

VARIAN MEDICAL SYSTEMS INC
Form 10-K
November 23, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

✓ ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended September 30, 2016

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: 1-7598

VARIAN MEDICAL SYSTEMS, INC.

(Exact name of Registrant as specified in its charter)

Delaware 94-2359345
(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification Number)

3100 Hansen Way, Palo Alto, California 94304-1038
(Address of principal executive offices) (Zip Code)

(650) 493-4000
(Registrant's telephone number, including area code)

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

Title of each class	Name of each exchange on which registered
Common Stock, \$1 par value	New York Stock Exchange

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 Section 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

(Do not check if a smaller reporting company)

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

As of April 1, 2016, the last business day of Registrant's most recently completed second fiscal quarter, the aggregate market value of shares of Registrant's common stock held by non-affiliates of Registrant (based upon the closing sale price of such shares on the New York Stock Exchange on April 1, 2016) was \$7,731,668,012. Shares of Registrant's common stock held by the Registrant's executive officers and directors and by each entity that owned 10% or more of Registrant's outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

At November 11, 2016, the number of shares of the Registrant's common stock outstanding was 93,410,047.

DOCUMENTS INCORPORATED BY REFERENCE

Definitive Proxy Statement for the Company's 2017 Annual Meeting of Stockholders—Part III of this Form 10 K

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this “Annual Report”), including the Management’s Discussion and Analysis of Financial Condition and Results of Operations (“MD&A”), contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, which provides a “safe harbor” for statements about future events, products and future financial performance that are based on the beliefs of, estimates made by and information currently available to the management of Varian Medical Systems, Inc. (“VMS”) and its subsidiaries (collectively “we,” “our,” “Varian” or the “Company”). The outcome of the events described in these forward-looking statements is subject to risks and uncertainties. Actual results and the outcome or timing of certain events may differ significantly from those projected in these forward-looking statements due to the factors listed under Item 1A, “Risk Factors,” and from time to time in our other filings with the Securities and Exchange Commission (“SEC”). For this purpose, statements concerning: industry or market segment outlook; market acceptance of or transition to new products or technology such as fixed field intensity-modulated radiation therapy, image-guided radiation therapy, stereotactic radiosurgery, volumetric modulated arc therapy, brachytherapy, software, treatment techniques, proton therapy and advanced X-ray tube and flat panel products; growth drivers; future orders, revenues, backlog, earnings or other financial results; timing of the proposed spin-off of our Imaging Components business; and any statements using the terms “believe,” “expect,” “anticipate,” “can,” “should,” “would,” “could,” “estimate,” “may,” “intended,” “potential,” and “possible” or similar forward-looking statements that involve risks and uncertainties that could cause our actual results and the outcome and timing of certain events to differ materially from those projected or management’s current expectations. By making forward-looking statements, we have not assumed any obligation to, and you should not expect us to, update or revise those statements because of new information, future events or otherwise.

PART I

Item 1. Business

Overview

We, Varian Medical Systems, Inc., are a Delaware corporation originally incorporated in 1948 as Varian Associates, Inc. We are the world’s leading manufacturer of medical devices and software for treating cancer and other medical conditions with radiotherapy, radiosurgery, proton therapy and brachytherapy. We are also a premier supplier of X-ray imaging components for medical, scientific, cargo screening, and industrial applications. Our mission is to explore and develop radiation technology that helps to protect and save lives and prevent harm. We seek to be a “Partner for Life” and to help save millions of lives every year everywhere. To meet this challenge, we offer tools for fighting cancer, taking X-ray images and protecting ports and borders.

Our operations are currently grouped into two reportable operating segments: Oncology Systems and Imaging Components. Our Ginzton Technology Center (“GTC”) and Varian Particle Therapy (“VPT”) business are reflected in the “Other” category, because these operating segments do not meet the criteria of a reportable operating segment. The operating segments were determined based on how our Chief Executive Officer, who is our Chief Operating Decision Maker (“CODM”), views and evaluates our operations. The CODM allocates resources to and evaluates the financial performance of each operating segment primarily based on operating earnings.

On May 23, 2016, we announced our intention to separate our Imaging Components business from the remainder of our business through a pro rata distribution of the common stock of a new company named Varex Imaging Corporation (“Varex”). The separation is subject to numerous conditions, including final approval by our Board of Directors. Please see the information in Item 1A, “Risk Factors,” which describes some of the risks and uncertainties associated with the proposed separation. For a further discussion of the planned separation, see Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Oncology Systems. Our largest business segment is Oncology Systems, which designs, manufactures, sells and services hardware and software products for treating cancer with conventional radiotherapy, and advanced treatments such as fixed field intensity-modulated radiation therapy (“IMRT”), image-guided radiation therapy (“IGRT”), volumetric modulated arc therapy (“VMAT”), stereotactic radiosurgery (“SRS”), stereotactic body radiotherapy (“SBRT”) and brachytherapy. Our software solutions also include informatics software for information management, clinical

knowledge exchange, patient care management, practice management and decision-making support for comprehensive cancer clinics, radiotherapy centers and medical oncology practices.

Our hardware products include linear accelerators, brachytherapy afterloaders, treatment simulation and verification equipment and accessories; and our software products include information management, treatment planning, image processing, clinical knowledge exchange, patient care management, decision-making support and practice management software. Our products

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enable radiation oncology departments in hospitals and clinics to perform conventional radiotherapy and brachytherapy treatments and offer advanced treatments such as IMRT, IGRT, VMAT, SRS and SBRT. Our products are also used by surgeons and radiation oncologists to perform radiosurgery. Furthermore, our software products help improve physician engagement and clinical knowledge-sharing, patient care management and management of cancer clinics, radiotherapy centers and oncology practices for better performance. Our worldwide customers include university research and community hospitals, private and governmental institutions, healthcare agencies, physicians' offices, oncology practices, radiotherapy centers and cancer care clinics.

Imaging Components. Our Imaging Components business segment designs, manufactures, sells and services X-ray imaging components for use in a range of applications, including radiographic or fluoroscopic imaging, mammography, special procedures, computed tomography, computer-aided diagnostics, and industrial applications. We provide a broad range of X-ray imaging components including X-ray tubes, flat panel digital image detectors, high voltage connectors, image processing software and workstations, computer-aided diagnostic software, collimators and automatic exposure control devices. We sell our X-ray imaging components to imaging system original equipment manufacturer ("OEM") customers that incorporate them into their medical diagnostic, dental, veterinary and industrial imaging systems, to independent service companies and directly to end-users for replacement purposes. Our Imaging Components business segment also designs, manufactures, sells and services security and inspection products, which include Linatron® X-ray accelerators, imaging processing software and image detection products for security and inspection purposes, such as cargo screening at ports and borders and nondestructive examination in a variety of applications. We generally sell security and inspection products to OEM customers who incorporate our products into their inspection systems.

Other. The "Other" category is comprised of VPT and the operations of the GTC.

Our VPT business develops, designs, manufactures, sells and services products and systems for delivering proton therapy, another form of external beam radiotherapy using proton beams, for the treatment of cancer. Although proton therapy has been in clinical use for more than four decades, it has not been widely deployed due to high capital cost. Our current focus is bringing our expertise in traditional radiation therapy to proton therapy to improve its clinical utility and to reduce its cost of treatment per patient, so that it is more widely accepted and deployed.

GTC, our scientific research facility, develops technologies for our current businesses or which may lead to new business areas, including technology to improve radiation therapy and X-ray imaging, as well as other technology for a variety of applications such as chemical or biological agents that work synergistically with radiation to improve treatment outcomes. Subsequent to fiscal year 2016, GTC was absorbed primarily into our Oncology Systems and Imaging Components businesses and is no longer a separate business.

The Americas region includes North America (primarily United States and Canada) and Latin America. The EMEA region includes Europe, Russia, the Middle East, India and Africa. The APAC region primarily includes East and Southeast Asia and Australia.

Our business is subject to various risks and uncertainties. You should carefully consider the factors described in Item 1A, "Risk Factors" in conjunction with the description of our business set forth below and the other information included in this Annual Report on Form 10-K.

Radiation Therapy and the Cancer Care Market

Radiotherapy is the use of certain types of focused energy to kill cancer cells and shrink tumors. Radiotherapy is commonly used either alone or in combination with surgery, chemotherapy or targeted drugs. One important advantage is that radiation has its greatest effect on replicating cells. When radiation interacts with a cell the therapeutic effect is primarily mediated by damaging cellular genetic material (chromosomes), which interrupts cell replication and results in eventual cellular death. Since the need for replication is particularly critical to the survival of a cancer and since normal tissues are better able to repair such damage, radiation tends to disproportionately kill cancer cells. The clinical goal in radiation oncology is to deliver the highest possible radiation dose directly to the tumor to kill the cancerous cells while minimizing radiation exposure to healthy tissue surrounding the tumor to limit or avoid complications, side effects and secondary effects caused by the treatment. This goal has been the driving force in the clinical care advancements in radiation oncology over the past two decades, from conventional radiotherapy to advanced forms of treatment such as IMRT, IGRT, VMAT, SRS, SBRT and proton therapy, and it has

certainly been one of the driving forces in our own product development plans.

The process for delivering radiotherapy typically consists of examining the patient, planning the treatment, simulating and verifying the treatment plan, providing quality assurance for the equipment and software, delivering the treatment, verifying

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that the treatment was delivered correctly and recording the history and results of the treatment. The team responsible for delivering the radiotherapy treatment generally is comprised of a physician specializing in radiation oncology, a medical physicist or dosimetrist for planning patient treatments, a medical physicist for conducting appropriate quality assurance procedures and a radiation therapist for positioning the patients for treatment and operating the machines. The most common form of radiotherapy involves delivering X-ray beams from outside of the patient's body, a process sometimes referred to as external beam radiotherapy. A device called a medical linear accelerator generates the high-energy X-ray beams and delivers the radiation to the patient lying on a treatment couch. The radiation source rotates around a patient delivering the radiation beam that is shaped to the tumor from different angles. This concentrates radiation at the tumor while at the same time minimizing the dose delivered to the surrounding healthy tissue. Conventional radiotherapy typically involves multiple, or fractionated, treatments of a tumor in up to 50 treatment sessions. The linear accelerator may also deliver electron beams for the treatment of diseases closer to the body surface.

IMRT is an advanced form of external beam radiotherapy in which the shape and intensity of the radiation beams are varied optimally (modulated) across the target region. IMRT allows the radiation dose to be more precisely conformed to the volume of the tumor, allowing physicians to deliver higher doses of radiation to the tumor than conventional radiation treatments, while limiting radiation dose to nearby healthy tissue. In this way, clinicians can design and administer an individualized treatment plan for each patient, targeting the tumor within millimeters. IMRT can be used to treat head and neck, breast, prostate, pancreatic, lung, liver, gynecological and central nervous system cancers. IMRT has become a well-accepted standard of treatment for cancer, and every year additional treatment centers, from university hospitals to local community clinics, adopt IMRT for their treatments. We are a leading global provider of products that enable IMRT for the treatment of cancer.

VMAT is a significant further advancement in IMRT that allows physicians to control three parameters simultaneously: (i) the rate at which the linear accelerator gantry rotates around the patient, (ii) the beam-shaping aperture and (iii) the rate at which the radiation dose is delivered to the patient. This creates a finely-shaped IMRT dose distribution that more closely matches the size and shape of the tumor, with faster treatment times. Our RapidArc® radiotherapy products plan and deliver VMAT treatments.

Physicians, hospitals and clinics place additional value on radiotherapy equipment and treatments, such as VMAT, that enable shorter treatment times and greater patient throughput. From the patient's standpoint, shorter treatment times means that the patient is immobilized on the treatment couch for a shorter time period. Shorter treatment sessions decrease waiting times and, since treatments are delivered in fractions over the course of many days, can mean fewer disruptions to a patient's daily routine. From the physicians' and hospitals' standpoint, shorter treatment times can lessen the chance of tumors moving during treatment and can increase patient throughput. Shorter treatment times and increased patient throughput can increase the number of treatments per day (which is a particular concern in countries with lower numbers of treatment machines per capita), and, as a result, can decrease the cost per treatment which in turn can mean greater access to advanced care for more patients.

IGRT is another advanced form of external beam radiotherapy complementing IMRT to enhance treatments. While IMRT helps physicians more precisely conform the beam to the tumor, IGRT allows physicians to see how a tumor moves or shrinks during a course of treatment, thereby improving treatment accuracy. This allows clinicians to tighten the margin of certainty around the tumor and spare more of the surrounding healthy tissue, potentially improving outcomes. We believe IGRT has become an accepted standard for treatment in the radiation oncology community. SRS and SBRT, often collectively referred to as radiosurgery, are advanced ablative radiation treatment procedures performed in a small number of treatment sessions with high doses of radiation. Radiosurgery typically incorporates image-guidance to focus many small beams of radiation from many orientations precisely on the target and to minimize dose to surrounding normal tissues. Radiation oncologists, surgeons and other oncology specialists increasingly recognize radiosurgery as a useful tool to treat cancerous and non-cancerous lesions anywhere in the body.

An alternative to external beam radiotherapy, brachytherapy involves the insertion of radioactive seeds, wires or ribbons directly into a tumor or body cavity near the tumor. These techniques tend to irradiate much less of the surrounding healthy tissue so that physicians can prescribe a higher total dose of radiation, typically over a shorter

period of time. Brachytherapy is often used for cancers of the head and neck, breast, uterus, cervix, soft tissue and prostate.

Proton therapy is another form of external beam radiotherapy that uses proton particles in the form of a beam generated with a cyclotron rather than X-ray beams from a linear accelerator. A proton beam's signature energy distribution curve, also known as the "Bragg peak," allows for greater precision in targeting tumor cells with an even lower dose to nearby healthy tissue than may be delivered with X-ray beams from a linear accelerator. This makes proton therapy a preferred option for treating certain cancers, particularly cancers in children and tumors near critical structures such as the optic nerve. Pencil-beam scanning

capability, which is an advanced way of delivering the proton beam, allows for greater sparing of healthy tissue compared to fan-beam scanning of the proton beam and external beam radiotherapy treatments. Although proton therapy has been in clinical use for more than four decades, it has not been widely deployed due to its high capital cost and the market is still developing. We believe we can apply our experience in traditional radiotherapy to proton therapy, reducing the cost of treatment per patient for existing clinical applications and expanding the use of proton therapy into a broader array of cancer types. We believe that proton therapy will over time become a more widely accepted method of treatment.

The radiation oncology market is growing globally due to a number of factors. Worldwide, the number of new cancer cases diagnosed annually is projected to increase from approximately 14 million in 2012 to almost 25 million by 2030, according to the September 2015 Lancet Oncology report compiled by the Global Task Force on Radiotherapy for Cancer Control. In addition, technological advancements have helped to improve the precision and applicability of radiotherapy and radiosurgery, potentially expanding the use of radiotherapy and radiosurgery equipment to treat a broader range of cases. Technological advances in hardware and software are also creating a market for replacing an aging installed base of machines that are unable to deliver new, higher standards of care.

The rise in cancer cases, together with the increase in sophistication of new treatment protocols, have created demand for more automated products that can be integrated into clinically practical systems to make treatments more rapid and cost effective. Technology advances leading to improvements in patient care, the availability of more advanced, automated and efficient clinical tools in radiation therapy, the advent of more precise forms of radiotherapy treatment (such as IMRT, IGRT, VMAT, SRS, SBRT, brachytherapy and proton therapy), and developing technology and equipment (such as EDGE™ and TrueBeam™) that enable treatments that reduce treatment times and increase patient throughput should drive the demand for our radiation therapy products and services.

International markets in particular are under-equipped to address the growing cancer incidence. Patients in many foreign countries must frequently endure long waits for radiotherapy. According to a peer-reviewed publication in the International Journal of Radiation Oncology Biology and Physics in 2014, radiotherapy is required in more than half of new cancer patients, particularly in low- and middle-income countries, and it is estimated that greater than 9,000 additional treatment machines will be required by 2020 in these countries alone. For example, China, India and Brazil are estimated to require over 3,800, 1,200 and 400 additional machines, respectively. This demand in emerging markets, coupled with ever increasing incidences of cancer, represent additional drivers for our continued growth in international markets.

Products

Oncology Systems

Our Oncology Systems business segment is the leading provider of advanced hardware and software products for treatment of cancer with conventional radiation therapy, and advanced treatments such as IMRT, IGRT, VMAT, SRS, SBRT and brachytherapy. Oncology Systems products address each major aspect of the radiotherapy process, including linear accelerators and accessory products for positioning the patient and delivering the X-ray beam; brachytherapy afterloaders for delivering radioactive implantable seeds; treatment planning software for planning treatment sessions and dose delivery; treatment simulation and verification equipment and quality assurance software for simulating and verifying treatment plans before treatment as well as verification of correct treatment delivery; and information management software for recording the history and results of treatments and other patient treatment information and data, including patient images. This business's other software products help improve physician engagement and clinical knowledge-sharing, patient care management and management of cancer clinics, radiotherapy centers and oncology practices for better performance.

The focus of our Oncology Systems business is addressing the key concerns of the market for advanced cancer care systems; improving efficiency, precision, cost-effectiveness and ease of delivery of these treatments; and providing greater access to advanced treatments. A core element of our business strategy is to provide our customers with highly versatile, proven products that are interoperable and can be configured and integrated into automated systems that combine greater precision, shorter treatment times and greater cost effectiveness and that improve the entire process of treating a patient. Our products and accessories for IMRT and IGRT allow clinicians to track and treat tumors using very precisely shaped beams, targeting the tumor as closely as currently possible and allowing the delivery of higher

doses to the tumor while limiting exposure of nearby healthy tissue. Additionally, the precision and versatility of our products and technology make it possible to use radiotherapy to treat metastatic cancers. With our treatment planning, verification and information management software products, a patient's treatment plans, treatment data and images are recorded and stored in a single database shared by each of our products, which enables better communication among products. Our products also allow multiple medical specialties - radiation oncology, neurosurgery, radiographic imaging and medical oncology, as well as clinicians in multiple locations - to share equipment, resources and information in a more efficient, cost-effective manner. Furthermore, the ability of our products and technology to

interoperate with each other and to interconnect into automated systems allows physicians to schedule and treat more patients within a set time period, which adds to the cost-effectiveness of our equipment.

Medical linear accelerators are the core device for delivering conventional external beam radiotherapy, IMRT, IGRT, VMAT, SRS and SBRT, and we produce versions of these devices to suit various clinical requirements. Our UNIQUE™ medical linear accelerator is a low-energy linear accelerator for the more price sensitive emerging markets, designed to meet the evolving needs of our IMRT and IGRT customers in these markets. The Clinac® iX linear accelerators deliver high-energy X-ray beams and are designed for more streamlined and advanced treatment processes, including IMRT and IGRT. We also produce the Trilogy™ linear accelerator, designed to be a versatile, cost-effective, precise high-energy device with a faster dose delivery rate and more precise isocenter compared to the Clinac iX. At the high end, the TrueBeam and EDGE systems for image-guided radiotherapy and radiosurgery are fully-integrated high-energy systems designed from the ground up to treat a moving target with higher speed and accuracy and complement our accelerator product line portfolio.

Our Millennium™ series of multi-leaf collimators and High Definition 120 (“HD 120”) multi-leaf collimators are used with a linear accelerator to define the size, shape and intensity of the generated beams. PortalVision™, our electronic portal-imager, is used to verify a patient’s position while on the treatment couch, which is critical for accurate treatments and simplifies quality assurance of individual treatment plans. We also offer an innovative real-time patient position monitoring product, the RPM™ respiratory gating system, which allows the linear accelerator to be synchronized with patient breathing to help compensate for tumor motion during treatment. In addition, we manufacture the Calypso® system (some features not approved for use in all markets), which can continuously track and monitor the position of implanted and surface Beacon® transponders. This technology allows the treatment beam to be precisely aimed to deliver the full, prescribed dose to the tumor, and minimize exposure of surrounding healthy tissues.

We also offer the EDGE radiosurgery suite, a combination of products for performing advanced radiosurgery using new real-time tumor tracking technology and motion management capabilities. The EDGE radiosurgery suite includes the EDGE radiosurgery accelerator and the Calypso System with Dynamic Edge™ Gating, and the PerfectPitch™ Couch with six degrees of freedom to accurately and precisely align the patient position. Our IGRT accessories include the On-Board Imager® (“OBI”) hardware accessory affixed to the linear accelerator that allows dynamic, real-time imaging of tumors while the patient is on the treatment couch and offers cone-beam computerized tomography (“CBCT”) imaging software capability to allow patient positioning based on soft-tissue anatomy. Using sophisticated image analysis tools, the CBCT scan can be compared with a reference CT scan taken previously to determine how the treatment couch should be adjusted to fine-tune and verify the patient’s treatment setup and positioning prior to delivery of the radiation. To deliver the most advanced forms of IGRT, our accelerators would typically have an OBI, CBCT, PortalVision and other IGRT-related hardware and software as accessories.

Our RapidArc radiotherapy products are a proprietary implementation of VMAT that coordinates beam shaping, dose rate and gantry speed to deliver a highly conformal dose distribution to the target tumor. RapidArc products enable the planning and delivery of image-guided IMRT in a single continuous rotation of up to 360 degrees rather than as a series of fixed fields. Our RapidArc products enable faster delivery of radiation treatment with the possibility of reduced opportunity for tumor movement during treatment, as well as greater patient throughput and lower cost per patient for the hospital or clinic. We believe RapidArc represents a significant advancement in IMRT cancer treatment.

At the end of fiscal year 2016, we launched the HyperArc™ High-Definition Radiotherapy product, which is designed to simplify, automate and improve the quality of intracranial SRS, making SRS accessible to more clinics and patients around the world. HyperArc is pending 510(k) clearance for sale in the United States. We expect that HyperArc will significantly improve the efficiency of sophisticated SRS procedures. HyperArc will be available only on the TrueBeam and Edge platforms.

Our software products enhance and enable the delivery of advanced radiotherapy treatments, from the initial treatment planning and plan quality assurance verification to the post-treatment recording of data and storing of patient information, as well as help improve physician engagement and clinical knowledge-sharing, patient care management and management of cancer clinics, radiotherapy centers and oncology practices for better performance. Prior to any

treatment, physicians must prescribe, or plan, the course of radiation delivery for the patient. We offer a range of treatment planning products that assist physicians in designing this plan. Our Eclipse™ treatment planning system provides physicians with 3D image viewing, treatment simulation, radiation dosage calculation and verification and other tools for generating treatment delivery plans for the patient. The Eclipse software utilizes a sophisticated technique known as inverse planning to enable physicians to rapidly develop optimal treatment plans based on a desired radiation dose outcome to the tumor and surrounding tissue. Clinics may use plan models included with Eclipse or can create models based on their own treatment methods and protocols. Our RapidPlan™ Knowledge-based Planning tool creates a new category for treatment planning systems in which statistical models can be used to predict the achievable quality of an IMRT treatment from a patient's anatomy. RapidPlan is designed to streamline the planning process by using shared clinical knowledge embedded in its statistical plan models. Our Insightive™ analytics

solution aggregates clinical and operational data and allows for improved decision making and practice management. Insightive enables oncology administrators and clinicians to use real-time information to discover patterns and trends through interactive dashboards and visualizations. During fiscal year 2016, we also created an interactive online group on the OncoPeer™ platform for clinicians to share knowledge-based RapidPlan cancer treatment models that can improve the efficiency and quality of treatment models and cancer care across multiple institutions. The OncoPeer cloud community is a platform where oncologists, clinicians and other oncology professionals can publish knowledge, share data, exchange treatment techniques and discuss best practices within a professional oncology network. Our treatment planning products include Varian Treatment™, which connects ARIA® Oncology Information Management System (“ARIA”) to third party linear accelerators and expands our software support of third party manufacturers. We continue to enhance our treatment planning products and work to integrate multi-criteria optimization radiotherapy treatment planning algorithms licensed from the Fraunhofer Institute which enable clinicians to quickly navigate solution space to find the ideal treatment plan for each patient. We aim to incorporate this technology along with other treatment planning software tools to enhance both treatment planning efficiency and quality.

Our ARIA information system is a comprehensive real-time information management system and database that records and verifies radiotherapy treatments carried out on the linear accelerator, records and stores patient data relating to chemotherapy treatment which may be prescribed by a physician in addition to radiotherapy, performs patient charting and manages patient information and patient image data. This gives clinics and hospitals the ability to manage treatment and patient information across radiation oncology and medical oncology procedures. Also, because ARIA is an electronic medical record, it can enable users to operate filmless and paperless oncology departments and cancer clinics. ARIA is ARRA-HITECH Stage II certified and supports the ICD-10 billing codes. Our FullScale™ oncology-specific information technology solutions take advantage of virtualization or cloud technologies to deploy our ARIA oncology information and Eclipse treatment planning systems in a way that enables treatment centers to take advantage of economies of scale. We have from time to time entered into agreements with a variety of companies to increase the capabilities of our ARIA Information Systems software. Most notable among these were agreements with Infor, pursuant to which it will provide a health data exchange solution to replace our proprietary Information Exchange Manager; and Tableau Software, pursuant to which it will provide an advanced data exploration and visualization platform.

Our Velocity™ software provides solutions at the clinical process level to aggregate unstructured treatment and imaging data from diverse systems. It allows for a more comprehensive view of a patient’s diagnostic imaging and treatment history and helps clinicians make more informed treatment decisions.

Qumulate™ is our cloud-based software technology that collects and analyzes machine performance data in a radiation therapy department and allows users to compare their machine performance data and trends against a community of users’ data.

During fiscal year 2016, we introduced 360 Oncology™, a first-of-its-kind software tool that enables tumor boards to more effectively coordinate patient care among the numerous specialists involved in cancer treatment. With Varian 360 Oncology care management, a clinic’s data, records and patient information are connected through a single platform, enabling the entire cancer-fighting team to coordinate care.

Our treatment simulators enable physicians to simulate radiation therapy treatments prior to delivery. We manufacture and sell Acuity™, a simulator that uses advanced amorphous silicon imaging technology and which has been designed to enhance IMRT treatments by integrating simulation more closely with treatment planning and by helping physicians better address tumor motion caused by breathing.

In addition to offering our own suite of equipment and software products for planning and delivering radiotherapy treatments, we have partnered with selected leaders in certain segments of the radiation therapy and radiosurgery market. In October 2016, we established a three-year strategic agreement with McKesson to supply its US Oncology Network and Vantage Oncology affiliated sites of care with treatment delivery systems and planning, service and radiotherapy information system solutions. Under the agreement we will collaborate with McKesson to establish interoperability between our Aria product and McKesson IT solutions which we anticipate will facilitate access to McKesson's networks for future conversion to Aria, Eclipse and Velocity at sites that do not currently utilize these

solutions. We have a strategic global partnership with Siemens AG (“Siemens”) through which, among other things, we represent Siemens diagnostic imaging products to radiation oncology clinics in most global markets, and Siemens, in turn, represents our equipment and software products for radiotherapy and radiosurgery to its healthcare customers in agreed upon countries. Furthermore, we and Siemens have developed interfaces to enable ARIA and Eclipse to connect with Siemens linear accelerators and imaging systems, and are exploring opportunities to co-develop new imaging and treatment solutions. We hold a minority equity interest in Augmenix, Inc. (“Augmenix”), a company that is developing hydrogel products to decrease irradiation of radiation sensitive tissue such as the rectum.

Our brachytherapy operations design, manufacture, sell and service advanced brachytherapy products, including VariSource™ HDR afterloaders and GammaMed™ HDR/PDR afterloaders, BrachyVision™ brachytherapy treatment planning system, applicators and accessories. Brachytherapy also develops and markets the VariSeed™ LDR prostate treatment planning system and the Vitesse™ software for real-time treatment planning for HDR prostate brachytherapy. Revenues from our Oncology Systems business segment represented 76%, 76% and 77% of total revenues for fiscal years 2016, 2015 and 2014, respectively. Our Oncology Systems business segment revenues include both product and service revenues. Product revenues in Oncology Systems accounted for 44%, 44% and 46% of total revenues for fiscal years 2016, 2015 and 2014, respectively. Service revenues in Oncology Systems accounted for 32%, 32% and 31% of total revenues for fiscal years 2016, 2015 and 2014, respectively. See further discussion in “Customer Services and Support.” For a discussion of Oncology Systems business segment financial information, see Note 17, "Segment Information" of the Notes to the Consolidated Financial Statements.

Imaging Components

Our Imaging Components business segment is a world leader in designing and manufacturing X-ray tubes, flat panel detectors, imaging software, and high voltage connectors, which are key components of X-ray imaging systems. We sell our products to OEM customers both for incorporation into new system configurations and as replacement components for installed systems. We conduct an active research and development program to focus on new technology and applications in both the medical and industrial X-ray imaging markets.

We manufacture X-ray tubes for four primary medical diagnostic radiology applications: CT scanners, radiographic or fluoroscopic imaging, special procedures, and mammography. We also offer a large line of industrial X-ray tubes, which consist of analytical X-ray tubes used for X-ray fluorescence and diffraction, as well as tubes used for non-destructive imaging and gauging and airport baggage inspection systems.

Our flat panel detectors, which are based on amorphous silicon imaging technologies, have broad application as an alternative to image intensifier tubes and X-ray film. Our flat panel detector products are being incorporated into next generation filmless medical diagnostic, dental, veterinary, and industrial inspection imaging systems and also serve as a key component of our OBI, which helps enable IGRT. We believe that imaging equipment based on amorphous silicon technologies is more stable and reliable, needs fewer adjustments, suffers less degradation over time than image intensifier tubes, and is more cost effective than X-ray film.

We also offer image processing tools for X-ray imaging systems for a variety of modalities including fluoroscopy, angiography, cardiology, mammography and general radiography. The image processing tools may be combined with our radiographic flat panel detectors to upgrade film-based X-ray imaging systems to digital systems.

We are currently in the process of introducing multiple new products which we believe will help promote the growth of our Imaging Components business. Through our acquisitions completed in fiscal year 2015, we broadened our portfolio of components by adding high voltage connectors, automatic exposure control devices and image processing software for computer-aided diagnosis. Changes in access to diagnostic radiology or the reimbursement rates associated with diagnostic radiology as a result of the Patient Protection and Affordable Care Act (the “Affordable Care Act”) in the United States and similar state proposals, or otherwise, could however affect demand for our products in our Imaging Components business.

Our Imaging Components business also designs, manufactures, sells and services Linatron X-ray accelerators, imaging processing software and image detection products for security and inspection purposes, such as cargo screening at ports and borders and nondestructive examination in a variety of applications. The Linatron Mi6 is a dual energy accelerator that can perform non-intrusive inspection of cargo containers and aid in automatically detecting and alerting operators when high-density nuclear materials associated with dirty bombs or weapons of mass destruction are present during cargo screening. The Linatron K-15 is a high-energy accelerator for inspection of very large, dense objects, including, for example, manufactured segments used in the Ariane rocket program in Europe and National Aeronautics and Space Administration rocket programs in the U.S.

Generally, we sell our security and inspection products to OEM customers who incorporate our products into OEM inspection systems. The OEM customers sell the systems to customs and other government agencies for use in overseas ports and borders to screen overland, rail, and sea cargo for contraband, weapons, narcotics and explosives, as well as for manifest verification. We also sell our security and inspection products to commercial enterprises in the

casting, power, aerospace, chemical, petro-chemical and automotive industries for nondestructive product examination purposes, such as industrial inspection and manufacturing quality control.

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Our security and inspection products are complemented by our Attila software that enables us to provide comprehensive radiation solutions for customers that integrate our high-energy X-ray technology into systems for cargo screening, industrial inspection and non-destructive testing. This software can benefit our customers in the design and verification of systems where radiation effects play a critical role in product performance, safety, or reliability.

Revenues from our Imaging Components business segment represented 19%, 20% and 22% of total revenues for fiscal years 2016, 2015 and 2014, respectively. For a discussion of the Imaging Components business segment financial information, see Note 17, "Segment Information" of the Notes to the Consolidated Financial Statements.

Other

Our VPT business develops, designs, manufactures, sells and services products and systems for delivering proton therapy, another form of external beam therapy using proton beams, for the treatment of cancer. Our ProBeam® system is capable of delivering precise intensity modulated proton therapy ("IMPT") using pencil beam scanning technology. During fiscal year 2016, we booked our first ProBeam Compact order. ProBeam Compact is our lower cost, single room proton therapy product launched in fiscal year 2014. Proton therapy is a preferred option for treating certain cancers, particularly tumors near critical structures such as the optic nerve and cancers in children. Although proton therapy has been in clinical use for more than four decades, it has not been widely deployed due to high capital cost. Proton therapy facilities are large-scale construction projects that are time consuming, involve significant customer investment and often complex project financing.

Our VPT technology and systems are in operation at the Paul Scherrer Institute in Villigen, Switzerland, the Rinecker Proton Therapy Center in Munich, Germany, the Scripps Proton Therapy Center in San Diego, California, the Maryland Proton Therapy Center ("MPTC") in Baltimore, Maryland and the Proton Therapy Center at Cincinnati Children's Hospital in Liberty Township, Ohio.

During fiscal years 2016, 2015 and 2014, we recorded two, six, and three VPT proton therapy product orders, respectively.

For certain proton therapy project orders, we may elect to provide a portion of the financing for the project, such as: In July 2015, we, through one of our subsidiaries, committed to loan up to \$91.5 million to MM Proton I, LLC in connection with a purchase agreement to supply a proton system to equip the New York Proton Center, including commitments to extend senior first lien loans and subordinated third lien loans. In June 2016, we assigned to Deutsche Bank AG ("Deutsche Bank") our entire \$73.0 million senior first lien loan commitment. As of September 30, 2016, we have loaned \$18.5 million under the subordinated third lien loan.

In May 2015, we, through one of our subsidiaries, committed to loan up to \$35.0 million to MPTC. As of September 30, 2016 we had loaned an aggregate of \$23.6 million to MPTC and in October 2016 loaned the remaining \$11.4 million of our commitment. During fiscal year 2016, we converted \$17.1 million in deferred payment arrangements, previously recorded as long-term unbilled accounts receivable, with MPTC to a long-term note receivable due September 30, 2018.

As of September 30, 2016, our outstanding loans to California Proton Treatment Center, LLC ("CPTC") to fund the development, construction and initial operations of the Scripps Proton Therapy Center were \$95.3 million.

See Note 16, "VPT Loans" of the Notes to the Consolidated Financial Statements for further discussion on our VPT loans.

GTC, our scientific research facility, invests in developing technologies that enhance our current businesses or which may lead to new business areas, including next generation digital X-ray imaging technology, volumetric and functional imaging, and improved X-ray sources and technology for security and cargo screening applications. In addition, GTC develops technologies and products that are designed to improve disease management by more precise targeting of radiation, as well as by employing targeted energy and molecular agents to enhance the effectiveness and broaden the application of radiation therapy. GTC is engaged in searching for chemical or biological agents that work synergistically with radiation to improve treatment outcomes.

Revenues from our "Other" category represented 5%, 4% and 1% of total revenues in fiscal year 2016, 2015 and 2014, respectively. For a discussion of segment financial information, see Note 17, "Segment Information" of the Notes to the Consolidated Financial Statements.

Marketing and Sales

We employ a combination of direct sales forces and independent distributors or resellers for the marketing and sales of our products worldwide. The recent environment has been characterized by fluctuations in gross orders and revenues in and among our geographic regions, with a greater percentage coming from emerging markets within our international region, as well as ongoing concerns about the global economy. As a U.S.-based company, the competitiveness of our product pricing is influenced by the fluctuation of the U.S. Dollar against other currencies. A stronger U.S. Dollar against foreign currencies would make our product pricing more expensive and less competitive compared to products sold in non-U.S. Dollar currencies. A stronger U.S. Dollar against foreign currencies would also lower our international revenues and gross orders when measured in U.S. Dollars. These conditions affected our business and demand for our products in fiscal year 2015 and the first half of fiscal year 2016. In fiscal years 2016, 2015 and 2014, we did not have a single customer that represented 10% or more of our total revenues.

Oncology Systems

For our Oncology Systems business segment, we sell direct in the United States and Canada and use a combination of direct sales and independent distributors in international regions. In September 2016, we acquired the radiotherapy business of Candela sp. z o.o. ("Candela"), the distributor of our radiotherapy equipment in Poland. This acquisition allows us to serve customers more effectively and improve access to advanced care for cancer patients in Poland. Through our strategic global partnership with Siemens, we represent Siemens diagnostic imaging products to radiation oncology clinics in most global markets. Siemens represents our equipment and software products for radiotherapy and radiosurgery to its healthcare customers in agreed upon countries. We sell our Oncology Systems products primarily to university research and community hospitals, private and governmental institutions, healthcare agencies, physicians' offices and cancer care clinics worldwide. These hospitals, institutes, agencies, physicians' offices and clinics replace equipment and upgrade treatment capability as technology evolves. Sales cycles for our external beam radiotherapy products typically can be quite lengthy since many of them are considered capital equipment and are affected by budgeting cycles. Our customers frequently fix capital budgets one or more years in advance. In recent years, we have seen the purchasing cycle lengthen as a result of the more complex decision-making process associated with larger dollar value transactions for more sophisticated IGRT and surgical equipment, and other technical advances.

During the last economic downturn, we saw customers' decision-making process further complicated and lengthened, especially in the United States, which caused hospitals, clinics and research institutions to more closely scrutinize and prioritize their capital spending in light of tightened capital budgets, tougher credit requirements, the general constriction in credit availability, and consolidation of providers. In addition, the last economic downturn caused customers to delay requested delivery dates. Because our product revenues are influenced by the timing of product shipments, which are tied to customer-requested delivery dates, these delivery delays increased the average order to revenue conversion cycle in the United States. Historically, this conversion cycle has been longer when new products are introduced or when we sell more products internationally. The lengthening of our order to revenue conversion cycle could reduce our revenues and margins. In addition, the same factors impacting the order to revenue conversion cycle may extend the receivables collection cycle and potentially increase bad debts.

Over the last few years, we have seen a greater percentage of Oncology Systems gross orders and revenues coming from emerging markets, which typically purchase lower-priced products, and which generally have lower gross margin percentages, compared to developed markets. We have also seen an increased portion of gross orders and revenues coming from services and software licenses, both of which have higher gross margin percentages than our hardware products. Additionally, we have been investing a higher portion of our Oncology Systems research and development budget in software and software-related products.

Reimbursement rates in the United States have generally supported a favorable return on investment for the purchase of new radiotherapy equipment. While we believe that improved product functionality, greater cost-effectiveness and prospects for better clinical outcomes with new capabilities such as IMRT, IGRT and VMAT tend to drive demand for radiotherapy products, large changes in reimbursement rates or reimbursement structure can affect customer demand and cause market shifts. We do not know what impact the Medicare Access & CHIP Reauthorization Act of 2015 ("MACRA") or the Patient Protection and Affordable Care Act (the "Affordable Care Act") or its potential repeal, or

changes in administration and policy resulting from the recent U.S. presidential election, will have on long-term growth or demand for our products and services. We believe, however, that growth of the radiation oncology market in the United States is being impacted as customers' decision-making processes are complicated by the uncertainties surrounding MACRA and the Affordable Care Act and reimbursement rates for radiotherapy and radiosurgery, and that this uncertainty will continue in future fiscal years. We also believe that the Affordable Care Act, the rise of Accountable Care Organizations and increased bundled payment arrangements are all causing healthcare

providers to re-evaluate their business models, and we are seeing increased consolidation of hospitals and clinics and more integration of systems and equipment across multi-site healthcare networks, which is impacting transaction size, timing and purchasing processes, all of which are contributing to increased uncertainty in the radiation oncology market as well as variability in our gross orders and revenues.

Total revenues for our Oncology Systems business segment were approximately \$2.5 billion, \$2.3 billion, and \$2.3 billion for fiscal years 2016, 2015 and 2014, respectively. We divide our market segments for Oncology Systems revenues by region into The Americas, EMEA, and APAC, and these regions constituted 50%, 30%, and 20%, respectively, of Oncology Systems revenues during fiscal year 2016; 52%, 30%, and 18%, respectively, of Oncology Systems revenues during fiscal year 2015; and 50%, 30%, and 20%, respectively, of Oncology Systems revenues during fiscal year 2014.

Imaging Components

Our Imaging Components business segment employs a combination of direct sales and independent distributors for sales in all of its regions and sells a high proportion of our X-ray imaging components products and security and inspection products to a limited number of OEM customers. The long-term fundamental growth driver of this business segment is the on-going success of our key OEM customers, and we expect that revenues from relatively few customers will continue to account for a high percentage of Imaging Components revenues in the foreseeable future. Our ten largest OEM customers represented 54%, 62% and 63% of our total Imaging Components segment revenues during fiscal years 2016, 2015 and 2014, respectively. A significant portion of our Imaging Components customers are outside of the United States and products in this business are generally priced in U.S. Dollars. As a result, the demand for Imaging Components products has been negatively impacted by the strengthening of the U.S. Dollar, which began in the fourth of quarter of fiscal year 2014, and this has caused our products to be priced higher compared to products sold in non-U.S. Dollar currencies. In addition, some customers have asked for additional discounts, delayed purchasing decisions, or moved to in-sourcing supply of such components or migrated to lower cost alternatives.

We also sell our security and inspection products to regional integrators outside the United States as well as commercial enterprises in the casting, power, aerospace, chemical, petro-chemical and automotive industries for use in non-destructive investigation and testing applications. We believe demand for our security and inspection products is driven primarily by cargo screening, border protection, and non-destructive testing needs domestically and internationally. This business is heavily influenced by domestic and international government policies on border and port security, political change and government budgets. International sales of certain of our Linatron X-ray accelerators are subject to U.S. export licenses that are issued at the discretion of the U.S. government. Orders and revenues for our security and inspection products have been and may continue to be unpredictable as governmental agencies may place large orders with us or with our OEM customers over a short period of time and then may not place additional orders until complete deployment and installation of previously ordered products. We have seen domestic and international governments postpone purchasing decisions and delay installations of products for security and inspection systems. These postponements and delays have been and may in the future be related to re-evaluating program priorities, evaluating funding options, and collaboration between individual government agencies. Furthermore, tender awards in this business may be subject to challenge by third parties, as we have