

VARIAN MEDICAL SYSTEMS INC  
Form 10-K  
November 25, 2015

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 October 2, 2015

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 3, 2015, 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 2, 2015) was \$9,373,307,322. 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 13, 2015, the number of shares of the Registrant's common stock outstanding was 96,884,737.

DOCUMENTS INCORPORATED BY REFERENCE

Definitive Proxy Statement for the Company's 2016 Annual Meeting of Stockholders—Part III of this Form 10 K

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VARIAN MEDICAL SYSTEMS, INC.  
INDEX

	Page
<u>PART I</u>	
<u>Item 1. Business</u>	<u>1</u>
<u>Item 1A. Risk Factors</u>	<u>21</u>
<u>Item 1B. Unresolved Staff Comments</u>	<u>43</u>
<u>Item 2. Properties</u>	<u>43</u>
<u>Item 3. Legal Proceedings</u>	<u>43</u>
<u>Item 4. Mine Safety Disclosures</u>	<u>43</u>
<u>PART II</u>	
<u>Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>44</u>
<u>Item 6. Selected Financial Data</u>	<u>47</u>
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>48</u>
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>72</u>
<u>Item 8. Financial Statements and Supplementary Data</u>	<u>75</u>
<u>Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	<u>123</u>
<u>Item 9A. Controls and Procedures</u>	<u>123</u>
<u>Item 9B. Other Information</u>	<u>123</u>
<u>PART III</u>	
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	<u>124</u>
<u>Item 11. Executive Compensation</u>	<u>124</u>
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>124</u>
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	<u>125</u>
<u>Item 14. Principal Accountant Fees and Services</u>	<u>125</u>
<u>PART IV</u>	
<u>Item 15. Exhibits and Financial Statement Schedules</u>	<u>126</u>
<u>Signatures</u>	<u>127</u>

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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; and any statements using the terms “believe,” “expect,” “anticipate,” “can,” “should,” “would,” “could,” “estimate,” “may,” “intend,” “potential,” and “possible” or similar statements are 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.

**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, as well as 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 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.

1

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**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, ionization chambers and automatic exposure control systems. 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 that enhance our current businesses or 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. GTC is also actively engaged in searching for chemical or biological agents that work synergistically with radiation to improve treatment outcomes.

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 or chemotherapy. 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 as high of a radiation dose as possible directly to the tumor to kill the cancerous cells while minimizing radiation exposure to healthy tissue surrounding the tumor so that complications, side effects and secondary effects can be limited. 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 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 for planning patient treatments and 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 X-ray beams and administers the treatment by rotating around a patient lying on a treatment couch and delivering the X-ray beam to the tumor from different angles in order to concentrate 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, intensity and angle of the radiation beams from a linear accelerator are varied, or modulated, across the target area. This form of radiotherapy allows for more precision by conforming the radiation beams more closely to the shape of the tumor and, therefore, allowing physicians to deliver higher doses of radiation than conventional radiation treatments, while limiting radiation delivered to nearby healthy tissue. In this way, clinicians can design and administer an individualized treatment plan for each patient, targeting the tumor as closely as a few 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 shape the beam to the tumor, IGRT goes further in allowing physicians to accommodate for a tumor moving or shrinking and, therefore improving accuracy. IGRT technologies provide dynamic, real-time visualization enabling precise treatment of small, moving and changing tumors with greater intensity and accuracy. This allows clinicians to deliver even higher doses of radiation to tumors with the goal of sparing more of the surrounding healthy tissue and 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 ionizing radiation. Radiosurgery is typically delivered with many small beams of radiation from many positions about the body, incorporating precise stereotactic image-guidance, which maximizes dose to the target and minimizes dose to surrounding normal tissues. Radiation oncologists, surgeons and other oncology specialists are increasingly recognizing 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 close to the cancerous area. These techniques, unlike external beam radiation therapy, tend to result in much less irradiation 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 tumors near critical structures such as the optic nerve and cancers in children. Pencil-beam scanning capability allows for greater sparing of healthy tissue compared to 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. The number of new cancer cases diagnosed annually is projected to increase from approximately 14 million in 2012 to almost 20 million by 2025, according to the International Agency for Research on Cancer (the "IARC") in the World Health Organization. The IARC's World Cancer

Report predicts that the increase in new cases will mainly be due to steadily aging populations in both developed and developing countries. 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 system for image-guided radiotherapy and radiosurgery is a fully-integrated high-energy system designed from the ground up to treat a moving target with higher speed and accuracy and complements 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 (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 commercially released the Calypso soft tissue Beacon transponder in fiscal year 2015 which is indicated for general, non-organ specific usage outside of the lung, including tumor sites that exhibit significant respiratory motion. Varian is conducting a confirmatory clinical study for 510(k) clearance for its Anchored Beacon® transponder for the lung. During fiscal year 2015, we launched VitalBeam™, which is designed to offer clinics an affordable option for implementing advanced image-guided radiotherapy. VitalBeam is positioned for customers that need a cost-effective technology package for offering high-quality, high-throughput radiation therapy, and for expanding clinical capabilities over time but not necessarily the full capacity of a TrueBeam linac. VitalBeam received 510(k) clearance in fiscal year 2015.

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.

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. 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.

During fiscal year 2015, we received 510(k) clearance for a new version of Varian Treatment™, which connects our ARIA® Oncology Information Management System (“ARIA”) to third party linear accelerators, expanding our software support of third party machines. To enhance our treatment planning product lines, we entered into a licensing agreement with the Fraunhofer Institute for a sophisticated multi-criteria optimization radiotherapy treatment planning tool that enables clinicians to quickly compare plans and select the optimal one without having to use a time-consuming trial-and-error process. We also purchased certain assets comprising a business from a sole proprietor for treatment planning software tools that will enhance both planning efficiency and treatment plan quality and allow oncologists to quickly adjust their intended dose distributions ahead of the treatment planning process.

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 received ARRA-HITECH Stage II certification and implemented the new ICD-10 billing codes in 2014. 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. In May 2015, we entered into a strategic alliance with FlatIron Health (“FlatIron”) to develop the next generation of cloud-based oncology informatics products, leveraging our expertise in radiation oncology and FlatIron's expertise in medical oncology. The alliance intends to enable software for an integrated cloud-based oncology information product suite. During fiscal year 2014, we also 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, a health data exchange solution to replace our proprietary Information Exchange Manager; and Tableau, an advanced data exploration and visualization platform.

During fiscal year 2015, we completed the integration of the software acquired in fiscal year 2014 from Velocity Medical Solutions LLC (“Velocity”) into our existing products at the clinical process level to aggregate unstructured treatment and imaging data from diverse systems. The integration allows for a more comprehensive view of a patient's diagnostic imaging and treatment history and helps clinicians make more informed treatment decisions. During fiscal year 2015, we integrated the dose calculation software acquired in fiscal year 2014 from Transpire, Inc. (“Transpire”) into our BrachyVision and Eclipse systems. The integration enables us to improve our image guidance tools and deliver high-precision radiotherapy for the treatment of cancer. 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.

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. 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%, 77% and 77% of total revenues for fiscal years 2015, 2014 and 2013, respectively. Our Oncology Systems business segment revenues include both product and service revenues. Product revenues in Oncology Systems accounted for 44%, 46% and 47% of total revenues for fiscal years 2015, 2014 and 2013, respectively. Service revenues in Oncology Systems accounted for 32%, 31% and 30% of total revenues for

6

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fiscal years 2015, 2014 and 2013, 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. During fiscal year 2015, through our acquisitions, we broadened our portfolio of components by adding high voltage connectors, ionization chambers, automatic exposure control systems 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 M-1 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. 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.

In August 2015, we acquired Claymount Investments B.V. (“Claymount”), a Netherlands-based supplier of X-ray imaging components. Claymount is a strategic supplier to many global medical X-ray equipment manufacturers and is one of the world's leading suppliers of high voltage connectors, ionization chambers and solid state automatic exposure control systems for controlling dose during medical X-ray imaging. Claymount enhances our ability to support a continuing industry-wide transition from analog to digital X-ray imaging and will allow us to expand our line of components and integrated subsystems.

In April 2015, we completed the acquisition of 73.5% of the then outstanding shares of MeVis Medical Solutions AG (“MeVis”), a company based in Bremen, Germany that provides image processing software and services for cancer screening.

7

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We intend to combine MeVis' image processing and analysis software with our portfolio of flat-panel detector and imaging workstation offerings to provide integrated solutions for cancer screening and computer aided detection. 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 20%, 22% and 22% of total revenues for fiscal years 2015, 2014 and 2013, 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. 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 and the Scripps Proton Therapy Center in San Diego, California. During fiscal years 2015, 2014 and 2013, we recorded six, three, and no VPT proton therapy product orders, respectively.

For certain proton therapy project orders, we may elect to provide a portion of the project financing, 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. As of October 2, 2015, we have loaned \$18.7 million under this loan, with the remainder to be drawn down primarily through fiscal 2018.

In May 2015, we, through one of our subsidiaries, committed to loan up to \$35.0 million to the Maryland Proton Therapy Center, which included rolling over an existing loan for \$10.0 million plus \$2.2 million of previously accrued interest. As of October 2, 2015, our outstanding commitment under the loan to MPTC was \$22.8 million, to be paid in four installments of \$5.7 million each on June 30, 2016, September 30, 2016, December 30, 2016 and March 31, 2017.

As of October 2, 2015, our outstanding loans to California Proton Treatment Center, LLC were \$83.9 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, continues to invest in developing technologies that enhance our current businesses or 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 is developing 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 also actively engaged in searching for chemical or biological agents that work synergistically with radiation to improve treatment outcomes.

Revenues from our "Other" category represented 4% of total revenues in fiscal year 2015, and 1% of total revenues in each of fiscal years 2014 and 2013. 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

8

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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 less competitive in the local currencies of our international customers. 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 could continue to do so in fiscal year 2016. In fiscal years 2015, 2014 and 2013, 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. 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 order to revenue conversion cycle could reduce our revenues and margins. In addition, our receivables may take longer to collect.

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 expect that this shift in geographic mix of gross orders and revenues will generally continue and may negatively impact Oncology Systems gross margin. Overall, we have 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.

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 Patient Protection and Affordable Care Act (the "Affordable Care Act") in the United States 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 the Affordable Care Act and reimbursement rates for radiotherapy and radiosurgery, and that this uncertainty will likely continue into the next fiscal year and result in a high degree of variability of gross orders and revenue from quarter-to-quarter. 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, and also contributing to the increased

variability.

Total revenues for our Oncology Systems business segment were approximately \$2.3 billion for fiscal years 2015, 2014 and 2013. We divide our market segments for Oncology Systems revenues into The Americas, EMEA, and APAC, and these regions constituted 52%, 30%, and 18%, respectively, of Oncology Systems revenues during fiscal year 2015; 50%, 30%, and 20%, respectively, of Oncology Systems revenues during fiscal year 2014; and 50%, 29%, and 21%, respectively, of Oncology Systems revenues during fiscal year 2013.

9

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### 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 62%, 63% and 63% of our total Imaging Components segment revenues during fiscal years 2015, 2014 and 2013, respectively. A significant portion of our Imaging Components customers are outside of the United States, and in fiscal year 2015, demand for Imaging Components products was negatively impacted by pricing pressures resulting from the strengthening of the U.S. Dollar. Because the products in Imaging Components are generally priced in U.S. Dollars, some customers asked for additional discounts, delayed purchasing decisions, or considered moving to in-sourcing supply of such components, or migrating to lower cost alternatives. We 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 linatrons 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, bid awards in this business may be subject to challenge by third parties, as we have previously encountered, which can make the conversion of some security and inspection products orders to revenue unpredictable. The market for border protection systems has slowed significantly and end customers, particularly in oil-based economies and war zones in which we have a significant customer base, are delaying system deployments or tenders and considered moving to alternative sources, resulting in a decline in the demand for security and inspection products which is expected to continue. Changes in access to diagnostic radiology or the reimbursement rates associated with diagnostic radiology as a result of the Affordable Care Act and similar state proposals will likely affect domestic demand for our products in our Imaging Components business.

Total revenues for our Imaging Components business segment were \$611.2 million, \$660.2 million and \$641.9 million for fiscal years 2015, 2014 and 2013, respectively. We divide our market segments for Imaging Components revenues by region into The Americas, EMEA, and APAC, and these regions constituted 35%, 26%, and 39%, respectively, of Imaging Components revenues during fiscal year 2015; 35%, 28%, and 37%, respectively, of Imaging Components revenues during fiscal year 2014 and 35%, 28%, and 37%, respectively, of Imaging Components revenues during fiscal year 2013.

### Other

In the VPT business, we primarily use direct sales specialists who collaborate with our Oncology Systems sales group globally on projects. Potential customers are government-sponsored hospitals and research institutions and research universities, which typically purchase products through public tenders, as well as private hospitals, clinics and private developers. While this market is still developing, there has been significant recent growth in this market and we believe that growth in this business will continue in the major metropolitan areas in the United States and abroad, driven by institutions that wish to expand their clinical offerings and increase their profile in their respective communities. We are investing substantial resources to grow this business. Proton therapy facilities are large-scale construction projects that are time consuming and involve significant customer investment and often complex project financing. Consequently, this business is vulnerable to general economic and market conditions, as well as

reimbursement rates. Customer decision-making cycles tend to be very long, and orders generally involve many contingencies. We have seen the tight credit markets constrain the ability of proton therapy projects to obtain financing.

**Backlog**

Backlog is the accumulation of all gross orders for which revenues have not been recognized and are still considered valid. Backlog also includes a small portion of billed service contracts that are included in deferred revenue. Backlog is stated at

10

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historical foreign currency exchange rates, and revenue is released from backlog at current exchange rates, with any difference recorded as a backlog adjustment. Orders may be revised or canceled, either according to their terms or as customers' needs change; consequently, it is difficult to predict with certainty the amount of backlog that will result in revenues. Our backlog at the end of fiscal year 2015 was \$3.5 billion, including approximately \$345 million in VPT backlog, of which we expect to recognize approximately 50% to 55% as revenues in fiscal year 2016. Our backlog at the end of fiscal year 2014 was \$3.2 billion, of which \$1.6 billion was recognized as revenues in fiscal year 2015. Our Oncology Systems backlog represented 82% and 84% of the total backlog at the end of fiscal years 2015 and 2014, respectively.

Gross orders are defined as the sum of new orders recorded during the period adjusted for any revisions to existing orders during the period. New orders are recorded for the total contractual amount, excluding certain pass-through items, once a written agreement for the delivery of goods or provision of services is in place and, for businesses other than VPT, when shipment of the product (or in the case of certain highly customized products in our Imaging Components business, construction of the product) is expected to occur within two years, so long as any contingencies are deemed perfunctory. However, we will not record security and inspection products orders from governmental agencies with bid protest provisions until the expiration of the bid protest period. For our VPT business, we record orders when construction of the related proton therapy treatment center is reasonably expected to start within two years, but only if any contingencies are either deemed perfunctory or if the existence and nature of material contingencies is disclosed. However, we will not record VPT orders if there are major financing contingencies, if a substantial portion of the financing for the project is not reasonably assured or if customer board approval contingencies are pending.

We perform a quarterly review to verify that outstanding orders in the backlog remain valid. Aged orders that are not expected to be converted to revenues are deemed dormant and are reflected as a reduction in the backlog amounts and net orders in the period identified. Backlog adjustments are comprised of dormancies, cancellations, foreign currency exchange rate adjustments, backlog from acquisitions and other adjustments. In fiscal years 2015, 2014 and 2013, our backlog adjustments were \$214.9 million, \$176.3 million and \$257.3 million, respectively.

#### Competition

Rapidly evolving technology, intense competition and pricing pressure characterize the markets for radiation therapy equipment and software products. We compete with companies worldwide, some of whom may have greater financial, marketing and other resources than we have. Our competitors could develop technologies and products that are more effective than those we currently use or produce or that could render our products obsolete or noncompetitive. Our smaller competitors could be acquired by companies with greater financial strength, which could enable them to compete more aggressively. Some of our suppliers or distributors could also be acquired by competitors, which could disrupt these supply or distribution arrangements and result in less predictable and reduced revenues. Furthermore, we believe that new competitors will enter our markets, as we have encountered new competitors as we enter new markets such as radiosurgery, VMAT and proton therapy. We have directed substantial product development efforts into (i) increasing the interconnectivity of our products for more seamless operation within a system, (ii) enhancing the ease of use of our software products and (iii) reducing setup and treatment times and increasing patient throughput. We have also maintained an "open systems" approach that allows customers to "mix and match" our various individual products, incorporate products from other manufacturers, share information with other systems or products and use the equipment for offering various methods of radiation therapy treatment. We have done this based on our belief that such interconnectivity will increase the acceptance and adoption of IMRT, IGRT and VMAT and will stimulate demand for our products. There are competitive "closed-ended" dedicated-use systems, however, that place simplicity of use ahead of flexibility. If we have misjudged the importance to our customers of maintaining an "open systems" approach, or if we are unsuccessful in our efforts to sustain interconnectivity, enhance ease-of-use and reduce setup and treatment times, our revenues could suffer.

Our Oncology Systems customers' equipment purchase considerations typically include: reliability, servicing, patient throughput, precision, price, payment terms, connectivity, clinical features, the ability to track patient referral patterns, long-term relationship and capabilities of customers' existing equipment. We believe we compete favorably with our competitors based upon our strategy of providing a complete package solution of products and services in the field of

radiation oncology and our continued commitment to global distribution and customer services, value-added manufacturing, technological leadership and new product innovation. To compete successfully, we must provide technically superior, clinically proven products that deliver more precise, cost effective, high quality clinical outcomes, together in a complete package of products and services, and to do so ahead of our competitors. Since our Oncology Systems products are generally sold on a basis of total value to the customer, our business may suffer when purchase decisions are based solely upon price, which can happen if hospitals and clinics give purchasing decision authority to group purchasing organizations. Further, additional competitors may delay customer purchasing decisions as customers evaluate the products of these competitors along with ours, potentially extending our sales cycle and adversely affecting our gross orders.

We are the leading provider of medical linear accelerators and related accessories. In radiotherapy and radiosurgery markets, we compete primarily with Elekta AB and Accuray Incorporated. Recently, ViewRay Incorporated introduced an MR-Cobalt therapy device that is expected to also compete with us in this market. With our information and image management, simulation, treatment planning and radiosurgery products, we also compete with a variety of companies, such as Philips Medical Systems, RaySearch Laboratories AB, Brainlab AG and Best Theratronics, Ltd. We also encounter some competition from providers of enterprise hospital information systems. With respect to our brachytherapy operations, our competitors are Elekta AB, MIM Software Inc. and Eckert & Ziegler BEBIG GmbH. In our Oncology Systems service and maintenance business, we compete with independent service organizations and our customers' internal service organizations.

In addition, as a radiotherapy and radiosurgery equipment provider, we also face competition from alternative cancer treatment methods, such as traditional surgery, chemotherapy, robotic surgery and drug therapies, among others. To compete successfully, we need to demonstrate and convince our customers of the advantages of radiation therapy over other cancer treatment alternatives. This may involve funding and, in some instances, sponsoring clinical research and studies relating to the efficacy, comparative effectiveness and safety of radiation therapy as compared to such other alternative treatments.

With respect to our medical imaging components within our Imaging Components business segment, we often compete with the in-house manufacturing operations of the major diagnostic imaging systems companies, which are the primary OEM customers for our medical imaging components. As a result, we must have a competitive advantage in one or more significant areas, which may include lower product cost, better product quality or superior technology and/or performance. We sell a significant volume of our X-ray tubes to OEM customers that have in-house X-ray tube production capability. In addition, we compete against other stand-alone, independent X-ray tube manufacturers such as Comet AG and IAE Industria Applicazioni Elettroniche Spa as well as small start-up manufacturers in China.

These companies compete with us for both the OEM business of major diagnostic imaging equipment manufacturers and the independent servicing business for X-ray tubes. The market for flat panel detectors is also very competitive. We incorporate our flat panel detectors into our equipment for IGRT within our Oncology Systems and also sell to a number of OEM customers, which incorporate our flat panel detectors into their medical diagnostic, dental, veterinary and industrial imaging systems. Our amorphous silicon based flat panel detector technology competes with other detector technologies such as amorphous selenium, charge-coupled devices and variations of amorphous silicon scintillators. We believe that our product provides a competitive advantage due to lower product cost and better product quality and performance. In the flat panel market, we primarily compete against Perkin-Elmer, Inc., Trixell S.A.S., Vieworks Co., Ltd., Canon, Inc., and Hamamatsu Corporation as well as emerging low cost manufacturers from China such as iRay Technology (Shanghai) Limited, and Jiangsu CareRay Medical Systems Co., Ltd.

With respect to our security and inspection products within our Imaging Components business segment, we compete with other OEM suppliers, primarily outside the United States in the security and inspection market. Currently, our major competitor is Nuctech Company Limited, and we have also seen some competition from Siemens. The market for our security and inspection products used for nondestructive testing in industrial applications is small and highly fractured, and there is no single major competitor in this nondestructive testing market.

The market for proton therapy products is still developing and is characterized by rapidly evolving technology, high competition and pricing pressure. Our ability to compete successfully depends, in part, on our ability to lower our product costs, develop and provide technically superior, clinically proven products that deliver more precise, cost-effective, high quality clinical outcomes, including integration of IGRT technologies such as integrated volumetric imaging. In the proton therapy market, we compete principally with Hitachi Heavy Industries, Ion Beam Applications S.A., Mevion Medical Systems, Inc. and Sumitomo Heavy Industries, Ltd. There are a number of smaller competitors that are also developing proton therapy products. We are the only established company in the field of radiation therapy to enter the particle therapy market directly.

#### Customer Services and Support

We warrant most of our Oncology Systems products for parts and labor for 12 months, and we offer a variety of post-warranty equipment service contracts and software support contracts to suit customers' requirements. Our domestic service centers are in Milpitas, California; Las Vegas, Nevada and Atlanta, Georgia. Our international

service centers are in France, United Kingdom, Switzerland, Denmark, Belgium, Germany, Netherlands, Spain, Italy, United Arab Emirates, Saudi Arabia, Russia, India, Japan, China, Malaysia, Singapore, Thailand, Australia, Brazil, South Korea, Hungary, Austria, Finland and Canada. We also have field service personnel throughout the world for Oncology Systems customer support services. Key Oncology Systems education operations are located in Las Vegas, Nevada; Beijing, China; Mumbai, India; Cham, Switzerland and Tokyo, Japan. Our network of service engineers and customer support specialists provide installation, warranty, repair, training and support services, project management, site planning, and professional services. We also have a distributed service parts network of regional hubs and forward-stocking locations across all major geographic areas. We generate service revenues by providing services to customers on a time-and-materials basis, replacement part sales and through post-warranty equipment service

contracts and software support contracts. Most of the field service engineers are our employees, but our products are serviced by employees of distributors and/or agents in a few foreign countries. Customers can access our extensive service network by calling any of our service centers.

We believe customer service and support are an integral part of our Oncology Systems competitive strategy. Growth in our service revenues has resulted from the increasing customer adoption of service contracts as the sophistication and installed base of our products increase. We also believe superior service plays an important role in marketing and selling medical products and systems, particularly as the products become more complex. Nevertheless, some of our customers use their own internal service organizations and/or independent service organizations to service equipment after the warranty period expires and therefore do not enter into agreements with us for extended service.

We generally warrant our medical imaging components and security and inspection products for 12 months. We provide technical advice and consultation for medical imaging components to major OEM customers from our offices in Salt Lake City, Utah; Charleston, South Carolina; Liverpool, New York and Downers Grove, Illinois and internationally in the Philippines, Japan, China, Netherlands and Germany. Our applications specialists and engineers make recommendations to meet the customer's technical requirements within the customer's budgetary constraints. We often develop specifications for a unique product, which will be designed and manufactured to meet a specific customer's requirements. We also maintain a technical customer support group in Charleston, South Carolina and Liverpool, New York to meet the technical support requirements of independent service companies that use our medical imaging components products. We provide technical support and service for our security and inspection products to major OEM customers from our offices in Las Vegas, Nevada and Lincolnshire, Illinois and internationally in France, United Kingdom, Italy, Japan and Belgium.

In the VPT business, we sell our proton therapy equipment generally with a 12-month warranty. We also generate service revenues by providing on-site proton therapy system technical operation and maintenance support services for relatively long-term periods (i.e., a five-year term or longer). We believe customer service and support are an integral part of our VPT competitive strategy.

#### Manufacturing and Supplies

We manufacture our medical linear accelerators in Palo Alto, California and in Beijing, China. Our treatment simulator systems and some accelerator subsystems are manufactured in Crawley, United Kingdom and some of our other accessory products in Baden, Switzerland; Helsinki, Finland; Toulouse, France; and Winnipeg, Canada. We manufacture our high dose rate brachytherapy systems in Crawley, United Kingdom and Haan, Germany and our brachytherapy treatment planning products in Charlottesville, Virginia. Calypso manufactures components of their tumor tracking and motion management products in Seattle, Washington. Our security and inspection linear accelerators are principally manufactured in Las Vegas, Nevada. We manufacture components and sub-systems for our proton therapy products and systems in Troisdorf, Germany. We manufacture our X-ray imaging component products in Salt Lake City, Utah; Charleston, South Carolina; Liverpool, New York; Downers Grove, Illinois; Bremen, Germany; Willich, Germany; Dinxperlo, Netherlands; Manila, Philippines; and Beijing, China. These facilities employ state-of-the-art manufacturing techniques, and several have been honored by the press, governments and trade organizations for their commitment to quality improvement. These manufacturing facilities are certified by International Standards Organization ("ISO") under ISO 9001 (for security and inspection products) or ISO 13485 (for medical devices).

Manufacturing processes at our various facilities include machining, fabrication, subassembly, system assembly and final testing. We have invested in various automated and semi-automated equipment for the fabrication and machining of the parts and assemblies that we incorporate into our products. We may, from time to time, invest further in such equipment. Our quality assurance program includes various quality control measures from inspection of raw materials, purchased parts and assemblies through on line inspection. We outsource the manufacturing of many major subassemblies and perform system design, assembly and testing in house. We believe outsourcing enables us to reduce or maintain fixed costs and capital expenditures, while also providing us with the flexibility to increase production capacity. We purchase material and components from various suppliers that are either standard products or customized to our specifications. We obtain some of the components included in our products from a limited group of suppliers or from a single source supplier, such as the radioactive sources for high dose afterloaders, klystrons for

linear accelerators; transistor arrays and cesium iodide coatings for flat panel detectors and specialized integrated circuits, X-ray tube targets, housings, glassframes and various other components; and radiofrequency components, magnets and gantry hardware for proton therapy systems. We require certain raw materials such as tungsten, lead and copper for Oncology Systems and security and inspection products; copper, lead, tungsten, rhenium, molybdenum zirconium, and various high grades of steel alloy for X-ray tubes, and high-grade steel, high-grade copper and iron for the VPT business. Worldwide demand, availability and pricing of these raw materials have been volatile, and we expect that availability and pricing will continue to fluctuate in the future.

## Research and Development

Developing products, systems and services based on advanced technology is essential to our ability to compete effectively in the marketplace. We maintain a research and development and engineering staff responsible for product design and engineering. Research and development expenses totaled \$245.2 million, \$234.8 million and \$208.2 million in fiscal years 2015, 2014 and 2013, respectively.

Our research and development are conducted both within the relevant product groups of our businesses and through GTC. GTC maintains technical expertise in X-ray technology, accelerator technology, imaging physics and applications, algorithms and software, electronic design, materials science and biosciences to prove feasibility of new product concepts and to improve current products. Present research topics include new imaging concepts, image based radiotherapy treatment planning and delivery, real-time accommodation of moving targets, functional imaging and combined modality therapy, manufacturing process improvements, improved X-ray tubes and large-area, high resolution digital X-ray sensor arrays for cone-beam CT and other applications. GTC is also pursuing the potential of combining advances in directed energy and imaging technology with the latest breakthroughs in biotechnology by employing targeted energy to enhance the effectiveness of biological and chemical therapeutic agents. In addition, GTC is investigating the use of X-ray and high-energy accelerator, detector, and image processing technology for security applications. GTC accepts some sponsored research contracts from external agencies such as the U.S. government or private sources.

Within Oncology Systems, our development efforts focus on enhancing the reliability and performance of existing products and developing new products. This development is conducted primarily in the United States, Switzerland, Canada, England, Finland, Germany, India and China. In addition, we support research and development programs at selected hospitals and clinics. Current areas for development within Oncology Systems include linear accelerator systems and accessories for medical applications, information systems, radiation treatment planning software, image processing software, imaging devices, simulation, patient positioning and equipment diagnosis and maintenance tools. Development for our high-energy linear accelerators is focused on improvements in accelerator technology, size, and mobility to address the needs of our customers in the market.

Within Imaging Components, development is primarily conducted at our Las Vegas, Nevada; Salt Lake City, Utah; Palo Alto, California; Liverpool, New York; Lincolnshire, Illinois and Downers Grove, Illinois facilities domestically and at our Netherlands, Germany and Switzerland facilities internationally and is primarily focused on developing and improving medical imaging component technology. Current X-ray tube development areas include improvements to tube life and tube stability and reduction of tube noise. We are also working on X-ray tube designs which will operate at higher power loadings and at higher CT rotational speed to enhance the performance of next generation CT scanners as well as generators for medical imaging. Research in imaging technology is aimed at developing new panel technologies for low cost radiographic imaging, wireless panel interfaces, better dose utilization in dental imaging, improved image quality for cone beam CT and new image processing tools for advanced applications.

Within VPT, our development efforts focus on integrating patient set-up, motion management and clinical workflow solutions originally developed in Oncology Systems as well as reducing the size of our proton therapy system. We expect that, in order to realize the full potential of the VPT business, we will need to invest substantial resources to continue to develop proton therapy technology.

## Product and Other Liabilities

Our business exposes us to potential product liability claims that are inherent in the manufacture, sale, installation, servicing and support of medical devices and other devices that deliver radiation. Because our products are involved in the intentional delivery of radiation to the human body and other situations where people may come in contact with radiation (for example, when our security and inspection products are being used to scan cargo), the collection and storage of patient treatment data for medical analysis and treatment delivery, the planning of radiation treatment and diagnostic imaging of the human body, and the diagnosing of medical problems, the possibility for significant injury and/or death exists. Our medical products operate within our customers' facilities and network systems, and under quality assurance procedures established by the facility that ultimately result in the delivery of radiation to patients. Human and other errors or accidents may arise from the operation of our products in complex environments, particularly with products from other vendors, where interoperability or data sharing protocol may not be optimized

even though the equipment or system operates according to specifications. As a result, we may face substantial liability to patients, our customers and others for damages resulting from the faulty, or allegedly faulty, design, manufacture, installation, servicing, support, testing or interoperability of our products with other products, or their misuse or failure, as well as liability related to the loss or misuse of private patient data. We may also be subject to claims for property damages or economic loss related to or resulting from any errors or defects in our products, or the installation, servicing and

14

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support of our products. Any accident or mistreatment could subject us to legal costs, litigation, adverse publicity and damage to our reputation, whether or not our products or services were a factor. In addition, if a product we design or manufacture were defective (whether due to design, labeling or manufacturing defects, improper use of the product or other reasons), or found to be so by a competent regulatory authority, we may be required to correct or recall the product and notify other regulatory authorities. We maintain limited product liability insurance coverage and currently self-insure professional liability/errors and omissions liability.

#### Government Regulation

##### U.S. Regulations

Laws governing marketing a medical device. In the United States, as a manufacturer and seller of medical devices and devices emitting radiation or utilizing radioactive by-product material, we and some of our suppliers and distributors are subject to extensive regulation by federal governmental authorities, such as the FDA, Nuclear Regulatory Commission (“NRC”), and state and local regulatory agencies, such as the State of California, to ensure the devices are safe and effective and comply with laws governing products which emit, produce or control radiation. Similar international regulations apply overseas. These regulations, which include the U.S. Food, Drug and Cosmetic Act (the “FDC Act”) and regulations promulgated by the FDA, govern, among other things, the design, development, testing, manufacturing, packaging, labeling, distribution, import/export, sale and marketing and disposal of medical devices, post market surveillance and reporting of serious injuries and death, repairs, replacements, recalls and other matters relating to medical devices, radiation emitting devices and devices utilizing radioactive by-product material. State regulations are extensive and vary from state to state. Our Oncology Systems equipment and software, as well as proton therapy systems offered by our VPT business, constitute medical devices subject to these regulations. Our X-ray tube products, imaging workstations and flat panel detectors are also considered medical devices. Under the FDC Act, each medical device manufacturer must comply with quality system regulations that are strictly enforced by the FDA.

Unless an exception applies, the FDA requires that the manufacturer of a new medical device or a new indication for use of, or other significant change in, existing currently marketed medical device obtain either 510(k) pre-market notification clearance or pre-market approval (“PMA”) before it can market or sell those products in the United States. The 510(k) clearance process is applicable when the device introduced into commercial distribution is substantially equivalent to a legally marketed device. The process of obtaining 510(k) clearance generally takes at least six months from the date the application is filed, but could take significantly longer, and generally requires submitting supporting testing data. After a product receives 510(k) clearance, any modifications or enhancements to a product that could significantly affect its safety or effectiveness, or that would constitute a major change in the intended use of the device, technology, materials, labeling, packaging, or manufacturing process may require a new 510(k) clearance. 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) pre-market notification clearance and can require the manufacturer to cease marketing and/or recall the product until 510(k) clearance is obtained. The FDA has issued draft guidance that, if finalized and implemented, will result in manufacturers needing to seek a significant number of new clearances for changes made to legally marketed devices. If we cannot establish that a proposed product is substantially equivalent to a legally marketed device, we must seek pre-market approval through a PMA application. Under the PMA process, the applicant submits extensive supporting data, including, in most cases, data from clinical studies, in the PMA application to establish reasonable evidence of the safety and effectiveness of the product. This process typically takes at least one to two years from the date the PMA is accepted for filing, but can take significantly longer for the FDA to review. To date, we have only manufactured Class I medical devices, which do not require PMA or 510(k) clearance, and Class II medical devices, which require 510(k) clearance. We do not manufacture any Class III medical devices, which require PMA. Our X-ray tubes and flat panel detectors are Class I medical devices, while all of the medical devices produced by our Oncology Systems business segment and the proton therapy systems manufactured by our VPT business are Class II medical devices.

Quality systems. Our manufacturing operations for medical devices, and those of our third-party manufacturers, are required to comply with the FDA’s Quality System Regulation (“QSR”), which addresses a company’s responsibility for

product design, testing, and manufacturing quality assurance, and the maintenance of records and documentation. The QSR requires that each manufacturer establish a quality systems program 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 relating to the devices. QSR compliance is necessary to receive and maintain FDA clearance or approval to market new and existing products. The FDA makes announced and unannounced periodic and on-going inspections of medical device manufacturers to determine compliance with the QSR. If in connection with these inspections the FDA believes the manufacturer has failed to comply with applicable regulations and/or procedures, it may issue observations that would necessitate prompt corrective action. If FDA inspection observations are not addressed and/or corrective action taken in a

timely manner and to the FDA's satisfaction, the FDA may issue a Warning Letter (which would similarly necessitate prompt corrective action) and/or proceed directly to other forms of enforcement action. Failure to respond timely to FDA inspection observations, a Warning Letter or other notice of noncompliance and to promptly come into compliance could result in the FDA bringing enforcement action against us, which could include the total shutdown of our production facilities, denial of importation rights to the United States for products manufactured in overseas locations and denial of export rights for U.S. products and criminal and civil fines.

The FDA and the Federal Trade Commission ("FTC") also regulate advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, that there are adequate and reasonable scientific data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading. We may not promote or advertise our products for uses not within the scope of our intended use statement in our clearances or approvals or make unsupported safety and effectiveness claims.

It is also important that our products comply with electrical safety and environmental standards, such as those of Underwriters Laboratories ("UL"), the Canadian Standards Association ("CSA"), and the International Electrotechnical Commission ("IEC"). In addition, the manufacture and distribution of medical devices utilizing radioactive material requires a specific radioactive material license. For the United States, manufacture and distribution of these radioactive sources and devices also must be in accordance with a model specific certificate issued by either the NRC or by an Agreement State. In essentially every country and state, installation and service of these products must be in accordance with a specific radioactive materials license issued by the applicable radiation control agency. Service of these products must be in accordance with a specific radioactive materials license. We are also subject to a variety of additional environmental laws regulating our manufacturing operations and the handling, storage, transport and disposal of hazardous materials, and which impose liability for the cleanup of any contamination from these materials. For a further discussion of these laws and regulations, see "Critical Accounting Estimates" in MD&A, and Note 9, "Commitments and Contingencies" of the Notes to the Consolidated Financial Statements."

Other applicable U.S. regulations. As a participant in the healthcare industry, we are also subject to extensive laws and regulations protecting the privacy and integrity of patient medical information that we receive, including the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), "fraud and abuse" laws and regulations, including, physician self-referral prohibitions, and false claims laws. From time to time, these laws and regulations may be revised or interpreted in ways that could make it more difficult for our customers to conduct their businesses, such as recent proposed revisions to the laws prohibiting physician self-referrals, and such revisions could have an adverse effect on the demand for our products, and therefore our business and results of operations. We also must comply with numerous federal, state and local laws of more general applicability relating to such matters as safe working conditions, manufacturing practices and fire hazard control.

The laws and regulations and their enforcement are constantly undergoing change, and we cannot predict what effect, if any, changes to these laws and regulations may have on our business. For example, national and state laws regulate privacy and may regulate our use of data. Furthermore, HIPAA was amended by the HITECH Act to provide that business associates who have access to patient health information provided by hospitals and healthcare providers are now directly subject to HIPAA, including the associated enforcement scheme and inspection requirements.

#### Medicare and Medicaid Reimbursement

The federal and state governments of the United States establish guidelines and pay reimbursements to hospitals and free-standing clinics for diagnostic examinations and therapeutic procedures under Medicare at the federal level and Medicaid at the state level. Private insurers often establish payment levels and policies based on reimbursement rates and guidelines established by the government.

The federal government and the Congress review and adjust rates annually, and from time to time consider various Medicare and other healthcare reform proposals that could significantly affect both private and public reimbursement for healthcare services, including radiotherapy and radiosurgery, in hospitals and free-standing clinics. In the past, we have seen our customers' decision-making process complicated by the uncertainties surrounding reimbursement rates for radiotherapy and radiosurgery in the United States, such as we experienced in 2012 with the reductions to reimbursement rates for radiation therapy proposed by CMS. State government reimbursement for services is determined pursuant to each state's Medicaid plan, which is established by state law and regulations, subject to

requirements of federal law and regulations.

The provisions of the Affordable Care Act went into effect in 2012. Specifically, one of the components of the law is a 2.3% excise tax on sales of most medical devices, which include our Oncology Systems products, which started on January 1, 2013. This tax has had and may continue to have a negative impact on our gross margin. Other elements of this legislation, including comparative effectiveness research, an independent payment advisory board, payment system reforms (including shared

16

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savings pilots) and other provisions, could meaningfully change the way healthcare is developed and delivered, and may materially impact numerous aspects of our business, including the demand and availability of our products, the reimbursement available for our products from governmental and third-party payors, and reduced medical procedure volumes.

Various healthcare reform proposals have also emerged at the state level, and we are unable to predict which, if any of these proposals will be enacted. We believe that the uncertainty created by healthcare reform in the United States has complicated our customers' decision-making process and impacted our Oncology Systems and VPT businesses, and may continue to do so.

The sale of medical devices including radiotherapy products, the referral of patients for diagnostic examinations and treatments utilizing such devices, and the submission of claims to third-party payors (including Medicare and Medicaid) seeking reimbursement for such services, are subject to various federal and state laws pertaining to healthcare "fraud and abuse." These laws include physician self-referral prohibitions, anti-kickback laws and false claims laws. Subject to enumerated exceptions, the federal physician self-referral law, also known as Stark II, prohibits a physician from referring Medicare or Medicaid patients to an entity with which the physician (or a family member) has a financial relationship, if the referral is for a "designated health service," which is defined explicitly to include radiology and radiation therapy services. Anti-kickback laws make it illegal to solicit, induce, offer, receive or pay any remuneration in exchange for the referral of business, including the purchase of medical devices from a particular manufacturer or the referral of patients to a particular supplier of diagnostic services utilizing such devices. False claims laws prohibit anyone from knowingly and willfully presenting, or causing to be presented, claims for payment to third-party payors (including Medicare and Medicaid) that are false or fraudulent, for services not provided as claimed, or for medically unnecessary services. The Office of the Inspector General prosecutes violations of fraud and abuse laws and any violation may result in criminal and/or civil sanctions including, in some instances, imprisonment and exclusion from participation in federal healthcare programs such as Medicare and Medicaid.

#### Foreign Regulations

Our operations, sales and service of our products outside the United States are subject to regulatory requirements that vary from country to country and may differ significantly from those in the United States. In general, our products are regulated outside the United States as medical devices by foreign governmental agencies similar to the FDA.

Marketing a medical device internationally. In order for us to market our products internationally, we must obtain clearances or approvals for products and product modifications. We are required to affix the CE mark to our products in order to sell them in member countries of the European Economic Area ("EEA"). The CE mark is an international symbol of adherence to certain essential principles of safety and effectiveness, which once affixed enables a product to be sold in member countries of the EEA. The CE mark is also recognized in many countries outside the EEA, such as Switzerland and Australia, and can assist in the clearance process. In order to receive permission to affix the CE mark to our products, we must obtain Quality System certification, e.g., ISO 13485, and must otherwise have a quality management system that complies with the EU Medical Device Directive. The ISO promulgates standards for certification of quality assurance operations. We are certified as complying with the ISO 9001 for our security and inspection products and ISO 13485 for our medical devices. Several Asian countries, including Japan and China, have adopted regulatory schemes that are comparable, and in some cases more stringent, than the EU scheme. To import medical devices into Japan, the requirements of Japan's New Medical Device Regulation must be met and a "shonin," the approval to sell medical products in Japan, must be obtained. Similarly, in China a registration certification issued by the State Food and Drug Administration and a China Compulsory Certification mark for certain products are required to sell medical devices in that country. Obtaining such certifications on our products can be time-consuming and can cause us to delay marketing or sales of certain products in such countries. Similarly, prior to selling a device in Canada, manufacturers of Class II, III and IV devices must obtain a medical device license. We sell Class II and Class III devices in Canada. Additionally, many countries have laws and regulations relating to radiation and radiation safety that also apply to our products. In most countries, radiological regulatory agencies require some form of licensing or registration by the facility prior to acquisition and operation of an X-ray generating device or a radiation source. The handling, transportation and the recycling of radioactive metals and source materials are also highly regulated.

A number of countries, including the members of the EU, have implemented or are implementing regulations that would require manufacturers to dispose, or bear certain disposal costs, of products at the end of a product's useful life and restrict the use of some hazardous substances in certain products sold in those countries. For a further discussion of these regulations, see "Critical Accounting Estimates" in MD&A and Note 9, "Commitments and Contingencies" of the Notes to the Consolidated Financial Statements."

Manufacturing and selling a device internationally. We are also subject to laws and regulations outside the United States applicable to manufacturers of radiation-producing devices and products utilizing radioactive materials, and laws and regulations of general applicability relating to matters such as environmental protection, safe working conditions,

manufacturing practices and other matters, in each case that are often comparable to, if not more stringent than, regulations in the United States. In addition, our sales of products in foreign countries are also subject to regulation of matters such as product standards, packaging requirements, labeling requirements, import restrictions, environmental and product recycling requirements, tariff regulations, duties and tax requirements. In some countries, we rely on our foreign distributors and agents to assist us in complying with foreign regulatory requirements.

Other applicable international regulations. In addition to the U.S. laws regarding the privacy and integrity of patient medical information, we are subject to similar laws and regulations in foreign countries covering data privacy and other protection of health and employee information. Particularly within Europe, data protection legislation is comprehensive and complex and there has been a recent trend toward more stringent enforcement of requirements regarding protection and confidentiality of personal data, as well as enactment of stricter legislation. We are also subject to international “fraud and abuse” laws and regulations, as well as false claims and misleading advertisement laws.

#### Anti-Corruption Laws and Regulations.

We are subject to the U.S. Foreign Corrupt Practices Act and anti-corruption laws, and similar laws in foreign countries, such as the U.K. Bribery Act of 2010, which became effective on July 1, 2011, and the Law “On the Fundamentals of Health Protection in the Russian Federation,” which became effective in January 2012. In general, there is a worldwide trend to strengthen anticorruption laws and their enforcement, and the healthcare industry and medical equipment manufacturers have been particular targets of these investigation and enforcement efforts. Any violation of these laws by us or our agents or distributors could create a substantial liability for us, subject our officers and directors to personal liability and also cause a loss of reputation in the market.

Transparency International’s 2014 Corruption Perceptions Index measured the degree to which public sector corruption is perceived to exist in 174 countries/territories around the world, and found that nearly seventy percent of the countries in the index, including many that we consider to be high growth areas for our products, such as China, India, Russia and Brazil, scored below 50, on a scale from 100 (very clean) to 0 (highly corrupt). We currently operate in many countries where the public sector is perceived as being more or highly corrupt and our strategic business plans include expanding our business in regions and countries that are rated as higher risk for corruption activity by Transparency International.

Increased business in higher risk countries could subject us and our officers and directors to increased scrutiny and increased liability. In addition, becoming familiar with and implementing the infrastructure necessary to comply with laws, rules and regulations applicable to new business activities and mitigating and protecting against corruption risks could be quite costly. Failure by us or our agents or distributors to comply with these laws, rules and regulations could delay our expansion into high-growth markets and could adversely affect our business.

#### Patent and Other Proprietary Rights

We place considerable importance on obtaining and maintaining patent, copyright and trade secret protection for significant new technologies, products and processes, because of the length of time and expense associated with bringing new products through the development process and to the marketplace.

We generally rely upon a combination of patents, copyrights, trademarks, trade secret and other laws, and contractual restrictions on disclosure, copying and transferring title, including confidentiality agreements with vendors, strategic partners, co-developers, employees, consultants and other third parties, to protect our proprietary rights in the developments, improvements and inventions that we have originated and which are incorporated in our products or that fall within our fields of interest. As of October 2, 2015, we owned 486 patents issued in the United States and 235 patents issued throughout the rest of the world and had 426 patent applications on file with various patent agencies worldwide. We intend to file additional patent applications as appropriate. We have trademarks, both registered and unregistered, that are maintained and enforced to provide customer recognition for our products in the marketplace. We also have agreements with third parties that provide for licensing of patented or proprietary technology, including royalty bearing licenses and technology cross licenses.

#### Environmental Matters

For a discussion of environmental matters, see “Critical Accounting Estimates” in MD&A and Note 9, “Commitments and Contingencies” of the Notes to the Consolidated Financial Statements, which discussions are incorporated herein

by reference.

**Financial Information about Geographic Areas**

We do business globally with manufacturing, engineering, and development in the United States, Europe, China, India and Canada with sales and service operations and customers throughout the world. More than half of our revenues are generated

18

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from our international regions. In addition to the potentially adverse impact of foreign regulations, see “Government Regulation—Foreign Regulations,” we also may be affected by other factors related to our international sales such as: lower average selling prices and profit margins; longer time periods from shipment to revenue recognition (which increases revenue recognition deferrals and time in backlog); and longer time periods from shipment to cash collection (which increases days sales outstanding (“DSO”)). To the extent that the geographic distribution of our sales continues to shift more towards international regions, our overall revenues and margins may suffer. We sell our products internationally predominantly in local currencies, but our cost structure is weighted towards the U.S. Dollar. Accordingly, there may be adverse consequences from fluctuations in foreign currency exchange rates, which may affect both the affordability and competitiveness of our products and our profit margins. In fiscal year 2015, the U.S. Dollar strengthened against the Euro, the Japanese Yen and other foreign currencies which had a negative impact on our financial performance, compared to the year-ago period. We engage in currency hedging strategies to offset the effect of fluctuations in foreign currency exchange rate, but the protection offered by these hedges depends upon the timing of transactions, the effectiveness of the hedges, the number of transactions that are hedged and and forecast volatility.

We are also exposed to other economic, political and other risks inherent in doing business globally. For an additional discussion of these risks, see Item 1A, “Risk Factors.”

For a discussion of financial information about geographic areas, see Note 17, “Segment Information” of the Notes to the Consolidated Financial Statements and MD&A, which discussions are incorporated herein by reference.

#### Employees

We had approximately 7,300 full time and part-time employees worldwide, including approximately 3,800 in the United States and approximately 3,500 elsewhere at October 2, 2015. None of our employees based in the United States are unionized or subject to collective bargaining agreements. Employees based in some foreign countries may, from time-to-time, be represented by works councils or unions or subject to collective bargaining agreements. We currently consider our relations with our employees to be good.

#### Information Available to Investors

As soon as reasonably practicable after our filing or furnishing the information to the SEC, we make the following available free of charge on the Investors page of our website <http://www.varian.com>: our annual reports on Form 10-K; quarterly reports on Form 10-Q; current reports on Form 8-K (including any amendments to those reports); and proxy statements. Our Code of Conduct, Corporate Governance Guidelines and the charters of the Audit Committee, Compensation and Management Development Committee, Ethics and Compliance Committee, Nominating and Corporate Governance Committee and Executive Committee are also available on the Investors page of our website. 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”).

#### Executive Officers of the Registrant

The biographical summaries of our executive officers, as of November 1, 2015, are as follows:

Name	Age	Position
Dow R. Wilson	56	President and Chief Executive Officer
Elisha W. Finney	54	Executive Vice President, Finance and Chief Financial Officer
Kolleen T. Kennedy	56	Executive Vice President and President, Oncology Systems
John W. Kuo	52	Senior Vice President, General Counsel and Corporate Secretary
Sunny S. Sanyal	51	Senior Vice President and President, Imaging Components Business
Clarence R. Verhoef	60	Senior Vice President, Finance and Corporate Controller

Dow R. Wilson was appointed President and Chief Executive Officer effective September 29, 2012. Mr. Wilson served as Corporate Executive Vice President and Chief Operating Officer from October 2011 through September 2012 and as Corporate Executive Vice President and President, Oncology Systems from August 2005 through September 2011. Mr. Wilson served as Corporate Vice President and President, Oncology Systems from January 2005 to August 2005. Prior to joining the Company in January 2005, Mr. Wilson was Chief Executive Officer of the Healthcare-Information Technologies business in General Electric (a diversified technology and services company),

from 2003 to 2005. During the previous 18 years, Mr. Wilson held

19

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various management positions within General Electric. Mr. Wilson holds a B.A. degree in English from Brigham Young University and an M.B.A. degree from Dartmouth's Amos Tuck School of Business. Mr. Wilson served on the board of directors of Saba Software, Inc. (an e-learning software provider) from August 2006 to March 2015 and as the lead independent director of that board from August 2011 to March 2013. Mr. Wilson was appointed to our Board of Directors effective September 29, 2012.

Elisha W. Finney was appointed Executive Vice President, Finance, in addition to being Chief Financial Officer, in February 2012. Ms. Finney served as Corporate Senior Vice President and Chief Financial Officer from January 2005 through January 2012 and as Corporate Vice President and Chief Financial Officer from April 1999 to January 2005. Ms. Finney has held various other positions, including Treasurer, during her 25 years with the Company. Ms. Finney holds a B.B.A. degree in risk management and insurance from the University of Georgia and an M.B.A. degree from Golden Gate University in San Francisco. Ms. Finney joined the board of Altera Corporation (a supplier of custom logic solutions) in August 2011.

Kolleen T. Kennedy was appointed Executive Vice President and President, Oncology Systems effective September 2014, and was our Senior Vice President and President, Oncology Systems from October 2011 to September 2014. From January 2006 through September 2011, Ms. Kennedy served as Vice President, Oncology Systems Customer Service and Support. Prior to that, Ms. Kennedy was the Company's Vice President, Oncology Systems Marketing, Product Management and Engineering from September 2004 to January 2006. Prior to becoming Vice President, Ms. Kennedy served in various marketing management positions since she joined the Company in 1997. Ms. Kennedy holds a B.S. degree in Radiation Oncology and a B.S. degree in Psychology, both from Wayne State University, as well as an M.S. in Medical Physics from the University of Colorado.

John W. Kuo was appointed Senior Vice President, in addition to being General Counsel and Corporate Secretary, in February 2012. Prior to that, he served as Corporate Vice President and General Counsel from July 2005 through January 2012 and as Corporate Secretary since February 2005. Mr. Kuo joined the Company as Senior Corporate Counsel in March 2003 and became Associate General Counsel in March 2004. Prior to joining the Company, Mr. Kuo was General Counsel and Secretary at BroadVision, Inc. (an e-commerce software provider) and held senior legal positions at 3Com Corporation (a networking equipment provider). Mr. Kuo has previously been with the law firms of Gray Cary Ware & Freidenrich (now DLA Piper) and Fulbright & Jaworski. Mr. Kuo holds a B.A. degree from Cornell University and a J.D. degree from Boalt Hall School of Law at the University of California at Berkeley.

Sunny S. Sanyal was appointed Senior Vice President and President, Imaging Components Business in February 2014. From August 2010 to January 2014, Mr. Sanyal served as the Chief Executive Officer of T-System Inc. (an information technology solutions and services provider). Mr. Sanyal worked for McKesson Corporation (a healthcare services and information technology company) as the Chief Operating Officer of McKesson Provider Technologies from December 2006 to July 2010 and as the Group President of McKesson's Clinical Information Systems division from April 2004 to December 2006. Previously, he held various management positions with GE Healthcare, Accenture and IDX Systems Corporation. Mr. Sanyal holds an M.B.A. degree from Harvard Business School, an M.S. degree in industrial engineering from Louisiana State University, and a B.E. degree in electrical engineering from the University of Bombay.

Clarence R. Verhoef was appointed Senior Vice President, Finance and Corporate Controller in August 2012. From May 2012 to August 2012, Mr. Verhoef served as the Company's Vice President and Operations Controller, and from September 2006 to May 2012, he served as the Controller for the Company's X-Ray Products business. Prior to joining the Company, from 2003 to September 2006, Mr. Verhoef served as the Chief Financial Officer of Techniscan Medical Systems Inc. (a developer of ultrasound technology), and prior to that held various finance management positions with GE Healthcare and other medical imaging equipment companies. Mr. Verhoef holds a B.S. degree in Finance from the University of Utah.



#### Item 1A. Risk Factors

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. Although the risk factors described below are the ones management deems significant, additional risks and uncertainties not presently known to us or that we presently deem less significant may also adversely affect our business operations. If any of the following risks or additional risks and uncertainties actually occur, our business, operating results, and financial condition could be adversely affected.

#### OUR SUCCESS DEPENDS ON THE SUCCESSFUL DEVELOPMENT, INTRODUCTION AND COMMERCIALIZATION OF NEW GENERATIONS OF PRODUCTS AND ENHANCEMENTS TO OR SIMPLIFICATIONS OF EXISTING PRODUCT LINES

Rapid change and technological innovation characterize the markets in which we operate. Our Oncology Systems products often have long development and government approval cycles, so we must anticipate changes in the marketplace, in technology and in customer demands. Our success depends on the successful development, introduction and commercialization of new generations of products (including linear accelerators, accessories, treatment systems and software products) and enhancements to and/or simplification of existing product lines. Our Oncology Systems products, including products such as EDGE and TrueBeam, are technologically complex and must keep pace with, if not be superior to, the products of our competitors in order to remain competitive. We are also expanding our software product lines and investing in the development of cloud and software-as-a-service (“SaaS”) solutions. Development and introduction of new software platforms and software delivery models, as well as different revenue models, can be highly complex and uncertain, both in our ability to develop and implement such platforms or models and in our customers’ acceptance of such platforms or models.

Our Imaging Components business, which sells primarily to a small number of imaging system OEM customers who use our products in their medical diagnostic, security and industrial imaging systems, must also continually introduce new products at competitive costs while also improving existing products with higher quality, lower costs and increased feature sets. Because this business competes in very price sensitive markets with other market players who are much larger and who may have “in-house” supplier of competing components, our ability to anticipate our customers’ demands, innovate and introduce new products at a competitive cost and improve quality, cost and features of our existing products is extremely critical to our success in this business. Our failure to do so can and has resulted in loss of customers and adverse impact to our financial performance. With a strong U.S. Dollar, our ability to meet our customers’ pricing expectations is particularly challenged and can result in erosion of product margin and market share.

We are investing in the growth of our Particle Therapy business, and expect that we will need to invest more to develop and commercialize new products and technology for this business. Accordingly, our products may require significant planning, design, development and testing, as well as significant capital commitments, involvement of senior management and other investments on our part. In addition, because of the large footprint and high price of many proton therapy systems, including ours, there is increasing demand for development of a smaller, more compact proton therapy system. Other companies currently offer smaller, less expensive proton therapy systems, and our ability to compete with these companies may depend on our ability to timely develop new technologies to reduce the size and price of our system or provide additional features and functionality that our competitors do not.

We may need to spend more time and money than we expect to develop and introduce new products or enhancements and, even if we succeed, they may not be sufficiently profitable such that we are able to recover all or a meaningful part of our investment. Once introduced, new products may adversely impact orders and sales of our existing products, or make them less desirable or even obsolete, which could adversely impact our revenues and operating results. In addition, certain costs, including installation and warranty costs, associated with new products may be proportionately greater than the costs associated with other products, and may therefore disproportionately adversely affect our gross and operating margins. If we are unable to lower these costs over time, our operating results could be adversely affected. Compliance with regulations, competitive alternatives, and shifting market preferences may also impact our success with new products or enhancements.

Our ability to successfully develop and introduce new products and product enhancements and simplifications, and the revenues and costs associated with these efforts, are affected by our ability to:

- properly identify customer needs or long-term customer demands;
- prove the feasibility of new products;
- limit the time required from proof of feasibility to routine production;
- timely and efficiently comply with internal quality assurance systems and processes;

- limit the timing and cost of regulatory approvals;
- accurately predict and control costs associated with inventory overruns caused by phase-in of new products and phase-out of old products;
- price our products competitively and profitably;
- manufacture, deliver and install our products in sufficient volumes on time, and accurately predict and control costs associated with manufacturing, installation, warranty and maintenance of the products;
- appropriately manage our supply chain;
- manage customer acceptance and payment for products;
  - manage customer demands for retrofits of both new and old products;
  - and
- anticipate, respond to and compete successfully with competitors.

Furthermore, we cannot be sure that we will be able to successfully develop, manufacture or introduce new products, treatment systems or enhancements, the roll-out of which involves compliance with complex quality assurance processes, including the Quality System Regulation (“QSR”) of the FDA. Failure to complete these processes timely and efficiently could result in delays that could affect our ability to attract and retain customers, or could cause customers to delay or cancel orders, causing our revenues and operating results to suffer.

New products generally take longer to install than well-established products. Because a portion of a product’s revenue is generally tied to installation and acceptance of the product, our recognition of revenue associated with new products may be deferred longer than expected. In addition, even if we succeed in our product introductions, potential customers may decide not to upgrade their equipment, or customers may delay delivery of some of our more sophisticated products because of the longer preparation and renovation of treatment rooms required. As a result, our revenues and other financial results could be adversely affected.

**MORE THAN HALF OF OUR REVENUES ARE INTERNATIONAL, AND ECONOMIC, POLITICAL AND OTHER RISKS ASSOCIATED WITH INTERNATIONAL SALES AND OPERATIONS COULD ADVERSELY AFFECT OUR SALES OR MAKE THEM LESS PREDICTABLE**

We conduct business globally. Our international revenues accounted for approximately 54%, 57% and 56% of our total revenues during fiscal years 2015, 2014 and 2013, respectively. As a result, we must provide significant service and support globally. We intend to continue to expand our presence in international markets and expect to expend significant resources in doing so. For example, we have aligned our resources to support sales and marketing efforts in emerging markets. We cannot be sure, however, that we will be able to meet our sales, service and support objectives or obligations in these international markets, or recover our investments. Our future results could be harmed by a variety of factors, including:

- currency fluctuations, such as the strengthening of the U.S. Dollar since the end of our fiscal year 2014, which has adversely affected our financial results and caused some customers to delay purchasing decisions or move to in-sourcing supply or migrate to lower cost alternatives or ask for additional discounts;
- the lower sales prices and gross margins usually associated with sales of our products in the international region, in particular emerging markets;
- the longer payment cycles associated with many foreign customers;
- difficulties in interpreting or enforcing agreements and collecting receivables through many foreign country’s legal systems;
- changes in the political, regulatory, safety or economic conditions in a country or region;
- the imposition by governments of additional taxes, tariffs, global economic sanctions programs (such as the Russia-Ukraine sanctions) or other restrictions on foreign trade;
- the longer periods from placement of orders to revenue recognition in the international region;
- any inability to obtain required export or import licenses or approvals;
- failure to comply with export laws and requirements, which may result in civil or criminal penalties and restrictions on our ability to export our products, particularly our industrial linear accelerator products;



failure to obtain proper business licenses or other documentation, or to otherwise comply with local laws and requirements regarding marketing, sales, service or any other business we conduct in a foreign jurisdiction, which may result in civil or criminal penalties and restrictions on our ability to conduct business in that jurisdiction; and the possibility that it may be more difficult to protect our intellectual property in foreign countries.

Although our orders and sales fluctuate from period to period, in recent years our international region has represented a larger share of our business. The more we depend on sales in the international region, the more vulnerable we become to these factors.

As of October 2, 2015, approximately 98% of our cash and cash equivalents were held abroad. If these funds were repatriated to the United States, a portion of this amount could be subject to additional taxation and our overall tax rate and our results of operations could suffer.

Our effective tax rate is impacted by tax laws in both the United States and in the countries in which our international subsidiaries do business. Earnings from our international region are generally taxed at rates lower than U.S. rates. A change in the percentage of our total earnings from the international region, a change in the mix of particular tax jurisdictions within the international region, or a change in currency exchange rates, could cause our effective tax rate to increase or decrease. Also, we are not currently taxed in the United States on certain undistributed earnings of certain foreign subsidiaries. These earnings could become subject to incremental foreign withholding or U.S. federal and state taxes should they either be deemed to be or actually are remitted to the United States, in which case our financial results would be adversely affected. In addition, changes in the valuation of our deferred tax assets or liabilities, changes in tax laws or rates, changes in the interpretation of tax laws or other changes beyond our control could adversely affect our financial position and results of operations.

#### **OUR RESULTS MAY BE IMPACTED BY CHANGES IN FOREIGN CURRENCY EXCHANGE RATES**

Because our business is global and payments are generally made in local currency, fluctuations in foreign currency exchange rates can impact our results by affecting product demand, or our revenues and expenses, and/or the profitability in U.S. Dollars of products and services that we provide in foreign markets. For example, since the fourth quarter of fiscal year 2014, the U.S. Dollar has strengthened significantly against the Euro and Japanese Yen, which adversely impacted our financial results in fiscal year 2015.

While we use hedging strategies to help offset the effect of fluctuations in foreign currency exchange rates, the protection these strategies provide is affected by the timing of transactions, and the effectiveness of the hedges, the number of transactions that are hedged and forecast volatility. If our hedging strategies do not offset these fluctuations, our revenues, margins and other operating results may be adversely impacted. Furthermore, movement in foreign currency exchange rates could impact our financial results positively or negatively in one period and not another, making it more difficult to compare our financial results from period to period.

In addition, our hedging program is designed to hedge currency movements on a relatively short-term basis (typically up to the next twelve month period). Therefore, we are exposed to currency fluctuations over the longer term.

Long-term movements in foreign currency exchange rates can also affect the competitiveness of our products in the local currencies of our international customers. Even though our international sales are mostly in local currencies, our cost structure is weighted towards the U.S. Dollar. The volatility of the U.S. Dollar that we have experienced over the last several years, and in particular the strengthening of the U.S. Dollar since the fourth quarter of fiscal year 2014, has affected the competitiveness of our pricing against our foreign competitors, some of which may have cost structures based in other currencies, either helping or hindering our international order and revenue growth, thereby affecting our overall financial performance and results. In addition, the negative impact of foreign currency exchange rates has caused some customers in our Imaging Components business to delay purchasing decisions or move to in-sourcing supply or migrate to lower cost alternatives or ask for additional discounts. Even if the U.S. Dollar weakens, these customers may continue using the alternative sources and demand for our products may not increase.

Changes in monetary or other policies here and abroad, including as a result of economic and or political instability, or in reaction thereto, would also likely affect foreign currency exchange rates. Furthermore, in the event that one or more European countries were to replace the Euro with another currency, our sales into these countries, or into Europe generally, would likely be adversely affected until such time as stable exchange rates are established.



**OUR RESULTS HAVE BEEN AND MAY CONTINUE TO BE AFFECTED BY CONTINUING WORLDWIDE ECONOMIC INSTABILITY**

The global economy has been impacted by a number of economic and political factors, including recently the Russia-Ukraine sanctions. In many markets, these conditions have shrunk capital equipment budgets, slowed decision-making, made financing for large equipment purchases more expensive and more time consuming to obtain, and made it difficult for our customers and our vendors to accurately forecast and plan future business activities. This, in turn, has caused our customers to be more cautious with, and sometimes freeze, delay or dramatically reduce, purchases and capital project expenditures. Some countries have adopted and may in the future adopt austerity or stimulus programs that could positively or negatively affect our results from period to period, making it difficult for investors to compare our financial results. An uncertain economic environment may also disrupt supply or affect our service business, as customers' constrained budgets may result in pricing pressure, extended warranty provisions and even cancellation of service contracts.

In addition, concerns over continued economic instability could make it more difficult for us to collect outstanding receivables. Historically, our business has felt the effects of market trends later than other sectors in the healthcare industry, such as diagnostic radiology, and we may experience the effects of any economic recovery later than others in the healthcare industry. A continued weak or deteriorating healthcare market would inevitably adversely affect our business, financial conditions and results of operations.

**WE FACE SIGNIFICANT COSTS IN ORDER TO COMPLY WITH LAWS AND REGULATIONS APPLICABLE TO THE MANUFACTURE AND DISTRIBUTION OF OUR PRODUCTS, AND FAILURE OR DELAYS IN OBTAINING REGULATORY CLEARANCES OR APPROVALS, OR FAILURE TO COMPLY WITH APPLICABLE LAWS AND REGULATIONS COULD PREVENT US FROM DISTRIBUTING OUR PRODUCTS, REQUIRE US TO RECALL OUR PRODUCTS AND RESULT IN SIGNIFICANT PENALTIES**

Our products and those of OEMs that incorporate our products are subject to extensive and rigorous government regulation in the United States. Compliance with these laws and regulations is expensive and time-consuming, and failure to comply with these laws and regulations could adversely affect our business. Furthermore, public media reports on misadministrations of radiotherapy in patients and focus on the role of the FDA in regulating medical devices has led to increased scrutiny of medical device companies and an increased likelihood of enforcement actions. U.S. laws governing marketing a medical device. In the United States, as a manufacturer and seller of medical devices and devices emitting radiation or utilizing radioactive by-product material, we and some of our suppliers and distributors are subject to extensive regulation by federal governmental authorities, such as the FDA, the Nuclear Regulatory Commission ("NRC") and state and local regulatory agencies, such as the State of California, to ensure the devices are safe and effective and comply with laws governing products which emit, produce or control radiation. These regulations govern, among other things, the design, development, testing, manufacturing, packaging, labeling, distribution, import/export, sale and marketing and disposal of our products.

Unless an exception applies, the FDA requires that the manufacturer of a new medical device or a new indication for use of, or other significant change in, an existing currently marketed medical device obtain either 510(k) pre-market notification clearance or pre-market approval ("PMA") before it can market or sell those products in the United States. Modifications or enhancements to a product that could significantly affect its safety or effectiveness, or that would constitute a major change in the intended use of the device, technology, materials, labeling, packaging, or manufacturing process also require a new 510(k) clearance. Although manufacturers make the initial determination whether a change to a cleared device requires a new 510(k) clearance, we cannot assure you that the FDA will agree with our decisions not to seek additional approvals or clearances for particular modifications to our products or that we will be successful in obtaining new 510(k) clearances for modifications. Obtaining clearances or approvals is time-consuming, expensive and uncertain, and the PMA process is more complex than the 510(k) clearance process. We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses of the product, which may limit the market for the product. If we were unable to obtain required FDA clearance or approval for a product or unduly delayed in doing so, or the uses of that product were limited, our business could suffer. In the past, our devices have generally been subject to 510(k)

clearance or exempt from 510(k) clearance. However, there are some in the regulatory field who believe that certain medical devices should be required to use the PMA approval process. If we were required to use the PMA process for future products or product modifications, it could delay or prevent release of the proposed products or modifications, which could harm our business.

Further, as we enter new businesses or pursue new business opportunities, such as radiosurgery and opportunities that require clinical trials, we become subject to additional laws, rules and regulations, including FDA and foreign rules and regulations that

are applicable to the clinical trial process and protection of study subjects. Becoming familiar with and implementing the infrastructure necessary to comply with these laws, rules and regulations is costly. In addition, failure to comply with these laws, rules and regulations could delay the introduction of new products and could adversely affect our business.

Quality systems. Our manufacturing operations for medical devices, and those of our third-party manufacturers, are required to comply with the FDA's QSR, as well as other federal and state regulations for medical devices and radiation emitting products. The FDA makes announced and unannounced periodic and on-going inspections of medical device manufacturers to determine compliance with QSR and in connection with these inspections issues reports, known as Form FDA 483 reports when the FDA believes the manufacturer has failed to comply with applicable regulations and/or procedures. If observations from the FDA issued on Form FDA 483 reports are not addressed and/or corrective action taken in a timely manner and to the FDA's satisfaction, the FDA may issue a Warning Letter and/or proceed directly to other forms of enforcement action. Similarly, if a Warning Letter were issued, prompt corrective action to come into compliance would be required. Failure to respond timely to Form FDA 483 observations, a Warning Letter or other notice of noncompliance and to promptly come into compliance could result in the FDA bringing enforcement action against us, which could include the total shutdown of our production facilities, denial of importation rights to the U.S. for products manufactured in overseas locations, adverse publicity and criminal and civil fines. The expense and costs of any corrective actions that we may take, which may include products recalls, correction and removal of products from customer sites and/or changes to our product manufacturing and quality systems, could adversely impact our financial results and may also divert management resources, attention and time. Additionally, if a Warning Letter were issued, customers could delay purchasing decisions or cancel orders, and we could face increased pressure from our competitors who could use the Warning Letter against us in competitive sales situations, either of which could adversely affect our reputation, business and stock price.

In addition, we are required to timely file various reports with the FDA, including reports required by the medical device reporting regulations ("MDRs"), that require that we report to regulatory authorities if our devices 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 the malfunction were to recur. If these reports are not filed on a timely basis, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business.

If we initiate a correction or removal of a device to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports have been and could be used against us by competitors in competitive situations and cause customers to delay purchase decisions, cancel orders or adversely affect our reputation.

Our medical devices utilizing radioactive material are subject to the NRC clearance and approval requirements, and the manufacture and sale of these products are subject to extensive federal and state regulation that varies from state to state and among regions. Our manufacture, distribution, installation and service (and decommissioning and removal) of medical devices utilizing radioactive material or emitting radiation also requires us to obtain a number of licenses and certifications for these devices and materials. Service of these products must also be in accordance with a specific radioactive materials license. Obtaining licenses and certifications may be time consuming, expensive and uncertain.

In addition, we are subject to a variety of environmental laws regulating our manufacturing operations and the handling, storage, transport and disposal of hazardous materials, and which impose liability for the cleanup of any contamination from these materials. In particular, the handling and disposal of radioactive materials resulting from the manufacture, use or disposal of our products may impose significant costs and requirements. Disposal sites for the lawful disposal of materials generated by the manufacture, use or decommissioning of our products may no longer accept these materials in the future, or may accept them on unfavorable terms.

The FDA and the FTC also regulate advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, that there are adequate and reasonable scientific data to substantiate the

claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including Warning Letters, and may be required to revise our promotional claims and make other corrections or restitutions.

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If we or any of our suppliers, distributors, agents or customers fail to comply with FDA, FTC and other applicable U.S. regulatory requirements or are perceived to potentially have failed to comply, we may face:

- adverse publicity affecting both us and our customers;
- increased pressures from our competitors;
- investigations by governmental authorities or Warning Letters;
- fines, injunctions, and civil penalties;
- partial suspensions or total shutdown of production facilities, or the imposition of operating restrictions;
- increased difficulty in obtaining required FDA clearances or approvals;
- losses of clearances or approvals already granted;
- seizures or recalls of our products or those of our customers;
- delays in purchasing decisions by customers or cancellation of existing orders;
- the inability to sell our products;
- difficulty in obtaining product liability or operating insurance at a reasonable cost, or at all; and
- civil fines and criminal prosecutions.

Other applicable U.S. regulations. As a participant in the healthcare industry, we are also subject to extensive laws and regulations protecting the privacy and integrity of patient medical information that we receive, including the HIPAA, “fraud and abuse” laws and regulations, including physician self-referral prohibitions, and false claims laws. From time to time, these laws and regulations may be revised or interpreted in ways that could make it more difficult for our customers to conduct their businesses, such as recent proposed revisions to the laws prohibiting physician self-referrals, and such revisions could have an adverse effect on the demand for our products, and therefore our business and results of operations. We also must comply with numerous federal, state and local laws of more general applicability relating to such matters as safe working conditions, manufacturing practices and fire hazard control. The laws and regulations and their enforcement are constantly undergoing change, and we cannot predict what effect, if any, changes to these laws and regulations may have on our business. For example, national and state laws regulate privacy and may regulate our use of data. Furthermore, HIPAA was amended by the HITECH Act to provide that business associates who have access to patient health information provided by hospitals and healthcare providers are now directly subject to HIPAA, including the new enforcement scheme and inspection requirements. Moreover, there has been a trend in recent years toward more stringent regulation and enforcement of requirements applicable to medical device manufacturers who receive or have access to patient health information.

Government regulation also may cause considerable delay or even prevent the marketing and full commercialization of future products or services that we may develop, and/or may impose costly requirements on our business. Insurance coverage is not commercially available for violations of law, including the fines, penalties or investigatory costs that we may incur as the consequence of regulatory violations; consequently, we do not have insurance that would cover this type of liability.

#### **DISRUPTION OF CRITICAL INFORMATION SYSTEMS OR MATERIAL BREACHES IN THE SECURITY OF OUR PRODUCTS MAY ADVERSELY AFFECT OUR BUSINESS AND CUSTOMER RELATIONS**

Information technology helps us operate efficiently, interface with and support our customers, maintain financial accuracy and efficiency, and produce our financial statements. There is an increasing threat of information security attacks that pose risk to companies, including Varian. Because the techniques used to obtain unauthorized access, 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 preventative measures. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology infrastructure, we could be subject to, among other things, transaction errors, processing inefficiencies, the loss of customers, business disruptions, or the loss of or damage to intellectual property through a security breach. Such security breaches could expose us to a risk of loss of information, litigation and possible liability to employees, customers and regulatory authorities. If our data management systems do not effectively collect, secure, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, or human error, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations will be impaired, perhaps materially. Any such impairment could materially and adversely affect our



financial condition, results of operations, cash flows and the timeliness with which we report our operating results internally and externally.

Moreover, we manufacture and sell hardware products that rely upon software systems to operate properly and software that deliver treatment instructions and store confidential patient information, and both types of products often are connected to and reside within our customers' information technology infrastructures. While we have implemented security measures to protect both our hardware and software products from unauthorized access, these measures may not be effective in fully securing these products, particularly since techniques used to obtain unauthorized access, or to sabotage systems, change frequently and generally are not recognized until launched against a target. Additionally, we are developing and offering cloud and SaaS software products which reside upon and are hosted by third party providers. A security breach, whether of our products, of our customers' network security and systems or of third party hosting services could disrupt treatments occurring on our products, disrupt access to our customers' stored information, such as the patient treatment delivery instructions, and could lead to the loss of, damage to or public disclosure of our customers' stored information, including patient health information. Such an event could have serious negative consequences, including possible patient injury, regulatory action, fines, penalties and damages, reduced demand for our solutions, an unwillingness of our customers to use our solutions, harm to our reputation and brand, and time-consuming and expensive litigation, any of which could have an adverse effect on our financial results.

#### COMPLIANCE WITH FOREIGN LAWS AND REGULATIONS APPLICABLE TO THE MANUFACTURE AND DISTRIBUTION OF OUR PRODUCTS MAY BE COSTLY, AND FAILURE TO COMPLY MAY RESULT IN SIGNIFICANT PENALTIES

Regulatory requirements affecting our operations and sales outside the United States vary from country to country, often differing significantly from those in the United States. In general, outside the United States, our products are regulated as medical devices by foreign governmental agencies similar to the FDA.

Marketing a medical device internationally. In order for us to market our products internationally, we must obtain clearances or approvals for products and product modifications. These processes (including for example in the European Union ("EU"), the European Economic Area ("EEA"), Switzerland, China, Japan and Canada) can be time consuming, expensive and uncertain, which can delay our ability to market products in those countries. Delays in receipt of or failure to receive regulatory approvals, the inclusion of significant limitations on the indicated uses of a product, the loss of previously obtained approvals or failure to comply with existing or future regulatory requirements could restrict or prevent us from doing business in a country or subject us to a variety of enforcement actions and civil or criminal penalties, which would adversely affect our business.

Within the EEA, we must affix a CE mark, a European marking of conformity that indicates that a product meets the essential requirements of the Medical Device Directive. This conformity to the Medical Device Directive is done through self-declaration and is verified by an independent certification body, called a "Notified Body." Once the CE mark is affixed, the Notified Body will regularly audit us to ensure that we remain in compliance with the applicable European laws and Medical Device Directive. By affixing the CE mark marking to our product, we are certifying that our products comply with the laws and regulations required by the EEA countries, thereby allowing the free movement of our products within these countries and others that accept CE mark standards. If we cannot support our performance claims and demonstrate compliance with the applicable European laws and Medical Device Directive, we would lose our right to affix the CE mark to our products, which would prevent us from selling our products within the EU/EEA/Switzerland territory and in other countries that recognize the CE mark. In September 2012, the European Commission adopted a Proposal for a Regulation of the European Parliament and of the Council on medical devices and a Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices which will, once adopted by the European Parliament and by the Council, replace the existing three medical devices directives. Since negotiation by member states of the available drafts are still ongoing, no publication of the new directive is expected until 2016. The new proposal imposes stricter requirements for the placing in the market of medical devices as well as on the Notified Bodies. We may be subject to risks associated with additional testing, modification, certification or amendment of our existing market authorizations, or we may be required to modify products already installed at our customers' facilities in order to comply with the official interpretations of these revised regulations.

In addition, we are required to timely file various reports with international regulatory authorities, including reports required by international adverse event reporting regulations, that require that we report to regulatory authorities if our devices 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 the malfunction were to recur. If these reports are not timely filed, regulators may impose sanctions, including temporarily suspending our market authorizations or CE mark, and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business.

Further, as we enter new businesses or pursue new business opportunities internationally, such as opportunities that require clinical trials, we may become subject to additional laws, rules and regulations. Becoming familiar with and implementing the infrastructure necessary to comply with these laws, rules and regulations is costly. In addition, failure to comply with these laws, rules and regulations could delay the introduction of new products and could adversely affect our business.

Manufacturing and selling a device internationally. We are also subject to laws and regulations that apply to manufacturers of radiation emitting devices and products utilizing radioactive materials, as well as laws and regulations of general applicability relating to matters such as environmental protection, safe working conditions, manufacturing practices and other matters. These are often comparable to, if not more stringent than, the equivalent regulations in the United States. Sales overseas are also affected by regulation of matters such as product standards, packaging, labeling, environmental and product recycling requirements, import and export restrictions, tariffs, duties and taxes.

In some countries, we rely on our foreign distributors and agents to assist us in complying with foreign regulatory requirements, and we cannot be sure that they will always do so. If we or any of our suppliers, distributors, agents or customers fail to comply with applicable international regulatory requirements or are perceived to potentially have failed to comply, we may face:

- adverse publicity affecting both us and our customers;
- investigations by governmental authorities;
- fines, injunctions, civil penalties and criminal prosecutions;
- increased difficulty in obtaining required approvals in foreign countries;
- losses of clearances or approvals already granted;
- seizures or recalls of our products or those of our customers;
- delays in purchasing decisions by customers or cancellation of existing orders; and
- the inability to sell our products in or to import our products into such countries.

Other applicable international regulations. We are subject to laws and regulations in foreign countries covering data privacy and other protection of health and employee information. Particularly within the EU/EEA/Switzerland area, data protection legislation is comprehensive and complex and there has been a recent trend toward more stringent enforcement of requirements regarding protection and confidentiality of personal data. Data protection authorities from the different member states of the EU may interpret the legislation differently, which adds to this complexity, and data protection is a dynamic field where guidance is often revised. Fully understanding and implementing this legislation could be quite costly and timely, which could adversely affect our business. Additionally, in some instances, in order to fulfill the requirements of applicable U.S. laws, we may be faced with deciding whether to comply with EU/EEA/Switzerland data protection rules. Failure or partial failure to comply with data protection rules and regulations across the EU/EEA/Switzerland area could result in substantial monetary fines. New data protection legislation that will entail substantial changes to the current legal framework, some stricter than before, some less strict, is expected to be enacted by the EU Commission in 2015.

We are also subject to international “fraud and abuse” laws and regulations, as well as false claims and misleading advertisement laws. From time to time, these laws and regulations may be revised or interpreted in ways that could make it more difficult for our customers to conduct their businesses, which could have an adverse effect on the demand for our products, and therefore our business and results of operations. The laws and regulations and their enforcement are constantly undergoing change, and we cannot predict what effect, if any, changes to these laws and regulations may have on our business.

#### THE AFFORDABLE CARE ACT INCLUDES PROVISIONS THAT MAY ADVERSELY AFFECT OUR BUSINESS AND RESULTS OF OPERATIONS, INCLUDING AN EXCISE TAX ON THE SALES OF MOST MEDICAL DEVICES

On March 23, 2010, President Obama signed into law the Affordable Care Act. The Affordable Care Act could adversely impact the demand for our products and services, and therefore our financial position and results of operations, possibly materially.

Specifically, one of the components of the law is a 2.3% excise tax on sales of most medical devices, which include our Oncology Systems and VPT products, which took effect on January 1, 2013. The Congressional Budget Office estimates that the total cost to the medical device industry could exceed \$30 billion over ten years. This tax has had and may continue to have a negative impact on our gross margin.

In addition, discussions relating to the Affordable Care Act have included the possibility for bundled reimbursement payments and accountable care organizations (“ACOs”). ACOs and bundled payment programs were established by the Affordable Care Act to reward integrated, efficient care and allow providers to share in any savings they achieve through the coordination of care and meeting certain mandated quality standards. ACOs and the bundled payment programs have primarily focused on primary care. However, some customers appear to be developing new partnerships across clinical specialties to prepare for the possibility of operating in an ACO environment and bundled reimbursement payments. These and other elements of the Affordable Care Act, including comparative effectiveness research, an independent payment advisory board, payment system reforms (including shared savings pilots) and the reporting of certain payments by us to healthcare professionals and hospitals (the “Physician Payment Sunshine Act”), could meaningfully change the way healthcare is developed and delivered, and may materially impact numerous aspects of our business, including the demand and availability of our products, the reimbursement available for our products from governmental and third-party payors, and reduced medical procedure volumes. We believe that growth of the radiation oncology market, which includes both traditional radiation therapy as well as proton therapy, in the United States is being adversely impacted as customers’ decision-making processes are complicated by the uncertainties surrounding the implementation of the Affordable Care Act and reimbursement rates for radiotherapy and radiosurgery, and that this uncertainty will likely continue into the next fiscal year and result in a high degree of variability of gross orders and revenue from quarter-to-quarter.

Various healthcare reform proposals have also emerged at the state level, and we are unable to predict which, if any of these proposals will be enacted. We are also unable to predict what effect ongoing uncertainty surrounding federal and state health reform proposals will have on our customer’s purchasing decisions. However, an expansion in government’s role in the U.S. healthcare industry may adversely affect our business, possibly materially.

#### CHANGES TO RADIATION ONCOLOGY AND OTHER REIMBURSEMENTS AND CHANGES IN INSURANCE DEDUCTIBLES AND ADMINISTRATION MAY AFFECT DEMAND FOR OUR PRODUCTS

Sales of our healthcare products indirectly depend on whether adequate reimbursement is available to our customers from a variety of sources, such as government healthcare insurance programs, including the Medicare and Medicaid programs; private insurance plans; health maintenance organizations; and preferred provider organizations. In general, employers and third-party payors in the United States have become increasingly cost-conscious, with higher deductibles imposed or encouraged in many medical plans. The imposition of higher deductibles tends to restrain individuals from seeking the same level of medical treatments as they might seek if the costs they bear are lower, particularly in the medical diagnostic portion of our business. Third-party payors have also increased utilization controls related to the use of our products by healthcare providers.

Furthermore, there is no uniform policy on reimbursement among third-party payors, and we cannot be sure that third-party payors will reimburse our customers for procedures using our products that will enable us to achieve or maintain adequate sales and price levels for our products. Without adequate support from third-party payors, the market for our products may be limited.

Once Medicare has made a decision to provide reimbursement for a given treatment, these reimbursement rates are generally reviewed and adjusted by Medicare annually. Private third-party payors, although independent from Medicare, sometimes use portions of Medicare reimbursement policies and payment amounts in making their own reimbursement decisions. As a result, decisions by CMS to reimburse for a treatment, or changes to Medicare’s reimbursement policies or reductions in payment amounts with respect to a treatment sometimes extend to third-party payor reimbursement policies and amounts for that treatment. We have seen our customers’ decision-making process complicated by the uncertainty surrounding Medicare reimbursement rates for radiotherapy and radiosurgery in the United States. From time to time, CMS and third-party payors may review and modify the factors upon which they rely to determine appropriate levels of reimbursement for cancer treatments. For example, CMS and third-party payors have begun to focus on the comparative effectiveness of radiation therapy versus other methods of cancer treatment, including surgery, and could modify reimbursement rates based on the results of comparative effectiveness studies. In addition, discussions relating to the Affordable Care Act have included the possibility for bundled reimbursement payments and ACOs. Any significant cuts in reimbursement rates or changes in reimbursement methodology or administration for radiotherapy, radiosurgery, proton therapy or brachytherapy, or concerns or proposals regarding

further cuts or changes in methodology or administration, could further increase uncertainty, influence our customers' decisions, reduce demand for our products, cause customers to cancel orders and have a material adverse effect on our revenues and stock price.

Foreign governments also have their own healthcare reimbursement systems and we cannot be sure that adequate reimbursement will be made available with respect to our products under any foreign reimbursement system.

WE ARE SUBJECT TO FEDERAL, STATE AND FOREIGN LAWS GOVERNING OUR BUSINESS PRACTICES WHICH, IF VIOLATED, COULD RESULT IN SUBSTANTIAL PENALTIES. ADDITIONALLY, CHALLENGES TO OR INVESTIGATION INTO OUR PRACTICES COULD CAUSE ADVERSE PUBLICITY AND BE COSTLY TO RESPOND TO AND THUS COULD HARM OUR BUSINESS

Laws and ethical rules governing interactions with healthcare providers. The Medicare and Medicaid “anti-kickback” laws, and similar state laws, prohibit payments or other remuneration that is intended to induce hospitals, physicians or others either to refer patients or to purchase, lease or order, or arrange for or recommend the purchase, lease or order of healthcare products or services for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid. These laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements we may have with hospitals, physicians or other potential purchasers of our products. They particularly impact how we structure our sales offerings, including discount practices, customer support, education and training programs, physician consulting, research grants and other service arrangements. These laws are broadly written, and it is often difficult to determine precisely how these laws will be applied to specific circumstances.

Federal and state “false claims” laws generally prohibit knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government payors that are false or fraudulent, or for items or services that were not provided as claimed. Although we do not submit claims directly to payors, manufacturers can be, and have been, held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by providing inaccurate billing or coding information to customers, or through certain other activities, including promoting products for uses not approved or cleared by the FDA, which is called off-label promotion. Violating “anti-kickback” and “false claims” laws can result in civil and criminal penalties, which can be substantial, and potential mandatory or discretionary exclusion from healthcare programs for noncompliance. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to defend, and thus could harm our business and results of operations. Additionally, several recently enacted state and federal laws, including laws in Massachusetts and Vermont, and the federal Physician Payment Sunshine Act, now require, among other things, extensive tracking and maintenance of databases regarding the disclosure of equity ownership and payments to physicians, healthcare providers and hospitals. These laws require us to implement the necessary and costly infrastructure to track and report certain payments to healthcare providers. Failure to comply with these new tracking and reporting laws could subject us to significant civil monetary penalties.

We are subject to similar laws in foreign countries where we conduct business. For example, within the EU, the control of unlawful marketing activities is a matter of national law in each of the member states. The member states of the EU closely monitor perceived unlawful marketing activity by companies. We could face civil, criminal and administrative sanctions if any member state determines that we have breached our obligations under its national laws. Industry associations also closely monitor the activities of member companies. If these organizations or authorities name us as having breached our obligations under their regulations, rules or standards, our reputation would suffer and our business and financial condition could be adversely affected.

Anti-corruption laws and regulations. We are also subject to the U.S. Foreign Corrupt Practices Act and anti-corruption laws, and similar laws in foreign countries, such as the U.K. Bribery Act of 2010, which became effective on July 1, 2011, and the Law “On the Fundamentals of Health Protection in the Russian Federation,” which became effective in January 2012. In general, there is a worldwide trend to strengthen anticorruption laws and their enforcement, and the healthcare industry and medical equipment manufacturers have been particular targets of these investigation and enforcement efforts. Any violation of these laws by us or our agents or distributors could create a substantial liability for us, subject our officers and directors to personal liability and also cause a loss of reputation in the market. Transparency International’s 2014 Corruption Perceptions Index measured the degree to which public sector corruption is perceived to exist in 174 countries/territories around the world, and found that nearly seventy percent of the countries in the index, including many that we consider to be high growth areas for our products, such as China, India, Russia and Brazil, scored below 50, on a scale from 100 (very clean) to 0 (highly corrupt). We currently operate in many countries where the public sector is perceived as being more or highly corrupt. Our strategic business plans include expanding our business in regions and countries that are rated as higher risk for corruption

activity by Transparency International. Becoming familiar with and implementing the infrastructure necessary to comply with laws, rules and regulations applicable to new business activities and mitigating and protecting against corruption risks could be quite costly. In addition, failure by us or our agents or distributors to comply with these laws, rules and regulations could delay our expansion into high-growth markets and could adversely affect our business. This notwithstanding, we will inevitably do more business, directly and potentially indirectly, in countries where the public sector is perceived to be more or highly corrupt and will be engaging in business in more countries perceived to be more or highly corrupt. Increased business in higher risk countries could subject us and our officers and directors to increased scrutiny and increased liability. In addition, we have conducted, and in the future expect to conduct internal investigations or face audits or investigations by one or more domestic or foreign government agencies, which could be costly and time-consuming, and could divert our management and key

personnel from our business operations. For example, in June 2015, one of our foreign subsidiaries was charged by the Department for Investigation and Penal Action of Lisbon with alleged improper activities relating to three tenders of medical equipment in Portugal during the period of 2003 to 2009. We previously undertook an internal investigation of this matter and voluntarily disclosed the results of this investigation to the U.S. Department of Justice and the U.S. Securities and Exchange Commission. At this time, we are unable to predict the ultimate outcome of this matter but intend to defend it vigorously. An adverse outcome under any such proceeding, investigation or audit could subject us to fines, or criminal or other penalties, which could adversely affect our business and financial results.

Competition laws. Due to our competitive position in many jurisdictions, compliance with competition laws is of increased importance to us. Regulatory authorities under whose laws we operate may have enforcement powers that can subject us to sanctions, and can impose changes or conditions in the way we conduct our business. In addition, an increasing number of jurisdictions also provide private rights of action for competitors or consumers to seek damages asserting claims of anti-competitive conduct. Increased government scrutiny of our actions or enforcement of private rights of action could adversely affect our business or damage our reputation. In addition, we have conducted, and in the future expect to conduct, internal investigations or face audits or investigations by one or more domestic or foreign government agencies, which could be costly and time-consuming, and could divert our management and key personnel from our business operations. An adverse outcome under any such investigation or audit could subject us to fines or criminal or other penalties, which could adversely affect our business and financial results.

#### PRODUCT DEFECTS OR MISUSE MAY RESULT IN MATERIAL PRODUCT LIABILITY OR PROFESSIONAL ERRORS AND OMISSIONS CLAIMS, LITIGATION, INVESTIGATION BY REGULATORY AUTHORITIES OR PRODUCT RECALLS THAT COULD HARM OUR FUTURE REVENUES AND REQUIRE US TO PAY MATERIAL UNINSURED CLAIMS

Our business exposes us to potential product liability claims that are inherent in the manufacture, sale, installation, servicing and support of medical devices and other devices that deliver radiation. Because our products are involved in the intentional delivery of radiation to the human body and other situations where people may come into contact with radiation (for example, when our security and inspection products are being used to scan cargo), the collection and storage of patient treatment data for medical analysis and treatment delivery, the planning of radiation treatment and diagnostic imaging of the human body, and the diagnoses of medical problems, the possibility for significant injury and/or death exists to the intended or unintended recipient of the delivery. Our medical products operate within our customers' facilities and network systems, and under quality assurance procedures established by the facility that ultimately result in the delivery of radiation to patients. Human and other errors or accidents may arise from the operation of our products in complex environments, particularly with products from other vendors, where interoperability or data sharing protocol may not be optimized even though the equipment or system operates according to specifications. As a result, we may face substantial liability to patients, our customers and others for damages resulting from the faulty, or allegedly faulty, design, manufacture, installation, servicing, support, testing or interoperability of our products with other products, or their misuse or failure. In addition, third party service providers could fail to adequately perform their obligations, which could subject us to further liability. We may also be subject to claims for property damages or economic loss related to or resulting from any errors or defects in our products, or the installation, servicing and support of our products. Any accident or mistreatment could subject us to legal costs, litigation, adverse publicity and damage to our reputation, whether or not our products or services were a factor. In connection with our products that collect and store patient treatment data, we may be liable for the loss or misuse of such private data, if those products fail or are otherwise defective.

Product liability actions are subject to significant uncertainty and may be expensive, time-consuming, and disruptive to our operations. For these and other reasons, we may choose to settle product liability claims against us, regardless of their actual merit. If a product liability action were finally determined against us, it could result in significant damages, including the possibility of punitive damages and our consolidated financial position, results of operations or cash flows could be materially adversely affected. Adverse publicity regarding any accidents or mistreatments, even ones that do not involve our products, could cause patients to be less receptive to radiotherapy or radiosurgery treatments, to question the efficacy of radiation therapy and radiosurgery and to seek other methods of treatment. Adverse publicity could also result in additional regulation of radiation therapy, radiosurgery, medical devices or the

healthcare industry in general, and adversely affect our ability to promote, manufacture and sell our products. Both adverse publicity and increased regulatory activities could negatively impact our business and results of operations. In addition, if a product we design or manufacture were defective (whether due to design, labeling or manufacturing defects, improper use of the product or other reasons) or found to be so by a competent regulatory authority, we may be required to correct or recall the product and notify other regulatory authorities. The adverse publicity resulting from a correction or recall, however imposed, could damage our reputation and cause customers to review and potentially terminate their relationships

with us. A product correction or recall could consume management time and have an adverse financial impact on our business, including incurring substantial costs, losing revenues and accruing losses under GAAP.

We maintain limited product liability insurance coverage and currently self-insure professional liability/errors and omissions liability. Our product liability insurance policies are expensive and have high deductible amounts and self-insured retentions. Our insurance coverage may also prove to be inadequate, and future policies may not be available on acceptable terms or in sufficient amounts, if at all. If a material claim is successfully brought against us relating to a self-insured liability or a liability that is in excess of our insurance coverage, or for which insurance coverage is denied or limited, we could have to pay substantial damages, which could have a material adverse effect on our financial position and results of operations.

**WE COMPETE IN HIGHLY COMPETITIVE MARKETS, AND WE MAY LOSE MARKET SHARE TO COMPANIES WITH GREATER RESOURCES OR THE ABILITY TO DEVELOP MORE EFFECTIVE TECHNOLOGIES, OR WE COULD BE FORCED TO REDUCE OUR PRICES**

Rapidly evolving technology, intense competition and pricing pressure characterize the markets for radiation therapy equipment and software. New competitors may enter our markets, and we have encountered new competitors as we have entered new markets such as radiosurgery, VMAT and proton therapy. Some of these competitors may have greater financial, marketing and other resources than we have. To compete successfully, we must provide technically superior, proven products that deliver more precise, cost-effective, high quality clinical outcomes, in a complete package of products and services, and do so ahead of our competitors. As our Oncology Systems products are generally sold on a basis of total value to the customer, our business may suffer when purchase decisions are based solely upon price, which can happen if hospitals and clinics give purchasing decision authority to group purchasing organizations. The shift in the proportion of sales within our international region towards emerging market countries, which typically have purchased less complex, lower-priced products compared to more developed countries, and which usually have stiffer price competition, could also adversely impact our results of operations. New competitors may also delay customer purchasing decisions as customers evaluate the products of these competitors along with ours, potentially extending our sales cycle and adversely affecting our gross orders.

In Imaging Components, we often compete with companies that have greater financial, marketing and other resources than we have. Some of the major diagnostic imaging systems companies, which are the primary OEM customers for our X-ray components, also manufacture X-ray components, including X-ray tubes, for use in their own imaging systems products. We must compete with these in-house manufacturing operations for business from their affiliated companies. In addition, we compete against other stand-alone, independent X-ray tube manufacturers who compete with us for both the OEM business of major diagnostic imaging equipment manufacturers and the independent servicing business for X-ray tubes. The market for flat panel detectors is also very competitive. As a result, we must have an advantage in one or more significant areas, which may include lower product cost, better product quality and/or superior technology and/or performance.

With our security and inspection products, we compete with other OEM suppliers, primarily outside of the United States. The market for our X-ray tube and flat panel products used for nondestructive testing in industrial applications is small and highly fragmented.

The market for proton therapy products is still developing and is characterized by rapidly evolving technology and pricing pressure. Our ability to compete successfully depends, in part, on our ability to lower our product costs, develop and provide technically superior, proven products that deliver more precise, cost-effective, high quality clinical outcomes, including integration of technologies such as our On-Board Imager (“OBI”) for IGRT and our motion management technologies.

In each of our business segments, existing competitors’ actions and new entrants may adversely affect our ability to compete. These competitors could develop technologies and products that are more effective than those we currently use or produce or that could render our products obsolete or noncompetitive. In addition, the timing of our competitors’ introduction of products into the market could affect the market acceptance and market share of our products. Some competitors offer specialized products that provide, or may be perceived by customers to provide, a marketing advantage over our mainstream cancer treatment products. Also, some of our competitors may not be subject to the same standards, regulatory and/or other legal requirements that we are subject to, and therefore, they could have a

competitive advantage in developing, manufacturing and marketing products and services. Any inability to develop, gain regulatory approval for and supply commercial quantities of competitive products to the market as quickly and effectively as our competitors could limit market acceptance of our products and reduce our sales. In addition, some of our smaller competitors could be acquired by larger companies that have greater financial strength, which could enable them to compete more aggressively. Our competitors could also acquire some of our suppliers or distributors, which could disrupt these supply or distribution arrangements and result in less predictable and reduced revenues in our businesses. Any of these competitive factors could negatively affect our pricing, sales, revenues, market share and gross margins and our ability to maintain or increase our operating margins.

**OPEN ARCHITECTURE IS BECOMING INCREASINGLY IMPORTANT, AND SALES OF OUR PRODUCTS COULD FALL IF WE FAIL TO ACHIEVE THIS**

As radiation oncology treatment becomes more complex, our customers are increasingly focusing on ease-of-use and interconnectivity. Our equipment and software are highly sophisticated and a high level of training and education is required in order to use them competently and safely-requirements made even more important because they work together within integrated environments. We have directed substantial product development efforts into (i) increasing the interconnectivity of our products for more seamless operation within a system, (ii) making our software products easier to use and (iii) reducing setup and treatment times to increase patient throughput. We have emphasized an “open systems” approach that allows customers to “mix and match” our individual products, incorporate products from other manufacturers, share information with other systems or products and use the equipment for offering various methods of radiation and chemotherapy treatment. We have done this based on our belief that such interconnectivity will increase the acceptance and adoption of IMRT, IGRT and VMAT and will stimulate demand for our products. There are competitive “closed-ended” dedicated-use systems, however, that place simplicity of use ahead of flexibility. If we have misjudged the importance to our customers of maintaining an “open systems” approach, or if we are unsuccessful in our efforts to increase interconnectivity, enhance ease-of-use and reduce setup and treatment times, our revenues could suffer.

Obtaining and maintaining interoperability and compatibility can be costly and time-consuming. While we try to use standard published protocols for communication with widely-used oncology products manufactured by other companies, if we cannot do this, we may need to develop individual interfaces so that our products communicate correctly with the other company products. When other companies modify the design or functionality of their products, this may affect their compatibility with our products. In addition, when we improve our products, customers may be reluctant to adopt our new technology due to potential interoperability issues. For example, a clinic may be unwilling to implement one of our new technologies because its third-party software does not yet communicate correctly with our new product. Our ability to obtain compatibility with products of other companies may depend on our ability to obtain adequate information from them regarding their products. In many cases, these third parties are our competitors and may schedule their product changes and delay their release of relevant information to place us at a competitive disadvantage. When we modify our products to make them interoperable or compatible with third-party products, we may be required to obtain additional regulatory clearances. This process is costly and could delay our ability to release our products for commercial use. It is also possible that, despite our best efforts, we may not be able to make our products interoperable or compatible with widely used third-party products or may only be able to do so at a prohibitive expense, making our products less attractive or more costly to our customers.

**PROTECTING OUR INTELLECTUAL PROPERTY CAN BE COSTLY AND WE MAY NOT BE ABLE TO MAINTAIN LICENSED RIGHTS, AND IN EITHER CASE OUR COMPETITIVE POSITION WOULD BE HARMED IF WE ARE NOT ABLE TO DO SO**

We file applications as appropriate for patents covering new products and manufacturing processes. We cannot be sure, however, that our current patents, the claims allowed under our current patents, or patents for technologies licensed to us will be sufficiently broad to protect our technology position against competitors. Issued patents owned by, or licensed to, us may be challenged, invalidated or circumvented, or the rights granted under the patents may not provide us with competitive advantages. We also cannot be sure that patents will be issued from any of our pending or future patent applications. Asserting our patent rights against others in litigation or other legal proceedings is costly and diverts managerial resources. For example, during September and October 2015, we filed several complaints in the U.S. and foreign courts and the U.S. International Trade Commission against Elekta AB and its subsidiaries alleging infringement of various patents relating to certain aspects of cone beam imaging, cone-beam gantries, volumetric modulated arc therapy, and MR-Linac. An unfavorable outcome in this or in any other such litigation or proceeding could harm us. In addition, we may not be able to detect patent infringement by others or may lose our competitive position in the market before we are able to do so.

We also rely on a combination of copyright, trade secret and other laws, and contractual restrictions on disclosure, copying and transferring title (including confidentiality agreements with vendors, strategic partners, co-developers, employees, consultants and other third parties), to protect our proprietary and other confidential rights. These

protections may prove inadequate, since agreements may still be breached and we may not have adequate remedies for a breach, and our trade secrets may otherwise become known to or be independently developed by others. In the event that our proprietary or confidential information is misappropriated, our business and financial results could be adversely impacted. We have trademarks, both registered and unregistered, that are maintained and enforced to provide customer recognition for our products in the marketplace, but unauthorized third parties may still use them. We also have agreements with third parties that license to us certain patented or proprietary technologies. In some cases products with substantial revenues may depend on these license rights. If we were to lose the rights to license these technologies, or our costs to license these technologies were to materially increase, our business would suffer.

**THIRD PARTIES MAY CLAIM WE ARE INFRINGING THEIR INTELLECTUAL PROPERTY, AND WE COULD SUFFER SIGNIFICANT LITIGATION OR LICENSING EXPENSES OR BE PREVENTED FROM SELLING OUR PRODUCTS**

There is a substantial amount of litigation over patent and other intellectual property rights in the industries in which we compete. Our competitors, like companies in many high technology businesses, continually review other companies' activities for possible conflicts with their own intellectual property rights. In addition, non-practicing entities may review our activities for conflicts with their patent rights. Determining whether a product infringes a third party's intellectual property rights involves complex legal and factual issues, and the outcome of this type of litigation is often uncertain. Third parties may claim that we are infringing their intellectual property rights. We may not be aware of intellectual property rights of others that relate to our products, services or technologies. From time to time, we have received notices from third parties asserting infringement and we have been subject to lawsuits alleging infringement of third-party patent or other intellectual property rights. For example, in September 2015, Elekta Ltd. and William Beaumont Hospital served the Company with a complaint alleging infringement of three patents related to certain aspects of cone beam imaging in conjunction with radiotherapy. This lawsuit is in the initial stages and we are not able to predict its ultimate outcome. We may incur substantial costs and expend significant management resources defending against these claims and our defense of these claims may ultimately not be successful. Any dispute regarding patents or other intellectual property could be costly and time-consuming, and could divert our management and key personnel from our business operations. We may not prevail in a dispute. We do not maintain insurance for intellectual property infringement, so costs of defense, whether or not we are successful in defending an infringement claim, will be borne by us and could be significant. If we are unsuccessful in defending or appealing an infringement claim, we may be subject to significant damages and our consolidated financial position, results of operations or cash flows could be materially adversely affected. If actual liabilities significantly exceed our estimates regarding potential liabilities, our consolidated financial position, results of operations or cash flows could be materially adversely affected. We may also be subject to injunctions against development and sale of our products, the effect of which could be to materially reduce our revenues. Furthermore, a third party claiming infringement may not be willing to license its rights to us, and even if a third party rights holder is willing to do so, the amounts we might be required to pay under the associated royalty or license agreement could be significant. As such, we could decide to alter our business strategy or voluntarily cease the allegedly infringing actions rather than face litigation or pay a royalty, which could adversely impact our business and results of operations.

**UNFAVORABLE RESULTS OF LEGAL PROCEEDINGS COULD MATERIALLY ADVERSELY AFFECT OUR FINANCIAL RESULTS**

From time to time, we are a party to or otherwise involved in legal proceedings, claims and government inspections or investigations and other legal matters, both inside and outside the United States, arising in the ordinary course of our business or otherwise. We are currently involved in various legal proceedings and claims, including product liability claims and intellectual property claims (such as the current litigation with Elekta Ltd. and William Beaumont Hospital), that have not yet been fully resolved and additional claims may arise in the future. Legal proceedings are often lengthy, taking place over a period of years with interim motions or judgments subject to multiple levels of review (such as appeals or rehearings) before the outcome is final. Litigation is subject to significant uncertainty and may be expensive, time-consuming, and disruptive to our operations. For these and other reasons, we may choose to settle legal proceedings and claims, regardless of their actual merit.

If a legal proceeding were finally resolved against us, it could result in significant compensatory damages, and in certain circumstances punitive or trebled damages, disgorgement of revenue or profits, remedial corporate measures or injunctive relief imposed on us. If our existing insurance does not cover the amount or types of damages awarded, or if other resolution or actions taken as a result of the legal proceeding were to restrain our ability to market one or more of our material products or services, our consolidated financial position, results of operations or cash flows could be materially adversely affected. In addition, legal proceedings, and any adverse resolution thereof, can result in adverse publicity and damage to our reputation, which could adversely impact our business.

**THE LOSS OF A SUPPLIER OR ANY INABILITY TO OBTAIN SUPPLIES OF IMPORTANT COMPONENTS COULD RESTRICT OUR ABILITY TO MANUFACTURE PRODUCTS, CAUSE DELAYS IN OUR ABILITY TO**

**DELIVER PRODUCTS, OR SIGNIFICANTLY INCREASE OUR COSTS**

We obtain some of the components included in our products from a limited group of suppliers or from a single source supplier, such as the radioactive sources for high dose afterloaders, klystrons for linear accelerators, transistor arrays and cesium iodide coatings for flat panel detectors, and specialized integrated circuits, X-ray tube targets, housings, glass frames and various other components; and radiofrequency components, magnets and gantry hardware for proton therapy systems. If we lose any of these suppliers, if their operations were substantially interrupted, or if any of them failed to meet performance or quality

specifications, we may be required to obtain and qualify one or more replacement suppliers. Such an event may then also require us to redesign or modify our products to incorporate new parts and/or further require us to obtain clearance, qualification or certification of these products by the FDA or obtain other applicable regulatory approvals in other countries. Events like these could significantly increase costs for the affected product and likely cause material delays in delivery of that and other related products. Although we have insurance to protect against business interruption loss, this insurance coverage may not be adequate or continue to remain available on acceptable terms, if at all. Furthermore, some of our single-source suppliers provide components for some of our rapidly growing product lines. Manufacturing capacity limitations of any of our suppliers or other inability of these suppliers to meet increasing demand could adversely affect us, resulting in curtailed growth opportunities for our affected product lines. Shortage of, and greater demand for, components and subassemblies could also increase manufacturing costs if the supply/demand imbalance increases the price of the components and subassemblies. Disruptions or loss of any of our limited- or sole-sourced components or subassemblies or the capacity limitations of the suppliers for these components or subassemblies, including the ones referenced above, could adversely affect our business and financial results and could damage our customer relationships.

#### **A SHORTAGE OR CHANGE IN SOURCE OF RAW MATERIALS COULD RESTRICT OUR ABILITY TO MANUFACTURE PRODUCTS, CAUSE DELAYS, OR SIGNIFICANTLY INCREASE OUR COST OF GOODS**

We rely upon the supplies of certain raw materials such as tungsten, lead, iridium and copper for Oncology Systems and security and inspection products; copper, lead, tungsten, rhenium, molybdenum zirconium, and various high grades of steel alloy for X-ray tubes, and high-grade steel, high-grade copper and iron for VPT. Worldwide demand, availability and pricing of these raw materials have been volatile, and we expect that availability and pricing will continue to fluctuate in the future. If supplies are restricted or become unavailable or if prices increase, this could constrain our manufacturing of affected products, reduce our profit margins or otherwise adversely affect our business.

Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, the SEC has promulgated rules regarding disclosure of the presence in a company's products of certain metals, known as "conflict minerals," which are metals mined from the Democratic Republic of the Congo and adjoining countries, as well as procedures regarding a manufacturer's efforts to identify the sourcing of those minerals from this region. Complying with these rules requires investigative efforts, which has and will continue to cause us to incur associated costs, and could adversely affect the sourcing, supply, and pricing of materials used in our products, or result in process or manufacturing modifications, all of which could adversely affect our results of operations.

#### **CONSOLIDATION AMONG OUR ONCOLOGY SYSTEMS CUSTOMERS COULD ADVERSELY AFFECT OUR SALES OF ONCOLOGY PRODUCTS**

We have seen and may continue to see some consolidation among our customers in our Oncology Systems business, as hospitals and clinics combine through mergers and acquisitions, and as they join group purchasing organizations or affiliated enterprises. In addition, we have seen and may continue to see integration of equipment and information systems among hospitals as they consolidate their networks. As customers consolidate and/or integrate, the volume of product sales to these customers might decrease. Alternatively, order size may increase, as what were previously more than one customer combine orders as one entity, or as groups of organizations combine their purchases. As a result, as orders increase in size and require more customer approvals, the purchasing cycle for our Oncology Systems products could lengthen. Both increased order size and extended purchasing cycles could cause our gross orders to be more volatile and less predictable. In addition, some customers appear to be developing new partnerships across clinical specialties to prepare for the possibility of operating in an ACO environment and the possibility of bundled reimbursement payments. Group purchasing organizations often focus on pricing as the determinant in making purchase decisions. A reduction in gross orders could affect the level of future revenues, which would adversely affect our operating results, financial condition, and the price of VMS common stock.

#### **WE SELL OUR IMAGING COMPONENTS TO A LIMITED NUMBER OF OEM CUSTOMERS, MANY OF WHICH ARE ALSO OUR COMPETITORS, AND A REDUCTION IN BUSINESS OR INABILITY TO PROPERLY FORECAST SALES BY ONE OR MORE OF THESE CUSTOMERS COULD REDUCE OUR SALES**

We sell our X-ray tube products to a limited number of OEM customers, many of which are also our competitors with in-house X-ray tube manufacturing operations. If these customers manufacture a greater percentage of their components in-house or otherwise lower external sourcing costs, such as we have begun to see as a result of the recent strengthening of the U.S. Dollar, we could experience reductions in purchasing volume by, or loss of, one or more of these customers. Such a reduction or loss has had and will likely continue to have a material adverse effect on our Imaging Components business. In addition, economic uncertainties over the past few years, natural disasters and other matters beyond our control have made it difficult for our OEM customers to accurately forecast and plan future business activities. Such economic uncertainties and natural disasters, as well

as other factors, have previously impacted our Imaging Components business resulting in inventory reduction efforts and slowdowns in sales at some of these customers. Similar inventory adjustments and slowdowns in sales could occur in the future. Our agreements for imaging components may contain purchasing estimates that are based on our customers' historical purchasing patterns, and actual purchasing volumes under the agreements may vary significantly from these estimates.

#### **ORDERS FOR OUR SECURITY AND INSPECTION PRODUCTS TEND TO BE UNPREDICTABLE**

Our Imaging Components business designs, manufactures, sells and services Linatron X-ray accelerators, imaging processing software and image detection products for security and inspection, such as cargo screening at ports and borders and nondestructive examination for a variety of applications, as well as industrial applications. We generally sell security and inspection products to OEMs who incorporate our products into their inspection systems, which are then sold to customs and other government agencies, as well as to commercial organizations in the casting, power, aerospace, chemical, petro-chemical and automotive industries. We believe growth in our security and inspection products will be driven by security cargo screening and border protection needs, as well as by the needs of customs agencies to verify shipments for assessing duties and taxes. Orders for our security and inspection products have been and may continue to be unpredictable as governmental agencies may place large orders with us or our OEM customers in a short time period, and then may not place any orders for a long time period thereafter. Because it is difficult to predict our OEM customer delivery, the actual timing of sales and revenue recognition varies significantly. The market for border protection systems has slowed significantly and end customers, particularly in oil-based economies and war zones in which we have a significant customer base, are delaying system deployments or tenders and considering moving to alternative sources, resulting in a decline in the demand for security and inspection products which is expected to continue.

In addition, demand for our security and inspection products is heavily influenced by U.S. and foreign governmental policies on national and homeland security, border protection and customs revenue activities, which depend upon government budgets and appropriations that are subject to economic conditions, as well as political changes. We have seen customers freeze or dramatically reduce purchases and capital project expenditures, delay projects, or act cautiously as governments around the world wrestle with spending priorities. As economic growth remains sluggish in various jurisdictions and appears to be deteriorating in others, and as concerns about levels of government employment and government debt continue, we expect that these effects will also continue. Furthermore, bid awards in this business may be subject to challenge by third parties, as we have previously encountered with a large government project. These factors make the timing of orders, sales and revenues in this business more unpredictable and could cause volatility in our revenues and earnings, and therefore the price of VMS common stock.

#### **IF WE ARE UNABLE TO PROVIDE THE SIGNIFICANT EDUCATION AND TRAINING REQUIRED FOR THE HEALTHCARE MARKET TO ACCEPT OUR PRODUCTS, OUR BUSINESS WILL SUFFER**

In order to achieve market acceptance for our radiation therapy products, we often need to educate physicians about the use of treatment procedures such as IMRT, IGRT, VMAT, SRS, SBRT or proton therapy, overcome physician objections to some of the effects of the product or its related treatment regimen, convince healthcare payors that the benefits of the product and its related treatment process outweigh its costs and help train qualified physicists in the skilled use of the product. For example, the complex and dynamic nature of IMRT and IGRT requires significant education of hospital personnel and physicians regarding the benefits of and practices associated with IMRT and IGRT. Further, the complexity and high cost of proton therapy requires similar significant education, as well as education regarding construction and facility requirements. We have devoted and will continue to devote significant resources on marketing and educational efforts to create awareness of IMRT, IGRT, VMAT stereotactic radiotherapy, SRS, SBRT and proton therapy generally, to encourage the acceptance and adoption of our products for these technologies and to promote the safe and effective use of our products in compliance with their operating procedures. Future products may not gain adequate market acceptance among physicians, patients and healthcare payors, even if we spend significant time and expense educating them about these products.

#### **OUR BUSINESS MAY SUFFER IF WE ARE NOT ABLE TO HIRE AND RETAIN QUALIFIED PERSONNEL**

Our future success depends, to a great degree, on our ability to retain, attract, expand, integrate and train our management team and other key personnel, such as qualified engineering, service, sales, marketing and other staff.

We compete for key personnel with other medical equipment and software manufacturers and technology companies, as well as universities and research institutions. Because this competition is intense, compensation-related costs could increase significantly if the supply of qualified personnel decreases or demand increases. If we are unable to hire and train qualified personnel, we may not be able to maintain or expand our business. Additionally, if we are unable to retain key personnel, we may not be able to replace them readily or on terms that are reasonable, which also could hurt our business.

**IF WE ARE NOT ABLE TO MATCH OUR MANUFACTURING CAPACITY WITH DEMAND FOR OUR PRODUCTS, OUR FINANCIAL RESULTS MAY SUFFER**

Many of our products have a long production cycle, and we need to anticipate demand for our products in order to ensure adequate manufacturing or testing capacity. If we are unable to anticipate demand and our manufacturing or testing capacity does not keep pace with product demand, we will not be able to fulfill orders in a timely manner, which may negatively impact our financial results and overall business. Conversely, if demand for our products decreases, the fixed costs associated with excess manufacturing capacity may harm our financial results.

**WE MAY NOT REALIZE EXPECTED BENEFITS FROM ACQUISITIONS OF OR INVESTMENTS IN NEW BUSINESSES, PRODUCTS, OR TECHNOLOGIES, WHICH COULD HARM OUR BUSINESS**

We need to grow our businesses in response to changing technologies, customer demands and competitive pressures. In some circumstances, we may decide to grow our business through the acquisition of complementary businesses, products or technologies rather than through internal development. For example, during fiscal year 2014, we acquired certain assets of Velocity and Transpire, and during fiscal year 2015, we acquired Claymount and a majority interest in MeVis. Identifying suitable acquisition candidates can be difficult, time-consuming and costly, and we may not be able to identify suitable candidates or successfully complete identified acquisitions. In addition, completing an acquisition can divert our management and key personnel from our current business operations, which could harm our business and affect our financial results. Even if we complete an acquisition, we may not be able to successfully integrate newly acquired organizations, products, technologies or employees into our operations, or may not fully realize some of the expected synergies.

Integrating an acquisition can also be expensive and time-consuming, and may strain our resources. It may cost us more to commercialize new products than we originally anticipated, as we experienced with our proton therapy systems, or cause us to increase our expenses related to research and development, either of which could adversely impact our results of operations. In many instances, integrating a new business will also involve implementing or improving internal controls appropriate for a public company into a business that lacks them. It is also possible that an acquisition could increase our risk of litigation, as a third party may be more likely to assert a legal claim following an acquisition because of perceived deeper pockets or perceived greater value of a claim. In addition, we may be unable to retain the employees of acquired companies, or the acquired company's customers, suppliers, distributors or other partners for a variety of reasons, including the fact that these entities may be our competitors or may have close relationships with our competitors.

Further, we may find that we need to restructure or divest acquired businesses, or assets of those businesses. Even if we do so, an acquisition may not produce the full efficiencies, growth or benefits we expected. If we decide to sell assets or a business, as we did in fiscal year 2008 with the scientific research instruments business that we acquired as part of our acquisition of ACCEL GmbH, it may be difficult to identify buyers or alternative exit strategies on acceptable terms, in a timely manner, or at all, which could delay the accomplishment of our strategic objectives. We may be required to dispose of a business at a lower price or on less advantageous terms, or to recognize greater losses, than we had anticipated.

If we acquire a business, we allocate the total purchase price to the acquired businesses' tangible assets and liabilities, identifiable intangible assets and liabilities based on their fair values as of the date of the acquisition, and record the excess of the purchase price over those fair values as goodwill. If we fail to achieve the anticipated growth from an acquisition, or if we decide to sell assets or a business, we may be required to recognize an impairment loss on the write down of our assets and goodwill, which could adversely affect our financial results. In addition, acquisitions can result in potentially dilutive issuances of equity securities or the incurrence of debt, contingent liabilities or expenses, or other charges, any of which could harm our business and affect our financial results.

Additionally, we have investments in privately held companies that are subject to risk of loss of investment capital. These investments are inherently risky, in some instances because the markets for the technologies or products these companies have under development may never materialize. If these companies do not succeed, we could lose some or all of our investment in these companies. For example, in fiscal year 2014, we recorded a charge relating to the impairment of a portion of a privately-held equity investment when we became aware of certain indicators of impairment.

**WE MAY FACE ADDITIONAL RISKS FROM THE ACQUISITION OR DEVELOPMENT OF NEW LINES OF BUSINESS**

From time to time, we may acquire or develop new lines of business, such as particle therapy. There are substantial risks and uncertainties associated with new lines of business, particularly in instances where the markets are not fully developed. Risks include developing knowledge of and experience in the new business, recruiting market professionals, increasing research and

37

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development expenditures, and developing and capitalizing on new relationships with experienced market participants. This may mean significant investment and involvement of our senior management to acquire or develop, then integrate, the business into our operations. Timelines for integration of new businesses may not be achieved and price and profitability targets may not prove feasible, as new products can carry lower gross margins than existing products. External factors, such as compliance with regulations, competitive alternatives, and shifting market preferences, may also impact whether implementation of a new business will be successful. Failure to manage these risks could have a material adverse effect on our business, results of operations and financial condition.

**WE WORK WITH DISTRIBUTORS FOR SALES IN SOME TERRITORIES, AND LOSING THEM COULD HARM OUR REVENUES IN THAT TERRITORY**

We have strategic relationships with a number of key distributors, including Siemens AG, for sales and service of our products. If these strategic relationships end and are not replaced, our revenues from product sales in these territories and/or ability to service our products in the territories serviced by these distributors could be adversely affected.

**FLUCTUATIONS IN OUR OPERATING RESULTS, INCLUDING QUARTERLY GROSS ORDERS, REVENUES, AND MARGINS, MAY CAUSE OUR STOCK PRICE TO BE VOLATILE, WHICH COULD CAUSE LOSSES FOR OUR STOCKHOLDERS**

We have experienced and expect in the future to experience fluctuations in our operating results, including gross orders, revenues and margins, from period to period. Drivers of orders include the introduction and timing of announcement of new products or product enhancements by us and our competitors, as well as changes or anticipated changes in third party reimbursement amounts or policies applicable to treatments using our products. The availability of economic stimulus packages or other government funding, or reductions thereof, may also affect timing of customer purchases. Many of our products require significant capital expenditures by our customers. Accordingly, individual product orders can be quite large in dollar amounts, which can extend the customer purchasing cycle. We have experienced this with our IGRT products, and it is especially true with our proton therapy products because of the high cost of the proton therapy equipment and the complexity of project financing. In addition, the budgeting cycles of hospitals and clinics for capital equipment purchases are frequently fixed well in advance. Economic uncertainty also tends to extend the purchasing cycle as potential customers more closely scrutinize and prioritize their capital spending budgets, and analyze appropriate financing alternatives. In addition, some of our more sophisticated equipment, such as IGRT and proton therapy products, requires greater site preparation and longer construction cycles, which can delay customer decision cycles and the placement of orders even further. When orders are placed, installation is accomplished and the revenues recognized affect our quarterly results.

Once orders are received and booked into backlog, factors that may affect whether these orders become revenue (or are cancelled or deemed dormant and reflected as a reduction in the net order amounts) and the timing of revenue include:

delay in shipment due, for example, to an unanticipated construction delay at a customer location where our products are to be installed, cancellations or reschedulings by customers, extreme weather conditions, natural disasters, port strikes or other labor actions;

a challenge to a bid award for one or more of our products;

delay in the installation and/or acceptance of a product;

failure to satisfy contingencies associated with an order;

the method of accounting used to recognize revenue;

a change in a customer's financial condition or ability to obtain financing; or

timing of necessary regulatory approvals or authorizations.

Our quarterly operating results, including our margins, may also be affected by a number of other factors, including:

changes in our or our competitors' pricing or discount levels;

changes in foreign currency exchange rates;

changes in the relative portion of our revenues represented by our various products, including the relative mix between higher margin and lower margin products;

changes in the relative portion of our revenues represented by our international region as a whole, by regions within the overall region, as well as by individual countries (notably those in emerging markets);



- fluctuation in our effective tax rate, which may or may not be known to us in advance;
- changes to our organizational structure, which may result in restructuring or other charges;
- disruptions in the supply or changes in the costs of raw materials, labor, product components or transportation services;
- disruptions in our operations, including our ability to manufacture products, caused by events such as earthquakes, fires, floods, terrorist attacks or the outbreak of epidemic diseases;
- the impact of changing levels of sales on sole purchasers of certain of our imaging components;
- the unfavorable outcome of any litigation or administrative proceeding or inquiry, as well as ongoing costs associated with legal proceedings; and
- accounting changes and adoption of new accounting pronouncements.

Because many of our operating expenses are based on anticipated capacity levels and a high percentage of these expenses are fixed for the short term, a small variation in the timing of revenue recognition can cause significant variations in operating results from quarter to quarter. Our overall gross margin may also be impacted by the gross margin of our proton therapy products, which are presently lower than the gross margins for our traditional radiotherapy products. If our gross margins fall below the expectation of securities analysts and investors, the trading price of VMS common stock would almost certainly decline.

We report our gross orders and backlog on a quarterly and annual basis. It is important to understand that, unlike revenues, gross orders and backlog are not governed by GAAP, and are not within the scope of the audit conducted by our independent registered public accounting firm; therefore, investors should not interpret our gross orders or backlog in such a manner. Also, for the reasons set forth above, our gross orders and backlog cannot necessarily be relied upon as accurate predictors of future revenues. Order cancellation or delays in customer purchase decisions or delivery dates will reduce our backlog and future revenues, and we cannot predict if or when orders will mature into revenues. Particularly high levels of cancellations in one period will make it difficult to compare our operating results for other periods. Our gross orders, backlog, revenues and net earnings in one or more future periods may fall below the expectations of securities analysts and investors. In that event, the trading price of VMS common stock would almost certainly decline.

#### **THE FINANCIAL RESULTS OF OUR VARIAN PARTICLE THERAPY BUSINESS MAY FLUCTUATE AND BE UNPREDICTABLE**

The development of our VPT business enables us to offer products for delivering image-guided, intensity-modulated proton therapy for the treatment of cancer. Our success in this area will depend upon the wide-spread awareness, acceptance and adoption by the oncology market of proton therapy systems for the treatment of cancer. However, this technology has not been widely adopted and future developments may not be adopted as quickly as others.

Since proton therapy projects are generally large, highly customized and more complex than projects in our Oncology Systems radiotherapy business, planning for these projects takes more of our time and uses more of our resources. Many of the components used in proton therapy equipment require long lead times, which may require an increase in our inventory levels. This may cause fluctuations in the operating results of VPT that may make it difficult to predict our results and to compare our results from period to period. The construction of a proton therapy facility requires significant capital investment and may involve complex project financing. Consequently, this business is vulnerable to deterioration in general economic and market conditions. The worldwide economic downturn resulted in a contraction in credit markets. This has made and may continue to make it more difficult for potential customers of this business to find appropriate financing for large proton therapy projects, which could cause them to delay or cancel their projects, or request that we participate in financing arrangements (such as we have for the Scripps Proton Therapy Center, Maryland Proton Therapy Center and The New York Proton Center) or make payment concessions in their agreements with us, which could impact our operating results. Challenges or delays in obtaining financing or commencing treatment could also impact the viability of one or more of our customers as a going concern. Changes in reimbursement rates for proton therapy treatments, or uncertainty regarding these reimbursement rates, such as we experienced in 2012 with the reductions to reimbursement rates for hospital based proton therapy centers in the United States by CMS, can affect growth or demand for our VPT products and services.

We compete for many proton therapy system sales through tenders, where parties compete on price and other factors. Many companies sell their products at a lower price than we do. If we are unable to lower our prices or our customers are not willing to pay for additional features and functionality that we may provide, there is a risk we will lose sales, and if we lower our prices to gain business, our margins and other financial results may suffer. Further, the award of certain proton therapy system orders

39

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may be subject to challenge by third parties, which can make these orders more unpredictable than orders for other products. Because an order for a proton therapy system can be relatively large and complex, the sales and customer decision cycles for proton therapy projects may take several years, and an order in one fiscal period (or the cancellation of an order as a result of bid challenge or otherwise) will cause our gross orders to vary significantly, making comparisons between fiscal periods more difficult. We expect that a limited number of customers will account for a substantial portion of VPT's business for the foreseeable future. In instances where one customer undertakes multiple proton center projects, an adverse event with respect to one project could cause an adverse event with respect to the other projects, which could adversely impact our operating results.

Our estimates as to future operating results include certain assumptions about the results of VPT's business. If we are incorrect in our assumptions, our financial results could be materially and adversely affected. It is possible that VPT could perform significantly below our expectations due to a number of factors that cannot be predicted with certainty, including future market conditions, revenue growth rates, and operating margins. These factors could adversely impact VPT's ability to meet its projected results, which could cause a portion or all of the goodwill of VPT to become impaired. As of October 2, 2015, the goodwill of VPT was \$50.0 million. If we determine that VPT's goodwill becomes impaired, we would be required to record a charge that could have a material adverse effect on our results of operations in such period.

#### **OUR VPT BUSINESS MAY SUBJECT US TO INCREASED RISK AND POTENTIAL LIABILITY**

VPT's business may subject us to increased risk and potential liability. For example, because proton therapy projects are large in scale and require detailed project planning, failure to deliver or delays in delivering on our commitments could result in greater than expected liabilities, as we could be required to indemnify business partners and customers for losses suffered or incurred if we are unable to deliver our products in accordance with the terms of customer contracts. Additionally, customers have in the past requested and may in the future request that the systems vendor, as the primary technology provider, provide guarantees for and suffer penalties in relation to the overall construction project, as well as in some situations participate in or provide project financing for the project. Since the cost of each proton therapy center project will often exceed \$100 million, the amount of potential liability and potential for financial loss would likely be higher than the levels historically assumed by us for our traditional radiation therapy business and may also exceed the project's value. Insurance covering these contingencies may be unobtainable or expensive. If we cannot reasonably mitigate or eliminate these contingencies or risks, our ability to competitively bid upon proton center projects will be negatively impacted or we may be required to assume material amounts of potential liability, all of which may have adverse consequences to us. In addition, we have encountered and may encounter additional challenges in the commercialization of the proton therapy products, which may increase our research and development costs and delay the introduction of our products. These and other unanticipated events could adversely affect our business and make our results of operations unpredictable.

#### **WE HAVE ENTERED INTO A CREDIT FACILITY AGREEMENT THAT RESTRICTS CERTAIN ACTIVITIES, AND FAILURE TO COMPLY WITH THIS AGREEMENT MAY HAVE AN ADVERSE EFFECT ON OUR BUSINESS, LIQUIDITY AND FINANCIAL POSITION**

We maintain a credit facility with debt outstanding that contains restrictive financial covenants, including financial covenants that require us to comply with specified financial ratios. We may have to curtail some of our operations to comply with these covenants. In addition, our revolving credit facility contains other affirmative and negative covenants that could restrict our operating and financing activities. These provisions limit our ability to, among other things, incur future indebtedness, contingent obligations or liens, guarantee indebtedness, make certain investments and capital expenditures, sell stock or assets and pay dividends, and consummate certain mergers or acquisitions. Because of the restrictions on our ability to create or assume liens, we may find it difficult to secure additional indebtedness if required. Furthermore, if we fail to comply with the credit facility requirements, we may be in default. Upon an event of default, if the credit agreement is not amended or the event of default is not waived, the lender could declare all amounts outstanding, together with accrued interest, to be immediately due and payable. If this happens, we may not be able to make those payments or borrow sufficient funds from alternative sources to make those payments. Even if we were to obtain additional financing, that financing may be on unfavorable terms.

**CHANGES IN INTERPRETATION OR APPLICATION OF GENERALLY ACCEPTED ACCOUNTING PRINCIPLES MAY ADVERSELY AFFECT OUR OPERATING RESULTS**

We prepare our financial statements to conform to GAAP. These principles are subject to interpretation by the Financial Accounting Standards Board (“FASB”), American Institute of Certified Public Accountants, the SEC and various other regulatory or accounting bodies. A change in interpretations of, or our application of, these principles can have a significant effect on our reported results and may even affect our reporting of transactions completed before a change is announced. In addition, when we are required to adopt new accounting standards, our methods of accounting for certain items may change,

which could cause our results of operations to fluctuate from period to period and make it more difficult to compare our financial results to prior periods.

As our operations evolve over time, we may introduce new products or new technologies that require us to apply different accounting principles, including ones regarding revenue recognition, than we have applied in past periods. Currently, we recognize revenues for our proton therapy systems and proton therapy commissioning contracts and for certain highly customized image detection systems in our Imaging Components business under contract accounting rules, which affects the timing of revenue recognition. We could be required to apply contract accounting rules to other businesses in the future. Under contract accounting rules, the use of the percentage-of-completion method involves considerable use of estimates in determining revenues, costs and profits and in assigning dollar amounts to relevant accounting periods, estimates which must be periodically reviewed and appropriately adjusted. For example, revenues recognized under the percentage-of-completion method are based on contract costs incurred to date compared with total estimated contract costs. In circumstances in which the final outcome of a contract cannot be precisely estimated but a loss on the contract is not expected, we recognize revenues under the percentage-of-completion method based on a zero profit margin until more precise estimates can be made. Recognizing revenues using the percentage-of-completion method based on a zero profit margin, as we had done with the revenues associated with the Scripps Proton Therapy Center in the earlier stages of the project lowers our gross margins and makes it more difficult to compare our financial results from quarter to quarter. In addition, if we were to recognize revenues for our proton therapy systems and services under either the completed contract method or outside of con