estimated by the Company based upon historical and expected forfeiture experience.

Furthermore, PSUs are based on our corporate financial performance targets in the Company’s compound annual revenue growth rate over a three-year period. The number of PSUs that will ultimately be awarded are contingent on our actual level of achievement compared to the corporate financial target performance targets.

The assumptions used in calculating the fair value of stock-based payment awards 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 income (expenses), net at each reporting date until the warrants are exercised or expired. The Company valued the 2017 and 2016 Placement Warrants at issuance using the Black-Scholes option pricing model and determined the fair value. The key inputs to the valuation model included expected volatility, risk-free rate, and an expected term.

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.

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 were a smaller reporting company, as defined in Rule 12b-2 of the Exchange Act, for the fiscal year ended December 31, 2021 and we therefore 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 shareholders 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 subsidiaries (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 25, 2022, expressed an unqualified opinion on the Company's internal control over financial reporting.

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 PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Recognition – Refer to Notes 2 and 7 in the Consolidated Financial Statements

Critical Audit Matter Description

Product revenue is derived from the sale of the MRIdian system and related services. Generally, each MRIdian contract contains multiple performance obligations. Such performance obligations mainly consist of (i) sale of the MRIdian system, 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 a SSP is not directly observable, the Company will estimate the SSP considering market conditions or internally approved pricing guidelines related to the performance obligations. Total product and service revenue recognized in the year ended December 31, 2021 was $70 million.

We identified revenue recognition as a critical audit matter due to the management judgment involved in the determination of each performance obligation and the allocation of revenue to each performance obligation. Performing audit procedures to evaluate management’s judgments in identifying performance obligations within a revenue arrangement as well as the judgements as to the SSP and allocation of consideration from a revenue arrangement to the individual performance obligations requires a high degree of auditor judgment due to the unique nature of each of the contracts and the multiple performance obligations included.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to revenue recognition included the following, among others:

- For each product revenue transaction tested which occurred during the year ended December 31, 2021, we analyzed the terms of the contracts to determine that all performance obligations were identified appropriately by management and considered by management in the revenue recognition allocation calculations utilized to record revenue. Additionally, we tested the allocation of the transaction price to each performance obligation to determine management recorded the revenue accurately and in the appropriate period.
- We evaluated the Company’s SSP analysis by analyzing inputs used in developing the SSP (i.e., agreeing to underlying observable prices, where applicable, or by evaluating the reasonableness of the methods and assumptions including observable prices, market conditions or internally approved pricing guidelines used by management to estimate the SSP), to determine if the SSP is appropriate for each performance obligation.
- We evaluated management’s ability to estimate the SSP by performing a retrospective review of the assumptions (observable prices, market conditions or internally approved pricing guidelines) utilized by management in determining SSP.

/s/Deloitte & Touche LLP
Denver, CO
February 25, 2022

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, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 218,348	$ 156,720
Accounts receivable	21,659	11,769
Inventory, net of allowance of $3,071 and $2,286, respectively	29,617	46,641
Deposits on purchased inventory	4,778	2,084
Deferred cost of revenue	3,342	1,954
Prepaid expenses and other current assets	5,803	5,257
Total current assets	283,547	224,425
Property and equipment, net	20,242	24,062
Restricted cash	1,460	1,460
Intangible assets, net	44	50
Right-of-use assets	9,661	10,129
Other assets	6,853	1,426
TOTAL ASSETS	$ 321,807	$ 261,552
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9,199	$ 9,984
Accrued liabilities	26,555	19,281
Customer deposits	20,784	15,463
Operating lease liability, current	2,561	2,089
Current portion of long-term debt	3,222	—
Deferred revenue, current portion	13,920	10,094
Total current liabilities	76,241	56,911
Deferred revenue, net of current portion	4,232	2,572
Long-term debt	54,031	56,940
Warrant liability	6,795	4,864
Operating lease liability, noncurrent	8,066	9,043
Other long-term liabilities	2,647	956
TOTAL LIABILITIES	152,012	131,286
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, par value $0.01 per share; 10,000,000 shares authorized at December 31, 2021 and 2020; no shares issued and outstanding at December 31, 2021 and 2020	—	—
Common stock, par value of $0.01 per share; 300,000,000 shares authorized at December 31, 2021 and 2020; 179,206,456 and 148,615,351 shares issued and outstanding at December 31, 2021 and 2020	1,782	1,476
Additional paid-in capital	905,145	755,874
Accumulated deficit	(737,132)	(627,084)
TOTAL STOCKHOLDERS' EQUITY	169,795	130,266
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 321,807	$ 261,552

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,		
	2021	2020	2019
Revenue:			
Product	$ 51,865	$ 42,742	$ 79,504
Service	17,779	13,800	7,803
Distribution rights	475	475	475
Total revenue	70,119	57,017	87,782
Cost of revenue:			
Product	51,780	49,347	80,446
Service	18,004	11,729	12,814
Total cost of revenue	69,784	61,076	93,260
Gross profit (loss)	335	(4,059)	(5,478)
Operating expenses:			
Research and development	31,849	25,008	23,794
Selling and marketing	16,044	15,181	25,806
General and administrative	56,091	61,729	65,717
Total operating expenses	103,984	101,918	115,317
Loss from operations	(103,649)	(105,977)	(120,795)
Interest income	13	791	1,721
Interest expense	(4,241)	(3,307)	(4,327)
Other income (expense), net	(2,171)	585	3,202
Loss before provision for income taxes	$ (110,048)	$ (107,908)	$ (120,199)
Provision for income taxes	—	—	—
Net loss attributable to common stockholders, basic and diluted	$ (110,048)	$ (107,908)	$ (120,199)
Net loss per share, basic and diluted	$ (0.67)	$ (0.73)	$ (1.18)
Weighted-average common shares used to compute net loss per share attributable to common stockholders, basic and diluted	164,521,064	147,895,561	102,001,954

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

VIEWRAY, INC.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity
(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
Balance at December 31, 2018	—	$ —	$ —	96,332,023	$ 952	$ 565,334	$ (398,977)	$ 167,309
Issuance of common stock from option exercises	—	—	—	2,219,251	23	9,618	—	9,641
Issuance of common stock from releases of restricted stock units	—	—	—	393,722	4	(4)	—	—
Tax withholding paid on behalf of employees for stock-based awards	—	—	—	—	—	(2,410)	—	(2,410)
Stock-based compensation	—	—	—	—	—	19,444	—	19,444
Issuance of common stock upon public offering (net of offering cost of $11,146)	—	—	—	47,782,500	478	137,935	—	138,413
Issuance of common stock from warrant exercises	—	—	—	464,199	5	(5)	—	—
Reclassification of warrant liability to additional paid-in capital upon warrant exercises	—	—	—	—	—	3,976	—	3,976
Net loss	—	—	—	—	—	—	(120,199)	(120,199)
Balance at December 31, 2019	—	$ —	$ —	147,191,695	$ 1,462	$ 733,888	$ (519,176)	$ 216,174
Issuance of common stock from option exercises	—	—	—	20,579	—	15	—	15
Issuance of common stock from releases of restricted stock units	—	—	—	1,214,786	12	(12)	—	—
Tax withholding paid on behalf of employees for stock-based awards	—	—	—	—	—	(1,376)	—	(1,376)
Stock-based compensation	—	—	—	—	—	22,805	—	22,805
Issuance of common stock from employee stock purchase plan	—	—	—	188,291	2	363	—	365
Write-down of offering costs related to previous issuance of common stock upon public offering	—	—	—	—	—	191	—	191
Net loss	—	—	—	—	—	—	(107,908)	(107,908)
Balance at December 31, 2020	—	$ —	$ —	148,615,351	$ 1,476	$ 755,874	$ (627,084)	$ 130,266
Issuance of common stock from option exercises	—	—	—	156,199	3	772	—	775
Issuance of common stock from releases of restricted stock units	—	—	—	4,015,380	40	(40)	—	—
Tax withholding paid on behalf of employees for stock-based awards	—	—	—	—	—	(4,600)	—	(4,600)
Stock-based compensation	—	—	—	—	—	23,871	—	23,871
Issuance of common stock upon public offerings (net of offering cost of $9,334)	—	—	—	26,231,500	262	128,364	—	128,626
Issuance of common stock from employee stock purchase plan	—	—	—	142,974	1	549	—	550
Fair value of warrants upon exercise	—	—	—	—	—	352	—	352
Issuance of common stock from warrant exercise (net exercise)	—	—	—	44,287	—	—	—	—
Issuance of common stock from warrant exercise (cash exercise)	—	—	—	765	—	3	—	3
Net loss	—	—	—	—	—	—	(110,048)	(110,048)
Balance at December 31, 2021	—	$ —	$ —	179,206,456	$ 1,782	$ 905,145	$ (737,132)	$ 169,795

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,		
	2021	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (110,048)	$ (107,908)	$ (120,199)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	5,984	6,419	4,655
Stock-based compensation	23,871	22,805	19,445
Accretion on asset retirement obligation	105	63	43
Change in fair value of warrant liability	2,284	(509)	(2,496)
Loss on disposal of property and equipment	—	139	3
Inventory lower of cost and net realizable value adjustment	883	150	—
Amortization of debt discount and interest accrual	919	729	703
Product upgrade reserve	1,000	(2,294)	3,794
Changes in operating assets and liabilities:			
Accounts receivable	(9,890)	5,048	20,050
Inventory	15,565	8,240	(5,951)
Deposits on purchased inventory	(2,694)	4,373	1,685
Deferred cost of revenue	(1,388)	(186)	1,755
Prepaid expenses and other assets	(5,550)	(1,356)	2,963
Accounts payable	(746)	(3,352)	2,759
Accrued expenses and other long-term liabilities	6,807	(292)	6,995
Customer deposits and deferred revenue	10,807	4,457	(15,771)
Net cash used in operating activities	(62,091)	(63,474)	(79,567)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(1,559)	(6,183)	(7,760)
Purchase of intangible and other assets	—	—	(57)
Net cash used in investing activities	(1,559)	(6,183)	(7,817)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from term loan modification	—	2,000	—
Payment of debt issuance costs	—	(815)	(168)
Proceeds from common stock public offerings, gross	137,884	—	149,559
Payment of offering costs related to common stock public offerings	(9,334)	(539)	(10,416)
Proceeds from employee stock purchase plan	550	365	—
Proceeds from the exercise of stock options	775	15	9,641
Proceeds from the exercise of warrants	3	—	—
Payments for taxes related to net share settlement of equity awards	(4,600)	(1,376)	(2,410)
Net cash provided by (used in) financing activities	125,278	(350)	146,206
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	61,628	(70,007)	58,822
CASH, CASH EQUIVALENTS AND RESTRICTED CASH — BEGINNING OF PERIOD	158,180	228,187	169,365
CASH, CASH EQUIVALENTS AND RESTRICTED CASH — END OF PERIOD	$ 219,808	$ 158,180	$ 228,187
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid for interest	$ 3,323	$ 3,262	$ 3,954
Cash paid for taxes	$ —	$ 43	$ 19
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Fair value of common stock warrants reclassed from liability to additional paid-in capital upon exercise	$ 352	$ —	$ 3,975
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 1,693	$ 643	$ 1,647
Transfer of property and equipment from inventory	$ 576	$ 1,698	$ 4,897
Purchase of property and equipment in accounts payable and accrued expenses	$ 82	$ 59	$ 657
Offering costs included in accounts payable and accrued expenses	$ 25	$ 460	$ 730

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

VIEWRAY, INC.
Notes to Consolidated Financial Statements

1. Background and Organization

ViewRay, Inc. ("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 U.S. Food and Drug Administration (“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 ("EEA") 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. In February 2019, the Company received 510(k) clearance from the FDA for advancements in MRI, 8 frames per second cine, and Functional imaging (T1/T2/DWI) and High-Speed MLC. In December 2019, we received the CE mark for these advancements in the EEA. In December 2021, the Company received 510(k) clearance from the FDA on its recent submission for new MRIdian features ("MRIdian A3i™) focused on enhancing on-table adaptive workflow efficiency and expanding clinical utility.

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 share 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, 2021, the Company incurred a net loss from operations of $110.0 million and used cash in operations of $62.1 million. The Company believes that its existing cash and cash equivalents balance of $218.3 million as of December 31, 2021, 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 accounting principles generally accepted in the United States (“U.S. GAAP”), and pursuant to the rules and regulations of the Securities and Exchanges Commission (the "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.

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. The carrying amounts of the Company’s cash equivalents approximate their fair values due to their short maturities.

Restricted Cash

At December 31, 2021 and 2020, the Company had an aggregate of $1.5 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, 2021 and 2020, no amounts were drawn on the letters of credit.

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	2021	2020	2019	2021	2020
Customer A	11 %	12 %	14 %	28 %	
Customer B				16 %	
Customer C				16 %	
Customer D				15 %	
Customer E		19 %			
Customer F		11 %			30 %
Customer G		10 %			20 %
Customer H					25 %

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 Credit Losses

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

There was no allowance for credit losses recorded at December 31, 2021 and 2020.

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, accrued liabilities current portion of long-term debt 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. Excess and obsolete inventories are written down based on historical sales and forecasted demand, as judged by management.

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 $0.9 million and $0.2 million during the years ended December 31, 2021 and 2020, respectively. There was no lower of cost and net realizable value adjustment during the year ended December 31, 2019.

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, 2021, 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 - 10 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

Leases

We determine if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets, and operating lease liabilities, current and noncurrent, on our consolidated balance sheets. We currently do not have any finance lease arrangements.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date of the lease in determining the present value of future payments. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. Our lease terms may include an option to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Leases with an initial term of 12 months or less are not recorded on the balance sheet; we recognize lease expense for these leases on a straight-line basis over the lease term.

Asset Retirement Obligations

In connection with two lease agreements and subsequent amendments, the Company has a legal obligation to remove long-lived assets constructed on the leased properties and to restore the leased properties to their 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 respective 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, when applicable.

At December 31, 2021, the Company had outstanding asset retirement obligations of $1.0 million, which was included in other long-term liabilities in the accompanying consolidated balance sheets. For the years ended December 31, 2021, 2020 and 2019, the Company recognized accretion expenses of $105 thousand, $63 thousand and $43 thousand, respectively 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, 2021, 2020 and 2019.

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, *Revenues from Contracts with Customers*, 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, beginning in the second quarter of 2019, the Company determined that the MRIdian system and installation of the MRIdian system, which had previously been one performance obligation, are now two performance obligations as they are capable of being distinct and are distinct within the context of the system contracts. This change occurred due primarily to changes in facts and circumstances, whereby there are now readily available resources outside the Company that can perform the system installations. 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. Additional details regarding revenue recognition are included in Note 7 – *Revenue*.

Research and Development Costs

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

Costs for the development of new software products and substantial enhancements to existing software products are expensed as incurred until technological feasibility has been established, at which time any additional costs would be capitalized. No costs associated with the development of software have been capitalized as the Company believes its current software development process is completed concurrent with the establishment of technological feasibility.

Stock-Based Compensation

Stock-based compensation expense for all stock-based payment awards granted is based on the grant date fair value. The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock awards. The Black-Scholes option-pricing model requires the use of highly subjective assumptions (see Note 13). 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 records the value of stock-based compensation to expense straight-line over the vesting period.

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, 2021 and 2020, the Company had $3.3 million and $2.4 million, respectively, in 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 income (expense), net. Upon exercise 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 attributable to common stockholders 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 August 2020, the Financial Accounting Standards Board (“FASB”) issued Accounting Standard Update (“ASU”) 2020-06, an update to ASC Topic 470, Subtopic - 20, Debt - Debt with Conversion and Other Options, and ASC Topic 815, Subtopic – 40, Derivatives and Hedging - Contracts in Entity's Own Equity. The ASU simplifies the guidance for certain financial instruments with characteristics of liability and equity, including convertible instruments and contracts on an entity’s own equity by reducing the number of accounting models for convertible instruments and amends guidance in ASC Topic 260, Earnings Per Share, relating to the computation of earnings per share for convertible instruments and contracts on an entity’s own equity. The ASU is effective for interim and annual reporting periods in fiscal years that begin after December 15, 2021, with early adoption permitted for fiscal years that begin after December 15, 2020. The Company does not expect significant changes to our consolidated financial statements and related notes in order to comply with ASU 2020-06.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). This ASU changes the methodology for measuring credit losses on financial instruments and the timing of when such losses are recorded. This ASU was adopted as of January 1, 2021 and there were no significant changes to our consolidated financial statements and related notes.

3. Balance Sheet Components

Property and Equipment, Net

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

	December 31,	
	2021	2020
Prototype	$ 17,730	$ 17,711
Machine and equipment	17,701	17,486
Leasehold improvements	14,088	14,196
Furniture and fixtures	1,295	1,295
Software	1,389	1,389
Construction in progress	1,397	486
Property and equipment, gross	53,600	52,563
Less: accumulated depreciation and amortization	(33,358)	(28,501)
Property and equipment, net	$ 20,242	$ 24,062

Depreciation and amortization expense related to property and equipment was $6.0 million, $6.4 million and $4.7 million during the years ended December 31, 2021, 2020 and 2019, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2021	2020
Accrued payroll and related benefits	$ 17,080	$ 12,810
Accrued accounts payable	$ 3,740	2,810
Payroll withholding tax, sales and other tax payable	$ 1,094	1,398
Accrued legal and accounting	$ 230	305
Product upgrade reserve	$ 2,500	1,500
Other	$ 1,911	458
Total accrued liabilities	$ 26,555	$ 19,281

Deferred Revenue

Deferred revenue consisted of the following (in thousands):

	December 31,	
	2021	2020
Deferred revenue:		
Product	$ 1,322	$ 1,888
Services	15,385	8,857
Distribution rights	1,445	1,921
Total deferred revenue	18,152	12,666
Less: current portion of deferred revenue	(13,920)	(10,094)
Noncurrent portion of deferred revenue	$ 4,232	$ 2,572

Other Long-Term Liabilities

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

	December 31,	
	2021	2020
Accrued interest, noncurrent portion	$ 704	$ 99
Asset retirement obligation	962	857
Other accrued costs	981	—
Total other-long term liabilities	$ 2,647	$ 956

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 3 liabilities. These 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, changes 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, 2021, warrants to purchase 119,420 shares of common stock, were exercised and the aggregate fair value upon exercise of $0.4 million, was reclassified from liabilities to additional paid-in-capital. There were no warrants exercised during the year ended December 31, 2020.

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, 2021, 2020 and 2019, the Company recorded a loss of $2.3 million, and a gain of $0.5 million, and $2.5 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, 2021			
	Level 1	Level 2	Level 3	Total
2017 Placement Warrants Liability	$ —	$ —	$ 5,030	$ 5,030
2016 Placement Warrants Liability	—	—	1,765	1,765
Total Warrant Liability	$ —	$ —	$ 6,795	$ 6,795

	At December 31, 2020			
	Level 1	Level 2	Level 3	Total
2017 Placement Warrants Liability	$ —	$ —	$ 3,675	$ 3,675
2016 Placement Warrants Liability	—	—	1,189	1,189
Total Warrant Liability	$ —	$ —	$ 4,864	$ 4,864

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

	Year Ended December 31,		
	2021	2020	2019
Fair value, beginning of period	$ 4,864	$ 5,373	$ 11,844
Change in fair value of Level 3 financial liabilities	2,284	(509)	(2,496)
Fair value of 2016 Placement Warrants at exercise	(2)	—	(3,457)
Fair value of 2017 Placement Warrants at exercise	(351)	—	(518)
Fair value, end of period	$ 6,795	$ 4,864	$ 5,373

5. Debt

SVB Term Loan

In December 2018, the Company entered into a term loan agreement (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 would have made 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.

On December 31, 2019, we entered into the First Amendment (the "First Amendment") to the SVB Term Loan by and among the Company, ViewRay Technologies, Inc. and SVB dated as of December 28, 2018. The First Amendment, among other things, amended the SVB Term Loan to (i) suspend testing of the minimum revenue financial covenant for the fiscal quarter ending December 31, 2019, (ii) provide for the minimum trailing twelve-month revenue thresholds under the minimum revenue financial covenant for periods ending on the last day of fiscal quarters in fiscal years subsequent to 2020 to be determined annually at the greater of (a) a 25% cushion to revenue forecasts provided by the Company to SVB and (b) 10% year-over-year annual growth, unless otherwise agreed, (iii) increase the minimum liquidity ratio financial covenant from 1.50:1.00 to 1.75:1.00 and (iv) increase the prepayment premium from 1.00% to 2.00% for amounts prepaid under the SVB Term Loan for prior to the maturity date thereof, subject to certain exceptions.

On October 30, 2020, the Company entered into the Second Amendment (the "Second Amendment") to the SVB Term Loan. The Second Amendment, among other things, amended the SVB Term Loan to (i) increase the term loan agreement principal amount from $56.0 million to $58.0 million, (ii) revise the thirty-six equal monthly payments of principal to begin on November 1, 2022, (iii) revise the maturity date to October 1, 2025, (iv) decrease the interest rate from a fixed rate of 6.3% to a floating rate of 2.4% above the Prime Rate, (v) increase the final payment from 3.15% of the original aggregate principal amount to 3.7% of the revised aggregate principal amount, (vi) revise the minimum trailing twelve-month revenue thresholds under the minimum revenue financial covenant for periods ending on the last day of fiscal quarters in fiscal years subsequent to 2020, (vii) decrease the minimum liquidity ratio financial covenant from 1.75:1.00 to 1.70:1.00, (viii) remove the minimum cash balance as a condition of the minimum revenue financial covenant and the minimum liquidity ratio financial covenant, and (ix) increase the prepayment premium from 2.00% to 3.00% for the first 30 months

of the term for amounts prepaid under the SVB Term Loan prior to the maturity date thereof, subject to certain exceptions. In connection with the execution of the Second Amendment, the Company agreed to pay the earned portion of the final payment, which equated to $0.8 million.

On October 29, 2021, the Company entered into the Third Amendment (the "Third Amendment") to the SVB Term Loan. The Third Amendment amended the SVB Term Loan to (i) decrease the minimum liquidity ratio financial covenant from 1.70:1.00 to 1.35:1.00, and (ii) increase the prepayment premium from 3.00% to 3.5% for the first 30 months of the term and from 2.00% to 2.50% thereafter for the remaining term, for amounts prepaid under the SVB Term Loan prior to the maturity date thereof, subject to certain exceptions.

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 does 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, 2021 are as follows (in thousands):

Year Ended December 31,		
2022	$	3,222
2023		19,333
2024		19,333
2025		16,112
Total future principal payments		58,000
Less: unamortized debt discount		(747)
Carrying value of long-term debt		57,253
Less: current portion		(3,222)
Long-term portion	$	54,031

6. Commitments and Contingencies

Leases

The Company leases office space in Oakwood Village, Ohio, Mountain View, California, and Denver, Colorado under non-cancelable operating lease agreements. The Company leases and occupies approximately 19,800 square feet of office space in Oakwood Village, Ohio, which expires in October 2026. The Company entered into an office lease agreement to lease approximately 25,500 square feet of office space located in Mountain View, California, with an expiration date of July 2025. Additionally, the Company entered into a lease agreement to lease additional office space in Mountain View, California of approximately 24,600 square feet, which will expire in December 2025. The Company has the option to extend the term of the lease for a period of up to five years. In March 2021, we entered into a lease agreement to lease approximately 12,800 square feet of office space in Denver, Colorado. The lease commenced on September 1, 2021 and will expire October 31, 2024.

In recognition of the right-of-use assets and the related lease liabilities, the option to extend the lease term has not been included as the Company is not reasonably certain that it will exercise any such option. At December 31, 2021, the weighted-average remaining lease term in years is 4.0 years and the weighted-average discount rate used is 7.6%. The Company recognized of $2.8 million, $3.1 million, and $2.9 million lease costs arising from lease transactions for the years December 31, 2021, 2020 and 2019, respectively.

During the years ended December 31, 2021, 2020, and 2019, the Company recognized the following cash flow transactions arising from lease transactions (in thousands):

	For the Year Ended December 31,		
	2021	2020	2019
Cash paid for amounts included in the measurement of lease liabilities	$ 2,848	$ 3,145	$ 2,451
Right-of-use assets obtained in exchange for new operating lease liabilities	1,693	643	1,647

At December 31, 2021, the future payments and interest expense for the operating leases are as follows (in thousands):

Year Ended December 31,	Future Payments
2022	$ 3,264
2023	3,357
2024	3,301
2025	2,096
2026	147
Thereafter	—
Total undiscounted cash flows	$ 12,165
Less: imputed interest	(1,538)
Present value of lease liabilities	$ 10,627

Rent expense for operating leases for the year ended December 31, 2019 using the accounting guidance in effect at that time was $1.4 million.

Legal Proceedings

In the normal course of business, the Company may become involved in legal proceedings. The Company will accrue a liability for legal proceedings when it is probable that a liability has been incurred and the amount can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. When only a range of possible loss 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.

Class Action Litigation

On September 13, 2019, a class action complaint for violation of federal securities laws was filed in U.S. District Court for the Northern District of Ohio against the Company, our chief executive officer, chief scientific officer, and former chief financial officer. On December 19, 2019, the court appointed Plymouth County Retirement Association as the lead plaintiff, and on February 28, 2020 the lead plaintiff filed an amended complaint asserting securities fraud claims against the Company, our chief executive officer, chief operating officer, chief scientific officer, and former chief executive officer and former chief financial officer. Now captioned Plymouth County Retirement Association v. ViewRay, Inc., et al., the amended complaint alleges that we violated federal securities laws by issuing materially false and misleading statements that failed to disclose adverse facts concerning our business, operations, and financial results, and seeks damages, interest, and other relief. On August 25, 2021, the District Court dismissed the lead plaintiff's second amended complaint, with prejudice. On September 17, 2021, the lead plaintiff filed notice of its intent to appeal the District Court's opinion and order dismissing the complaint to the Sixth Circuit Court of Appeals. The lead plaintiff filed its opening appellate brief on January 14, 2022, and the defendants' response is due March 15, 2022. We believe the appeal is without merit and intend to vigorously defend the litigation.

Stockholder Derivative Lawsuit

On July 22, 2020, a stockholder derivative lawsuit, captioned Gile derivatively on behalf of ViewRay, Inc. v. ViewRay Inc., et al., was filed against ViewRay (as a nominal defendant) and certain of its current and former officers and directors in the U.S. District Court for the Northern District of Ohio. This action alleges, purportedly on behalf of ViewRay, that the officers and directors violated Section 14(a) of the Securities Exchange Act of 1934, breached their fiduciary duties, wasted corporate assets, and were unjustly enriched based on factual assertions substantially similar to those in the class action complaint described above. The complaint seeks, among other things, damages awarded to ViewRay, restitution and disgorgement of profits in an unspecified amount, and corporate reforms. Due to the overlap between the allegations in the derivative complaint and those in the putative securities class action complaint, this lawsuit is presently stayed, pending a decision on the appeal by the Sixth Circuit Court of Appeal.

Given the early stage of each of the litigation matters described above, at this time we are unable to reasonably estimate possible losses or form a judgment that an unfavorable outcome is either probable or remote. 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 in 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.

Purchase Commitments

At December 31, 2021, the Company had $6.4 million in outstanding firm purchase commitments.

7. Revenue

The Company derives revenue primarily from the sale of MRIdian systems and related services as well as support and maintenance services on sold systems. Revenue is categorized as product revenue, service revenue and distribution rights revenue.

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

	Years Ended December 31,		
U.S.	**2021**	**2020**	**2019**
Product	$ 31,769	$ 8,428	$ 41,985
Service	10,399	7,739	4,251
Total U.S. revenue	$ 42,168	$ 16,167	$ 46,236
Outside of U.S. ("OUS")			
Product	$ 20,096	$ 34,314	$ 37,519
Service	7,380	6,061	3,552
Distribution rights	475	475	475
Total OUS revenue	$ 27,951	$ 40,850	$ 41,546
Total			
Product	$ 51,865	$ 42,742	$ 79,504
Service	17,779	13,800	7,803
Distribution rights	475	475	475
Total revenue	$ 70,119	$ 57,017	$ 87,782

Arrangements with Multiple Performance Obligations

The Company frequently enters into sales arrangements that include multiple performance obligations. Such performance obligations mainly consist of (i) sale of MRIdian systems, (ii) installation of MRIdian systems, and (iii) 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 ("SSP"), is determined based on observable prices at which the Company separately sells the products and services. If a 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.

Certain revenue contracts have terms that result in the control of the system transferring to the customer upon delivery and inspection, as opposed to historically upon customer acceptance. For contracts in which control of the system transfers upon delivery and inspection, the Company recognizes revenue for the systems at the point in time when delivery and inspection by the customer has occurred. For these same contracts, the Company recognizes installation revenue over the period of installation as the installation services are performed and control is transferred to the customer. For all contracts in which control continues to transfer upon post-implementation customer acceptance, revenue for the system and installation will continue to be recognized upon customer acceptance.

Certain customer contracts with distributors do not require ViewRay installation at the ultimate user site, and the distributors may either perform the installation themselves or hire another party to 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 shipped, 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.

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 credit losses. 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 $5.4 million and $0.1 million were reported within other assets in the consolidated balance sheets at December 31, 2021 and 2020, respectively. 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.

Trade receivables are evaluated for expected credit losses 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 credit losses. The Company generally does not require collateral for trade receivables. There was no allowance for credit losses recorded at December 31, 2021 or 2020.

Customer deposits represent payments received in advance of system installation. For domestic and international sales, advance payments received prior to inventory shipments are recorded as customer deposits. Advance payments are subsequently reclassified to deferred revenue upon inventory shipment. 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 normal operating cycle are classified as current liabilities.

Deferred cost of revenue consists of cost for inventory items that have been shipped, but revenue recognition has not yet occurred. 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, 2021, 2020 and 2019, the Company recognized $9.3 million, $8.3 million and $10.9 million, respectively, of revenues that were 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. For the year ended December 31, 2019, the Company recognized $0.9 million in revenue from performance obligations satisfied in a prior period. The cumulative catch-up adjustment resulted from a change in transaction price related to variable consideration that was constrained in prior periods.

8. 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 $0.3 million, $0.7 million and $1.0 million during the years ended December 31, 2021, 2020 and 2019, respectively, and were recorded as product cost of revenue in the consolidated statements of operations and comprehensive loss. There were no minimum royalty payments in excess of 1% of net sales during the years ended December 31, 2021, 2020 and 2019.

9. 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, Itochu 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 for each of the years ended December 31, 2021, 2020 and 2019.

10. Equity Financing

Public Offering of Common Stock

On December 3, 2019, we entered into an underwriting agreement with Piper Jaffray & Co., as representatives of several underwriters (the "December 2019 Underwriters"), in connection with the issuance and sale of 47,782,500 shares of our common stock, which included the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $3.13 per share. We completed the offering on December 6, 2019 and received aggregate net proceeds of approximately $138.4 million, after deducting the underwriting discounts and commissions and offering expenses payable by us.

On January 4, 2021, the Company entered into an underwriting agreement with Piper Sandler & Co., as representative of the several underwriters named therein (the "January 2021 Underwriters"), with respect to the issuance and sale of 11,856,500 shares of our common stock, which included the full exercise of the January 2021 Underwriters' option to purchase additional shares, at a price to the public of $4.85 per share. The Company completed the offering on January 7,

2021 and received net proceeds of approximately $53.5 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company.

On November 16, 2021, the Company entered into an underwriting agreement with Piper Sandler & Co. and Stifel, Nicolaus & Company, Incorporated, as representatives of the several underwriters named therein (the “November 2021 Underwriters”), with respect to the issuance and sale by the Company of 14,375,000 shares of our common stock, which included the full exercise of the November 2021 Underwriters' option to purchase additional shares, at a price to the public of $5.60 per share. The Company completed the offering on November 18, 2021, and received net proceeds of approximately $75.1 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company.

At-The-Market Offering of Common Stock

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 an at-the-market offering program with FBR, now known as B. Riley Securities. Under this at-the-market offering program, the Company did not sell any shares of its common stock during the years ended December 31, 2019 or 2020. This shelf registration statement expired in February 2022.

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. 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, 2021 and 2020.

12. Warrants

Equity Classified Common Stock Warrants

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 2015 Placement Warrants to purchase 159,010 shares. The remaining 39,750 shares of 2015 Placement Warrants expired in July and August 2020 and none remained outstanding at December 31, 2021.

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, 2021.

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%

The allocated proceeds from the 2018 Offering Warrants of $6.6 million was recorded in additional paid-in-capital.

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, 2020	Warrants Outstanding at December 31, 2020	Warrants Exercised during the Year Ended December 31, 2021	Warrants Outstanding at December 31, 2021
2017 Placement Warrants	January 2017	7 years	$ 3.17	—	1,618,890	118,868	1,500,022
2016 Placement Warrants	August and September 2016	7 years	$ 2.95	—	537,263	552	536,711
Total				—	2,156,153	119,420	2,036,733

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%

The following table summarizes the change in fair value the Company recognized related to its 2017 and 2016 Placement Warrants in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2021, 2020, and 2019:

	December 31, 2021	December 31, 2020	December 31, 2019
Gain (loss) on 2017 Placement Warrants	$ (1,705)	$ 367	$ 2,554
Gain (loss) on 2016 Placement Warrants	(579)	142	(59)
	$ (2,284)	$ 509	$ 2,496

The fair value of the 2017 and 2016 Placement Warrants at December 31, 2021 and 2020 was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions:

	2017 Placement Warrants		2016 Placement Warrants	
	December 31, 2021	December 31, 2020	December 31, 2021	December 31, 2020
Expected term (in years)	2.0	3.0	1.6	2.6
Expected volatility	86.0%	86.9%	85.5%	86.3%
Risk-free interest rate	0.4%	0.2%	0.3%	0.2%
Expected dividend yield	0%	0%	0%	0%

13. Stock-Based Compensation

As of December 31, 2021, the Company had an active stock-based incentive compensation plan, an employee stock purchase plan and an equity inducement plan: the 2015 Equity Incentive Award Plan (as amended and restated, the “2015 Plan”), the 2015 Employee Stock Purchase Plan (as amended and restated, the “ESPP”), and the 2018 Equity Inducement Award Program (the “2018 Plan”), respectively. All new equity compensation grants are issued under these three plans; however, outstanding awards previously issued under inactive plans will continue to vest and remain exercisable in accordance with the terms of the respective plans.

The 2015 Plan and the 2018 Plan provide for the grant of stock and stock-based awards including stock options, restricted stock units (including deferred stock units) and stock appreciation rights. Additionally, stock units may be issued as performance-based stock units to align stock compensation awards to the attainment of annual or long-term performance goals. As of December 31, 2021, there were 5.8 million shares available for grant under the 2015 Plan and 2018 Plan.

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,		
	2021	2020	2019
Cost of revenue	$ 1,018	$ 965	$ 2,645
Research and development	2,538	2,288	3,910
Selling and marketing	1,615	1,091	1,365
General and administrative	18,700	18,461	11,525
Total stock-based compensation expense	$ 23,871	$ 22,805	$ 19,445

Our stock-based compensation expense is based on the value of the portion of share-based payment awards that are ultimately expected to vest, assuming estimated forfeitures at the time of grant. Stock-based compensation relating to stock-based awards granted to consultants was insignificant for the years ended December 31, 2021, 2020 and 2019.

Restricted Stock Units, Deferred Stock Units and Performance Stock Units:

The Company grants restricted stock units, deferred stock units, and performance stock units (collectively "Incentive Stock Units" or "ISUs").

Restricted Stock Units ("RSUs") are granted to the Company's board of directors and employees for their services. Deferred Stock Units ("DSUs") are granted to the Company's board of directors at their election in lieu of retainer and committee service fees. The DSUs granted to board members 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, the occurrence of a change in control event, or the tenth anniversary of the grant date. The RSUs and DSUs granted to employees and/or board members vest in equal annual or monthly installments over one to three years from the grant date and are subject to the participants continuing service to the Company over that period.

In March 2021, the Company introduced a performance share plan (the "2021 PSU Plan") as a component of its equity grants for 2021. The 2021 PSU Plan provides for the award of performance share units ("PSUs") to employees which vest based on the achievement of performance targets related to the Company's compound annual revenue growth rate over a three-year period.

The grant date fair values of ISUs are based on the closing market price of our common stock on the grant date. Stock-based compensation expense, net of forfeitures, is recognized on a straight-line basis over the requisite service period. For PSUs, compensation expense is updated for the Company's expected performance level against performance goals at the end of each reporting period, which involves judgment as to achievement of certain performance metrics.

The weighted-average grant date fair value of ISUs granted in fiscal year 2021, 2020 and 2019 was $4.87 per share, $2.80 per share and $3.63 per share, respectively.

The table below summarizes the Company's activity and related information for its ISUs:

	RSUs and DSUs		PSUs	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2020	8,046,399	$ 3.41	—	$ —
Granted	2,704,909	$ 4.92	746,723	$ 4.66
Vested	(4,875,305)	$ 3.75	—	$ —
Cancelled or forfeited	(339,078)	$ 3.41	(39,635)	$ 4.66
Unvested at December 31, 2021	5,536,925	$ 4.04	707,088	$ 4.66
Vested and unreleased	194,446		—	
Outstanding at December 31, 2021	5,731,371		707,088	

The total grant date fair value of ISUs awarded was $16.8 million, $17.0 million and $12.2 million for the years ended December 31, 2021, 2020 and 2019, respectively. The total fair value of ISUs vested was $27.5 million, $5.1 million and $6.4 million for the years ended December 31, 2021, 2020 and 2019, respectively.

At December 31, 2021, total unrecognized stock-based compensation cost related to ISUs, net of estimated forfeitures, was $14.9 million, which is expected to be recognized over a weighted-average period of 1.7 years. As of December 31, 2021, 6.0 million shares of ISUs are expected to vest.

Stock Options:

Stock option awards are generally granted with an exercise price equal to the market price of our stock at the date of grant and with a four-years vesting schedule. Stock option awards generally expire 10 years from the date of grant.

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

	Number of Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
				(In thousands)
Options outstanding at December 31, 2020	8,142,348	$ 7.14	7.3	$ 2,638
Options granted	—	—		
Options exercised	(156,199)	4.97		
Options cancelled or forfeited	(790,751)	9.05		
Options outstanding at December 31, 2021	7,195,398	$ 6.98	6.1	$ 5,203
Options exercisable at December 31, 2021	5,958,569	$ 7.05	5.9	$ 3,847
Options vested and expected to vest at December 31, 2021	7,117,391	$ 7.00	6.1	$ 5,050

There were no options granted to employees for the year ended December 31, 2021. The weighted-average grant date fair value of options granted to employees was $1.20 and $4.67 per share for the years ended December 31, 2020 and 2019.

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 nominal for the years ended December 31, 2021, and 2020, and $7.8 million for the year ended December 31, 2019.

At December 31, 2021, total unrecognized stock-based compensation cost related to stock options granted to employees, net of estimated forfeitures, was $4.3 million, which is expected to be recognized over a weighted-average period of 1.2 years.

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.

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. The Company has not paid and does not anticipate paying cash dividends on its common stock; therefore, the expected dividend yield is assumed to be zero.

During the fourth quarter of 2020, the Company began to determine volatility by solely using the Company's own historical volatility measurements, since more than four years of historical data became available in the public market. Prior to the fourth quarter of 2020, the Company determined the volatility for stock options granted based on the average historical price volatility for the Company and industry peers over a period equivalent to the expected term of the stock options grants.

The forfeiture rate of stock options is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures have been estimated by the Company based upon historical and expected forfeiture experience.

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,	
	2020	2019
Expected term (in years)	6.0	6.0
Expected volatility (%)	68.8%	60.7%
Risk-free interest rate (%)	0.7%	2.4%
Expected dividend yield (%)	0%	0%

Employee Stock Purchase Plan:

In July 2015, the Company adopted the Employee Stock Purchase Plan ("ESPP"). Certain employees, as defined by the ESPP, are eligible to participate in the ESPP if employed by the Company for at least 20 hours per week during at least five months per calendar year. Participating employees may contribute up to the lesser of 15% of their eligible earnings or $30,000 during each offering period, provided that in no event shall a participating employee be permitted to purchase more than 3,000 shares of common stock during each offering period.

The purchase price of common stock purchased under the ESPP is currently equal to 85% of the lesser of the fair market value of a share of common stock on: 1) the first trading day of an offering period and 2) the last trading of each offering period. At December 31, 2021, 3.5 million shares were reserved for issuance under the ESPP, respectively. No more than 3.5 million shares of common stock may be issued under the ESPP. As of December 31, 2021, 0.3 million shares have been issued under the ESPP and 3.2 million shares remained available for future issuance under the ESPP.

Purchase rights granted under the ESPP are valued using the Black-Scholes pricing model. During 2021, the grant date for the two offering periods was April 1, 2021 and July 1, 2021. As such, the expected stock price volatility for the Company's common stock for the ESPP purchase rights was estimated by taking the average historic price volatility of the Company industry peers based on daily price observations over a period equivalent to the expected term of the offering period. The expected term represents the period of time the ESPP purchase rights are expected to be outstanding and approximates the offering period. The latest offering period and related purchase was completed on December 31, 2021. As such, there was no unrecognized compensation cost related to the ESPP as of December 31, 2021. Total compensation expense was $0.3 million and $0.1 million for the years ended December 31, 2021 and 2020. There was no compensation expense related to the ESPP for the year ended December 31, 2019.

The fair value of each purchase right granted under the ESPP was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,		
	2021	2020	2019
Expected term (in years)	0.50	0.25 - 0.50	N/A
Expected volatility (%)	84.2% - 86.0%	83.0%	N/A
Risk-free interest rate (%)	0.05% - 0.09%	0.09% - 0.17%	N/A
Expected dividend yield (%)	—%	—%	N/A

14. Income Taxes

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,		
	2021	2020	2019
Expected income tax benefit at the federal statutory rate	21.0 %	21.0 %	21.0 %
State taxes, net of federal benefit	0.0	0.0	0.0
Change in federal statutory rate	0.0	0.0	0.0
Non-deductible stock compensation	(3.1)	0.2	0.0
Non-deductible items and other	(1.7)	(3.6)	(2.8)
Federal and state credits	0.7	0.5	0.6
Change in valuation allowance	(16.9)	(18.1)	(18.8)
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, 2021 and 2020 (in thousands):

	Year Ended December 31,	
	2021	2020
Deferred tax assets		
Net operating loss carryforwards	$ 140,581	$ 121,346
Research and development tax credits	9,149	6,949
Reserves and accruals	4,781	4,984
Operating lease liability	2,615	2,588
Other	6,738	4,702
Total deferred tax assets	163,864	140,569
Less: Valuation allowance	(161,487)	(138,214)
Net deferred tax assets	2,377	2,355
Deferred tax liabilities		
Right-of-use assets	(2,377)	(2,355)
Total deferred tax liabilities	(2,377)	(2,355)
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 $23.3 million and $21.0 million during the year ended December 31, 2021 and 2020, respectively.

At December 31, 2021, the Company had federal net operating loss carryforwards of $605.5 million, which begin to expire in the year ending December 31, 2024, and $258.6 million related to state net operating loss carryforwards, which begin to expire in the year ending December 31, 2021. The Company had federal research and development tax credit carryforwards of $7.5 million, and state carryforwards of $5.0 million at the year ended December 31, 2021. The federal credits begin to expire in the year ending December 31, 2027 and the state credits carryforward indefinitely.

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 2022 and three ownership changes were identified, which had a corresponding limitation of tax attributes. Future owner or equity shifts could result in additional 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, 2021 and 2020, the Company’s unrecognized tax benefits consist of the following (in thousands):

	Year Ended December 31,	
	2021	2020
Unrecognized tax benefit, beginning of period	$ 2,681	$ 2,158
Gross increases — current year tax positions	704	548
Gross increases — prior year tax positions	—	—
Gross decreases — prior year tax positions	(28)	(25)
Unrecognized tax benefit, end of period	$ 3,357	$ 2,681

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security ("CARES") Act was signed into law. The CARES Act includes provisions relating to refundable payroll tax credits, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to the tax deprecation methods for qualified improvement property. The impact of the CARES act is estimated to be immaterial on the Company’s income tax expense.

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, 2019. The Company’s matching contribution to the 401(k) Plan was $0.7 million, $1.1 million, and $0.9 million for the years ended December 31, 2021, 2020, and 2019, respectively.

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,		
	2021	2020	2019
Net loss attributable to common stockholders, basic and diluted	$ (110,048)	$ (107,908)	$ (120,199)
Weighted-average common shares used in computing net loss per share, basic and diluted	164,521,064	147,895,561	102,001,954
Net loss per share, basic and diluted	$ (0.67)	$ (0.73)	$ (1.18)

Diluted earnings per share (“EPS”) includes the dilutive effect of common stock equivalents and is computed using the weighted-average number of common stock and common stock equivalents outstanding during the reporting period. Diluted EPS for the years ended December 31, 2021, 2020, and 2019 excluded common stock equivalents because the effect of their inclusion would be anti-dilutive or would decrease the reported loss per share.

The following table sets forth securities outstanding that could potentially dilute the calculation of diluted earnings per share:

	Year Ended December 31,		
	2021	2020	2019
Options to purchase common stock	7,195,398	8,142,348	11,165,846
Warrants to purchase common stock - liability classified	2,036,733	2,156,153	2,156,153
Warrants to purchase common stock - equity classified	1,418,116	1,418,116	1,457,866
Unvested restricted stock units	6,244,013	8,046,399	4,379,777

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 shipping address of the customers' location (in thousands):

	Year Ended December 31,		
	2021	2020	2019
United States	$ 42,168	$ 16,167	$ 46,236
France	7,868	7,025	12,235
Taiwan	4,870	10,710	—
United Kingdom	1,173	6,060	5,974
Rest of world	14,040	17,055	23,337
Total revenue	$ 70,119	$ 57,017	$ 87,782

At December 31, 2021 and 2020, nearly all long-lived assets are located in the United States.

18. Related Party Transactions

As discussed in Note 8, the Company pays a royalty to UFRF, a stockholder in the Company, related to a licensing agreement.

In November 2019, the Company entered into a distribution agreement with Chindex Shanghai International Trading Company Limited, or Chindex, which became effective in February 2020. Chindex is a subsidiary of Fosun International Limited, or Fosun. Kevin Xie, Ph.D., a member of the Company's board of directors, was previously designated by Fosun for election to the board pursuant to a Securities Purchase Agreement related to the Company's 2017 direct registered offering of common stock.

Under the distribution agreement, Chindex will act as the Company's distributor and regulatory agent for the sale and delivery of its MRIdian products within the People's Republic of China, excluding Hong Kong, Macau and Taiwan. The distribution agreement has an initial term of five years with an option to renew for an additional five years. Under the distribution agreement, the Company will supply its products and services to Chindex based on an agreed upon price between the Company and Chindex. In accordance with the agreement, Chindex agreed to pay ViewRay an upfront fee, portions of which may be refundable under certain conditions, of $3.5 million, payable in three installments: (i) the first installment of $1.5 million due approximately 60 days after the effectiveness of the distribution agreement; (ii) the second installment of $1.0 million due on the first anniversary from the effective date of the agreement; and (iii) the third installment of $1.0 million due on the second anniversary from the effective date of the agreement. The Company has received the first and second installment of this payment as of December 31, 2021.

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, 2021 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(f) or 15d-15(f) of the Exchange Act during the fourth quarter of 2021 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 is not intended to provide absolute assurance that a material misstatement of our consolidated financial statements would be prevented or detected. 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, 2021 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.

Deloitte & Touche LLP has issued its report on the effectiveness of the Company's internal control over financial reporting. That report appears below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of ViewRay Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of ViewRay Inc. and subsidiaries (the "Company") as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2021, of the Company and our report dated February 25, 2022, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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.

/s/Deloitte & Touche LLP
Denver, CO
February 25, 2022

Item 9B. OTHER INFORMATION

None.

Item 9B. DISCLOSURES REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors, Executive Officers and Corporate Governance

The information in our Proxy Statement for the 2021 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—Delinquent Section 16(a) Reports" is incorporated herein by reference.

In addition, the information in our Proxy Statement for the 2022 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

The Company has 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. The Company intends 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

The Company maintains 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 2022 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 2022 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 2022 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 2022 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	Certificate of Amendment of Amended and Restated Certificate of Incorporation of ViewRay, Inc., dated June 11, 2021.	8-K	3.1	6/11/21	
3.3	Amended and Restated Bylaws of ViewRay, Inc.	8-K	3.2	5/10/18	
3.4	Second Amended and Restated Bylaws of ViewRay, Inc.	8-K	3.2	6/11/21	
3.5	Certificate of Merger of Acquisition Sub with and into ViewRay Technologies, Inc.	S-1/A	3.3	12/16/15	
4.1	Form of Common Stock Certificate.	S-1/A	4.1	12/16/15	
4.2	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	
4.3	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	
4.4	Description of Securities.	10-K	4.5	3/12/20	
10.1(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	
10.1(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	
10.1(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	
10.2	Office Lease, effective June 19, 2014, by and between BXP Research Park LP and ViewRay Incorporated.	S-1/A	10.8	12/16/15	
10.3†	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	
10.4(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	
10.4(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	
10.4(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	
10.4(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	
10.4(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	
10.4(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	

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Date Filed	
10.4(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	
10.4(h)	Amendment No. 7 to the Development and Supply Agreement, effective November 15, 2015, by and between ViewRay Incorporated and Siemens Aktiengesellschaft, Healthcare Sector.	10-K	10.11(h)	3/12/20	
10.4(i)+	Amendment No. 8 to the Development and Supply Agreement, effective September 19, 2019, by and between ViewRay Incorporated and Siemens Aktiengesellschaft, Healthcare Sector.	10-K	10.11(i)	3/12/20	
10.5#	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	
10.6#	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	
10.7(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	
10.7(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	
10.8#	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	
10.9(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	
10.9(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	
10.9(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	
10.10#	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	
10.11(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	
10.11(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	
10.12(a)†	ViewRay Incorporated 2008 Stock Incentive Plan.	S-1/A	10.24(a)	12/16/15	
10.12(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	
10.12(c)†	Form of Incentive Stock Option and Reverse Vesting Agreement under the 2008 Plan.	S-1/A	10.24(c)	12/16/15	
10.12(d)†	Form of Nonstatutory Stock Option and Reverse Vesting Agreement under the 2008 Plan.	S-1/A	10.24(d)	12/16/15	
10.13(a)†	ViewRay, Inc. 2015 Equity Incentive Award Plan.	S-1/A	10.26(a)	12/16/15	
10.13(b)†	Form of Option Agreement under the 2015 Plan.	S-1/A	10.26(b)	12/16/15	
10.13(c)†	Form of Restricted Stock Agreement under the 2015 Plan.	S-1/A	10.26(c)	12/16/15	
10.13(d)†	Form of Restricted Stock Unit Agreement under the 2015 Plan.	S-1/A	10.26(d)	12/16/15	
10.13(e)†	ViewRay, Inc. Amended and Restated 2015 Equity Incentive Award Plan.	S-8	99.1	6/26/20	
10.13(f)†	Amended and restated 2015 Equity Incentive Award Plan Performance Share Award Grant Notice.	10-Q	10.10	11/5/21	
10.14†	Form of Indemnification Agreement for directors and executive officers.	S-1/A	10.27	12/16/15	
10.15(a)†	ViewRay, Inc. 2015 Employee Stock Purchase Plan.	S-1/A	10.29	12/16/15	

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Date Filed	
10.15(b)†	ViewRay, Inc. 2015 Employee Stock Purchase Plan, as amended February 27, 2020.	10-K	10.26(b)	3/12/20	
10.16	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	
10.17	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	
10.18	Warrant Agreement, effective February 25, 2018, by and between ViewRay Inc. and Strong Influence Limited.	10-K	10.42	3/12/18	
10.19	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	
10.20	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	
10.21†	Employment Agreement, dated July 22, 2018, by and between ViewRay Inc. and Scott Drake.	10-Q	10.5	8/7/18	
10.22†	ViewRay, Inc. 2018 Equity Inducement Award Program.	S-8	99.1	8/10/18	
10.23(a)	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	
10.23(b)	First Amendment dated as of December 31, 2019 to Loan and Security Agreement by and among Silicon Valley Bank, ViewRay, Inc. and ViewRay Technologies, Inc.	8-K	10.1	12/31/19	
10.23(c)	Second Amendment dated as of October 30, 2020 to Loan and Security Agreement, by and among ViewRay, Inc., ViewRay Technologies, Inc. and Silicon Valley Bank.	8-K	10.1	11/5/20	
10.23(d)	Third Amendment dated as of October 29, 2021 to Loan and Security Agreement, by and among ViewRay, Inc., ViewRay Technologies, Inc. and Silicon Valley Bank.	8-K	10.1	11/1/21	
10.24†	Amendment to Employment Agreement, dated December 20, 2018 by and between ViewRay Inc. and Scott Drake.	10-K	10.51	3/15/19	
10.25†	Offer Letter to Zachary Stassen dated April 20, 2020.	8-K	10.1	4/30/20	
10.26	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	
10.27+	Agreement made as of October 1, 2020, by and among ViewRay Technologies, Inc., ViewRay, Inc. and Siemens Healthcare GmbH.	8-K	10.1	10/7/20	
21	List of Subsidiaries.				X
23.1	Consent of Deloitte & Touche LLP.				X
31.1	Certification of Principal Executive Officer Required under Securities Exchange Act Rule 13a-14(a) and 15d-14(a).				X
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.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL Document				X
101.SCH	Inline XBRL Taxonomy Schema Document.				X
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document.				X
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Label Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document.				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL 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.
+ Certain confidential information contained in this exhibit has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

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 February 25, 2022.

VIEWRAY, INC.

By: /s/ Scott Drake
Scott Drake
Chief Executive Officer

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)	February 25, 2022
/s/ Zachary Stassen Zachary Stassen	Chief Financial Officer (Principal Financial and Accounting Officer)	February 25, 2022
/s/ Daniel Moore Daniel Moore	Chairman of the Board	February 25, 2022
/s/ Caley Castelein, M.D. Caley Castelein, M.D.	Director	February 25, 2022
/s/ B. Kristine Johnson B. Kristine Johnson	Director	February 25, 2022
/s/ Karen N. Prange Karen N. Prange	Director	February 25, 2022
/s/ Brian K. Roberts Brian K. Roberts	Director	February 25, 2022
/s/ Phillip M. Spencer Phillip M. Spencer	Director	February 25, 2022
/s/ Gail Wilensky, Ph.D. Gail Wilensky, Ph.D.	Director	February 25, 2022
/s/ Kevin Xie, Ph.D. Kevin Xie, Ph.D.	Director	February 25, 2022

Subsidiaries

Entity	**Jurisdiction of Organization**
ViewRay Technologies, Inc. (formerly known as ViewRay Incorporated)	Delaware
ViewRay GmbH	Germany

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. 333-26111 on Form S-3, and Registration Statements No. 333-224013, No. 333-226797, No. 333-227383, No. 333-216794, No. 333-210472, No. 333-230460, and No. 333-239507 on Form S-8 of our reports dated February 25, 2022, relating to the consolidated financial statements of ViewRay, Inc. and its subsidiaries and the effectiveness of the Company's internal control over financial reporting appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2021.

/s/ Deloitte & Touche LLP
Denver, CO
February 25, 2022

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: February 25, 2022

/s/ Scott Drake

Scott Drake

Title: Chief Executive Officer and President
(Principal Executive 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, 2021 (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: February 25, 2022

By: /s/ Scott Drake
Name: Scott Drake
Title: Chief Executive Officer
(Principal Executive Officer)

Dated: February 25, 2022

By: /s/ Zachary Stassen
Name: Zachary Stassen
Title: Chief Financial Officer
(Principal Financial 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, Zachary Stassen, 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: February 25, 2022

/s/ Zachary Stassen

Zachary Stassen

Title: Chief Financial Officer
(Principal Financial Officer)