

VARIAN MEDICAL SYSTEMS INC

Form 10-K

November 23, 2011

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended September 30, 2011

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

(State or other jurisdiction of

incorporation or organization)

3100 Hansen Way, Palo Alto, California

(Address of principal executive offices)

94-2359345

(I.R.S. Employer

Identification Number)

94304-1030

(Zip Code)

(650) 493-4000

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(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

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

Large accelerated filer ☒

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

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

As of April 1, 2011, the last business day of Registrant's most recently completed second fiscal quarter, the aggregate market value of shares of Registrant's common stock held by non-affiliates of Registrant (based upon the closing sale price of such shares on the New York Stock Exchange on April 1, 2011) was approximately \$6,340,402,987. Shares of Registrant's common stock held by the Registrant's executive officers and directors and by each entity that owned 5% 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 15, 2011, the number of shares of the Registrant's common stock outstanding was 112,557,988.

DOCUMENTS INCORPORATED BY REFERENCE

Definitive Proxy Statement for the Company's 2012 Annual Meeting of Stockholders Part III of this Form 10-K

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report"), including the Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A"), contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which provides a "safe harbor" for statements about future events, products and future financial performance that are based on the beliefs of, estimates made by and information currently available to the management of Varian Medical Systems, Inc. ("we," "our" 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 "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 products; growth drivers; future orders, revenues, backlog, earnings or other financial results; and any statements using the terms "believe," "expect," "expectation," "anticipate," "can," "should," "would," "could," "estimate," "appear," "based on," "may," "intended," "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

General

We, Varian Medical Systems, Inc., are a Delaware corporation and were originally incorporated in 1948 as Varian Associates, Inc. In 1999, we transferred our instruments business to Varian, Inc. ("VI"), a wholly owned subsidiary, and transferred our semiconductor equipment business to Varian Semiconductor Equipment Associates, Inc. ("VSEA"), a wholly owned subsidiary. We retained the medical systems business, principally the sales and service of oncology products and the sales of x-ray tubes and imaging subsystems. On April 2, 1999, we spun off VI and VSEA, which resulted in a non-cash dividend to our stockholders and which we refer to as the "Spin-offs" in this Annual Report on Form 10-K. Immediately after the Spin-offs, we changed our name to Varian Medical Systems, Inc. We have been involved in the medical systems business since 1959. An Amended and Restated Distribution Agreement dated as of January 14, 1999 and other associated agreements govern our ongoing relationships with VI and VSEA. In May 2010, VI became a wholly owned subsidiary of Agilent Technologies, Inc. In November 2011, VSEA became a wholly owned subsidiary of Applied Materials, Inc.

Overview

We are the world leader in the design, manufacture, sale and service of equipment and software products for treating cancer with radiotherapy, stereotactic radiotherapy, stereotactic body radiotherapy ("SBRT"), stereotactic radiosurgery ("SRS") and brachytherapy. We also design, manufacture, sell and service x-ray tubes for original equipment manufacturers ("OEMs"); replacement x-ray tubes; and flat panel digital image detectors for filmless x-ray imaging (commonly referred to as "flat panel detectors" or "digital image detectors") in medical, dental, veterinary, scientific and industrial applications. We design, manufacture, sell and service linear accelerators, digital image detectors, image processing

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software and image detection products for security and inspection purposes. We also develop, design, manufacture, sell and service proton therapy products and systems for cancer treatment.

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 an additional 100,000 lives per year with our technology, products and services. To meet this challenge, we offer tools for fighting cancer, taking x-ray images and protecting ports and borders.

Oncology Systems designs, manufactures, sells and services hardware and software products for treating cancer. Our products include linear accelerators, brachytherapy afterloaders, treatment simulation and verification equipment and accessories; as well as information management, treatment planning and image processing software. Our products enable radiation oncology departments in hospitals and clinics to perform conventional radiotherapy treatments and offer advanced treatments such as fixed field intensity-modulated radiation therapy (IMRT), image-guided radiation therapy (IGRT), volumetric modulated arc therapy, and stereotactic radiotherapy, as well as to treat patients using brachytherapy techniques, which involve temporarily implanting radioactive sources. Our products are also used by surgeons and radiation oncologists to perform radiosurgery. Our customers worldwide include university research and community hospitals, private and governmental institutions, healthcare agencies, doctors' offices and cancer care clinics.

Our TrueBeam system and our service contract business were significant contributors to growth in Oncology Systems net orders and revenues in fiscal year 2011 over fiscal year 2010. In fiscal year 2011, we acquired a privately-held supplier of devices for delivery of brachytherapy treatment and invested in a minority equity interest in Augmenix, Inc. (Augmenix), a privately-held company that is developing hydrogel products to decrease irradiation of radiation sensitive tissue such as the rectum through creating greater spatial separation between the sensitive tissue (e.g., rectum) and the treated area (e.g., prostate) during treatments. In October 2011, we acquired Calypso Medical Technologies, Inc. (Calypso), a privately-held supplier of specialized products and software for real-time tumor tracking and motion management during radiosurgery and radiotherapy.

X-ray Products designs, manufactures and sells x-ray tubes and flat panel detectors for use in a range of applications, including radiographic or fluoroscopic imaging, mammography, special procedures and industrial applications; and x-ray tubes for use in computed tomography (CT) scanning. Our x-ray tubes and flat panel detectors are sold to large imaging system OEM customers that incorporate them into their medical diagnostic, dental, veterinary, and industrial imaging systems. For replacement purposes, our x-ray tubes and our flat panel detectors are sold to small OEMs, independent service companies and directly to end-users.

We have two other businesses and our Ginzton Technology Center (GTC) that we report together under the Other category. Our Security and Inspection Products (SIP) business designs, manufactures, sells and services Linac[®] x-ray accelerators, imaging processing software and image detection products (including IntellIX[™]) for security and inspection purposes, such as cargo screening at ports and borders and nondestructive examination in a variety of applications. We generally sell SIP products to OEMs who incorporate our products into their inspection systems.

Our Varian Particle Therapy (VPT) business develops, designs, manufactures, sells and services products and systems for delivering proton therapy, another form of external beam radiation therapy using proton beams, for the treatment of cancer. Our current focus is commercializing our proton therapy system and bringing our expertise in traditional radiation therapy to proton therapy to improve its clinical utility and to reduce its cost of treatment per patient.

In the fourth quarter of fiscal year 2011, we booked an \$88 million order from California Proton Treatment Center, LLC (CPTC) to provide our ProBeam proton therapy system for the five-room Scripps Proton Therapy Center being developed in San Diego, California. We also have a 10-year operations and maintenance agreement valued at approximately \$60 million to service the ProBeam

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system once the Scripps Proton Therapy Center opens, which is scheduled for 2013. In addition, we are participating with ORIX Capital Markets, LLC (ORIX) in a \$165 million loan facility to finance the completion and startup operations of Scripps Proton Therapy Center. We are providing \$115 million of the loan commitment and ORIX is providing a \$50 million of the loan commitment. See Note 16, Variable Interest Entity of the Notes to the Consolidated Financial Statements for further discussion.

The GTC 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, including security and cargo screening. The 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 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, with the goal of damaging as many cancer cells as possible, while limiting harm to nearby healthy tissue. 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. That 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, 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 comprises a physician specializing in radiation oncology, a physicist for planning the treatment and a radiation therapist for 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 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 radiation 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 conforms the radiation beams more closely to the shape of the tumor and allows physicians to deliver higher doses of radiation than conventional radiation, while more effectively limiting the amount of radiation delivered to nearby healthy tissue. In this way, clinicians can design and administer

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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 additional treatment centers, from university hospitals to local community clinics, adopt IMRT for their treatments every year. We are a leading global provider of products that enable IMRT for the treatment of cancer.

IGRT is another advanced form of external beam radiotherapy complementing IMRT to enhance treatments. While IMRT helps physicians shape the beam to the tumor, IGRT goes further in allowing physicians to accommodate for a tumor moving or shrinking. This allows the delivery of even higher doses of radiation to tumors with the goal of sparing even more of the surrounding healthy tissue. IGRT technologies compensate for daily changes and movements in tumors and enable dynamic, real-time visualization and precise treatment of small, moving and changing tumors with greater intensity and accuracy. With the greater precision offered by IGRT, clinics and hospitals are potentially able to improve outcomes by concentrating even still higher doses of radiation at the tumors. We believe IGRT has become an accepted standard for treatment in the radiation oncology market.

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 eradicate cancerous and non-cancerous lesions anywhere in the body.

Volumetric modulated arc therapy 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. Volumetric modulated arc therapy enables faster treatments and greater precision. Our RapidArc™ radiotherapy products plan and deliver volumetric modulated arc therapy treatments.

Physicians, hospitals and clinics place additional value on radiotherapy equipment and treatments, such as volumetric modulated arc therapy, 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 to more patients.

An alternative to external beam radiotherapy, brachytherapy involves the insertion of radioactive seeds, wires or ribbons directly into a tumor or into a 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

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signature energy distribution curve, also known as the Bragg peak, allows for greater accuracy 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 the high capital cost and the market is still developing. We have entered the proton therapy market because 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 by more than 65 percent from 12.7 million new cases in 2008 to more than 21.3 million in 2030, 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 match new, higher standards of care.

The rise in cancer cases, together with the increase in sophistication of new treatment processes, 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, volumetric modulated arc therapy, stereotactic radiotherapy, SRS, SBRT, brachytherapy and proton therapy), and developing technology and equipment that enable treatments (such as volumetric modulated arc therapy) 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. Several nations with growing economies, including China, India, and Brazil, are beginning to invest in expanding their radiation oncology capability to address the needs of their growing and aging populations. As an example, China, India and Brazil are estimated to have less than one linear accelerator per million people in their population. By comparison, the United States has an estimated 13 linear accelerators per million people in its population. This capacity shortfall, coupled with ever increasing incidences of cancer, represent additional drivers for our continued growth in international markets.

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 weaker U.S. dollar against foreign currencies would make our product pricing more competitive in the local currencies of our international customers. A weaker U.S. dollar against foreign currencies would also benefit our international revenues and net orders when measured in U.S. dollars. Since fiscal year 2009, all of our businesses have been operating in a very tough environment marked by the credit crisis and economic downturn in the United States and the sovereign debt crisis in Europe, both regions being significant markets for our businesses. In Oncology Systems, the economic downturn shrunk customer capital equipment budgets, slowed decision making and made financing more expensive and time consuming. Our X-ray Products business saw weak net orders and revenues as a result of customer inventory reduction efforts. We saw governments postpone purchasing decisions and delay deployments of products for security and inspection systems. We have seen the very

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tight credit markets constrain the ability of proton projects to get financing. While we believe we have been successfully navigating within this tough environment and economic activity has shown some improvement in the United States, recovery has been sluggish and we cannot predict the strength or sustainability of an economic recovery, in general or specifically in the healthcare industry. In addition, issues related to sovereign debt in Europe have significantly disturbed the global financial markets. Certain European governments have taken or are planning to take austerity measures in order to meet their debt obligations and to avoid intensifying the sovereign debt crisis. The ongoing concerns about the U.S. and Euro zone economies and the sovereign debt crisis in Europe have weakened and may continued to weaken global demand, thus slowing down economic activities in faster growing export-centric countries, such as China. The worldwide economic instability may continue to affect our business and demand for our products in fiscal year 2012.

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, IMRT, IGRT, volumetric modulated arc therapy, stereotactic radiotherapy, 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 the radioactive implantable seeds; treatment planning software for planning treatment sessions and dose delivery; treatment simulation and verification equipment and accessories and quality assurance software for simulating and verifying the treatment plans before treatment and verifying that a treatment was delivered correctly afterwards; and information management software for recording the history and results of treatments and other patient treatment information and data, including patient x-ray images.

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, clinically 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 makes 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—to share equipment, resources and information in a more 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.

Linear accelerators are the core device for delivering conventional external beam radiotherapy IMRT, IGRT and volumetric modulated arc therapy treatments, and we produce versions of these devices to suit various requirements. Our Clinac® medical linear accelerators are used to treat cancer by producing therapeutic electrons and x-ray beams that target tumors and other abnormalities. The Clinac iX linear accelerators 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, ultra-

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precise device with a faster dose delivery rate and smaller isocenter compared to the Clinac iX. Trilogy was developed with IGRT and stereotactic radiotherapy in mind, but is also capable of delivering conventional, 3D conformal radiotherapy, IMRT and volumetric modulated arc therapy. Trilogy has the precision necessary to deliver radiosurgery for neurosurgical treatments and is the accelerator that is at the core of the Novalis Tx™ product offering, a combination of products from Varian and Brainlab AG (Brainlab), targeted to neurosurgeons. The UNIQUE™ low-energy linear accelerator, which was developed to address more price sensitive markets in international regions, is capable of integrating our accessory products (including RapidArc) to deliver IMRT, IGRT and volumetric modulated arc therapy. In the second quarter of fiscal year 2010, we introduced the TrueBeam system for image-guided radiotherapy and radiosurgery. TrueBeam is a fully-integrated system designed from the ground up to treat a moving target with higher speed and accuracy and complements, at the high end, our accelerator product line portfolio. In April 2011, we received approval by the State Food & Drug Administration in China to market and sell our TrueBeam system in China. In the third quarter of fiscal year 2011, we received Shonin approval from the Japanese Ministry of Health, Labor and Welfare to market the TrueBeam system in Japan. Through September 30, 2011, we had received orders for 380 TrueBeam systems since its introduction, a majority of which came from North America. A minority of these orders represented upgrades from other linear accelerators already in our backlog. The TrueBeam system was a key contributor to Oncology Systems net order and revenue growth in fiscal year 2011 over fiscal year 2010.

We also manufacture and market linear accelerator accessories that enhance efficiency and enable delivery of advanced treatments such as IMRT, IGRT, stereotactic radiotherapy, SRS, SBRT and volumetric modulated arc therapy. 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.

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 a cone-beam computerized tomography (CBCT) imaging software accessory that works with the OBI 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. Therefore, 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 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 and greater patient throughput and lower cost per patient for the hospital or clinic. RapidArc radiotherapy products are a proprietary implementation of volumetric modulated arc therapy that coordinates beam shaping, dose rate and gantry speed to deliver a highly conformal dose distribution to the target tumor. We believe RapidArc represents a significant advancement in IMRT cancer treatment.

In October 2011, we acquired Calypso, a privately-held supplier of specialized products and software for real-time tumor tracking and motion management during radiosurgery and radiotherapy, for \$10 million plus potential contingent consideration upon achievement of certain milestones. This acquisition enables us to offer real-time, non-ionizing tumor tracking tools for enhancing the precision of cancer treatments.

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Our treatment planning and information management 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. Prior to any treatment, physicians must plan the course of radiation delivery for the patient. We offer a range of treatment planning products that assist physicians in compiling 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.

Our Argus software manages the planning, recording and analysis of quality assurance data for linear accelerators. Finally, our ARIA Oncology Information Management System (ARIA) 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.

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. With General Electric Medical Systems (GE) in North America, we have established the See and Treat Cancer Care program for radiation therapy that allows us to offer a suite of diagnostic and cancer treatment tools combining our comprehensive set of radiation therapy products with GE's advanced diagnostic imaging systems. We have also established a strategic relationship with Brainlab to market and sell to neurosurgeons a radiosurgical suite of Brainlab products with our Trilogy Tx linear accelerator or our TrueBeam STx. We have a 2.5% equity ownership in Brainlab.

We also hold a minority equity interest in and an exclusive option to purchase the remaining equity interest of Augmenix.

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 HDR prostate treatment planning. In March 2011, we acquired a privately-held supplier of devices for delivery of brachytherapy treatment of cancer for approximately \$8 million. This acquisition enabled Oncology Systems to expand its product offerings for brachytherapy treatment of cancer.

Revenues from our Oncology Systems business segment represented 78%, 79% and 81% of total revenues for fiscal years 2011, 2010 and 2009, respectively. Our Oncology Systems business segment revenues also include service revenues. See 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.

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X-ray Products

Our X-ray Products business segment is a world leader in designing and manufacturing x-ray tubes and flat panel detectors, which are key components of x-ray imaging systems. We sell our products to OEMs for both 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 found broad application as an alternative to image intensifier tubes and x-ray film. These flat panel detectors 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 and suffers less degradation over time than image intensifier tubes and is more cost effective than x-ray film. Our product offering of flat panel detectors also includes a family of radiographic panels, which may be used on digital radiography systems or may be used to convert film-based systems to digital systems.

Revenues from X-ray Products represented 18%, 17% and 15% of total revenues in fiscal years 2011, 2010 and 2009. For a discussion of the X-ray Products business segment financial information, see Note 17, *Segment Information* of the Notes to the Consolidated Financial Statements.

Other

Our SIP business 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-i 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. IntellX is an imaging product for cargo screening.

Generally, we sell our SIP products to OEMs who incorporate our products into their inspection systems, which are then sold to customs and other government agencies who use them in overseas ports and borders to screen for contraband, weapons, stowaways, narcotics and explosives, as well as for manifest verification. We also sell our SIP products to commercial organizations in the casting, power, aerospace, chemical, petro-chemical and automotive industries for nondestructive product examination purposes, such as industrial inspection and manufacturing quality control.

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. 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.

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Proton therapy facilities are large-scale construction projects that are time consuming; involve significant customer investment and often complex project financing. Consequently, this business is vulnerable to general economic and market conditions. Customer decision-making cycles tend to be very long, and orders generally involve many contingencies. As with our SIP business, bid awards in this business may be subject to challenge by third parties. We are investing substantial resources to build this new business. We currently have one proton therapy system in operation at a customer facility in Munich, Germany and, as of the end of fiscal year 2011, four treatment gantries at the facility were treating patients. This equipment was partially installed, and not yet commissioned, at the time of the acquisition of ACCEL Instruments GmbH (ACCEL, which has since changed its name to Varian Medical Systems Particle Therapy GmbH). We have Conformité Européenne (CE) mark to market our proton therapy systems within the European Economic Area (EEA) and, as of January 2011, we received 510(k) clearance in the United States for our proton therapy system.

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.

SIP, VPT and GTC report their results from operations as part of the Other category. Combined revenues from these operations represented 4% of total revenues in each of fiscal years 2011, 2010 and 2009. For a discussion of segment financial information, see Note 17, Segment Information of the Notes to the Consolidated Financial Statements.

Customer Services and Support

We maintain service centers in Milpitas, California; Las Vegas, Nevada; Marietta, Georgia; Buc, France; Crawley, United Kingdom; Zug, Switzerland; Herlev (Copenhagen), Denmark; Diegem (Brussels), Belgium; Darmstadt, Germany; Houten, The Netherlands; Alcobendas (Madrid), Spain; Cernusco (Milan), Italy; Manama, Bahrain; Moscow, Russia; Mumbai, Delhi, and Chennai, India; Tokyo, Osaka, Sendai, Nagoya, and Fukuoka, Japan; Beijing, Chengdu, Shanghai and Hong Kong, China; Kuala Lumpur, Malaysia; Singapore; Bangkok, Thailand; Belrose, Australia; and Sao Paulo, Brazil; as well as 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, and Zug, Switzerland. Our network of service engineers and customer support specialists provide installation, warranty, repair, training and support services, and professional services. We also have a distributed service parts network of regional hubs and forward-stocking locations across all major geographies. We generate service revenues by providing services to customers on a time-and-materials basis 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 dealers and/or agents in a few foreign countries. Customers can access our extensive service network by calling any of our service centers.

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.

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

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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 x-ray tubes and flat panel detector products in our X-ray Products business segment for 12 to 24 months, although for some x-ray tubes the warranty period is based on the number of times the product is used. We provide technical advice and consultation for x-ray tubes and imaging subsystems products to major OEM customers from our offices in Salt Lake City, Utah; Charleston, South Carolina; Tokyo, Japan; Beijing, China and Willich, 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 to meet the technical support requirements of independent service companies that use our x-ray tube and flat panel detector products.

We generally warrant our SIP products for 12 months. We provide technical support and service for these products to major OEM customers from our offices in Las Vegas, Nevada; Lincolnshire, Illinois; and Buc, France; Manama, Kingdom of Bahrain; Crawley, United Kingdom; Milano, Italy; and Brussels, Belgium. We use the Oncology Systems Customer Support Services organization in Asia, Australia and South America.

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 5-year term or longer). We believe customer service and support are an integral part of our VPT competitive strategy.

Marketing and Sales

We employ a combination of direct sales forces and independent distributors or resellers in North America, Europe, Australia and major parts of Asia and Latin America for the marketing and sales of our products worldwide. In fiscal years 2011, 2010 and 2009, we did not have a single customer that represented 10% or more of our total revenues.

For our Oncology Systems segment, we sell direct in North America and use a combination of direct sales and independent distributors in international regions. We also have direct-to-consumer advertising campaigns to increase consumer awareness of Oncology Systems' products. 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 recent 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 and the general constriction in credit availability. In addition, the recent economic downturn had 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 had 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

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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. Continuing growth in demand for our Oncology Systems products depends in part on the strength and sustainability of an economic recovery in the United States and in the Euro zone. Even though economic activity has shown some improvement, recovery has been sluggish and we cannot predict the strength or sustainability of an economic recovery, in general or specifically in the healthcare industry.

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 volumetric modulated arc therapy tend to drive demand for radiotherapy products, large changes in reimbursement rates or reimbursement structure can affect customer demand and cause market shifts. We have seen our customers decision-making process complicated by the uncertainty surrounding Medicare reimbursement rates for radiotherapy and radiosurgery in the United States, such as in 2009 when there were proposed reductions in Medicare reimbursement rates for radiotherapy and radiosurgery at free-standing clinics. In addition, we do not know what impact the Affordable Health Care for America Act and similar state proposals will have on long-term growth or demand for our products and services in our Oncology Systems business. International reimbursement rates for radiation therapy tend to be low in national health systems, yet international markets continue to invest in better treatment capability, albeit often after it has been proven in the North American region or in other leading research centers worldwide.

Total Oncology Systems revenues, including service revenues, were \$2.0 billion, \$1.9 billion and \$1.8 billion for fiscal years 2011, 2010 and 2009, respectively. We divide our market segments for Oncology Systems revenues into North America, Europe, Asia and rest of the world, and these regions constituted 48%, 32%, 15% and 5%, respectively, of Oncology Systems revenues during fiscal year 2011; 46%, 33%, 17% and 4%, respectively, of Oncology Systems revenues during fiscal year 2010; and 54%, 29%, 14%, and 3%, respectively, of Oncology Systems revenues during fiscal year 2009.

Our X-ray Products 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 tube products and flat panel products to a limited number of OEMs that incorporate our products into their imaging systems. 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 X-ray Products revenues in the foreseeable future. Our OEM customers include Toshiba Corporation, Carestream Health, Inc., Hitachi Medical Corporation, GE Healthcare, Planmeca Oy, Imaging Sciences International, Inc., Agfa Healthcare NV, and Sound Technologies, Inc. These OEM customers represented 64%, 62% and 61% of our total X-ray Products segment revenues during fiscal years 2011, 2010 and 2009, respectively, with the remaining revenues coming from a large number of small OEMs and independent services companies. Changes in access to diagnostic radiology or the reimbursement rates associated with diagnostic radiology as a result of the Affordable Health Care for America Act and similar state proposals will likely affect demand for our products in our X-ray Products business.

Total revenues for our X-ray Products segment were \$469 million, \$403 million and \$331 million for fiscal years 2011, 2010 and 2009, respectively. We divide our market segments for X-ray Products revenues by region into North America, Europe, Asia and rest of the world, and these regions constituted 29%, 21%, 49% and 1%, respectively, of X-ray Products revenues during fiscal year 2011; 32%, 17%, 50% and 1%, respectively, of X-ray Products revenues during fiscal year 2010; and 33%, 15%, 49% and 3%, respectively, of X-ray Products revenues during fiscal year 2009.

Our SIP business also uses a combination of direct sales and independent distributors and sells a high proportion of its products to a limited number of OEMs that incorporate our products into their systems. As with X-ray Products, this business depends on the success of our OEM customers, and we expect that revenues from relatively few customers will continue to account for a high percentage of SIP

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revenues in the foreseeable future. We supply Linatron linear accelerators and detector products to OEMs such as Smiths Detection, Rapiscan Systems, Inc. and American Science & Engineering, Inc. We also sell our SIP products to commercial organizations in the casting, power, aerospace, chemical, petro-chemical and automotive industries.

Use of our SIP technology in security cargo screening and border protection is still in its early stages, but we believe demand for our SIP products will be driven primarily by cargo screening and border protection needs. This business is heavily influenced by governmental policies on homeland security, political change and government budgets. Orders and revenues for our SIP 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 any orders for a long time period thereafter. Furthermore, bid awards in this business may be subject to challenge by third parties, as we have previously encountered with a large government project, which can make the certainty of some SIP orders unpredictable.

In the VPT business, we use direct sales specialist representatives who collaborate globally with our Oncology Systems sales group on projects. Potential customers are government-sponsored hospitals and research institutions and research universities, which typically purchase products through public tenders, and, to a lesser extent, private hospitals, clinics and private developers. While this market is still developing, we believe that growth in this business will initially develop 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.

Competition

Rapidly evolving technology, intense competition and pricing pressure characterize the markets for radiation therapy equipment and software products, including our Oncology Systems products. We compete with companies worldwide. Some of our competitors have greater financial, marketing and other resources than we have. 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. 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, volumetric modulated arc therapy and proton therapy. We have directed substantial product development efforts into (i) greater 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 emphasized maintaining 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 volumetric modulated arc therapy and will stimulate demand for our products. We face competition though from closed-ended dedicated-use systems 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 enable greater 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, long-term relationship with customers and capabilities of customers existing equipment. We believe we compete favorably with our competitors based upon our strategy of providing

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a complete package of products and services in the field of radiation oncology and our continued commitment to global distribution and customer service, 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. In addition, 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 net orders.

We are the leading provider of medical linear accelerators and related accessories. In radiotherapy and radiosurgery markets, we compete primarily with Elekta AB, Siemens Medical Solutions, Accuray Incorporated and Tomotherapy Incorporated (which was recently acquired by Accuray Incorporated). With our information and image management, simulation, treatment planning and radiosurgery products, we also compete with a variety of companies, such as Elekta AB, Philips Medical Systems, Best Theratronics, Ltd., Nucletron B.V. and Siemens Medical Solutions. We also encounter some competition from providers of hospital information systems. With respect to our brachytherapy operations, our competitors are Nucletron B.V. (which was recently acquired by Elekta AB) and IBt Bebig s.a. In our Oncology Systems the 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.

In x-ray imaging components and subsystems, 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. 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 OEMs such as Toshiba Corporation, Hitachi Medical Corporation, Philips Medical Systems and GE Healthcare, all of which 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. 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 OEMs, 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. For flat panel detectors, our significant customers include Carestream Health, Inc. and Toshiba Corporation and we primarily compete against Perkin-Elmer, Inc., Trixell S.A.S., Samsung Electronics and Canon, Inc.

In our SIP business, we compete with other OEM suppliers, primarily outside of the United States in the security and inspection market, and our major competitor is Nuctech Company Limited. The market for our SIP 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.

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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 OBI. In the proton therapy market, we compete principally with Hitachi Medical Corporation, Ion Beam Applications S.A., Mevion Medical Systems, Inc. (formerly Still River Systems, Inc.) and Sumitomo Heavy Industries, Ltd. There are a number of smaller competitors that are also developing proton therapy products.

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 \$171 million, \$157 million and \$147 million in fiscal years 2011, 2010 and 2009, 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, 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.

Within X-ray Products, development is conducted at our Salt Lake City, Utah and Palo Alto, California facilities and is primarily focused on developing and improving x-ray imaging component and subsystem products. 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 x-ray tubes to enhance the performance of our flat panel detectors. Research in flat panel imaging technology is aimed at developing new panel technologies for low cost radiographic imaging, flexible panel interfaces and cone beam CT.

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

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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 certain components of their tumor tracking and motion management products in Seattle, Washington. Our SIP linear accelerators and certain radiographic products are manufactured in Las Vegas, Nevada. We manufacture components and sub-systems for our proton therapy products and systems in Troisdorf, Germany and we plan to develop additional manufacturing facilities as needed for this business. We manufacture our x-ray imaging component and subsystem and flat panel detector products in Salt Lake City, Utah; Charleston, South Carolina; Willich, Germany; 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 SIP) 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 material, purchased parts and assemblies through on-line inspection. We also receive subassemblies from third-party suppliers and integrate them into a finished system. We outsource the manufacturing of many major subassemblies and perform system design, assembly and testing in-house. We believe outsourcing enables us to reduce 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 SIP; 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.

Backlog

Our backlog at the end of fiscal year 2011 was \$2.5 billion, of which we expect to recognize approximately 50% to 55% as revenues in fiscal year 2012. Our backlog at the end of fiscal year 2010 was \$2.2 billion, of which \$1.2 billion was recognized as revenues in fiscal year 2011. Our Oncology Systems backlog represented 88% and 91% of the total backlog at the end of fiscal years 2011 and 2010, respectively. Except for VPT orders, we only recognize orders when product shipment or construction of certain highly customized SIP products is expected to occur within two years and only if any contingencies are deemed perfunctory. In addition, we do not recognize SIP orders from governmental agencies with bid protest provisions until the expiration of the bid protest period. For our VPT business, we recognize orders when construction of the related proton therapy treatment center is reasonably expected to start within two years. Also, we only recognize orders for VPT products with contingencies if we deem the contingencies perfunctory or if we publicly disclose the existence and nature of material contingencies. However, orders will not be recognized if there are major financing contingencies or

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customer board approval contingencies pending. Backlog also includes a small portion of service contracts when they become billable, as well as the amount of deferred revenue and revenue related to acceptance. We perform a semi-annual review to verify that orders in our backlog remain valid. This review identifies aged orders and confirms these orders with our internal sales organization or our customers. Aged orders which are not expected to be converted to revenues during this backlog review are deemed dormant and are no longer included in the reported backlog. 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. In fiscal years 2011, 2010 and 2009, we adjusted orders down by \$95 million, \$124 million (which includes the cancellation of a \$62 million proton therapy system order from Skandion Kliniken) and \$71 million, respectively, of orders due to adjustments, revisions or cancellations. Our reported net orders are net of all backlog adjustments.

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; other situations where people may come in contact with radiation (for example, when our SIP 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 with products from other vendors, where interoperability or data sharing protocol may not be optimized even though the equipment or system operate 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, 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 support of our products. Any accident or mistreatment could subject us to legal costs, 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 is defective (whether due to design, labeling or manufacturing defects, improper use of the product or other reasons), we may be required to recall the product and notify regulatory authorities. We maintain limited product liability insurance coverage and currently self-insure professional liability/errors and omissions liability.

Government Regulation

U.S. Regulations

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 Food and Drug Administration (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

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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 and flat panel detectors produced by X-ray Products are also considered medical devices. Future products in any of our business segments may constitute medical devices and be subject to regulation. These laws require that manufacturers adhere to certain standards designed to ensure that the medical devices are safe and effective. 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, an existing currently marketed medical device obtain either 510(k) pre market notification clearance or pre-market approval (PMA) before the manufacturer can market and sell those products in the United States. The 510(k) clearance process is applicable when the device introduced into commercial distribution is not substantially equivalent to a legally marketed device or the device is about to be significantly changed or modified in design components, method of manufacture or intended use. The process of obtaining 510(k) clearance generally takes at least three to six months from the date the application is filed, but could take significantly longer, and generally requires submitting supporting design and testing data, which can be extensive and can lengthen the process considerably. After a product receives 510(k) clearance, any modifications or enhancements 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 recently issued a 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 submit 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 segment and the proton therapy systems manufactured by our VPT business are Class II medical devices.

Quality systems, audits and failure to comply. 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 and may issue reports, known as FDA Form 483 reports when the FDA believes the manufacturer has failed to comply with applicable regulations and/or procedures. If these observations are not promptly and adequately responded to, the FDA may issue a Warning Letter and/or proceed

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directly to other forms of corrective action against us, including total shutdown of production facilities, denial of importation rights to the United States for products manufactured in overseas locations and criminal and civil fines. Inspections usually occur every two years. We have responded to observations issued in a FDA Form 483 related to the May 2011 inspections of our Oncology Systems manufacturing facilities located in Helsinki, Finland and Haan, Germany. These observations generally include issues with complaint investigations, corrective actions and preventive actions, filings required under medical device reporting regulations and purchasing controls.

The FDA and the Federal Trade Commission (FTC) also regulate the advertising 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 general, 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 by-product material requires a specific radioactive material license. Manufacture and distribution of these radioactive sources and devices also must be in accordance with an approved NRC certificate, or an Agreement State registration certificate. 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 MD&A Environmental Remediation Liabilities.

If we or any of our suppliers or distributors fail to comply with FDA and other applicable regulatory requirements or are perceived to potentially have failed to comply, we may face a number of adverse consequences, including adverse publicity affecting both us and our customers; government investigations; partial suspensions or total shutdown of production facilities, or the imposition of operating restrictions; losses of clearances or approvals already granted; or seizures or recalls of our products or those of our customers.

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 or have access to, 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, HIPAA was amended by the Health Information Technology for Economic and Clinical Health Act (the HITECH Act), enacted as part of the American Recovery and Reinvestment Act of 2009. The HITECH Act significantly increases the civil money penalties for violations of patient privacy rights protected under HIPAA. Furthermore, 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

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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 may flow to us as the consequence of regulatory violations; consequently, we do not have insurance that would cover this type of liability.

Medicare and Medicaid Reimbursement

The federal and state governments of the U.S. 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. We have seen our customers' decision-making process complicated by the uncertainty surrounding Medicare reimbursement rates for radiotherapy and radiosurgery in the United States. 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 Balanced Budget Act of 1997 revised the Medicaid program to give each state more control over coverage and payment issues. In addition, the U.S. Centers for Medicare and Medicaid Services (CMS) has granted many states waivers to allow for greater control of the Medicaid program at the state level. The impact on our business of this greater state control on Medicaid payment for diagnostic services remains uncertain.

We are continuing to evaluate the Affordable Health Care for America Act and its potential impact on our business. Specifically, one of the components of the new law is a 2.3% excise tax on sales of most medical devices, which include our Oncology Systems products, starting in 2013. This tax may put increased pressure on medical device manufacturers and purchasers, and may lead our customers to reduce their orders for products we produce or to request that we reduce the prices we charge for our products in order to offset the tax. Other elements of this new legislation, including comparative effectiveness research, an independent payment advisory board, payment system reforms (including shared 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 we expect that this uncertainty will persist until there is greater clarity on how the Affordable Health Care for America Act and state proposals will affect healthcare providers.

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

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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 Conformité Européenne (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 European Union (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 SIP 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 MD&A Critical Accounting Estimates and Environmental Remediation Liabilities.

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

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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 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 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. We are also subject to international fraud and abuse laws and regulations, as well as false claims and misleading advertisement laws.

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 September 30, 2011, we owned 300 patents issued in the United States and 102 patents issued throughout the rest of the world and had 362 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 Government Regulation Foreign Regulations and MD&A Environmental Remediation Liabilities, which discussions are incorporated herein by reference.

Financial Information about Geographic Areas

We do business globally with manufacturing in the United States, Europe and China and with sales and service operations and customers throughout the world. Roughly half of our revenues are generated 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)). So 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. We do engage in currency hedging strategies to offset the effect of currency exchange fluctuations, but the protection offered by these hedges depends upon the timing of transactions, forecast volatility, effectiveness of such hedges and the extent of currency fluctuation.

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

For a discussion of financial information about geographic areas, see Note 17, Segment Information of the Notes to the Consolidated Financial Statements.

Discontinued Operations

In September 2008, we approved a plan to sell the scientific research instruments business (Research Instruments) that we acquired as part of our acquisition of ACCEL in order to focus our efforts on the development of the proton therapy systems portion of the business. Research Instruments developed, manufactured and serviced highly customized scientific instrument components and systems for fundamental and applied physics research primarily for national research laboratories worldwide. The sale of Research Instruments was completed in the second quarter of fiscal year 2009.

In fiscal year 2011, we recognized a loss of \$9.7 million for additional costs to settle the remaining customer contract related to Research Instruments. As of September 30, 2011, we had no remaining obligations related to Research Instruments. We have classified Research Instruments as a discontinued operation in our Consolidated Statements of Earnings and Consolidated Balance Sheets for all periods presented. See Note 18, Discontinued Operations of the Notes to the Consolidated Financial Statements for detailed discussion. Research Instruments was previously included with the VPT business, which is reported under the Other category in Note 17, Segment Information of the Notes to the Consolidated Financial Statements.

Employees

We had approximately 5,700 full-time and part-time employees worldwide, 3,300 in the United States and 2,400 elsewhere at September 30, 2011. 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 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; and current reports on Form 8-K (including any amendments to those reports); and our proxy statements. Our Code of Business Ethics, Corporate Governance Guidelines and the charters of the Audit Committee, Compensation and Management Development Committee and Nominating and Corporate Governance 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).

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Executive Officers of the Registrant

The biographical summaries of our executive officers, as of November 1, 2011, as of are as follows:

Name	Age	Position
Timothy E. Guertin	62	President and Chief Executive Officer
Dow R. Wilson	52	Corporate Executive Vice President and Chief Operating Officer
Elisha W. Finney	50	Corporate Senior Vice President, Finance and Chief Financial Officer
Kolleen T. Kennedy	52	Corporate Senior Vice President and President, Oncology Systems
Robert H. Kluge	65	Corporate Senior Vice President and President, X-ray Products
Tai-yun Chen	59	Corporate Vice President, Finance and Corporate Controller
John W. Kuo	48	Corporate Vice President, General Counsel and Corporate Secretary

Timothy E. Guertin has been Chief Executive Officer since February 2006 and President since August 2005. Previously, Mr. Guertin served as Chief Operating Officer from October 2004 to February 2006, and Corporate Executive Vice President from October 2002 to August 2005. Mr. Guertin also served as President of our Oncology Systems business unit from 1992 to January 2005. Mr. Guertin was Corporate Vice President from 1992 to 2002. Mr. Guertin has held various other positions in the medical systems business during his 35 years with the Company. Mr. Guertin holds a B.S. degree in electrical engineering and computer science from the University of California at Berkeley.

Dow R. Wilson was appointed Corporate Executive Vice President and Chief Operating Officer effective October 2011. Mr. Wilson served 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. Previously, Mr. Wilson served as General Manager, Surgical, x-ray and Interventional Businesses and General Manager, Functional Imaging of the Healthcare-Information Technologies business from 2002 to 2003, and was General Manager, Computed Tomography of the Healthcare-Information Technologies business from 2000 to 2002. During the previous 15 years, Mr. Wilson held 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 has served on the board of directors of Saba Software, Inc. (an e-learning software provider) since August 2006 and in August 2011 was named the lead independent director of that board.

Elisha W. Finney was appointed Corporate Senior Vice President, Finance, in addition to being Chief Financial Officer, in January 2005. Ms. Finney was Corporate Vice President and Chief Financial Officer from April 1999 to January 2005. Ms. Finney has held various other positions, including Treasurer, during her 23 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 was appointed a director of Thoratec Corporation (a medical device manufacturer) in June 2007 and joined the board of Altera Corporation (a supplier of custom logic solutions) in August 2011.

Kolleen T. Kennedy was appointed Corporate Senior Vice President and President, Oncology Systems effective October 2011. 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.B.A. in Medical Physics from the University of Colorado.

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Robert H. Kluge was appointed Corporate Senior Vice President and President, X-ray Products of the Company in February 2008. Prior to that, Mr. Kluge served as Corporate Vice President and President, X-ray Products from December 1999 to February 2008 and as Vice President and General Manager of our X-ray Products business from 1993 to December 1999. Before joining the Company in 1993, Mr. Kluge held various positions with Picker International (an x-ray systems manufacturer). Mr. Kluge holds a B.A. degree in economics and an M.B.A. degree in finance from the University of Wisconsin.

Tai-yun Chen was appointed Corporate Vice President, Finance and Corporate Controller in August 2006. From February 2006 to August 2006, Ms. Chen served as the Company's Operations Controller. Prior to that, from January 2002 to February 2006, Ms. Chen was the Company's Assistant Corporate Controller, and from 2000 to January 2002 Ms. Chen was the Company's Director of Corporate Accounting. Ms. Chen has served in various accounting management positions throughout the Company during her 28 years with the Company. Ms. Chen holds a bachelor's degree in economics from the National Chung Chi University in Taiwan and a master's degree in managerial economics from the University of California at Santa Barbara.

John W. Kuo was appointed Corporate Vice President, General Counsel in July 2005 and Corporate Secretary in 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) in 2002 and held senior legal positions at 3Com Corporation (a networking equipment provider) from 1997 to 2002. 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.

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 impair our business operations. If any of the following risks actually occur, our business, operating results, and financial condition could be adversely affected.

IF OUR PRODUCTS AND PRODUCT LINES FAIL TO CONTINUE TO MEET CUSTOMER DEMANDS, OUR PRODUCTS MAY BECOME LESS USEFUL OR OBSOLETE AND OUR OPERATING RESULTS WILL SUFFER

We believe that IMRT, including volumetric modulated arc therapy, and IGRT have become accepted standards for treatment in the radiation oncology market. Demand for our IMRT and IGRT products have been the drivers for our net orders and revenues in Oncology Systems and, because of the significance of Oncology Systems, on our business in general. We recently introduced TrueBeam, a new line of linear accelerators for radiotherapy and radiosurgery, and UNIQUE, a low-energy linear accelerator for more price sensitive markets in international regions, to meet the evolving needs of our IMRT and IGRT customers. We believe TrueBeam will be a valuable tool for clinicians in the fight against cancer and to stimulate faster replacement of older systems in our installed base. We also believe that our RapidArc products for volumetric modulated arc therapy, are a significant advance in IMRT treatments and can help drive longer term demand for our linear accelerators and IMRT- and IGRT-related products. Orders for these new products and products lines have contributed greatly to our recent orders growth and are keys to our future success. If our customers do not purchase these products or if future studies call into question the effectiveness of these or our other IMRT or IGRT products (including other volumetric modulated arc therapy products) or show negative side effects, or if other more effective technologies are introduced, our net orders, revenues and financial results could suffer. As more institutions buy or upgrade to achieve IMRT and IGRT capabilities, the market for these

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products (including volumetric modulated arc therapy products) may become saturated. Alternatively, the marketplace may conclude that functions and features of our products should no longer be an element of a generally accepted diagnostic or treatment regimen. If this occurs, the market for our products may be adversely affected and they may become less useful or obsolete.

Our X-ray Products business sells products primarily to a small number of imaging system OEM customers who use our products in their medical diagnostic and industrial imaging systems. To succeed, we must provide x-ray tube and flat panel detector products that meet customer demands for lower cost, better product quality and superior technology and performance. If we are unable to continue to innovate our X-ray Products technology and anticipate our customers' demands in the areas of cost, quality, technology and performance, then our customers may purchase from other tube or panel manufacturers (including the in-house operations of some of these customers), which would negatively impact this business.

In both the Oncology Systems and X-ray Products businesses, and in our other product lines, we may be unable to accurately anticipate changes in our markets and the direction of technological innovation and demands of our customers. Our competitors may develop products or processes that are superior to what we can then offer. If this occurs, the market for our products may be adversely affected and they may become less useful or obsolete. Any development adversely affecting the markets for our products would force us to reduce production volumes or to discontinue manufacturing one or more of our products or product lines and would reduce our revenues and earnings.

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

Rapid change and technological innovation characterize the Oncology Systems market. Our 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, treatment systems and enhancements to and/or simplification of existing product lines. Our Oncology Systems products, including new products such as TrueBeam and RapidArc, are technologically complex and must keep pace with, if not be superior to, the products of our competitors. Our X-ray Products business must also continually develop improved and lower cost products. We are making significant investments in long-term growth initiatives, such as development of our SIP and VPT businesses, and expect that we will need to invest more to develop and commercialize the products and technology for these businesses. Accordingly, many of 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. 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 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, and could adversely impact our revenues and operating results. 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;
- prove the feasibility of new products;
- limit the time required from proof of feasibility to routine production;
- comply with internal quality assurance systems and processes timely and efficiently;

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- 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 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 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 not decide 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.

SLIGHTLY 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 55%, 57% and 50% of revenues from continuing operations during fiscal years 2011, 2010 and 2009, 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, although we cannot be sure we will be able to meet our sales, service and support objectives or obligations, or recover our investments. Accordingly, our future results could be harmed by a variety of factors, including:

- the difficulties in enforcing agreements and collecting receivables through many foreign country's legal systems;
- the longer payment cycles associated with many foreign customers;

- currency fluctuations;
- changes in the political, regulatory, safety or economic conditions in a country or region;
- the imposition by foreign countries of additional taxes, tariffs or other restrictions on foreign trade;
- the lower sales prices and gross margins usually associated with sales of our products in the international region;

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- the longer period in the international region from shipment to revenue recognition that generally results in greater revenue recognition deferrals and higher backlog;
- any inability to obtain export licenses and other 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 September 30, 2011, 97% of our cash and cash equivalents were held abroad. If these funds were repatriated to the United States, they 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 respective 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, or a change in the mix of particular tax jurisdictions within the international region 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 or actually remitted to the United States, or if tax laws change, in which case our financial results could be adversely affected. In addition, Congress has considered proposals that would significantly change U.S. taxation of U.S.-based multinational corporations. Although we cannot predict whether or in what form Congress would enact any such proposals, legislation of this type could negatively impact our effective tax rate and adversely affect our financial results.

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

Since fiscal year 2008, the global economy has been impacted by the sequential effects of the subprime lending crisis; the credit market crisis; collateral effects on the finance and banking industries; volatile currency exchange rates and energy costs; concerns about inflation (deflation), slower economic activity, consumer confidence, corporate profits and capital spending, adverse business conditions, liquidity and unemployment; and concerns over the downgrade of U.S. sovereign debt and continued sovereign debt uncertainties in Europe and other foreign countries. 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 and reduced their confidence. This, in turn, has caused our customers to freeze, delay or dramatically reduce purchases and capital project expenditures. Even though economic activity has shown some improvement, recovery has been sluggish and we cannot predict the strength or sustainability of an economic recovery, in general or specifically in the healthcare industry. It has taken time for our customers to establish new budgets and may take more time for them

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to fully return to normal purchasing patterns. Project delays may continue, particularly as they relate to large scale or government projects, which may be affected by austerity measures. Alternatively, in the past, some countries, including Japan, have adopted and may in the future adopt government stimulus programs to revitalize their economies and improve healthcare and medical services. The availability of stimulus programs in the future could positively affect our results in one period and adversely affect our results in other periods, making it difficult for investors to compare our financial results between fiscal periods. Weak economic recovery may also disrupt supply if vendors consolidate or go out of business. As with our customers and vendors, these economic conditions make it more difficult for us to accurately forecast and plan our future business activities. 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, 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, existing currently marketed medical device obtain either 510(k) pre-market notification clearance or 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 may also require a new 510(k) clearance. The FDA has recently issued a 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. Although manufactures 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. 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

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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, in the United States, our devices have generally been subject to 510(k) clearance or exempt from 510(k) clearance. The 510(k) clearance process is generally less time-consuming, expensive and uncertain than the PMA process. However, there are some in the regulatory field who believe that certain medical devices should be required to use the PMA approval process, or a special more time-consuming 510(k) clearance process, rather than the current 510(k) clearance process. If we were required to use either of these lengthy processes for future products or product modifications, it could delay or prevent release of the proposed products or modifications, which could harm our business. The FDA recently announced its 510(k) clearance reform plan. We are currently analyzing how this plan, if fully implemented, may affect us and our ability to obtain product clearances.

Further, as we enter new businesses or pursue new business opportunities, such as opportunities that require clinical trials, we may become subject to additional laws, rules and regulations, including FDA 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 could be quite 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, audits and failure to comply. 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. Currently, we are responding to and working with the FDA to fully resolve Form FDA 483 observations issued in May 2011 related to the inspections of our Oncology Systems manufacturing facilities located in Helsinki, Finland and Haan, Germany. These observations generally include issues with complaint investigations, corrective actions and preventive actions, filings required under medical device reporting regulations and purchasing controls. While in the past, we have received Form 483 observations that we successfully resolved with the FDA, we cannot be certain that we will have similar success in promptly resolving these observations.

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

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reports are not filed timely, 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 by competitors against us 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 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.

If we or any of our suppliers, distributors 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;

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- 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 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, HIPAA was amended by the HITECH Act, enacted as part of the American Recovery and Reinvestment Act of 2009. The HITECH Act significantly increases the civil money penalties for violations of patient privacy rights protected under HIPAA. Furthermore, 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 may flow to us as the consequence of regulatory violations; consequently, we do not have insurance that would cover this type of liability.

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 clearance is obtained and the CE mark is affixed to the device,

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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. Significant revisions to some of the applicable regulations governing requirements for medical devices in the EU/EEA/Switzerland went into effect in March 2010. These revisions have introduced additional uncertainty into the marketing authorization process for medical devices in Europe. Until medical device manufacturers and European regulatory agencies, including Notified Bodies and competent authorities, have greater experience with interpreting and applying the revised regulations, 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 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 could be quite 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 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 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.

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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. law relating to data privacy, 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.

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 HEALTHCARE FOR AMERICA 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 Health Care for America Act. While we are continuing to evaluate this legislation and its potential impact on our business, and many of its provisions are yet to be implemented, it may adversely affect 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 new law is a 2.3% excise tax on sales of most medical devices, which include our Oncology Systems products, starting in 2013. The Congressional Budget Office estimates that the total cost to the medical device industry could exceed \$20 billion over ten years. This tax may put increased pressure on medical device manufacturers and purchasers, and may lead our customers to reduce their orders for products we produce or to request that we reduce the prices we charge for our products in order to offset the tax. Other elements of this new legislation, 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.

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 business, and we expect that this uncertainty will persist until there is greater clarity on how the Affordable Health Care for America Act and state proposals will affect healthcare providers. We are unable to predict what effect ongoing uncertainty surrounding these matters will have on our customers' purchasing decisions. However, an expansion in government's role in the U.S. healthcare industry may adversely affect our business, possibly materially.

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CHANGES TO RADIATION ONCOLOGY REIMBURSEMENTS 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, third-party payors in the United States are increasingly cost-conscious, and we cannot be sure that they will reimburse our customers at levels sufficient to enable us to achieve or maintain sales and price levels for our products in this market. Without adequate support from third-party payors, the market for our products may be limited. There is no uniform policy on reimbursement among third-party payors, nor can we be sure that procedures using our products will qualify for appropriate levels of reimbursement from third-party payors. 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. If comparative effectiveness studies are not available, or if available studies show that other cancer treatments are more effective than radiotherapy or radiosurgery, reimbursement rates for radiotherapy or radiosurgery could be reduced. Any significant cuts in reimbursement rates for radiotherapy, radiosurgery, proton therapy or brachytherapy, or concerns or proposals regarding further cuts, 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.

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 expenses and/or the profitability in U.S. dollars of products and services that we provide in foreign markets.

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 those strategies, the number of transactions that are hedged, forecast volatility and the extent to which exchange rates change. If our hedging strategies do not offset these fluctuations, our revenues and other operating results may be harmed. In addition, 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. Furthermore, on July 21, 2010, President Obama signed into law the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act). The Dodd-Frank Act contains provisions which may impact our existing hedging strategies, but we cannot predict those effects at this time.

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In addition, long-term movements in foreign currency exchange rates can also affect the competitiveness of our products in the local curr