VARIAN MEDICAL SYSTEMS INC Form 10-K November 24, 2008 **Table of Contents** 

# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-K**

ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT  $\mathbf{X}$ **OF 1934** 

For the fiscal year ended September 26, 2008

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

94-2359345 (I.R.S. Employer

incorporation or organization)

Identification Number)

3100 Hansen Way, Palo Alto, California

94304-1030 (Zip Code)

(Address of principal executive offices)

(650) 493-4000

# Edgar Filing: VARIAN MEDICAL SYSTEMS INC - Form 10-K

(Registrant s telephone number, including area code)

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

Title of each class Common Stock, \$1 par value Preferred Stock Purchase Rights Name of each exchange on which registered

New York Stock Exchange 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 x 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 x

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 x 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 x

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 x Non-accelerated filer " 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 x

As of March 28, 2008, 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 March 28, 2008) was approximately \$5,891,417,083. Shares of Registrant s common stock held by the Registrant s executive officers and directors and by each entity that owns 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 17, 2008, the number of shares of the Registrant s common stock outstanding was 124,248,017.

## DOCUMENTS INCORPORATED BY REFERENCE

Definitive Proxy Statement for the Company s 2009 Annual Meeting of Stockholders Part III of this Form 10-K

# VARIAN MEDICAL SYSTEMS, INC.

# **INDEX**

		Page
	PART I	
Item 1.	<u>Business</u>	3
	Executive Officers of the Registrant	25
Item 1A.	Risk Factors	26
Item 1B.	<u>Unresolved Staff Comments</u>	50
Item 2.	<u>Properties</u>	50
Item 3.	<u>Legal Proceedings</u>	51
Item 4.	Submission of Matters to a Vote of Security Holders	51
	PART II	
Item 5.	Market for the Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	52
Item 6.	Selected Financial Data	54
Item 7.	Management s Discussion and Analysis of Financial Condition and Results of Operations	56
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	82
Item 8.	Financial Statements and Supplementary Data	85
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	138
Item 9A.	Controls and Procedures	138
Item 9B.	Other Information	138
	PART III	
Item 10.	Directors, Executive Officers and Corporate Governance	139
Item 11.	Executive Compensation	139
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	140
Item 13.	Certain Relationships and Related Transactions, and Director Independence	140
Item 14.	Principal Accountant Fees and Services	140
	PART IV	
Item 15.	Exhibits and Financial Statement Schedules	141
	Signatures	145

2

#### FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the Management s Discussion and Analysis of Financial Condition and Results of Operations, or 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, or 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. intended, potential, are emerging and possible or similar statements are forward-looking statements based on, may, 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., or VI, a wholly owned subsidiary, and transferred our semiconductor equipment business to Varian Semiconductor Equipment Associates, Inc., or 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 engaged in aspects of 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.

# Overview

We are the world leader in the design, manufacture, sale and service of equipment and software products for treating cancer with radiotherapy, stereotactic radiosurgery and brachytherapy. We also design, manufacture, sell and service x-ray tubes for original equipment manufacturers, or 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, manufacturer, sell and service linear accelerators, digital image detectors, image processing software and image detection products for security and inspection purposes. We also develop, design, manufacture and service proton therapy products and systems for cancer treatment.

Oncology Systems, which is our largest business segment, 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 the advanced treatment processes of fixed field intensity-modulated radiation therapy, or IMRT, image-guided radiation therapy, or IGRT, volumetric modulated arc therapy, or VMAT, and stereotactic radiotherapy, as well as to treat patients using brachytherapy techniques, which involve radiation treatment of tumors with implanted radioactive sources. Our products are also used by neurosurgeons to perform stereotactic radiosurgery. Our customers include comprehensive cancer treatment clinics, university research and community hospitals, private and governmental institutions, healthcare agencies, doctors offices and cancer care clinics worldwide.

X-ray Products, which is our other business segment, designs, manufactures and sells x-ray imaging components and subsystems, namely: (i) x-ray tubes for use in a range of applications including computed tomography, or CT, scanning, radioscopic or fluoroscopic imaging, mammography, special procedures and industrial applications; and (ii) flat panel detectors for filmless x-ray imaging, which is an alternative to image intensifier tubes for fluoroscopy and x-ray film and computed radiography, or CR, systems for radiography. Our x-ray tubes and flat panel detectors are sold to a limited number of large imaging system OEM customers that incorporate these x-ray imaging components and subsystems into their medical diagnostic imaging systems and industrial imaging systems. Our x-ray tubes are also sold directly to end-users for replacement purposes. Our flat panel detectors are also being incorporated into next generation imaging equipment, including equipment for IGRT and for dental CT scanning and veterinary x-ray imaging.

In December 2007, we acquired Pan-Pacific Enterprises, Inc., or Pan-Pacific, an independent distributor of medical x-ray tubes and other imaging components in China. Pan-Pacific, which is reported under our X-ray Products segment, serves as a sales channel for our x-ray tubes and flat panel detectors in China.

We have three other businesses that we report together under the Other category. Our Security and Inspection Products, or 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. SIP also designs, manufactures, sells and services IntellX<sup>TM</sup>, an imaging product for cargo screening. We generally sell SIP products to OEMs who incorporate our products into their inspection systems, which are then sold to customs and other government agencies, as well as to commercial private parties in the casting, power, aerospace, chemical, petro-chemical and automotive industries. In April 2008, we opened a new manufacturing facility for SIP products in Las Vegas.

Our ACCEL Proton Therapy business develops, designs, manufactures and services products and systems for delivering proton therapy, another form of external beam radiation therapy using proton beams for the treatment of cancer. We acquired the ACCEL Proton Therapy business in January 2007 to expand our product offerings in proton therapy, which as a treatment modality is still largely in the clinical research phases and not yet widely utilized. Our current focus is commercializing the proton therapy system and bringing our expertise in traditional radiation therapy to proton therapy to improve its clinical utility and to reduce its cost per patient.

Our Ginzton Technology Center, or GTC, develops 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.

The acquisition of ACCEL Instruments GmbH, or ACCEL, in January 2007 also included a scientific research instruments business, or Research Instruments, which develops, manufactures and installs

4

highly customized components and systems for physics research primarily for national research laboratories worldwide. In the fourth quarter of fiscal year 2008, we approved a plan to sell Research Instruments in order to focus our efforts on developing the ACCEL Proton Therapy business. Research Instruments was previously included with ACCEL Proton Therapy business in the Other category. In accordance with the provisions of Statement of Financial Accounting Standards, or SFAS, No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, or SFAS 144, we have classified Research Instruments as a discontinued operation in our Consolidated Statements of Earnings and Consolidated Balance Sheets for all periods presented. For information regarding the Research Instruments business, see Discontinued Operations below.

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**

Radiation therapy, which is also referred to as radiotherapy, is the use of certain types of focused energy, or radiation, 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. Radiation therapy is commonly used either alone or in combination with surgery or chemotherapy. An important advantage of radiation therapy is that radiation acts with some selectivity on cancer cells. When a cell absorbs radiation, the radiation affects the cell s genetic structure and inhibits its replication, leading to its gradual death. Cancerous cells must replicate in order to cause disease; therefore the radiation they absorb can disproportionately damage them. The process for delivering radiation therapy treatment typically consists of examining the patient, planning the therapeutic approach (which is also known as treatment planning), simulating and verifying the treatment plan, providing quality assurance for the devices involved in the treatment process and the treatment plan itself, delivering treatment, verifying that the treatments were delivered correctly, recording the history and results of treatment and obtaining reimbursement for the radiotherapy services provided. A medical doctor specializing in radiation oncology, a physicist for planning the treatment and a radiation therapist for operating the machines generally comprise the team responsible for delivering the radiation therapy treatments.

Currently, the most common type of radiotherapy uses and delivers x-ray beams generated externally from outside of the patient s body. This is 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 that is 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 but deliver lower doses to the healthy tissue around the tumor. Conventional radiation therapy typically would involve 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 more superficial diseases.

IMRT is an advanced form of external beam radiation therapy in which the shape, intensity and angle of the radiation beams from a linear accelerator are varied, or modulated, across the target area of the patient being treated. This conforms the radiation beams more closely to the shape and contours of the tumor and allows doctors to deliver higher doses of radiation to tumors than conventional radiation, while better limiting the amount of radiation directed at nearby healthy tissue. In this way, clinicians can design and deliver an individualized treatment plan for each patient, targeting the patient s tumor as closely as possible. 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 more clinics every year, from university hospitals to local community clinics, continue to adopt IMRT for their treatments. We are a leading provider of products to enable IMRT treatment of cancer.

5

IGRT is another advanced form of external beam radiation therapy technology complementing IMRT to enhance radiation therapy treatments. While IMRT helps doctors shape and conform the radiation beam to that of the tumor, IGRT goes to the next step of allowing doctors to accommodate for tumor movement and avoid more healthy tissue that otherwise would be irradiated when a tumor moves or shrinks. This enables the delivery of even higher doses of radiation to tumors in a more effective manner, while sparing 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 higher doses of radiation at the tumors. We believe treatments using IGRT technology are becoming widely accepted in radiation therapy and radiosurgery, with North America ahead of international regions in the timing of IGRT adoption. About 80% of worldwide orders taken for our high energy linear accelerators in fiscal year 2008 included our On-Board Imager® product, or OBI, which enables IGRT. As of September 26, 2008, we have installed more than 1,000 units of OBI for our high-energy linear accelerators.

Stereotactic radiosurgery (also referred to as stereotactic body radiotherapy) is an advanced radiation treatment procedure that employs linear accelerators and IGRT technology to eradicate cancerous, non-cancerous and abnormal lesions anywhere in the body, by delivering a few very precisely placed, high dose beams of radiation. Customers are recognizing IGRT and stereotactic radiosurgery as significant enhancements in curative radiation therapy.

VMAT is a significant advancement in IMRT that allows doctors to control three parameters simultaneously: (i) the rate with 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. VMAT improves treatment precision by sparing more healthy tissue, makes treatments faster and offers the possibility of greater comfort for patients. Our RapidArc products plan and deliver VMAT treatments.

It appears that doctors, hospitals and clinics place additional value on radiation therapy equipment and treatments, such as VMAT, that enable shorter treatment times and greater patient throughput. From the patients—standpoint, shorter treatment times offer the possibility of greater comfort since treatments often require that the patient be immobilized while on the treatment couch which can be quite uncomfortable. Further, shorter treatment sessions can mean fewer disruptions to a patient—s daily routine since treatments are delivered in fractions over the course of many days. From the doctors—and patient-care standpoint, a shorter treatment time helps to reduce the opportunity for a tumor to move during treatment and, with greater throughput of patients, waiting time for patients to receive treatment at facilities is lessened (which is a particular concern in countries with lower numbers of treatment machines per capita). From the hospitals—and clinics—standpoint, a shorter treatment time can lower the cost per treatment with greater patient throughput and can help attract more patients by offering greater access to advanced care.

We have experienced strong demand for our RapidArc products since their introduction in the second quarter of fiscal year 2008, with most of the orders coming from North America, where early adopters are concentrated. We continue to experience strong demand for our products that enable IGRT as North America has widely adopted IGRT technology in radiation therapy and radiosurgery and the international regions have continued to show increased demand for IGRT products. We believe regional fluctuations in demand are consistent with an observed historical pattern where the international regions follow North America in the adoption of new technology. We are currently experiencing faster adoption rates among the early adopters for our RapidArc products and IGRT products, which may lead to more compressed growth phase cycles and may result in greater fluctuation in our Oncology Systems net orders and revenues.

6

As an alternative to the external beam radiation therapy methods described above, brachytherapy treatments involve the insertion of radioactive seeds, wires or ribbons directly into a tumor or into a body cavity close to the cancerous area. These modalities, unlike external beam radiation therapy, do not require the radiation to pass through surrounding healthy tissue in order to reach the tumor and the doctor can give a higher total dose of radiation in a shorter time. Brachytherapy is often used for cancers of the head and neck, breast, uterus, thyroid, cervix and prostate.

Proton therapy is another form of external beam radiation therapy that uses beams of protons generated using a cyclotron rather than x-ray beams from a linear accelerator. The advantage of proton therapy is that a proton beam signature energy distribution curve, also known as the Bragg peak, allows for greater accuracy in targeting tumor cells with less dose to nearby healthy tissue. This makes proton therapy a preferred option for treating certain kinds of cancers, particularly tumors near the optic nerve and cancers in pediatric cases. Proton therapy, at present, is largely in the clinical research phases, with technology undergoing rapid development, and it is not yet a widely utilized treatment modality. We have entered the proton therapy market because we believe we can apply our experience in traditional radiation therapy to proton therapy, improving clinical utility and reducing cost per patient for existing clinical applications and expanding the use of proton therapy into a broader array of cancer types. Even though we currently manage this business under our Other category as one of our emerging business lines, we believe that proton therapy will evolve in the market to be considered one of several forms of accepted radiation therapy treatment modalities.

The radiation oncology market is growing globally due to a number of factors. Annual cancer rates around the world are projected to increase by 50% to 15 million new cases in the year 2020, as indicated by the World Cancer Report issued by the International Agency for Research on Cancer in the World Health Organization. According to the World Cancer Report, the predicted sharp increase in new cases will mainly be due to steadily aging populations in both developed and developing countries and also due to current trends in smoking prevalence and the growing adoption of unhealthy life styles. For example, the U.S. Census Report indicates that the population over 65 years of age in the United States is expected to increase by 41% to 48 million in 2015 from 34 million in 2000. The U.S. chart data from the National Cancer Institute s Surveillance, Epidemiology, and End Results program also indicates that the number of cases diagnosed annually could double in the United States to 2.6 million by 2050.

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, stereotactic radiotherapy, stereotactic radiosurgery, VMAT, brachytherapy and, ultimately, proton therapy, and developing technology and equipment that enable treatments such as VMAT which lowers treatment times and increases patient throughput should drive the demand for our radiation therapy products and services.

The international markets in particular are under-equipped with radiation therapy systems to address the growing cancer incidence. Cancer patients in many foreign countries must frequently endure long waits for radiotherapy treatment. Many of these countries are now expanding and upgrading their radiotherapy services to care for their cancer patients. The relatively weak U.S. dollar has also effectively made pricing more competitive for U.S.-based companies such as ours, although a strengthening of the U.S. dollar, such as what has recently occurred, could have the opposite effect. Shortages of radiotherapy equipment in the international markets and greater cancer incidences represent additional drivers for continued growth in the international markets.

7

#### **Products**

# Oncology Systems

Our Oncology Systems business segment is the leading provider of advanced hardware and software products for radiation treatment of cancer with conventional radiation therapy, IMRT, IGRT, stereotactic radiotherapy and stereotactic radiosurgery, brachytherapy and VMAT. Our Oncology Systems products address each major aspect of the radiation therapy process, including linear accelerators and accessory products for positioning the patient and delivering the x-ray beam, brachytherapy afterloaders, treatment planning software for planning the therapeutic approach, 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 recording the history and results of treatment 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, including the continuing demand for enhanced capabilities and quality of radiation therapy treatments; improved efficiency, precision, cost-effectiveness, comfort to the patient 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, lower treatment times and greater cost effectiveness and that enhance the entire process of treating a patient. Our products and accessories for IMRT and IGRT allow clinicians to track and treat tumors using shaped beams very precisely, thereby targeting the tumor as closely as possible and allowing the delivery of higher doses of radiation to the tumor, while limiting exposure of nearby healthy tissue. 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 effective communication among products. Additionally, the precision and versatility of our products and technology makes possible the use of radiation therapy to treat metastatic lesions, thereby allowing for multiple medical specialties radiation oncology, neurosurgery, 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 doctors to schedule and treat more patients within a set time period, which adds to the cost-effectiveness of our products and technology.

Linear accelerators are the core device for delivering conventional external beam radiation therapy, IMRT, IGRT and VMAT treatment procedures and we produce versions of these devices to suit various facility requirements and treatment needs. Our Clinac® medical linear accelerators are used to treat cancer by producing therapeutic electrons and x-ray beams that target tumors and other abnormalities in a patient. The Clinac iX series is the latest in this product line and these accelerators are designed to facilitate more streamlined and advanced treatment processes including IMRT and IGRT. We also produce the Trilogy linear accelerator, designed to be a very versatile, cost-effective, ultra-precise radiotherapy treatment product with a faster dose delivery rate and smaller isocenter compared to our Clinac iX. Trilogy was developed with IGRT and stereotactic radiotherapy in mind, but is also capable of delivering conventional, 3D conformal radiotherapy, IMRT and VMAT. Additionally, Trilogy has the precision necessary to deliver stereotactic radiosurgery for neurosurgical treatments and is the accelerator that is at the core of the Novalis Tx product offering, a new combination of products from us and BrainLAB AG, or BrainLAB, targeted to neurosurgeons. In fiscal year 2008, we made a 2.5% equity investment in BrainLAB.

We also manufacture and market accessory products for the linear accelerators that enhance their capabilities and efficiency in delivering radiotherapy treatments and that allow for delivery of advanced treatments such as IMRT, IGRT, stereotactic radiotherapy, stereotactic radiosurgery and VMAT. Our

8

Millennium series of multi-leaf collimators and High Definition 120, or HD 120, multi-leaf collimators are accessory devices that are used with a linear accelerator to define the size, shape and intensity of the radiation beams generated by the linear accelerator. PortalVision, our electronic portal-imager, is used to verify a patient s treatment position while on the treatment couch, which is critical for accurate delivery of radiotherapy treatments. In addition, PortalVision allows for streamlined 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 the course of treatment.

Our accessory products designed specifically for enabling IGRT include our OBI and a cone-beam computerized tomography product, or CBCT, which is used with OBI. The OBI is a hardware accessory to the linear accelerator that allows dynamic, real-time imaging of tumors while the patient is on the treatment couch. CBCT is an imaging software accessory that works with the OBI to allow patient positioning based on soft-tissue anatomy. Using sophisticated image analysis tools, CBCT allows comparison of the CBCT scan with a reference CT scan taken previously to determine how the treatment couch should be moved to fine-tune the patient s treatment setup for accuracy prior to delivery of the radiation. Therefore, to deliver the most advanced forms of IGRT, a Clinac iX or Trilogy accelerator would typically also have an OBI, CBCT, PortalVision and other IGRT-related hardware and software as accessories. We also have in our product portfolio the SonArray ultrasound imaging device for patient positioning and stereotactic treatment planning software for use in developing treatment plans for stereotactic radiosurgery.

In fiscal year 2008, we introduced our new RapidArc radiotherapy products, which employ a special form of IMRT that is delivered in a single continuous rotation of up to 360 degrees, rather than as a series of fixed fields. These products are capable of planning and delivering an image-guided IMRT treatment in a single revolution of the radiation treatment beam around the patient for a quicker delivery of treatment and greater comfort to the patient. Our RapidArc products enable quicker delivery of radiation treatment with the possibility greater comfort to the patient, reduced opportunity for tumor movement during treatment and greater patient throughput and lower cost per patient for the hospital or clinic. RapidArc is a proprietary implementation of VMAT to control the beam shape, dose rate and gantry speed in a concerted manner to deliver a highly conformal dose distribution to the target tumor. We believe RapidArc represents a significant advancement in IMRT cancer treatment and can help drive longer term demand for our linear accelerators and our IMRT-related accessory products.

Our treatment planning and information management software products enhance and enable the delivery of advanced radiation therapy treatments, from the initial treatment planning and plan quality assurance verification to the post-treatment recording of treatment and image data and storing of patient information. Prior to any treatment, particularly IMRT, IGRT, stereotactic radiosurgery and RapidArc, physicians must plan the course of radiation delivery for the patient. To assist physicians with developing these treatment delivery plans, we offer a range of treatment planning products. Our Eclipse treatment planning system provides doctors 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 line of software products allows the management and verification of quality control data. Finally, our ARIA Oncology Information Management System, or ARIA, is the latest information management software system; it integrates the features of our previous products, VARiS®Vision and VARiS MedOncology, with new enhancements to form a more comprehensive real-time information management system and database. ARIA enables users to operate filmless and paperless cancer clinics. ARIA also records and verifies radiotherapy treatment procedures carried out on the linear accelerator, performs patient charting and manages patient information and patient image data. In addition, ARIA records and stores patient data relating to chemotherapy treatment procedures,

9

# Edgar Filing: VARIAN MEDICAL SYSTEMS INC - Form 10-K

## **Table of Contents**

which may be prescribed by a physician in addition to radiation therapy. This gives clinics and hospitals the ability to manage treatment and patient information across radiation oncology and medical oncology procedures.

Our treatment simulators enable physicians to simulate radiation therapy treatments prior to treatment delivery. In addition to PortalVision, we also manufacture and sell Acuity, a simulator that uses advanced amorphous silicon imaging technology and which has been designed to facilitate IMRT treatments both by integrating simulation more closely with treatment planning and by helping physicians better address tumor motions caused by breathing.

Dynamic Adaptive Radiotherapy, or DART, is our vision of the future for radiation therapy treatments where better clinical practices and outcomes are achieved through usage of imaging, planning and delivery of radiation therapy in order to adjust dynamically and in real-time for patient motion, breathing, and anatomical and physiological changes that occur during the course of treatment. Product enhancements that allow for cost-efficient decision support, as well as data collection and analysis for the development of more broadly shared treatment standards are also key aspects of DART. We expect that the guiding principles of DART will contribute to continuing product development and business growth for our Oncology Systems business.

In addition to offering our own suite of equipment and software products for planning and delivering radiation therapy treatments, we have partnered with selected leaders in certain segments of the radiation therapy and radiosurgery market. With General Electric Medical Systems, or GE, in North America, we have established a See and Treat Cancer Care program for radiation therapy, that allows us to offer radiation oncology facilities an interoperable suite of cancer treatment tools that combines our comprehensive set of radiation therapy products with GE s advanced diagnostic imaging systems. We have also a strategic relationship with BrainLAB for the sale and marketing of the Novalis Tx.

Novalis Tx is a radiosurgical device that integrates our Trilogy Tx linear accelerator and our HD 120 multi-leaf collimator with specialty positioning and software products offered by BrainLAB that is targeted to neurosurgeons. The Novalis TX offering works with a variety of our other accessory products, including our OBI, and our Eclipse treatment planning system and ARIA information management software.

Our brachytherapy business designs, manufactures, sells and services advanced brachytherapy products, including treatment planning software, high dose rate products, the VariSource and GammaMed afterloaders, the BrachyVision treatment planning system, applicators and accessories. BrachyTherapy also develops and markets the VariSeed treatment planning system for permanent prostate seed implants.

Revenues from our Oncology Systems business segment represented 81%, 82% and 84% of total revenues for fiscal years 2008, 2007 and 2006, 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 14 Segment Information of the Notes to the Consolidated Financial Statements.

# X-ray Products

Our X-ray Products business segment is a world leader in designing and manufacturing components and subsystems for x-ray imaging, including x-ray-generating tubes and flat panel detectors. X-ray tubes and flat panel detectors are key components of x-ray imaging systems. We sell our products to OEMs for new system configurations and replacement x-ray tubes 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/fluoroscopic imaging, special procedures, and mammography. We also offer a large line of

10

# Edgar Filing: VARIAN MEDICAL SYSTEMS INC - Form 10-K

# **Table of Contents**

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. They are also being incorporated into dental CT scanning and veterinary x-ray imaging systems. 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 will be more cost effective over time than x-ray film.

The fundamental growth driver of this business segment is the on-going success of key x-ray OEMs that incorporate our x-ray tube products and flat panel detectors into their medical diagnostic, dental, veterinary and industrial imaging systems. The sales our flat panel detector products were the key contributors for revenues growth for X-ray Products in fiscal year 2008. Revenues from X-ray Products represented 15%, 15% and 14% of total revenues in fiscal years 2008, 2007 and 2006, respectively. For a discussion of the X-ray Products business segment financial information, see Note 14, Segment Information of the Notes to the Consolidated Financial Statements.

#### Other

Through our SIP business, we design, manufacture, sell and service Linatron<sup>®</sup> 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 for a variety of applications.

The Linatron M-i is a dual energy accelerator that can 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 and can perform non-intrusive inspection of cargo containers. The Linatron K-15 is a high-energy accelerator for inspection of very large, dense objects, including, for example, the solid rocket boosters on NASA s Space Shuttle. In addition, SIP designs, manufactures, sells and services IntellX, an imaging product for cargo screening. Generally, we sell our SIP Products to OEMs who incorporate our products into their inspection systems. The OEMs then sell their systems to customs and other government agencies as well as to commercial private parties in the casting, power, aerospace, chemical, petro-chemical and automotive industries.

Our SIP products are primarily used in overseas ports and borders to screen for contraband, weapons, stowaways, narcotics and explosives, as well as for manifest verification. Our SIP products and technology can also be employed for a variety of applications in industrial inspection and manufacturing quality control. We believe growth in the SIP business will be driven by cargo screening and border protection needs, as well as by the needs of customs agencies to verify shipments for assessing duties and taxes. As a result, this business is heavily influenced by U.S. and foreign governmental policies on national and homeland security, border protection and customs revenue activities; these activities depend upon government budgets and appropriations and are subject to political change. In addition, this business depends on the success of our OEM customers.

Our ACCEL Proton Therapy business develops, designs, manufactures and services products and systems for delivering proton therapy, another form of external beam radiation therapy using proton beams for the treatment of cancer. Proton therapy, as a clinical treatment modality, is still not yet widely utilized and the technology is still developing. We see a high level of interest in the worldwide marketplace for this type of technology, and we intend to leverage our experience in traditional radiation therapy to help advance proton therapy. We are investing substantial resources to commercialize our advanced proton technology and to build this new business. Proton therapy facilities, nevertheless, are large scale construction projects that take three years or more to complete. With the cost of a multiple-gantry system in excess of \$60 million and the total cost for a center approaching \$100 million, significant

11

customer investment and perhaps complex project financing will be required. Consequently, the customers decision-making cycle is very long and orders for proton therapy systems generally involve many contingencies. Since we currently will not book these orders until contingencies are eliminated, we do not expect to book any orders for proton therapy systems in the short term and do not expect to start generating significant proton therapy systems revenues until fiscal year 2010 at the earliest. Given the heavy reliance of customers of this business on credit and large-scale project financing, this business may be the most vulnerable to general economic turmoil and contraction in credit markets.

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. In the area of industrial security, GTC was engaged in a joint research project that ended in fiscal year 2008 with the Palo Alto Research Center, a subsidiary of Xerox Corporation, to develop technology for security and cargo screening applications at airports and seaports under a grant from the United States Department of Commerce. The research and development efforts of GTC are designed to provide a technology base for new products for our existing and future businesses.

SIP, ACCEL Proton Therapy and GTC report their results from operations as part of the Other category. Combined revenues from these operations represented 4%, 3%, 2% of total revenues in fiscal years 2008, 2007 and 2006. For a discussion of segment financial information, see Note 14 Segment Information of the Notes to the Consolidated Financial Statements.

## **Customer Services and Support**

We maintain service centers in Milpitas, California; Las Vegas, Nevada; Des Plaines, Illinois; Clark, New Jersey; Marietta, Georgia; Richardson, Texas; Corona, California; Buc, France; Crawley, UK; Zug, Switzerland; Copenhagen, Denmark; Brussels, Belgium; Houten, The Netherlands; Madrid, Spain; Milan, Italy; Manama, Bahrain; Mumbai, India; Tokyo and Osaka, Japan; Beijing, 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 logistics and education operations for Oncology Systems are located in Las Vegas, Nevada. Our network of service engineers and customer support specialists provide installation, warranty, repair, training and support services, and professional services. 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 twelve months. We offer a variety of post-warranty equipment service contracts and software support contracts that permit customers to contract for the level of equipment maintenance and/or software support they require.

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 capability, availability and responsiveness play an important role in marketing and selling medical products and systems, particularly as the technological complexity of the product portfolio increases. Nevertheless, some of our customers use their own internal service organizations and/or independent service organizations to service equipment after the warranty period expires. Therefore, we cannot assure full conversion to maintenance or service contracts after this period.

12

We warrant our x-ray tubes and flat panel detector products in our X-ray Products business segment generally for a period of twelve months. For some x-ray tube products, 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; 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 tube installers that use our x-ray tube products.

We warrant our Linatrons and imaging products sold by our SIP business generally for a period of twelve months. We provide technical support and service for our Linatrons and imaging products to major OEM customers from our offices in Las Vegas, Nevada; Lincolnshire, Illinois; and Buc, France. We utilize the Oncology Systems Customer Support Services organization in Japan, Asia, Australia and South America.

# **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. We did not have a single customer in fiscal years 2008, 2007 and 2006 that represented 10% or more of our total revenues.

For our Oncology Systems segment, we use our direct sales forces to make all of our North American sales and a combination of direct sales forces and independent distributors for sales in the international regions. We sell our Oncology Systems products primarily to comprehensive cancer treatment clinics, university research and community hospitals, private and governmental institutions, healthcare agencies, doctors offices and cancer care clinics worldwide. As a result of on-going technological development, these clinics, hospitals, institutes, agencies and doctors offices replace equipment and upgrade treatment capability. Sales cycles for our external beam radiation therapy products typically can be quite lengthy since many of our products are considered capital equipment and are affected by budgeting cycles of hospitals, clinics, institutes, agencies and doctors offices, which frequently fix capital budgets one or more years in advance. Additionally, we have seen the purchasing cycle lengthening for some customers, which we believe results from a more complex decision-making process associated with larger dollar value transactions for more sophisticated IGRT and surgical equipment, and other technical advances. A customer s decision-making process may be further complicated as the current worldwide economic turmoil causes hospitals, clinics and research institutions to more closely scrutinize and prioritize their capital spending budgets. Our revenues are also influenced by the timing of product shipments which are tied to planned customer-requested delivery dates. Also, as newly introduced products and international revenues comprise a greater portion of our orders and shipments, the average time period within which orders convert into revenues could lengthen, our margins may fall and our deferred revenues may increase. In addition, our receivables may take longer to collect.

Reimbursement rates in the United States have generally supported a return on investment for the purchase of a new system with IMRT, IGRT and VMAT capabilities in less than 18 months. However, we believe that reimbursements for existing and new treatment processes play a relatively minor role in the market for new external beam radiotherapy equipment and that the prospect of better clinical outcomes continues to be a primary growth driver for new equipment purchases. 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.

13

Total Oncology Systems revenues, including service revenues were \$1.7 billion, \$1.4 billion and \$1.3 billion for fiscal years 2008, 2007 and 2006, respectively. We divide our market segments for Oncology Systems revenues into North America, Europe, Asia and rest of the world, and these regions constituted 52%, 31%, 12% and 5%, respectively of Oncology Systems revenues during fiscal year 2008; 52%, 32%, 11% and 5%, respectively of Oncology Systems revenues during fiscal year 2007 and 53%, 30%, 11% and 6%, respectively, of Oncology Systems revenues during fiscal year 2006.

Our X-ray Products segment employs a combination of direct sales force and independent distributors for sales in all of its regions and sells a high proportion of its products, including x-ray tube products and flat panel detectors, to a limited number of OEMs that incorporate our products into their imaging systems. 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. We supply x-ray tube products and flat panel detectors to OEMs such as Toshiba Corporation, Hitachi Medical Corporation, Philips Medical Systems, GE Healthcare, Sound Technologies, Inc. and Imaging Sciences International, Inc. These OEMs for our x-ray tube products and flat panel detectors represented 62%, 63% and 69% of our total X-ray Products segment revenues during fiscal years 2008, 2007 and 2006, respectively, with the remaining revenues coming from a large number of small OEMs and independent services companies. Total revenues for our X-ray Products segment were \$305 million, \$258 million and \$228 million for fiscal years 2008, 2007 and 2006, 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 35%, 15%, 47% and 3%, respectively, of X-ray Products revenues during fiscal year 2008; 37%, 14%, 46% and 3%, respectively, of X-ray Products revenues during fiscal year 2006.

Our SIP business uses a combination of a direct sales force and independent distributors for sales and sells a high proportion of its products, including Linatron linear accelerators, imaging processing software and image detection products to a limited number of OEMs that incorporate our products into their systems. We expect that revenues from relatively few customers will continue to account for a high percentage of SIP s revenues in the foreseeable future. We supply Linatron linear accelerators and detector products to OEMs such as American Science & Engineering, Inc., L-3 Communications, Rapiscan Systems, Science Applications International Corporation and Smiths Detection. SIP also supplies Linatron linear accelerators and detectors to a wide variety of customers in the non-destructive testing field in the United States and to foreign governments, as well as in industries such as automotive, aerospace, casting and other fields.

In the ACCEL Proton Therapy business, we use direct sales specialist representatives who collaborate with our Oncology Systems sales group on projects globally. Potential customers are government-sponsored hospitals and research institutions and research universities, which typically purchase product through public tenders, and, to a lesser extent, private hospitals and clinics. 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. Proton therapy facilities, nevertheless, are large scale construction projects and involve complex project financing. Consequently, the customers—decision-making cycle is very long and orders for proton therapy systems generally involve many contingencies. Since we currently will not book these orders until contingencies are eliminated, we do not expect to book any orders for proton therapy systems in the short term and do not expect to start generating significant proton therapy systems revenues until fiscal year 2010 at the earliest. Given the heavy reliance of customers of this business on credit and large-scale project financing, this business may be the most vulnerable to general economic turmoil and contraction in credit markets.

# Competition

The market for radiation therapy products, including our Oncology Systems products, is characterized by rapidly evolving technology, intense competition and pricing pressure. We compete with companies

14

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 rapid technological changes occurring in our markets will lead to the entry of new competitors, as well as our encountering new competitors as we apply our technologies in new market segments such as stereotactic radiosurgery, VMAT and proton therapy. For example, we have directed substantial product development efforts into (i) tighter interconnectivity of our products for more seamless operation within a system, (ii) simplifying the usability of our software products and (iii) lowering setup and treatment times and increasing patient throughput, while maintaining an open systems approach that allows customers the flexibility to mix and match individual products, incorporate products from other manufacturers, share information with other systems or products and use the equipment for offering various modalities of radiation therapy treatment methodologies. We anticipate that these efforts will increase acceptance and adoption of IMRT, VMAT and IGRT and will foster greater demand for our products from new customers and upgrades from existing customers. Conversely, one competitor is offering linear accelerator products that are closed-ended, dedicated-use systems that emphasize simplicity of use while sacrificing the ability for customers to customize the system to their individual needs, incorporate products from other manufacturers, share information with other systems or products, or use the equipment for differing modalities of radiation therapy treatment methodologies. If we have misjudged the importance to our customers of maintaining an open systems approach while enabling greater interconnectivity, simplicity-of-use and lowering setup and treatment times or if we are unsuccessful in these efforts to enable greater interconnectivity, enhance simplicity-of-use efforts and setup and treatment times, our revenues could fail to increase or could decrease.

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 sell our products on a total value to the customer basis. We believe we compete favorably with our competitors based upon our strategy of providing 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. We strive to provide technologically superior, clinically proven products for substantially all aspects of radiation therapy that deliver more precise, cost-effective, high quality clinical outcomes that meet or exceed customer quality and service expectations. However, our ability to compete may be adversely affected when purchase decisions are based solely upon price, since our products are generally sold on a total value to the customer basis. This may occur if hospitals and clinics give purchasing decision authority to group purchasing organizations that focus solely on pricing as the primary determinant in making purchase decisions. Therefore, the impact of purchase decisions based solely on price could have a negative effect on our pricing, sales, revenues, market share and gross margins and our ability to maintain or increase our operating margins.

We are the leading provider of medical linear accelerators and related accessories. In radiotherapy and radiosurgery markets, we compete primarily with Siemens Medical Solutions, Elekta AB (which recently acquired Computerized Medical Systems, Inc.), Tomotherapy Incorporated and 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, North American Scientific, Inc., Nucletron B.V. and Siemens Medical Solutions. We also have begun to encounter some competition from providers of hospital information systems. With respect to our BrachyTherapy operations, our primary competitor is Nucletron B.V. For the service and maintenance business for our Oncology Systems products, we compete with independent service organizations and our customers internal service organizations.

15

The market for x-ray imaging components and subsystems is extremely competitive, with our competitors frequently having 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 tubes, also manufacture x-ray tubes for use in their own imaging systems products. While we believe we are one of the leading independent suppliers of x-ray tubes, 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 and/or superior technology and 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. Our significant customers include Toshiba Corporation, Sound Technologies, Inc. and Imaging Sciences International Inc. We primarily compete against Perkin-Elmer, Inc., Trixell S.A.S., and Canon, Inc. in our flat panel detector product line.

Our SIP products are sold to OEMs, who incorporate our products into their inspection systems, which are then sold to customs and other government agencies, as well as to commercial private parties in the casting, power, aerospace, chemical, petro-chemical and automotive industries. We compete with other OEM suppliers in the security and inspection market primarily outside of the United States, and our major competitor in this market is Nuctech Company Limited. The market for our SIP products used for nondestructive testing in industrial applications is small and highly fractured. There is no single major competitor in this nondestructive testing market.

The market for proton therapy products is still developing and is characterized by rapidly evolving technology, high competition and pricing pressure. Our ability to compete successfully depends, in part, on our ability to complete the development of our commercial proton therapy system, lower our product costs, develop and provide technologically superior, clinically proven products that deliver more precise, cost-effective, high quality clinical outcomes, including integration of IGRT technologies such as OBI. There are several competitors in the proton therapy market, some of which may have access to government support and/or may not be as focused on maintaining profitability and/or may be willing to forsake profitability for market share. In the proton therapy market, we compete principally with Ion Beam Applications S.A., Hitachi Medical Corporation, Siemens Medical Solutions and Still River Systems, Inc. The presence of competitors may delay customer purchasing decisions as customers evaluate the products of these competitors along with ours.

# **Research and Development**

Developing products, systems and services based on advanced technological concepts is essential to our ability to compete effectively in the marketplace. We maintain a product research and development and engineering staff responsible for product design and engineering. Research and development expenses totaled \$136 million, \$117 million and \$100 million in fiscal years 2008, 2007 and 2006, respectively.

Our research and development are conducted both within the relevant product groups of our businesses and through GTC. GTC maintains technical competencies in x-ray technology, accelerator technology, imaging physics and applications, algorithms and software, electronic design, materials science and

16

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. GTC is also 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 are focused towards enhancing the reliability and performance of existing products and to develop new products. This development is conducted primarily in the United States, Switzerland, Canada, England, Finland and India. 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 therapy treatment planning software, image processing software, imaging devices, simulation, patient positioning and equipment diagnosis and maintenance tools. Much of the Oncology Systems development efforts relate to our next generation linear accelerators; enhancements to IGRT and IMRT, such as our RapidArc technology and our HD120 multi-leaf collimator; our Monte Carlo and dose calculation algorithms for our treatment planning software products; and our new electronic health records within our information management software.

Within X-ray Products, development is conducted at our Salt Lake City, Utah and Mountain View, California facilities and is primarily focused on developing and improving x-ray imaging component and subsystem products. Current x-ray tube development areas include bearing coating to improve tube life and reduce tube noise, and ceramic design to improve the high voltage stability of x-ray tubes. 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. Research in flat panel imaging technology is aimed at developing new panel technologies for low cost radiographic imaging, flexible panel interfaces, cone beam CT, and high speed multi-slice CT detectors.

We expect that, in order to realize the full potential of the ACCEL Proton Therapy business, we will need to invest substantial resources to properly develop and commercialize its proton therapy technology and to build this new business, including developing manufacturing facilities.

# **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, England 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, England and Haan, Germany and our brachytherapy treatment planning products in Charlottesville, Virginia. Our SIP linear accelerators and certain radiographic products are manufactured in Las Vegas, Nevada, and Lincolnshire, Illinois. We manufacture components and sub-systems for our proton therapy products and systems in Bergisch Gladbach and Troisforf, Germany. We manufacture our x-ray imaging component and subsystem and flat panel detector products in Salt Lake City, Utah; Charleston, South Carolina; and Willich, Germany. 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. Except for the Lincolnshire, Illinois facility, these manufacturing facilities are certified by International Standards Organization, or ISO, under ISO 9001(for SIP) or ISO 13485 (for medical devices).

17

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 get 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 source wires for high-dose afterloaders, klystrons for linear accelerators, array sensors for use in our imaging panels, sesium iodide coatings for the arrays, and specialized integrated circuits, x-ray tube targets, housings, glassframes and various other x-ray tube components. We rely upon the supplies of 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 Products, and high-grade steel and high-grade copper for ACCEL Proton Therapy. Demand for these raw materials both within the United States and from foreign countries, such as China, has increased dramatically. As a result, the availability of these raw materials has been and may continue to be limited and their prices have increased significantly as a result. While recently, we have begun to experience a decrease in certain prices, we expect that the availability and pricing of these raw materials will continue to fluctuate in the future.

# **Backlog**

Our backlog at the end of fiscal year 2008 was \$1.9 billion, of which we expect to recognize approximately 58% to 63% as revenues in fiscal year 2008. Our backlog at the end of fiscal year 2007 was \$1.7 billion, of which \$984 million was recognized as revenues in fiscal year 2008. Our Oncology Systems backlog represented 90% and 91% of the total backlog at the end of fiscal years 2008 and 2007, respectively. We recognize orders for all products that are scheduled to be shipped within two years, except for ACCEL Proton Therapy products, where we would recognize orders that are scheduled to be shipped within four years. Backlog also includes a small portion of service contracts when they become billable. We also include in backlog the amount of deferred revenue related to products that have been delivered but have outstanding contractual obligations or related to acceptance. Semi-annually, we perform a review to determine that our backlog represents valid orders that will be converted to revenues within a reasonable period of time. The backlog review entails identifying aged orders and confirming these orders with our internal sales organization or our customers. Aged orders which are not expected to be converted to revenues as a result of the backlog review are deemed dormant and are no longer included in the reported backlog. Deferred revenue includes (i) the amount equal to the greater of the fair value of the installation services for hardware products or the amount of the payment that is contractually linked to acceptance and (ii) the entire sale price applicable to products shipped but for which installation and/or final acceptance have not been completed. Orders may be revised or canceled, either according to their terms or as customers needs change; consequently, it is impossible to predict with certainty the amount of backlog that will result in revenues. In fiscal years 2008, 2007 and 2006, we reversed \$70 million, \$62 million and \$41 million, respectively, of orders due to adjustments, revisions or can

# **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

18

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. 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.

Additionally, while the proton therapy market is still developing and proton therapy as a treatment modality being is not yet widely utilized, customers are requesting that the systems vendor, as the primary technology provider, provide guarantees for and suffer penalties in relation to the overall construction project. Since each proton center project may cost up to \$100 million, the amount of potential liability may be higher than the levels historically assumed by us for our traditional radiation therapy business. If we cannot reasonably mitigate or eliminate these contingencies, our ability to competitively bid upon proton center projects will be negatively impacted and we may be required to assume material amounts of potential liability, all of which may have adverse consequences to our ACCEL Proton Therapy business. As of November 12, 2008, we have not accepted an order for proton therapy products and systems with significant contingent liabilities or performance guarantees.

# **Government Regulation**

## U.S. Regulation

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 FDA, and state and local regulatory agencies, such as the State of California, to ensure such devices are safe and effective and comply with laws governing products which emit, produce or control radiation. Such regulations, which include the U.S. Food, Drug and Cosmetic Act, or the FDC Act, and regulations promulgated by the FDA, govern the design, development, testing, manufacturing, packaging, labeling, distribution, import/export, possession, marketing, disposal, clinical investigations involving humans, sale and marketing of medical devices, post-market surveillance, repairs, replacements, recalls and other matters relating to medical devices, radiation producing 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 ACCEL 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 as such. 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 requirements applicable to good manufacturing practices.

Our manufacturing operations for medical devices are required to comply with the FDA s Quality System Regulation, or QSR, which addresses a company s responsibility for quality systems, the requirements of good manufacturing practices and relate to 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. Compliance with the QSR is necessary to receive FDA clearance or approval to market new products and is necessary for a manufacturer to be able to continue to market cleared or approved product offerings. Among other things, these regulations require that manufacturers establish performance requirements before production. The FDA makes announced and unannounced inspections of medical device manufacturers and may issue reports, known as Form FDA 483 reports (listing instances where the manufacturer has

19

failed to comply with applicable regulations and/or procedures), or Warning Letters citing failure to comply with applicable regulations or procedures which, if not adequately responded to, could result in the FDA bringing enforcement action against us, including criminal and civil fines and total shutdown of production facilities and criminal prosecution. Inspections usually occur every two years. Our last inspection occurred in June 2008.

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 medical device obtain either 510(k) pre market notification clearance or pre market approval application, or PMA, before the manufacturer may take orders for and sell those products in the United States. For proton therapy systems, a 510(k) pre market notification clearance is required prior to the system being used for treating patients. The 510(k) clearance process is applicable when the new product being developed is substantially equivalent to an existing commercially available product. The process of obtaining 510(k) clearance generally takes at least one to three months from the date the application is filed and generally requires submitting supporting design data, which can be extensive and can extend the process for a considerable period of time beyond three months. 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. 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 must generally conduct at least one clinical protocol and submit extensive supporting data and clinical information in the PMA application to prove the safety and effectiveness of the product. This process typically takes at least one to two years from the date the pre-market approval is accepted for filing, but can take longer for the FDA to review. To date, we have produced Class 1 medical devices, which require no pre-market approvals or clearances, and Class 2 medical devices, which require only 510(k) clearance. Our x-ray tubes and flat panel detectors are Class 1 medical devices, while all of the products produced by our Oncology Systems segment and the proton therapy systems manufactured by our ACCEL business are Class 2 medical devices.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising of our products to ensure that the claims we make are consistent with our regulatory clearances, that there is scientific data to substantiate the claims and that our advertising is neither false nor misleading. In general, we may not promote or advertise our products for uses not within the scope of 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, or UL, the Canadian Standards Association, or CSA, and the International Electrotechnical Commission, or 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 Nuclear Regulatory Commission, or NRC certificate, or an Agreement State registration certificate. Further, 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 Management s Discussion and Analysis of Financial Condition and Results of Operations Environmental Matters.

20

Beyond the above-mentioned regulations, the healthcare industry and we, as a participant in the healthcare industry, are subject to extensive federal, state and local laws and regulations on a broad array of additional subjects. Further, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, sets national standards for some types of electronic health information transactions and the data elements used in those transactions and standards to ensure the integrity and confidentiality of patient health information.

The healthcare industry is also subject to a number of fraud and abuse laws and regulations, including physician self-referral prohibitions, anti-kickback laws, and false claims laws. See Medicare and Medicaid Reimbursement for a description of these laws and regulations. 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.

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:

- adverse publicity affecting both us and our customers;
- increased pressure from our competitors;
- investigations or Warning Letters;
- fines, injunctions, and civil penalties;
- partial suspensions or total shutdown of production facilities, or the imposition of operating restrictions;
- losses of clearances or approvals already granted, or the refusal of future requests for clearance or approval;
- seizures or recalls of our products or those of our customers;
- the inability to sell our products; and
- criminal prosecutions.

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. In addition, new laws and regulations may be adopted, which adversely affect our business. There has been a trend in recent years, both in the United States and internationally, toward more stringent regulation and enforcement of requirements applicable to medical device manufacturers and requirements regarding protection and confidentiality of personal data.

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 furnished to patients 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

# Edgar Filing: VARIAN MEDICAL SYSTEMS INC - Form 10-K

and radiosurgery, in hospitals and freestanding clinics. 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

21

and Medicaid Services, or 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.

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

# Foreign Regulation

Our operations and sales 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. We are also subject to laws and regulations outside the United States applicable to manufacturers of radiation-producing devices and products utilizing radioactive materials, and laws and regulations of general applicability relating to matters such as environmental protection, safe working conditions, manufacturing practices and other matters, in each case that are often comparable to, if not more stringent than, regulations in the United States. In addition, our sales of products in foreign countries are also subject to regulation of matters such as product standards, packaging requirements, labeling requirements, import restrictions, environmental and product recycling requirements, tariff regulations, duties and tax requirements. We rely in some countries on our foreign distributors to assist us in complying with foreign regulatory requirements.

The European Union, or EU, implemented a medical device directive that requires us to affix the Conformité Européene, or CE, mark to our products in order to sell the products in member countries of the EU. The CE mark is an international symbol of adherence to certain essential principles of safety and effectiveness mandated in applicable European medical device directives, which once affixed, enables a product to be sold in member countries of the EU. The CE mark is also recognized in many countries outside the EU, such as Australia, and can assist in the clearance process. In order to receive permission to affix the CE mark to our products, we must obtain Quality System certification, *e.g.*, ISO 13485, and must otherwise have a quality management system that complies with the EU medical device directives. The ISO promulgates standards for certification of quality assurance operations. We are certified as complying with the ISO 9001 for our Security Inspection Products and ISO 13485 for our medical devices. Several Asian countries, including Japan and China, have adopted regulatory schemes that are comparable, and in some cases more stringent, than the EU scheme. To import medical devices into Japan, the requirements of Japan s New Medical Device Regulation must be met and a *shonin*, the approval to sell medical products in Japan, must be obtained. Similarly in China, a registration certification issued by the State Food and Drug Administration and a China Compulsory Certification,

22

or CCC 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 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 some of the costs of disposal, of their products at the end of their useful lives, and to restrict the use of some hazardous substances in certain products sold in those countries. For a further discussion of these regulations, see Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Estimates and Contingencies. Also, many countries where we sell our products have legislation protecting the confidentiality of personal information and the circumstances under which such information may be released for inclusion in our databases, or released to third parties.

# **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 26, 2008, we owned 206 patents issued in the United States and 70 patents issued throughout the rest of the world and we have 355 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. For example, we are licensed under certain patents related to our flat panel detectors and under certain patent applications for technology related to our RapidArc treatment planning product.

# **Environmental Matters**

For a discussion of environmental matters, see Government Regulation Foreign Regulation and Management s Discussion and Analysis of Financial Condition and Results of Operations Environmental Matters.

# Financial Information about Geographic Areas

We do business globally with manufacturing in the United States, Europe and China; and sales 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 Regulation, 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

23

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, or 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. Also, 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, because we sell our products internationally predominantly in local currencies, but our cost structure is weighted towards the U.S. dollar. 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.

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 in Item 1A.

For a discussion of financial information about geographic areas, see Note 14 Segment Information of the Notes to the Consolidated Financial Statements.

## **Discontinued Operations**

In September 2008, we approved a plan to sell the Research Instruments division of ACCEL, which develops, manufactures and services highly customized scientific instrument components and systems for fundamental and applied physics research primarily for national research laboratories worldwide. The operations of Research Instruments are conducted from Bergisch Gladbach, Germany. The market for Research Instruments is characterized by a few large projects in the multi-million to billion-dollar range and a number of national accelerator projects ranging from one to five hundred million dollars. The timing of these research projects, and their associated orders and revenues, may be unpredictable due to public funding, which can be subject to governmental and political factors. This results in engineering and manufacturing resources fluctuating over time. Research Instruments was previously included with the ACCEL Proton Therapy business, which is reported under the Other category in our Consolidated Financial Statements. We decided to sell Research Instruments in order to focus exclusively on the development of our ACCEL Proton Therapy business. In accordance with SFAS 144, 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 15 Discontinued Operations and Assets Held for Sale in Notes to Consolidated Financial Statements for detailed discussion.

# **Employees**

Including employees of Research Instruments, we had approximately 4,900 full-time and part-time employees worldwide, 3,000 in the United States and 1,900 elsewhere at September 26, 2008. 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 Securities and Exchange Commission, or SEC, we make the following available free of charge on our investor relations page of our website <a href="http://www.varian.com">http://www.varian.com</a>; our annual reports on Form 10-K; quarterly reports on Form 10-Q; current reports on Form 8-K (including any amendments to those reports); and 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 investor relations page of our website. Additionally, we will provide copies of our reports, proxy statements, Code of Business Ethics,

24

Corporate Governance Guidelines and committee charters, without charge, to any stockholder upon written request to the Corporate Secretary at our principal executive offices. Please note that information on, or that can be accessed through, our website is not deemed filed with the SEC and is not to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended (the Securities Act ), or the Securities Exchange Act of 1934, as amended (the Exchange Act ).

# **Executive Officers of the Registrant**

The biographical summaries of our executive officers as of are as follows:

Name	Age	Position
Timothy E. Guertin	59 President and Chi	ief Executive Officer
Dow R. Wilson	49 Corporate Execut	ive Vice President and President, Oncology Systems
Elisha W. Finney	47 Corporate Senior	Vice President, Finance and Chief Financial Officer
Robert H. Kluge	62 Corporate Senior	Vice President and President, X-ray Products
Tai-yun Chen	56 Corporate Vice P	resident, Finance and Corporate Controller
John W. Kuo	45 Corporate Vice P	resident, General Counsel and Corporate Secretary

Timothy E. Guertin became Chief Executive Officer in February 2006 and President in August 2005. Previously, Mr. Guertin served as Chief Operating Officer from October 2004 to February 2006, and Executive Vice President from October 2002 to July 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 32 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 President, Oncology Systems in August 2005. 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 also has served on the board of directors of Saba Software, Inc. (an e-learning software provider) since August 2006.

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 during her 20 years with the Company including Treasurer. 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.

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 25 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 counsel 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 Rudnick Gray Cary) 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. The risks and uncertainties described below are not the only ones we face. 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 materially adversely affected.

IF WE ARE UNABLE TO ANTICIPATE OR KEEP PACE WITH CHANGES IN THE MARKETPLACE AND THE DIRECTION OF TECHNOLOGICAL INNOVATION AND CUSTOMER DEMANDS, OUR PRODUCTS MAY BECOME LESS USEFUL OR OBSOLETE AND OUR OPERATING RESULTS WILL SUFFER

The marketplace for our radiation therapy products, including our Oncology Systems products, is characterized by rapid change and technological innovation. Because our products often have long development and government approval cycles, we must anticipate changes in the marketplace and the direction of technological innovation and customer demands. For example, most of our recent product introductions in our Oncology Systems business segment have related to IMRT, IGRT, and VMAT, and enhancements of existing products through greater systems integration and simplification.

We believe that IMRT has become a well-accepted standard of treatment in the radiation oncology market. However, if future studies contradict current knowledge about IMRT or call into question the effectiveness of our IMRT products or show negative side effects, or if other more effective technologies are introduced, our revenues could fail to increase or could decrease. Our success will depend upon the continued acceptance and success of IMRT in general and acceptance of our products utilizing this technology in particular. However, as more institutions purchase IMRT-equipped linear accelerators or upgrade their existing accelerators with IMRT technology, the market for IMRT products may become saturated and we could face competition from newer technologies. We have seen and continue to expect that the rate of growth for IMRT equipment will be lower than what we have experienced previously, particularly in the North American market where a majority of our customer sites have the products and accessories necessary to perform IMRT. Our future success, therefore, will depend on our ability to accurately anticipate and capitalize on new customer demands through technological innovations and changes, including new technologies for treatment such as IGRT and VMAT, as well as new products such as our RapidArc products.

26

IGRT is a further advanced radiation therapy technology complementing IMRT to enhance radiation therapy treatments, and we continue to invest in product development relating to IGRT treatment capabilities. We are experiencing customers accept IGRT as the next significant enhancement in curative radiation therapy, and demand for our products for IGRT has been one of the main contributors to recent net orders and revenue growth in our Oncology Systems business segment. Our future success will also depend upon the wide-spread awareness, acceptance and adoption by the radiation oncology market of IGRT and our IGRT products as an evolutionary technology and methodology for radiotherapy treatment of cancers. We believe hospitals and clinics are converting to this new clinical process as early IGRT sites demonstrate the efficiency and effectiveness of IGRT. Our efforts to increase awareness and adoption of our IGRT products may not be successful. If our assumptions regarding the future importance of IGRT are incorrect, if IGRT fails to be effective as a treatment methodology, or if IGRT fails to become widely accepted, orders and revenues could fail to increase or could decrease.

The acquisition of ACCEL should enable us to develop and offer products for delivering image-guided, intensity-modulated proton therapy for the treatment of cancer. While we intend to continue to invest in product development relating to proton therapy treatment capabilities, acceptance of this technology may be slower than with our other cancer treatment technologies due to the relatively large scale, higher costs and complex project financing associated with implementing a proton therapy system. Risks associated with this business could increase, given the heavy reliance of customers of this business on credit and large-scale project financing, which may be more difficult to obtain with the current general economic turmoil and contraction in credit markets. Our future success will depend upon the wide-spread awareness, acceptance and adoption by the oncology market of proton therapy systems for the treatment of cancer. Our efforts to increase awareness and adoption of our proton therapy systems may not be successful. If proton therapy fails to be effective as a treatment modality, or if proton therapy fail to become widely utilized, our orders and revenues may not materialize.

As radiation oncology treatment becomes more complex, our customers are increasingly interested in the interconnectivity and simplicity of use of our various products for treating patients. For example, our linear accelerators, treatment simulators, treatment verification products and treatment planning and information management software products are highly sophisticated and require a high level of training and education in order to use them competently and safely. The complexity and training requirements are further increased by the products capability of operating together within integrated environments. We have directed substantial product development efforts into (i) tighter interconnectivity of our products for more seamless operation within a system, (ii) simplifying the usability of our software products and (iii) lowering setup and treatment times and increasing patient throughput, while maintaining an open systems approach that allows customers the flexibility to mix and match individual products, incorporate products from other manufacturers, share information with other systems or products and use the equipment for offering various modalities of radiation therapy treatment methodologies. We anticipate that these efforts will increase the acceptance and adoption of IMRT, VMAT and IGRT and will foster greater demand for our products from new customers and upgrades from existing customers. However, we face competition from closed-ended dedicated-use systems that emphasize simplicity of use while sacrificing the ability for customers to customize the system to their individual needs, incorporate products from other manufacturers, share information with other systems or products, or use the equipment for differing modalities of radiation therapy treatment methodologies. If we have misjudged the importance to our customers of maintaining an open systems approach while enabling greater interconnectivity, simplicity-of-use and lowering setup and treatment times, or if we are unsuccessful in these efforts to enable greater interconnectivity, enhance simplicity-of-use efforts and setup and treatment times, our revenues could fail to increase or could decrease.

Our X-ray Products business segment sells products primarily to a limited number of large imaging system OEM customers who incorporate our products into their medical diagnostic imaging systems and industrial imaging systems. Some of these companies also manufacture x-ray tubes or flat panel detectors for their own systems. We, therefore, compete with these in-house x-ray tube and flat panel detector

27

manufacturing operations for business from their affiliated systems businesses. To succeed, we must provide x-ray tube and flat panel detector products that meet our customer demands for lower cost, better product quality and/or 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 revenues could fail to increase or could decrease as our customers purchase from their internal manufacturing operations or from other independent x-ray tube or flat panel detector manufacturers.

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 improved products or processes, or the marketplace may conclude that the tasks our products were designed to do is no longer 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. 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.

IF WE ARE UNABLE TO DEVELOP NEW GENERATIONS OF PRODUCTS AND ENHANCEMENTS TO EXISTING PRODUCTS, WE MAY BE UNABLE TO ATTRACT OR RETAIN CUSTOMERS OR GAIN ACCEPTANCE OF OUR PRODUCTS BY CUSTOMERS

Our success depends upon the successful development, introduction and commercialization of new generations of products, treatment systems and enhancements to and/or simplification of existing products. Our Oncology Systems products are technologically complex and must keep pace with, among other things, new product introductions of our competitors. Our X-ray Products business segment must also continually innovate to develop products with lower cost, better product quality and superior technology and performance. Accordingly, many of our products require significant planning, design, development and testing at the technological, product and manufacturing process levels. In addition, we are making significant investments in long-term growth initiatives, such as development of our SIP and ACCEL Proton Therapy businesses, and expect that further efforts will be necessary to develop and commercialize some of the products and technology of these businesses. These activities require significant capital commitments, involvement of our senior management and other investments on our part, which we may be unable to recover. Our timeline for the development of new products or enhancements may not be achieved and price and profitability targets may not prove feasible. Commercialization of new products may prove challenging, and we may be required to invest more time and money than expected to successfully introduce these products. External factors, such as compliance with regulations, competitive alternatives, and shifting market preferences, may also impact the successful implementation of new products or enhancements. In addition, a few of our research and development projects are funded by government contracts. Changes in government priorities and our ability to attract similar funding may affect our overall research effort and ultimately, our ability to develop successful new products and product enhancements.

Our ability to successfully develop and introduce new products, treatment systems 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 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;

28

# Edgar Filing: VARIAN MEDICAL SYSTEMS INC - Form 10-K

# **Table of Contents**

- 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;
- manufacture and deliver our products in sufficient volumes on time, and accurately predict and control costs associated with manufacturing, installation, warranty and maintenance of the products;
- 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 efforts.

Additionally, our ability to gain healthcare market acceptance and demand for our new radiation therapy products and treatment procedures may be also affected by the budgeting cycles of hospitals and clinics for capital equipment purchases, which are frequently fixed one or more years in advance, and which may lengthen sales and ordering timeframes. In addition, even if customers accept new products or product enhancements, the revenues from these products may not be sufficient to offset the significant costs associated with making them available to customers.

We cannot be sure that we will be able to successfully develop, manufacture or phase in new products, treatment systems or product enhancements. The roll-out of new products, systems and product enhancements involves compliance with complex quality assurance processes, including the Quality System Regulation, or QSR, of the U.S. Food and Drug Administration, or the FDA. Failure to complete these processes timely and efficiently could result in delayed introduction of new products, treatment systems and product enhancements. Without the successful introduction of new products, systems and product enhancements, we may be unable to attract and retain customers, causing our revenues and operating results to suffer. Additionally, if we fail to successfully manage the transition from old products to new products, systems and product enhancements, our customers may delay or cancel orders, which would adversely affect our revenues and operating results.

In addition, the installation times associated with new products generally are longer than with well-established products. Because recognition of a portion of the revenue associated with products is generally tied to installation and acceptance of the product, our recognition of revenue associated with new products may be deferred longer than expected. While we will work to decrease the installation times associated with new products, such as we have done with installation times for OBI, we cannot assure you that these plans will be successful or have a meaningful impact on reducing associated revenue recognition deferrals. Furthermore, even if our plans to decrease installation times are successful, 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 may be adversely impacted over a longer period of time, and our financial results could be adversely affected.

ROUGHLY 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 52%, 51% and 49% of revenues during fiscal years 2008, 2007 and 2006, respectively. As a result, we must provide significant service and support on a worldwide basis, and we have sales and service offices located in Europe, Asia, South America and Australia. In addition, we have manufacturing and research operations in England, Germany, Switzerland, France, Finland and China. We also invested in the

expansion of our China x-ray business through our acquisition of Pan-Pacific. We have invested and will continue to invest substantial financial and management resources to develop an international infrastructure to meet the needs of our customers. We intend to continue to expand our presence in international markets, although we cannot be sure we will be able to compete successfully in the international markets, generate new business, or meet the service and support needs of our customers there. 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;

business and results of operations to suffer.

- the possibility that foreign countries may impose additional withholding taxes or otherwise tax our foreign income, impose tariffs or adopt other restrictions on foreign trade;
- the fact that international regions typically have a longer period from shipment to revenue recognition resulting in greater revenue recognition deferrals, higher backlog and a lower gross margin on our products;
- our ability 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;
- changes in the political, regulatory, safety or economic conditions in a country or region; and
- the possibility that it may be more difficult to protect our intellectual property in foreign countries.

  Historically, our international sales have had lower average selling prices and gross margins. So, as the geographic distribution of our orders and sales shifts increasingly towards our international regions, our overall rate of orders growth (measured in U.S. dollars) could slow down and overall revenues and gross margins may be negatively affected.

In addition, we generally retain cash received through international operations in our local subsidiaries. As of September 26, 2008, 94% 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

we would not receive the full benefit of such repatriation. Additionally, this could cause our overall tax rate to increase. This could cause our

# OUR RESULTS MAY BE ADVERSELY AFFECTED BY CHANGES IN FOREIGN CURRENCY EXCHANGE RATES

Since we sell our products internationally and have international operations, we are also subject to market risk due to fluctuations in foreign currency exchange rates, which may affect product demand, our expenses and/or the profitability in U.S. dollars of products and services provided by us in foreign markets where payment for our products and services or of our expenses is made in the local currency. We manage this risk through established policies and procedures that include the use of derivative financial instruments. We have historically entered into foreign currency forward exchange contracts to mitigate the effects of operational (sales orders) and balance sheet exposures to fluctuations in foreign currency exchange rates. Our forward exchange contracts generally range from one to twelve months in maturity.

Although we engage in hedging strategies that may offset the effect of fluctuations in foreign currency exchange rates, the protection these strategies provide will be affected by the timing of transactions, and the effectiveness of those strategies, the number of transactions that are hedged, forecast volatility and

the extent of movement of foreign currency exchange rates. If our hedging strategies are not effective in offsetting the effect of fluctuations in foreign currency exchange rates, our revenues and other operating results may be harmed. In addition, because currencies fluctuate and we engage in hedging strategies over time, movement in foreign currency exchange rates could impact our financial results positively or negatively in one period and not another, and therefore make comparing our financial results from period to period more difficult. Also because our hedging strategy is to protect the gross margin dollars on our orders, currency exchange rate fluctuations that positively affect our revenues may result in erosion of gross margin.

In addition, long-term movements in foreign currency exchange rates could affect the competitiveness of our products. Even though sales of our products internationally occur predominantly in local currencies, our cost structure is weighted towards the U.S. dollar, and some of our competitors may have cost structures based in other currencies, so our overall margins and pricing competitiveness may be adversely affected. The weakening U.S. dollar that we have experienced over the last several years has made our pricing more competitive with our foreign competitors, which has been a contributor to our international order and revenue growth. The strengthening of the U.S. dollar against other countries—currencies that we have experienced more recently may make our pricing less competitive and result in slower growth in our international orders and revenues, which then could negatively affect our overall financial performance and results. Changes in monetary or other policies here and abroad, including as a result of the current economic turmoil or in reaction thereto, or in the United States as a result of a change in the Presidential administration, will likely affect foreign currency exchange rates.

WE FACE SIGNIFICANT COSTS IN ORDER TO COMPLY WITH LAWS AND REGULATIONS APPLICABLE TO THE MANUFACTURE AND DISTRIBUTION OF OUR PRODUCTS, AND IF WE FAIL OR ARE DELAYED IN OBTAINING REGULATORY CLEARANCES OR APPROVALS OR FAIL TO COMPLY WITH APPLICABLE LAWS AND REGULATIONS, WE MAY BE UNABLE TO DISTRIBUTE OUR PRODUCTS OR MAY BE SUBJECT TO SIGNIFICANT PENALTIES

Our products and the products of OEMs that incorporate our products are subject to extensive and rigorous government regulation, both in the United States and in foreign countries. 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.

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. We are also subject to similar international regulations depending on the countries we sell our devices in. These regulations govern, among other things, the design, development, testing, manufacturing, packaging, labeling, distribution, import/export, sale and marketing and disposal of our products.

Unless an exception applies, the FDA requires that the manufacturer of a new medical device or a new indication for use of, or other significant change in an existing medical device obtain either 510(k) pre-market notification clearance or pre-market approval before we, as a manufacturer of medical devices, can take orders for or sell those products in the United States. In addition, modifications or enhancements to a product that could significantly affect its safety or effectiveness, or that would constitute a major change in the intended use of the device, technology, materials, labeling, packaging, or manufacturing process may require a new 510(k) clearance. Obtaining FDA and/or international clearances or approvals is time-consuming, expensive and uncertain. We may fail to obtain the necessary clearances or approvals or may be unduly delayed in doing so. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses of the

31

product, which may limit the market for those products. If we were unable to obtain required FDA and/or international approval or clearance for a product or unduly delayed in doing so, or the uses of that product were limited, our business would suffer. In the past, in the U.S., our devices have either 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 pre-market approval, or PMA, process. If we were required to use the PMA approval process for future products or product modifications, it could delay or prevent release of the proposed products or modifications, and could cause our business to suffer.

In order for us to market our products within the European Union, we must meet the CE marking requirements. A CE mark is a European marking of conformity that indicates that a product complies with the essential requirements of the applicable European laws or directives by meeting the relevant regulatory requirements and when used as intended, works properly and is acceptably safe. This conformity to the applicable directives is done through self-declaration and is verified by an independent certification body, called a Notified Body, before the CE mark can be affixed. After the CE mark is affixed to the device, which we would do once conformity is verified, the Notified Body would regularly audit us to ensure that we remain in compliance with the applicable European laws or directives. CE marking is required on products in the countries of the European Economic Area, or EEA, and provides a means for us to demonstrate that our products comply with of the laws required by the EEA countries to allow free movement of trade within the EEA countries. If we are unable to support our performance claims and demonstrate compliance with the applicable European laws and directives to our Notified Body and/or competent authorities, we may risk losing our CE mark, which would prevent us from selling our products within the European Union.

We face similar medical device regulations in Asia, specifically in China and Japan. In both Japan and China, we are required to obtain approvals for future products and product modifications, which could have long approval times resulting in a significant delay to our ability to market products in those countries. We may also face regulatory requirements in other countries aside from those identified, and those requirements may be more or less restrictive, and which we may not be able to meet. This may limit or prevent our ability to market our products in one or more other countries or regions.

Our manufacturing operations are required to comply with the FDA s QSR, and other federal and state regulations for medical devices and radiation emitting products that address a company s responsibility for complying with the quality systems regulations, which include, the requirements for current good manufacturing practices. The FDA makes announced and unannounced inspections of medical device manufacturers to determine compliance with QSR and in connection with these inspections has issued, and in the future may issue, reports, known as Form FDA 483 reports (listing instances where the manufacturer has failed to comply with applicable regulations and/or procedures), or Warning Letters citing failure to comply with applicable regulations or procedures. If a Warning Letter were issued, we would be required to take prompt corrective action to come into compliance. Failure to respond timely to a Warning Letter or other notice of noncompliance and to come into compliance could result in the FDA bringing enforcement action against us, which could include the total shutdown of our production facilities and criminal and civil fines. 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.

The FDA and the FTC, also regulates advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, that there is scientific data to substantiate the claims and that our advertising is neither false nor misleading. If the FDA or FTC determines that any of our advertising or promotional claims are not permissible, we may be subject to enforcement actions and may be required to revise our promotional claims or make other corrections or restitutions.

32

In addition, we are required to timely file various reports with the FDA and other international regulatory authorities, including reports required by the medical device reporting, or MDR regulations, and similar international adverse event reporting regulations, which require that we report to regulatory authorities if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed 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 Corrections and Removals 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 and other international regulatory agencies regarding the quality and safety of our devices.

Our medical devices utilizing radioactive material are subject to the Nuclear Regulatory Commission, or NRC, clearance and approval requirements, and the manufacture and sale of these products are subject to extensive international, federal and state regulation that varies from state to state and among countries or 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. 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. There can be no assurance disposal sites for the lawful disposal of materials generated by the manufacture, use or decommissioning of our products will continue to accept such materials in the future, or under terms which are favorable.

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, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and similar data privacy laws and regulations in foreign countries, fraud and abuse laws and regulations, including, physician self-referral prohibitions, anti-kickback laws and false claims laws. 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.

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:

- adverse publicity affecting both us and our customers;
- increased pressures from our competitors;
- investigations 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, or the refusal of future requests for clearance or approval;

• seizures or recalls of our products or those of our customers;

33

#### **Table of Contents**

- delays in purchasing decisions by customers or cancellation of existing orders;
- the inability to sell our products; and
- criminal prosecutions.

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. In addition, new laws and regulations may be adopted, which adversely affect our business. There has been a trend in recent years, both in the United States and internationally, toward more stringent regulation and enforcement of requirements applicable to medical device manufacturers and requirements regarding protection and confidentiality of personal data.

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.

## WE FACE SIGNIFICANT COSTS IN ORDER TO COMPLY WITH FOREIGN LAWS AND REGULATIONS APPLICABLE TO THE MANUFACTURE AND DISTRIBUTION OF OUR PRODUCTS.

Our operations and sales 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. We are also subject to laws and regulations outside the United States applicable to manufacturers of radiation-producing devices and products utilizing radioactive materials, and laws and regulations of general applicability relating to matters such as environmental protection, safe working conditions, manufacturing practices and other matters, in each case that are often comparable, if not more stringent, than regulation in the United States. In addition, our sales of products in foreign countries are subject to regulation of matters such as product standards, packaging requirements, labeling requirements, environmental and product recycling requirements, import and export restrictions, tariff regulations, duties and tax requirements. In some countries, we rely on our foreign distributors to assist us in complying with foreign regulatory requirements. We may be required to incur significant time and expense in obtaining and maintaining regulatory approvals. Delays in receipt of or failure to receive regulatory approvals, 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 the applicable country or subject us to a variety of enforcement actions, which would adversely affect our business.

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

The Medicare and Medicaid anti-kickback laws, and several similar state laws, prohibit payments or other remuneration that is intended to induce hospitals, physicians or others either to refer patients or to purchase, lease or order, or arrange for or recommend the purchase, lease or order of healthcare products or services for which payment may be made under federal healthcare programs, such as Medicare and Medicaid. These laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. In particular, these laws influence, among other

34

things, how we structure our sales offerings, including discounts and rebate practices, customer support, education and training programs, physician consulting, research grants and other service arrangements. These laws are broadly written, and it is often difficult to determine precisely how these laws will be applied to specific circumstances.

Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or for items or services that were not provided as claimed. Although we do not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to cause the submission of false or fraudulent claims by providing inaccurate billing or coding information to customers, or through certain other activities, including promoting products for uses not approved or cleared by the FDA, which is called off-label promotion. Anti-kickback and false claims laws prescribe civil and criminal penalties, which can be substantial, and potential exclusion from healthcare programs for noncompliance. Moreover, even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could harm our business and results of operations.

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

In addition, we are subject to the U.S. Foreign Corrupt Practices Act, antitrust and anti-competition laws, and similar laws in foreign countries, any violation of which could create a substantial liability for us and also cause a loss of reputation in the market. From time to time, we may face audits or investigations by one or more government agencies, compliance with which could be costly and time-consuming, and could divert our management and key personnel from our business operations. An adverse outcome under any such investigation or audit could subject us to fines or other penalties, which could adversely affect our business and financial results.

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

Our business exposes us to potential product liability claims that are inherent in the manufacture, sale, installation, servicing and support of medical devices and other devices that deliver radiation. Because our products are involved in the intentional delivery of radiation to the human body, 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 are used as part of an overall process that takes place within our customers—facilities and network systems, and under quality assurance, or QA, procedures established by the facility that ultimately result in the delivery of radiation to patients. Additionally, human and other errors or accidents may arise from the fact that our products operate 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

35

patients, our customers or others for damages resulting from the faulty or allegedly faulty design, manufacture, installation, servicing, support, testing, interoperability or the misuse of our products. 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. With any accident, we could be subject to legal costs, adverse publicity and damage to our reputation, whether or not our products or services were a factor. Furthermore, adverse publicity regarding accidents or mistreatments involving radiation therapy could adversely impact our business by negatively affecting the reputation of radiation therapy in general, causing patients to question the efficacy of radiation therapy as a viable treatment for cancer and seek other modalities of treatment.

In addition, if a product we designed or manufactured were 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. The adverse publicity resulting from a recall could cause customers to review and potentially terminate their relationships with us. These recalls, especially if accompanied by unfavorable publicity or cancellation of customer orders and service contracts, could result in our incurring substantial costs and management time, losing revenues and damaging our reputation, each of which would harm our business. Further, product recalls may also result in unexpected loss accruals under generally accepted accounting principles in the United States of America, or GAAP, that may cause our quarterly results to fluctuate.

We maintain limited product liability insurance coverage and currently self-insure professional liability/errors and omission liability. The product liability insurance policies that we maintain are expensive and have high deductible amounts and self-insured retentions. In the future, these policies may not be available on acceptable terms or in sufficient amounts, if at all. In addition, the insurance coverage we have obtained may not be adequate. A material claim successfully brought against us relating to a self-insured liability or a liability that is in excess of our insurance coverage, or for which insurance coverage is denied or limited would require us to pay damage amounts that could be substantial and have a material adverse effect on our financial position and results of operation.

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

The markets for radiation therapy equipment and software are characterized by rapidly evolving technology, intense competition and pricing pressure. Some of our competitors have greater financial, marketing and other resources than we have. Also, we believe that the rapid technological changes occurring in our markets will lead to the entry of new competitors into our markets, as well as our encountering new competitors as we apply our technologies in new market segments such as stereotactic radiosurgery, VMAT and proton therapy. Our ability to compete successfully depends, in part, on our ability to provide technologically 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. Our ability to compete in the radiation therapy market may be adversely affected when purchase decisions are based solely upon price, since our products are generally sold on a total value to the customer basis. This may occur if hospitals and clinics give purchasing decision authority to group purchasing organizations that focus solely on pricing as the primary determinant in making purchase decisions. In addition, the presence of additional competitors may delay customer purchasing decisions as customers evaluate the products of these competitors along with ours. These delays can extend our sales cycle and therefore adversely affect our net orders and operating results. In radiotherapy and radiosurgery markets, we compete primarily with Siemens Medical Solutions, Elekta AB (which recently acquired Computerized Medical Systems, Inc.), Tomotherapy Incorporated and Accuray Incorporated. With our information and image management, simulation, treatment planning

36

#### **Table of Contents**

and radiosurgery products, we also compete with a variety of companies, such as Elekta AB, Philips Medical Systems, North American Scientific, Inc., Nucletron B.V. and Siemens Medical Solutions. We also have begun to encounter some competition from providers of hospital information systems. With respect to our BrachyTherapy operations, our primary competitor is Nucletron B.V. For the service and maintenance business for our Oncology Systems products, we compete with independent service organizations and our customers internal service organizations.

The market for x-ray imaging components and subsystems is extremely competitive, with our competitors frequently having 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 tubes, also manufacture 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 and we primarily compete against Perkin-Elmer, Inc., Trixell S.A.S., and Canon, Inc. in our flat panel detector product line.

In our SIP business, we compete with other OEM suppliers, primarily outside of the United States, and our major competitor in this market is Nuctech Company Limited. The market for our SIP products used for nondestructive testing in industrial applications is small and highly fractured. There is no single major competitor in this nondestructive testing market.

The market for proton therapy products is still developing and is characterized by rapidly evolving technology, high competition and pricing pressure. Our ability to compete successfully depends, in part, on our ability to complete the development of our commercial proton therapy system, lower our product costs, develop and provide technologically 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 Ion Beam Applications S.A., Hitachi Medical Corporation, Siemens Medical Solutions and Still River Systems, Inc. The presence of competitors may delay customer purchasing decisions as customers evaluate the products of these competitors along with ours.

In each of our business segments, existing competitors—actions and new entrants may adversely affect our ability to compete. These competitors could develop technologies and products that are more effective than those we currently use or produce or that could render our products obsolete or noncompetitive. In addition, the timing of our competitors—introduction of products into the market could affect the market acceptance and market share of our products. Some competitors offer specialized products that are or may be perceived by customers to provide a marketing advantage over our mainstream cancer treatment products. Also, some of our competitors may not be subject to or operate under the same standards, regulatory and/or other legal requirements that we do, and therefore, they could have a competitive advantage in developing, manufacturing and marketing products and services. Any inability to develop, gain regulatory approval for and supply commercial quantities of competitive products to the market as quickly and effectively as our competitors could limit market acceptance of our products and reduce our sales. In addition, some of our smaller competitors could be acquired by larger companies that have greater financial strength, which could enable them to compete more aggressively. Our competitors could also acquire some of our suppliers or distributors, which could disrupt these supply or distribution arrangements and result in less predictable and reduced revenues in

37

our businesses. Any of these competitive factors could negatively affect our pricing, sales, revenues, market share and gross margins and our ability to maintain or increase our operating margins.

INTEROPERABILITY OF OUR PRODUCTS WITH ONE ANOTHER AND THEIR COMPATIBILITY WITH THIRD-PARTY PRODUCTS IS BECOMING INCREASINGLY IMPORTANT, AND IF WE ARE UNABLE TO MAKE OUR PRODUCTS INTEROPERATE WITH ONE ANOTHER OR COMPATIBLE WITH WIDELY USED THIRD-PARTY PRODUCTS, SALES OF OUR PRODUCTS COULD DECREASE

As radiation therapy becomes more and more complex, our customers are increasingly concerned about the interoperability and compatibility of the various products they use in providing treatment to patients. For example, our linear accelerators, treatment simulators, treatment verification products, treatment planning and information management software products are designed to interoperate with one another, and to be compatible with other widely used third-party radiation oncology products. Obtaining and maintaining this interoperability and compatibility is costly and time-consuming. When third parties modify the design or functionality of their products, it can require us to modify our products to ensure compatibility. Conversely, when we implement design improvements to our products, customers may be reluctant to adopt our new technology due to interoperability issues; for example, a clinic may be unwilling to implement one of our new technologies because its third-party software network provider does not yet have a proper software interface available. In addition, our ability to obtain compatibility with third-party products can depend on the third parties—providing us with adequate information regarding their products. In many cases, these third parties are our competitors and may time their product changes, and their sharing of relevant information with us, to place us at a competitive disadvantage. Further, we could be required to obtain additional regulatory clearances for any modification of our products due to interoperable or compatible with widely used third-party products or may only be able to do so at a prohibitive expense, making our products less attractive or more costly to our customers.

## WE MAY INCUR SUBSTANTIAL COSTS IN PROTECTING OUR INTELLECTUAL PROPERTY, AND IF WE ARE NOT ABLE TO DO SO, OUR COMPETITIVE POSITION WOULD BE HARMED

We file applications as appropriate for patents covering new products and manufacturing processes. We cannot be sure, however, that our current patents, the claims allowed under our current patents, or patents for technologies licensed to us will be sufficiently broad to protect our technology position against competitors. Issued patents owned by, or licensed to, us may be challenged, invalidated or circumvented, or the rights granted under the patents may not provide us with competitive advantages. We also cannot be sure that patents will be issued from any of our pending or future patent applications. We could incur substantial costs and diversion of management resources if we have to assert our patent rights against others in litigation or other legal proceedings. An unfavorable outcome in any such litigation or proceeding could harm us. In addition, we may not be able to detect patent infringement by others or may lose our competitive position in the market before we are able to do so.

We also rely on a combination of copyright, trade secret and other laws, and contractual restrictions on disclosure, copying and transferring title (including confidentiality agreements with vendors, strategic partners, co-developers, employees, consultants and other third parties), to protect our proprietary rights. We cannot assure you that these protections will prove adequate, that agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known to or be independently developed by others. We have trademarks, both registered and unregistered, that are maintained and enforced to provide customer recognition for our products in the marketplace. We cannot assure you that unauthorized third parties will not use our

38

trademarks. We also have agreements with third parties that license to us certain patented or proprietary technologies. If we were to lose the rights to license these technologies, or our costs to license these technologies were to materially increase, our business would suffer.

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

The industries in which we compete are characterized by a substantial amount of litigation over patent and other intellectual property rights. Our competitors, like companies in many high technology businesses, continually review other companies products for possible conflicts with their own intellectual property rights. Determining whether a product infringes a third party s intellectual property rights involves complex legal and factual issues, and the outcome of this type of litigation is often uncertain. Third parties may claim that we are infringing their intellectual property rights, and we may be found to infringe those intellectual property rights. We may not be aware of intellectual property rights of others that relate to our products, services or technologies. From time to time, we have received notices from third parties asserting infringement and we have been subject to lawsuits alleging infringement of third-party patent or other intellectual property rights. Any dispute regarding patents or other intellectual property could be costly and time-consuming, and could divert our management and key personnel from our business operations. We cannot assure you that we would prevail in any such dispute. We also do not maintain insurance for such intellectual property infringement. Therefore, if we are unsuccessful in defending any such infringement claim, we may be subject to significant damages or injunctions against development and sale of our products, or may be required to enter into costly royalty or license agreements. We cannot assure you that any licenses required would be made available to us on acceptable terms or at all.

SINCE WE DEPEND UPON A LIMITED GROUP OF SUPPLIERS, AND IN SOME CASES SOLE SOURCE SUPPLIERS, FOR SOME PRODUCT COMPONENTS, THE LOSS OF A SUPPLIER OR ANY INABILITY TO OBTAIN SUPPLIES OF THESE COMPONENTS COULD REDUCE OUR ABILITY TO MANUFACTURE PRODUCTS, CAUSE MATERIAL DELAYS IN OUR ABILITY TO DELIVER PRODUCTS, OR SIGNIFICANTLY INCREASE OUR COSTS; SHORTAGES OF KEY RAW MATERIALS COULD HAVE A SIMILAR EFFECT

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 source wires for high-dose afterloaders, klystrons for linear accelerators, array sensors for use in our imaging panels, sesium iodide coatings for the arrays, and specialized integrated circuits, x-ray tube targets, housings, glassframes and various other x-ray tube components. If we lose any of these suppliers or if their operations were substantially interrupted, we would be required to obtain and qualify one or more replacement suppliers, which may then also require us to redesign or modify our products to incorporate new parts and/or further require us to obtain clearance, qualification or certification of such product by the FDA or other applicable regulatory approvals in other countries. Events like these could significantly increase costs for the affected product and likely cause material delays in delivery of that and other related products.

Although we have obtained limited insurance to protect against business interruption loss, we cannot assure you that this insurance coverage will be adequate or that it will continue to remain available on acceptable terms, if at all. Additionally, some of these suppliers, including our single-source suppliers, supply components for certain of our product lines that are growing rapidly. Manufacturing capacity limitations of any of these suppliers or other inability of these suppliers to meet increasing demand could adversely affect us, resulting in curtailed growth opportunities for any of our product lines. Shortage of and greater demand for components and subassemblies could also increase manufacturing costs by increasing prices. Disruptions or loss of any of our limited- or sole-source components or subassemblies or the capacity limitations of the suppliers for these components or subassemblies, including the ones referenced above,

39

could adversely affect our business and financial results and could damage our customer relationships. In addition, we rely upon the supplies of 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 Products, and high-grade steel and high-grade copper for the ACCEL Proton Therapy business. Demand for these raw materials both within the United States and from foreign countries, such as China, has increased dramatically. As a result, the availability of these raw materials has been and may continue to be limited and their prices have increased significantly. While recently, we have begun to experience a decrease in pricing, we expect that the availability and pricing of these raw materials will continue to fluctuate in the future. This could constrain our manufacturing of affected products, reduce our profit margins or otherwise adversely affect our business.

## CONSOLIDATION AMONG OUR ONCOLOGY SYSTEMS CUSTOMERS COULD ADVERSELY AFFECT OUR SALES OF ONCOLOGY PRODUCTS AND THEREFORE OUR FINANCIAL RESULTS

We have begun to see some consolidation among our customers in our Oncology Systems business, as hospitals and clinics are combined through mergers and acquisitions, and as they join group purchasing organizations or affiliated enterprises. As customers consolidate, the volume of product sales to these customers might decrease. Alternatively, order size may increase as what were previously more than one customer combine orders as one entity. As a result, the purchasing cycle for our Oncology Systems products could lengthen, as orders increase in size and require more approvals. Both increased order size and extended purchasing cycles could cause our net orders for these products to be more volatile and less predictable. In addition, group purchasing organizations often focus on pricing as the determinant in making purchase decisions. A reduction in net orders could affect the level of future revenues, which would adversely affect our operating results, financial condition, and the price of VMS common stock.

WE SELL OUR X-RAY TUBES TO A LIMITED NUMBER OF OEM CUSTOMERS, MANY OF WHOM ARE ALSO OUR COMPETITORS, AND THE LOSS OR REDUCTION IN PURCHASING VOLUME BY ONE OR MORE OF THESE CUSTOMERS OR CONSOLIDATION AMONG OEMS IN THE X-RAY TUBE PRODUCTS MARKET COULD REDUCE OUR SALES OF X-RAY TUBE PRODUCTS

We sell our x-ray tube products to a limited number of OEM customers, many of which are also our competitors, for incorporation into diagnostic imaging systems. The loss of, or reduction in purchasing volume by, one or more of these customers would have a material adverse effect on our X-ray Products business. There has been a consolidation of diagnostic imaging systems manufacturers over the past few years. The ongoing consolidation of customers who purchase our x-ray tube products, including the consolidation of these customers into companies that already manufacture x-ray tubes, could result in less predictable and reduced sales of our x-ray tube products. In addition, our OEM customers products, which also use our x-ray tubes, could lose market share to competitive products or technologies and, thereby, result in a reduction in our orders and revenues.

WE SELL OUR LINATRON® X-RAY ACCELERATORS TO OEM CUSTOMERS WHO DEPEND ON CUSTOMER DELIVERY AND ACCEPTANCE SCHEDULES, WHICH MAY CAUSE ORDERS FOR OUR SECURITY AND INSPECTION PRODUCTS TO BE UNPREDICTABLE

Our SIP business designs, manufactures, sells and services Linatron x-ray accelerators, imaging processing software and image detection products for security and inspection, such as cargo screening at ports and borders and nondestructive examination for a variety of applications. We generally sell SIP products to OEMs who incorporate our products into their inspection systems, which are then sold to customs and other government agencies, as well as to commercial private parties in the casting, power, aerospace, chemical, petro-chemical and automotive industries. We believe growth in the SIP business will be driven by security cargo screening and border protection needs, as well as by the needs of customs

40

agencies to verify shipments for assessing duties and taxes. However, use of linear accelerator and imaging technology in security cargo screening and border protection is in its early stages. Orders for our SIP products have been and may continue to be unpredictable and the actual timing of sales and revenue recognition will vary significantly, as it is difficult to predict our OEM customer delivery and acceptance schedules.

In addition, our SIP business is heavily influenced by U.S. and foreign governmental policies on national and homeland security, border protection and customs revenue activities, all of which depend upon government budgets and appropriations that are subject to political changes, which may cause uncertainty and variability in the timing of orders. Thus, orders in any quarter or period are not necessarily directly correlated to the level of sales or revenues in any particular future quarter or period. This unpredictability in orders, sales and revenue timing could cause volatility in our revenues and earnings, and therefore the price of VMS common stock.

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

In order to achieve market acceptance for our radiation therapy products, we are often required to educate physicians about the use of a new treatment procedure such as IMRT, IGRT, VMAT, stereotactic radiosurgery or proton therapy, overcome physician objections to some of the effects of the product or its related treatment regimen, convince healthcare payors that the benefits of the product and its related treatment process outweigh its costs and help train qualified physicists in the skilled use of our products. For example, the complexity and dynamic nature of IMRT and IGRT requires significant education of hospital personnel and physicians regarding the benefits of IMRT and IGRT and the required departures from their customary practices. Further, the complexity and high cost of proton therapy requires similar significant education, as well as education regarding construction and facility requirements. We have expended and will continue to expend significant resources on marketing and educational efforts to create awareness of IMRT, IGRT, VMAT, stereotactic radiosurgery and proton therapy generally and to encourage acceptance and adoption of our products for IMRT, IGRT, VMAT, stereotactic radiosurgery and proton therapy. The timing of our competitors introduction of products and the market acceptance of their products may also make this educational process more difficult. We cannot be sure that any products we develop will gain any significant market acceptance and market share among physicians, patients and healthcare payors, even if the required regulatory approvals are obtained.

# WE MAY NOT BE ABLE TO MAINTAIN OR EXPAND OUR BUSINESS IF WE ARE NOT ABLE TO RETAIN, HIRE AND INTEGRATE SUFFICIENTLY QUALIFIED PERSONNEL

Our future success depends, to a significant extent, on our ability to attract, expand, integrate, train and retain our management team, qualified engineering personnel, technical personnel and sales and marketing staff. The loss of services of key employees could adversely affect our business. Competition for key personnel can be intense. We compete for key personnel with other medical equipment and software manufacturers and technology companies, as well as universities and research institutions. Because the competition for qualified personnel is intense, costs related to compensation could increase significantly if supply decreases or demand increases. If we are unable to hire, train or retain qualified personnel, we will not be able to maintain and expand our business.

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

As a manufacturer of products with a long production cycle, we need to anticipate demand for our products in order to ensure adequate manufacturing or testing capacity. We cannot assure you that we

41

will be able to anticipate demand adequately or to adjust our resources appropriately. If our manufacturing or testing capacity does not keep pace with product demand, we will not be able to fulfill orders in a timely manner, which in turn may have a negative effect on our financial results and overall business. Conversely, if demand for our products decreases, the fixed costs associated with excess manufacturing capacity may adversely affect our financial results.

WE MAY ATTEMPT TO ACQUIRE NEW BUSINESSES, PRODUCTS OR TECHNOLOGIES, AND IF WE ARE UNABLE TO SUCCESSFULLY COMPLETE THESE ACQUISITIONS OR TO INTEGRATE ACQUIRED BUSINESSES, PRODUCTS, TECHNOLOGY OR EMPLOYEES, WE MAY FAIL TO REALIZE EXPECTED BENEFITS OR HARM OUR EXISTING BUSINESS

Our success will depend, in part, on our ability to expand our product offerings and grow our businesses in response to changing technologies, customer demands and competitive pressures. In some circumstances, as a strategy to achieve quicker time to market for new products or technology, or to enter new markets, we may determine to grow our business through the acquisition of complementary businesses, products or technologies rather than through internal development. For example, in fiscal year 2008 we acquired Pan-Pacific, an independent distributor of medical x-ray tubes and other imaging components in China. The identification of suitable acquisition candidates can be difficult, time-consuming and costly, and we may not be able to identify suitable candidates or successfully complete identified acquisitions. In addition, the completion of an acquisition could divert our management and key personnel from our business operations, which could harm our business and affect our financial results. Furthermore, even if we complete an acquisition, we may not be able to successfully integrate newly acquired organizations, products or technologies or employees into our operations, or may not be able to realize some of the synergies expected from an acquisition. The process of integration could be expensive, time-consuming and may strain our resources. For example, we may encounter challenges in the commercialization of new products and may have to invest more than originally anticipated in order to do so, as we are experiencing with the ACCEL proton therapy systems. These additional expenditures could be significant and could cause our results of operations to suffer. In many instances, integrating a new business will also involve implementing or improving internal controls appropriate for a public company at a business that lacks them. In addition, we may be unable to retain the employees of acquired companies, or the acquired company s customers, suppliers, distributors or other partners for a variety of reasons, including the fact that these entities may be our competitors or may have close relationships with our competitors. Further, we may find that we need to restructure or eventually divest acquired businesses or assets of those businesses, such as we have decided with respect to Research Instruments. We cannot be certain that restructuring activities will produce the full efficiencies and benefits we expect. Consequently, we may not achieve anticipated growth or other benefits from an acquisition, which could harm our existing business. If we decide to sell assets or a business, we may encounter difficulty in finding buyers or alternative exit strategies on acceptable terms in a timely manner, or at all, which could delay the accomplishment of our strategic objectives, or we may dispose of a business at a price or on terms that are less than we had anticipated. In this instance, we may be required to recognize an impairment loss on our assets and goodwill, which could adversely affect our business and financial operations. In addition, acquisitions could result in potentially dilutive issuances of equity securities or the incurrence of debt, contingent liabilities or expenses, or other charges such as in-process research and development, any of which could harm our business and affect our financial results.

We account for our acquisitions under the purchase method of accounting. Under this method, we allocate the total purchase price to the acquired businesses tangible assets and liabilities, identifiable intangible assets and in-process research and development costs based on their fair values as of the date of the acquisition, and record the excess of the purchase price over those fair values as goodwill. If we fail to achieve the anticipated growth from an acquisition, or if we determine to dispose of an acquired business, as with Research Instruments, we may be required to write down the value of our intangible assets and goodwill, which may harm of our financial results.

42

#### THE ACQUISITION OR DEVELOPMENT OF NEW LINES OF BUSINESS MAY SUBJECT US TO ADDITIONAL RISKS

From time to time, we may acquire or develop new lines of business, such as proton therapy. There are substantial risks and uncertainties associated with these efforts, particularly in instances where the markets are not fully developed. Risks include developing knowledge of and experience in the new business, recruiting professionals to manage the new business lines, increasing research and development expenditures, and developing and capitalizing on new marketing relationships with experienced market participants. Each new business may require the investment of additional capital and the significant involvement of our senior management to acquire or develop, then integrate, the new line of business into our operations. Initial timetables for the introduction and development of new lines of business may not be achieved and price and profitability targets may not prove feasible, as new products can carry lower gross margins. External factors, such as compliance with regulations, competitive alternatives, and shifting market preferences, may also impact whether implementation of a new line of business will be successful. Failure to successfully manage these risks in the development and implementation of new lines of business could materially and adversely affect our business, results of operations and financial condition.

#### WE MAY NOT BE ABLE TO SUCCESSFULLY COMPLETE THE SALE OF OUR RESEARCH INSTRUMENTS BUSINESS

In September 2008, we approved a plan to sell Research Instruments. We may face difficulties and incur costs associated with this sale, which could adversely affect our financial condition and results of operations. Transitioning a disposed business involves a number of risks, including but not limited to difficulties in separating operations, services, products and personnel; the potential impairment of relationships with our existing customers; the disruption of our business and the potential loss of key employees. The sale of Research Instruments will require a substantial amount of management, administrative and operational resources. These demands may distract our employees from the day-to-day operation of our other businesses. The number of potential buyers for Research Instruments is limited, which may make it more difficult to complete the sale on reasonable terms, or at all. In addition, we have incurred and prior to the sale of Research Instruments may still incur additional charges associated with the impairment of goodwill and other long-lived assets and continuing losses from this discontinued operation, which would reduce net earnings and could be material.

In addition, we may not be able to successfully negotiate the sale of Research Instruments, which could result in additional charges to the income statements related to restructuring of this operation. If we are not able to fully implement our plans for any reason, our results of operations or our operating margins may be adversely affected.

## COMPLETION OF THE SALE OF RESEARCH INSTRUMENTS MAY RESTRICT OUR ABILITY TO COMPETE IN CERTAIN MARKET SECTORS

It is possible that in order to sell Research Instruments, we may be required to agree to refrain from competing, either directly or indirectly, with the research instruments business or from entering certain market sectors for a defined period of time.

## WE UTILIZE DISTRIBUTORS FOR A PORTION OF OUR SALES, THE LOSS OF WHICH COULD HARM OUR REVENUES IN THE TERRITORY SERVICED BY THESE DISTRIBUTORS

We have strategic relationships with a number of key distributors for sales and service of our products, principally in foreign countries. If these strategic relationships are terminated and not replaced, our revenues and/or ability to service our products in the territories serviced by these distributors could be adversely affected.

43

## HEALTHCARE REFORMS, CHANGES IN HEALTHCARE POLICIES AND CHANGES TO THIRD-PARTY REIMBURSEMENTS FOR RADIATION ONCOLOGY SERVICES MAY AFFECT DEMAND FOR OUR PRODUCTS

The United States government has in the past, and may in the future, consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect both private and public reimbursement for healthcare services. State and local governments, as well as a number of foreign governments, are also considering or have adopted such policies. These policies have included, and may in the future include, rationing of government-funded reimbursement for healthcare services and imposing price controls on medical products and services providers. Future significant changes in the healthcare systems in the United States or elsewhere, including those that may reduce reimbursement rates for our products or procedures using our products and those changes that may be proposed by the new U.S. Presidential administration, could have a negative impact on the demand for our products and services and our business. A number of U.S. healthcare reforms are currently being discussed and/or proposed, but it is unclear which, if any, of these reforms might be enacted by the U.S. Congress and signed into law by the new Presidential administration. We are unable to predict what healthcare reform legislation or regulations, if any, will be enacted in the United States or elsewhere, whether other healthcare legislation or regulations affecting our business may be proposed or enacted in the future, or what effect any legislation or regulation would have on our business.

In addition, sales of some of our products indirectly depend on whether adequate reimbursement is available to our customers for the treatment provided by those products from third-party healthcare payors, such as government healthcare insurance programs, including the Medicare and Medicaid programs, private insurance plans, health maintenance organizations and preferred provider organizations. 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. As a result, decisions by the Centers for Medicare and Medicaid Services, or 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. While we believe reimbursement policies and amounts are not a major factor in our customer purchasing decisions for radiotherapy products, a dramatic change in the availability and amount of reimbursement for treatments using our products could influence our customers—decisions. Any sharp cuts in overall reimbursement rates for radiotherapy, radiosurgery, proton therapy or brachytherapy could increase uncertainty and reduce demand for our products and have a material adverse effect on our revenues and stock price.

As a general matter, third-party payors are increasingly challenging the pricing of medical procedures or limiting or prohibiting reimbursement for specific services or devices, 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. 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 reimbursement from third-party payors. Foreign governments also have their own healthcare reimbursement systems, and there is an emerging private sector. We cannot be sure that adequate reimbursement will be made available with respect to our products under any foreign reimbursement system.

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

We have experienced and expect in the future to experience fluctuations in our operating results, including net orders, revenues and gross margins. Many of our products require significant capital

44

expenditures by our customers. Accordingly, individual product orders can be quite large in dollar amounts, which can extend the customer purchasing cycle. We have experienced this with our IGRT products, and expect this to be even greater with our proton therapy products because of the high cost of the equipment and the complexity of project financing. With the current general economic turmoil and contraction in credit markets, the purchasing cycle may extend even further as potential customers more closely scrutinize and prioritize their capital spending budgets, and analyze appropriate financing alternatives. With larger projects, such as the purchase of a proton therapy system, the contraction in credit markets could cause customers to delay or cancel their projects, or request participation in financing arrangements or payment concessions in their agreements with us, which could negatively impact our cash flows and results of operations. In addition, some of our more sophisticated equipment, such as IGRT and proton therapy products, requires greater site preparation and longer construction cycles, which can delay installation. For proton therapy products, this can delay the customer decision cycles even further. The timing of when individual orders are placed, installation is accomplished and the revenues recognized could have an effect our quarterly results.

Once orders are received, factors that may affect whether these orders become revenues and the timing include:

- delay in shipment due, for example, to longer construction projects or unanticipated construction delays at customer locations where our
  products are to be installed, cancellations or rescheduling by customers, extreme weather conditions, natural disasters, port strikes or
  manufacturing difficulties;
- delay in the installation and/or acceptance of a product;
- a change in a customer s financial condition or ability to obtain financing; or
- appropriate regulatory approvals or authorizations.

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

- changes in our or our competitors pricing or discount levels;
- changes or anticipated changes in third-party reimbursement amounts or policies applicable to treatments using our products;
- revenues becoming affected by seasonal influences;
- timing of revenue recognition;
- changes in foreign currency exchange rates;
- changes in the relative portion of our revenues represented by our various products, including the relative mix between higher margin and lower margin products;
- changes in the relative portion of our revenues represented by the international regions;

- timing of the announcement, introduction and delivery of new products or product enhancements by us and by our competitors;
- fluctuation in our effective tax rates resulting from various factors, which may or may not be known to us in advance;
- disruptions in the supply or changes in the costs of raw materials, labor, product components or transportation services;
- disruptions in our operations, including our ability to manufacture products, caused by events such as earthquakes, fires, floods, terrorist attacks or the outbreak of epidemic diseases;
- changes in the general economic conditions or tightening of credit available to our customers in the regions in which we do business;

45

#### **Table of Contents**

- the possibility that unexpected levels of cancellations of orders may affect certain assumptions upon which we base our forecasts and predictions of future performance;
- the impact of changing levels of sales to sole purchasers of certain of our x-ray products;
- the unfavorable outcome of any litigation;
- misleading information in the financial community; and
- accounting adjustments, such as those relating to accounting reserves for product recalls, reserves for excess and obsolete inventories, share-based compensation expense as required under Statement of Financial Accounting Standards No. 123 (revised 2004), or SFAS 123(R), accounting for income taxes, and adoption of new accounting pronouncements.

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

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

#### OUR RESULTS OF OPERATIONS MAY BE ADVERSELY IMPACTED BY A WORLDWIDE MACROECONOMIC DOWNTURN

In 2008, general worldwide economic conditions have experienced a downturn due to the sequential effects of the subprime lending crisis, general credit market crisis, collateral effects on the finance and banking industries, volatile currency exchange rates and energy costs, concerns about inflation, slower economic activity, decreased consumer confidence, reduced corporate profits and capital spending, adverse business conditions and liquidity concerns. These conditions may make it difficult for our customers, our vendors and us to accurately forecast and plan future business activities. We cannot predict the timing or duration of any economic slowdown or the timing or strength of a subsequent economic recovery, in general or specifically in the healthcare industry. If the healthcare market significantly deteriorates due to these macroeconomic effects, our business, financial conditions and results of operations will likely be materially and adversely affected.

#### THE FINANCIAL RESULTS OF OUR PROTON THERAPY BUSINESS MAY FLUCTUATE AND BE UNPREDICTABLE

Our proton therapy projects are highly customized and vary in size and complexity. Planning for these projects will take more time and use more resources than those in the radiotherapy business conducted in our Oncology Systems segment. Due to its relatively large scale, the construction of a proton therapy facility requires significant capital investment and may involve complex project financing. If we are required to establish special purpose entities to finance and manage a proton therapy project, we may be

46

required to consolidate these special purpose entities in our financial statements, or guarantee performance and assume liabilities that are in excess of the project value, which could negatively impact our financial results. Further, the current worldwide economic turmoil and contraction in credit markets may make it more difficult for customers of this business to find appropriate financing for large proton therapy projects, which could cause them to delay or cancel their projects, or request participation in financing arrangements or payment concessions in their agreements with us. In addition, due to their size and complexity, the sales and customer decision cycles for proton therapy projects may take several years. As a result, the timing of these projects may vary significantly from period to period, and our operating results and the trading price of VMS common stock may be adversely affected.

In addition, many of the components used in proton therapy equipment require a long lead time, which may translate into an increase in our levels of inventory. This may cause fluctuations in the operating results of our Proton Therapy business that may make it difficult to predict our operating results and to compare our financial results from period to period. This could have an adverse effect on the trading price of VMS common stock.

Moreover, entrance into the proton therapy business may subject us to increased risk and potential liability. For example, because proton therapy projects are large in scale and require detailed project planning, failure to deliver on our commitments could result in greater than expected liabilities, as we could be required to indemnify business partners and customers for losses suffered or incurred if we are unable to deliver our products in accordance with the terms of customer contracts. These indemnification provisions could be limited to a percentage of the value of the project; however, due to the high dollar value of proton therapy projects, the liability that we would assume may nevertheless be substantial. Additionally, while the proton therapy market is still developing and proton therapy as a treatment modality is not yet widely utilized, customers are requesting that the systems vendor, as the primary technology provider, provide guarantees for and suffer penalties in relation to the overall construction project. Since each proton therapy center project may cost up to \$100 million, the amount of potential liability may be higher than the levels historically assumed by us for our traditional radiation therapy business. Insurance covering these contingencies may be unobtainable. If we cannot reasonably mitigate or eliminate these contingencies, our ability to competitively bid upon proton center projects will be negatively impacted and we may be required to assume material amounts of potential liability, all of which may have adverse consequences to our ACCEL Proton Therapy business. In addition, we have encountered and may encounter additional challenges in the commercialization of the proton therapy products, which may increase our research and development costs and delay the introduction of our products. This and other unanticipated events could adversely affect our business and make our results of operations unpredictable.

WE ARE IN THE PROCESS OF UPGRADING AND MODIFING OUR ENTERPRISE RESOURCE PLANNING AND OTHER KEY SOFTWARE APPLICATIONS, WHICH COULD CAUSE UNEXPECTED PROBLEMS TO OCCUR AND COULD DISRUPT THE MANAGEMENT OF OUR BUSINESS

We are in the process of upgrading and modifying the enterprise resource planning, or ERP, system used for our worldwide operations, as well as other key software applications used in our global operations. Our ERP system is integral to our ability to accurately and efficiently maintain our books and records, record transactions, manage our personnel records, provide critical information to our management and prepare our financial statements. The upgrade involves some process re-engineering, and has been costly, difficult and time-consuming to implement. In addition, we may encounter future difficulties, costs or other challenges with this upgrade, any of which may disrupt our business, divert management time, cause us to incur additional costs or result in significant deficiencies or material weakness in our internal control over financial reporting. Corrections and improvements may be required as we upgrade and modify our systems, procedures and controls, and could cause us to delay the project, incur additional costs and require additional management attention, placing burdens on our internal resources.

47

If we fail to manage these changes effectively, it could adversely affect our ability to manage our business and, as a further consequence, affect our operating results. Moreover, we have capitalized the costs associated with this upgrade on our financial statements. If this project is not successful and cannot be completed, we would have to recognize the costs associated with the project as operating expenses in the quarter that we realize that it cannot be completed. This expense recognition would have an adverse impact on our operating results, and this could have an adverse effect on the trading price of VMS common stock.

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

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

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

We prepare our financial statements to conform with GAAP. These principles are subject to interpretation by the Financial Accounting Standards Board, American Institute of Certified Public Accountants, the Public Company Accounting Oversight Board, the Securities and Exchange Commission and various other regulatory or accounting bodies. A change in interpretations of, or our application of, these principles can have a significant effect on our reported results and may even affect our reporting of transactions completed before a change is announced. Additionally, as we are required to adopt new accounting standards, our methods of accounting for certain items may change, which could cause our results of operations to fluctuate from period to period. For example, as a result of our adoption of FIN 48, our effective tax rate and other related financial metrics have fluctuated and may in the future fluctuate more than they have in prior periods.

As our operations evolve over time, we may introduce new products or new technologies that require us to apply different accounting principles, including those regarding revenue recognition, than we have applied in past periods. For example, if we develop products that contain more software components, we may be required to recognize revenue for the software components together with the hardware components in accordance with software revenue recognition rules, which could delay recognition of some revenue. Additionally, while we recognize revenue for many of our Oncology Systems products in accordance with Staff Accounting Bulletin No. 104 Revenue Recognition and SOP No. 97-2, Software Revenue Recognition, as amended by SOP No. 98-9, Software Revenue Recognition with Respect to Certain Agreements, we recognize revenues for certain contracts for products and services in the ACCEL

48

Proton Therapy business and certain products and services in the SIP business, under the percentage-of-completion method in accordance with SOP 81-1, *Accounting for Performance of Construction-Type and Certain Product Type Contracts*, which affects the timing of revenue recognition. We could be required to apply this method to other businesses in the future. Under the percentage-of-completion method of accounting, sales and gross profit are recognized as work is performed based on the relationship between actual costs incurred and total estimated costs at the completion of the contract. If a loss is expected on a contract, the estimated loss would be charged to cost of sales in the period the loss is identified. Because the percentage-of-completion method involves considerable use of estimates in determining revenues, costs and profits and in assigning dollar amounts to relevant accounting periods, and because the estimates must be periodically reviewed and appropriately adjusted, if our estimates are not accurate or circumstances change over time, we would be required to adjust revenues or even record a contract loss, and our financial results could suffer. The application of different types of accounting principles and related potential adjustments may make it more difficult to compare our financial results from quarter to quarter, and the trading price of VMS common stock could suffer or become more volatile as a result.

## THE NATURE OF OUR BUSINESS EXPOSES US TO ENVIRONMENTAL CLAIMS, CLEANUP COSTS, OR EXPENSES, WHICH COULD CAUSE US TO PAY SIGNIFICANT AMOUNTS

We are subject to a variety of environmental laws around the world regulating the handling, storage, transport and disposal of hazardous materials and which impose liability for the cleanup of any contamination from these materials; these laws may create increased costs for some of our operations. Although we follow procedures that we consider appropriate under existing regulations, these procedures can be costly and we cannot completely eliminate the risk of contamination or injury from these hazardous materials; in the event of such an incident, we could be held liable for any damages that result. We do not maintain insurance for clean up costs or third-party claims resulting from environmental contamination which could occur in the future. We do, however, maintain insurance policies that may provide coverage for cleanup costs or third-party claims resulting from some historical occurrences of environmental contamination although this insurance coverage may be inadequate to cover these costs or claims. We could also be assessed fines or penalties for failure to comply with environmental laws and regulations.

In addition, we may be required to incur significant additional costs to comply with future changes in existing environmental laws and regulations or new laws and regulations. For example, several countries, including many in the EU, are requiring medical equipment manufacturers to bear some or all of the cost of product disposal at the end of the product suseful life, thus creating increased costs for our operations. The EU has also adopted a directive that may require the adoption of restrictions on the use of certain hazardous substances in certain of our products sold in the EU. This directive along with another that requires material disclosure information to be provided upon request, could create increased costs for our operations. All of these costs, and any future violations or liabilities under environmental laws or regulations, could have a material adverse effect on our business.

## AS A STRATEGY TO ASSIST OUR SALES EFFORTS, WE MAY OFFER EXTENDED PAYMENT TERMS, WHICH MAY POTENTIALLY RESULT IN HIGHER DSO AND GREATER PAYMENT DEFAULTS

We offer longer or extended payment terms for qualified customers in some circumstances. During fiscal year 2008, customer contracts with longer or extended payment terms amounted to approximately 4% of total Oncology Systems revenues. While we qualify customers to whom we offer longer or extended payment terms, we cannot assure you that the financial positions of these customers will not change adversely over the longer time period given for payment. In such an event, we may experience an increase in payment defaults, which will affect our net earnings. Also, longer or extended payment terms have and may in the future result in an increase in our days sales outstanding.

49

## OUR OPERATIONS ARE VULNERABLE TO INTERRUPTION OR LOSS DUE TO NATURAL OR OTHER DISASTERS, POWER LOSS, STRIKES AND OTHER EVENTS BEYOND OUR CONTROL, WHICH WOULD ADVERSELY AFFECT OUR BUSINESS

We conduct a significant portion of our activities, including manufacturing, administration and data processing at facilities located in the State of California and other seismically active areas that have experienced major earthquakes in the past, as well as other disasters. We carry limited earthquake insurance. This coverage may not be adequate or continue to be available at commercially reasonable rates and terms. A major earthquake or other disaster affecting our facilities (such as a major fire, flood or terrorist attack), or those of our suppliers, could significantly disrupt our operations, and delay or prevent product manufacture and shipment during the time required to repair, rebuild or replace our or our suppliers manufacturing facilities; these delays could be lengthy and result in large expenses. If any of our customers facilities are adversely affected by a disaster, shipments of our products could be delayed even further. In addition, our facilities, particularly those located in the western states of the United States, may be subject to a shortage of available electrical power and other energy supplies. Any shortages may increase our costs for power and energy supplies or could result in blackouts, which could disrupt the operations of our affected facilities and harm our business. Further, our products are typically shipped from a limited number of ports, and any disaster, strike or other event blocking shipment from these ports could delay or prevent shipments and harm our business.

## THE EFFECT OF TERRORISM OR AN OUTBREAK OF EPIDEMIC DISEASES MAY NEGATIVELY AFFECT SALES AND HINDER OUR OPERATIONS

Concerns about terrorism, the effects of a terrorist attack or an outbreak of epidemic diseases such as Severe Acute Respiratory Syndrome and Avian Influenza (especially in our major markets of North America or Europe) could have a negative effect on our business operations, those of our suppliers and customers, and the ability to travel, resulting in adverse consequences on our revenues and financial performance.

#### SINCE OUR STOCKHOLDER RIGHTS PLAN EXPIRED, WE COULD FACE A HIGHER RISK OF A TAKEOVER

Our stockholder rights plan expires in December 2008. We may not be able to implement a similar stockholder rights plan, which could put us at risk for a take-over, distract our management and adversely affect our business.

#### Item 1B. Unresolved Staff Comments

None.

#### Item 2. Properties

As of September 26, 2008, we owned or leased a total of approximately 1.7 million square feet of floor space for our office, manufacturing, research and development and other services worldwide. Our executive offices and our Oncology Systems management and some of our Oncology Systems manufacturing facilities are located in Palo Alto, California on 30 acres of land under leaseholds which expire in 2056. We own these facilities which contain 255,234 square feet of aggregate floor space. We also own 47,037 square feet of floor space and 2 acres of land in Crawley, England. In Beijing, China we own 138,618 square feet of space which resides on 5 acres of land under a leasehold that expires in 2056. Our X-ray Products business segment is located in Salt Lake City, Utah, where we own 38 acres of land and 340,812 square feet of floor space. In Las Vegas, Nevada, we own 147,071 square feet of floor space and 8 acres of land for our SIP manufacturing, Oncology Systems customer services and support operations. Two Las Vegas buildings and the related land have been pledged as collateral against loans

50

#### **Table of Contents**

with a balance of \$6.1 million at September 26, 2008. The Ginzton Technology Center, located in Mountain View, California is under a land and improvements lease that expires in 2012. Our other facilities are leased.

We are occupying substantially all of our currently available productive space to develop, manufacture, service and market our products. We believe that our facilities and equipment are generally well maintained and in good operating condition.

In October 2008, to support the growth in our operations and our longer term objective of co-locating our operations, we consummated an agreement with VI for their surrender to us, for \$21 million to be paid over a two-year period, of their sublease of a building containing approximately 210,000 square feet of floor space and the related leasehold interest for the land, which extends to 2056, located adjacent to our corporate headquarter in Palo Alto, California.

#### Item 3. Legal Proceedings

The following summarizes the current status of our previously reported legal proceedings.

After the spin-offs, we retained the liabilities related to the medical systems business. In addition, under the agreement governing the spin-offs, we agreed to manage and defend liabilities related to legal proceedings and environmental matters arising from corporate or discontinued operations. Each of VI and VSEA must generally indemnify us for one-third of these liabilities (after adjusting for any insurance proceeds we realize or tax benefits we receive), including specified environmental-related liabilities and to fully assume and indemnify us for liabilities arising from each of their operations before the spin-offs. For a discussion of environmental-related liabilities, see MD&A Environmental Matters.

From time to time, we are involved in other legal proceedings arising in the ordinary course of our business and, from time-to-time, acquired as part of business acquisitions that we make. See MD&A Other Matters. While we cannot assure you as to the ultimate outcome of any legal proceeding or other loss contingency involving us, management does not believe any pending matter will be resolved in a manner that would have a material adverse effect on our business.

#### Item 4. Submission of Matters to a Vote of Security Holders

None.

51

#### PART II

#### Item 5. Market for the Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is traded on the New York Stock Exchange, or NYSE, under the symbol VAR. The following table sets forth the high and low sales prices for our common stock as reported in the consolidated transaction reporting system for the NYSE in fiscal years 2008 and 2007.

	High	Low
Fiscal Year 2008		
First Quarter	\$ 53.22	\$ 40.22
Second Quarter	\$ 54.71	\$ 41.37
Third Quarter	\$ 53.29	\$ 43.64
Fourth Quarter	\$ 65.84	\$ 48.58
Fiscal Year 2007		
First Quarter	\$ 56.00	\$ 46.77
Second Quarter	\$ 50.21	\$ 44.01
Third Quarter	\$ 49.04	\$ 39.45
Fourth Quarter	\$ 45.23	\$ 37.30

Since the spin-offs and becoming Varian Medical Systems, Inc., we have not paid any cash dividends on our common stock. We have no current plan to pay cash dividends on our common stock, and will review that decision periodically. Further, our existing unsecured term loan and revolving credit facility agreements contain provisions that limit our ability to pay cash dividends. Specifically, dividends would not be permitted if, when aggregated with other transactions, we would not be in compliance with our financial covenants. See Note 6 Credit Facilities of the Notes to the Consolidated Financial Statements for more information on our revolving credit facility.

As of November 17, 2008, there were approximately 3,627 holders of record of our common stock.

#### PERFORMANCE GRAPH

This graph shows the total return on Varian Medical Systems, Inc. common stock and certain indices from September 26, 2003 until the last day of fiscal year 2008.

#### COMPARISON OF FIVE YEAR CUMULATIVE TOTAL RETURN\*

AMONG VARIAN MEDICAL SYSTEMS, INC.,

THE S&P 500 INDEX AND

THE S & P HEALTHCARE EQUIPMENT INDEX

\* \$100 invested on 9/26/03 in stock or on 9/30/03 in index-including reinvestment of dividends. Indexes calculated on month-end basis.

	9/26/03	10/1/04	9/30/05	9/29/06	9/28/07	9/26/08
Varian Medical Systems, Inc.	100.00	122.29	139.49	188.49	147.89	215.99
S&P 500	100.00	113.87	127.82	141.62	164.90	128.66
S&P Health Care Equipment	100.00	124.06	122.91	118.51	142.38	141.47

The performance graph and related information shall not be deemed to be soliciting material or to be filed with the SEC or to be deemed to be incorporated by reference to any filing under the Securities Act or the Exchange Act.

53

#### **Stock Repurchase Program**

The following table provides information with respect to the shares of VMS common stock repurchased by VMS during the fourth quarter of fiscal year 2008.

Period	Total Number of Shares Purchased	Pa	age Price iid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
June 28, 2008 July 25, 2008	450,000	\$	50.91	450,000	6,890,000
July 26, 2008 August 22, 2008	361,945(1)	\$	62.73(1)	350,000	6,540,000
August 23, 2008 September 26, 2008	650,000	\$	61.95	650,000	5,890,000
Total	1,461,945	\$	58.74	1,450,000	

On July 24, 2007, our Board of Directors approved the repurchase of 12,000,000 shares of our common stock over a period beginning on July 30, 2007 through December 31, 2008. As of September 26, 2008, 5,890,000 shares remained available for repurchase under the July 2007 authorization. On November 17, 2008, we announced that our Board of Directors had authorized the repurchase of an additional 8,000,000 shares of our common stock from January 1, 2009 through December 31, 2009. We expect repurchases will be made in accordance with Rule 10b-18 and include plans designed to satisfy the Rule 10b5-1 safe harbor. Shares will be retired upon repurchase.

(1) Consists of 11,945 shares of VMS common stock that were tendered to VMS in satisfaction of tax withholding obligations for vested restricted common stock granted under the Company s employee stock plans.

#### Item 6. Selected Financial Data

We derived the following selected financial data from our audited consolidated financial statements for the five fiscal years from September 27, 2003 to September 26, 2008. The following financial data should be read in conjunction with our consolidated financial statements and the accompanying notes and the MD&A included elsewhere herein.

#### **Summary of Operations:**

(In millions, except per share amounts)	2008	2007	Fiscal Years 2006	2005	2004
Revenues	\$ 2,069.7	\$ 1,755.1	\$ 1,597.8	\$ 1,382.6	\$ 1,235.5
Earnings from continuing operations before taxes	426.0	346.0	318.7	308.3	258.0
Taxes on earnings(1)	130.7	103.1	75.1	101.7	90.3
Earnings from continuing operations	295.3	242.9	243.6	206.6	167.7
Earnings (Loss) from discontinued operations, net of taxes(2)	(15.8)	(3.4)	1.5		
	, ,	, ,			
Net earnings(1)(3)	\$ 279.5	\$ 239.5	\$ 245.1	\$ 206.6	\$ 167.7
1,00 001111185(1)(0)	Ψ 2//10	Ψ 20>10	<b>4</b> 2.0.1	Ψ 200.0	Ψ 10,.,
Net earnings (loss) per share Basic(1)(3)(4)					
Continuing operations	\$ 2.37	\$ 1.91	\$ 1.86	\$ 1.56	\$ 1.23
Discontininued operations(2)	(0.13)	(0.03)	0.01	,	, ,,,,,,
1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1	(2, 2)	(3,332)			
Net earnings per share	\$ 2.24	\$ 1.88	\$ 1.87	\$ 1.56	\$ 1.23
The curinings per share	Ψ 2.2 .	Ψ 1.00	Ψ 1.07	Ψ 1.50	Ψ 1.23
Net earnings (loss) per share Diluted(1)(3)(4)					
Continuing operations	\$ 2.31	\$ 1.86	\$ 1.80	\$ 1.50	\$ 1.18
Discontininued operations(2)	(0.12)	(0.03)	0.01		
, , , , , , , , , , , , , , , , , , ,		(1111)			
Net earnings per share	\$ 2.19	\$ 1.83	\$ 1.81	\$ 1.50	\$ 1.18
The currings per share	Ψ 2.17	Ψ 1.03	φ 1.01	Ψ 1.50	Ψ 1.10
Financial Position at Fiscal Year End:					
Working capital	\$ 612.7	\$ 378.5	\$ 512.1	\$ 473.0	\$ 434.2
Total assets					
	40.4	49.4	57.3	60.0	58.5
Short-term borrowings		41.0			
Stockholders equity	1,027.2	821.5	797.3	659.0	624.2
Long-term debt (including current maturities) Short-term borrowings		41.0			

- (1) During fiscal year 2006, we repatriated approximately \$128 million in foreign earnings pursuant to the American Jobs Creation Act of 2004 and recorded a \$12 million net tax benefit. We also recorded a net tax benefit of \$7.2 million in fiscal year 2006 related to adjustments of certain prior years—state and federal temporary differences.
- (2) In September 2008, we approved a plan to sell Research Instruments. Accordingly, the Company classified the operating results as a discontinued operation in the Consolidated Statement of Earnings for all periods presented. The net loss of \$15.8 million and \$3.4 million was reported in discontinued operations for fiscal years 2008 and 2007, respectively.

In fiscal year 1995, Varian Associates, Inc. completed the sale of its Electron Devices business segment. The transaction was accounted for as discontinued operations. In fiscal year 2006, we recognized a pre-tax gain from discontinued operations of \$2.5 million and a related tax expense of \$1.0 million. The net gain of \$1.5 million resulted from the release of a reserve for certain contingencies associated with the Electron Devices business segment. Following release of that reserve, we no longer had any asset or liability related to discontinued operations.

(3) For fiscal years 2008, 2007 and 2006, net earnings included share-based compensation expense, net of taxes, of \$27.4 million, \$29.7 million and \$26.9 million, respectively, under SFAS 123(R). For fiscal years 2005 and 2004, net earnings included share-based compensation expense related to restricted stock, net of taxes, of \$0.7 million and \$0.8 million, respectively, which were recorded under

Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees. See Note 11 Employee Stock Plans of the Notes to the Consolidated Financial Statements.

(4) On June 14, 2004, our Board of Directors declared a two-for-one stock split in the form of a 100% stock dividend. The distribution of the shares was made on July 30, 2004 to stockholders of record as of June 30, 2004. All references to the number of shares and per share amounts of our common stock have been retroactively restated to reflect the increased number of shares resulting from the two-for-one stock split.

55

#### Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

#### Overview

In fiscal year 2008, total revenues from continuing operations grew 18% and net orders from continuing operations rose 15% over fiscal year 2007 results. Both of our business segments contributed to the increases in revenues and net orders. Compared to the prior fiscal year, Oncology Systems revenues in fiscal year 2008 increased 16% and net orders increased 14%. The significant growth in the flat panel detector product line drove X-ray Products revenues and net orders to increase 19% and 24%, respectively, over the prior fiscal year. Revenues in our Other businesses rose 62% in fiscal year 2008 over the year-ago period, while net orders declined 7%. Backlog at the end of fiscal year 2008 rose 14% from the end of fiscal year 2007 to \$1.9 billion.

Net earnings from continuing operations per diluted share increased 24% to \$2.31 in fiscal year 2008 from \$1.86 in fiscal year 2007, with net earnings from continuing operations increasing 22% to \$295 million in fiscal year 2008 from \$243 million in fiscal year 2007. In the fourth quarter of fiscal year 2008, we approved a plan to sell Research Instruments in order to focus exclusively on the development of our ACCEL Proton Therapy business. Accordingly, Research Instruments is classified as a discontinued operation for all periods presented and we have segregated the net assets and operating results of Research Instruments from continuing operations on our Consolidated Balance Sheets and in our Consolidated Statement of Earnings. Unless otherwise stated, the discussion herein pertains to our continuing operations. Research Instruments was previously included in the Other category. The Research Instruments business reduced total net earnings per diluted share by \$0.12 for fiscal year 2008 to \$2.19.

Oncology Systems. Our largest business segment is Oncology Systems, which designs, manufacturers, sells and services hardware and software products for radiation treatment of cancer with conventional radiation therapy, IMRT, IGRT, stereotactic radiotherapy and stereotactic radiosurgery, brachytherapy and VMAT.

Oncology Systems net orders grew in fiscal year 2008 over fiscal year 2007 primarily driven by demand for our new RapidArc radiotherapy products since their introduction in the second quarter of fiscal year 2008. We also experienced growth in demand in both the North American and the international regions for our high energy linear accelerators and our service contracts. Growth in demand for our accessory products that enable IGRT (including our OBI) primarily in the international region also contributed. A weaker U.S. dollar against foreign currencies in fiscal year 2008 compared to fiscal year 2007 also contributed to the international net order growth between the fiscal years.

In fiscal year 2008, we experienced strong demand for our new RapidArc products, with more than 300 orders booked in the year. We believe RapidArc will contribute to the growth in our Oncology Systems revenues in fiscal year 2009. Most of the orders for RapidArc came from North America, where early adopters are typically concentrated. We believe RapidArc represents a significant advancement in IMRT cancer treatment and can help drive longer term demand for our linear accelerators and our IMRT-related accessory products.

Customers are also recognizing IGRT and stereotactic radiosurgery as significant enhancements in curative radiation therapy. We believe treatments using IGRT technology are becoming widely accepted in radiation therapy and radiosurgery, with North America ahead of international regions in the timing of IGRT adoption. About 80% of worldwide orders taken for our high energy linear accelerators during fiscal year 2008 included our OBI. Through September 26, 2008, we had shipped more than 1,000 units of OBI for our high-energy linear accelerators.

We believe regional fluctuations in demand are consistent with an observed historical pattern where the international regions follow North America in the adoption of new technology. We are also experiencing faster early adoption rates for our RapidArc products and IGRT products than historical adoption rates for our other products, which may lead to more compressed growth cycles. As was the case in fiscal year

56

2008, we believe that growth in our net orders, revenues and gross margin may also be influenced by the fluctuation of exchange rates of the U.S. dollar against foreign currencies. The weakening U.S. dollar that we have experienced over the last several years has made our pricing more competitive with our foreign competitors, which has been a contributor to our international order and revenue growth. The strengthening of the U.S. dollar against other foreign currencies may make our pricing less competitive and result in slower growth in our international orders and revenues, which then could negatively affect our overall financial performance and results. Additionally, we have seen the purchasing cycle lengthen for some customers, which we believe results from a more complex decision-making process associated with larger dollar value transactions for more sophisticated IGRT and surgical equipment and other technical advances. Revenues are also influenced by the timing of product shipments which are tied to planned customer-requested delivery dates. These factors may result in greater fluctuation in our Oncology Systems net orders and revenues.

Our success in Oncology Systems largely depends upon our ability to retain leadership in technological innovation, the reliability and cost effectiveness of our products, the efficacy of our treatment technology and external economic influences. Factors affecting the adoption rate of new technologies such as IGRT and VMAT could include their more-widely demonstrated efficacy and acceptance of these technologies and our internal efficiency in design, documentation and testing, and deployment and installation of our new technologies and products. Additional factors could include customer training on the use of our new technologies or related products and our ability to educate customers about the cost effectiveness of our new technologies and clinical outcome advantages. External economic influences could include financial strength of our customers, the availability of credit to our customers, consolidation among our customers, currency exchange rates, significant changes to Medicare and Medicaid reimbursement rates for radiotherapy and brachytherapy procedures and radiosurgery in the United States, government budgeting and tendering cycles and governmental healthcare policies. The general worldwide economic downturn we have seen in 2008 may make it difficult for our customers, our vendors and us to accurately forecast and plan future business activities. A customer s decision-making process may be further complicated as the current worldwide economic turmoil causes hospitals, clinics and research institutions to more closely scrutinize and prioritize their capital spending budgets. We cannot predict the timing or duration of any economic slowdown or the timing or strength of a subsequent economic recovery, in general or specifically in the healthcare industry. If the healthcare market significantly deteriorates due to these macroeconomic effects, our business, financial condition and results of operations will likely be materially and adversely affected.

*X-Ray Products.* Our X-ray Products business segment manufactures and sells (i) x-ray tubes for use in a range of applications including computed tomography, or CT, scanning, radiographic or fluoroscopic imaging, mammography, special procedures and industrial applications and (ii) flat panel digital image detectors for filmless x-ray imaging (commonly referred to as flat panel detectors or digital image detectors), which are an alternative to image intensifier tubes for fluoroscopy and x-ray film and computed radiography, or CR, systems for radiography.

X-ray Products growth in net orders and revenues in fiscal year 2008 over fiscal year 2007 was primarily due to strong growth in our flat panel detector product line which we believe will continue to contribute to our growth as flat panel detectors, which enable filmless x-ray, replace traditional film and image-intensifier x-ray products in many medical applications. Rising costs of raw materials due to increased worldwide demand, which we have seen over the last two years, continued to affect the X-ray Products business through most of fiscal year 2008, though we have recently seen decreases in some commodity prices for our materials as the economic downturn has become more worldwide and global demand for such commodities have lessened. In December 2007, we acquired Pan-Pacific, an independent distributor of medical x-ray tubes and other imaging components in China, for approximately \$2.0 million, plus an additional contingent earn out payment of up to \$3.5 million. Pan-Pacific enhances the sales channel for x-ray tubes and flat panel products in China.

57

#### **Table of Contents**

Our success in our X-ray Products business depends upon our ability to anticipate changes in our markets, the direction of technological innovation and the demands of our customers. Factors affecting the success of our X-ray Products business include our ability to develop products with lower cost, better quality and superior technology and performance, and to maintain strong relationships with our OEM customers. The general worldwide economic downturn we have seen in 2008 may make it difficult for our OEM customers, our vendors and us to accurately forecast and plan future business activities. If the markets for our customers significantly deteriorate due to these macroeconomic effects, our business and results of operations may be adversely affected.

*Other*. The Other category is comprised of Security and Inspection Products, or SIP (including Bio-Imaging Research, Inc., or BIR, which we acquired in the third quarter of fiscal year 2007), the ACCEL Proton Therapy business, and the operations of the Ginzton Technology Center, or GTC.

SIP 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 for a variety of applications.

We are now seeing wider deployment of our Linatron x-ray accelerators for cargo screening and border protection as customers are placing orders for multiple units. While we are optimistic about SIP s long-term potential and encouraged by the increased interest in our SIP products, use of this technology in security cargo screening and border protection is still in its early stages. Orders and revenues for our SIP products may be unpredictable as governmental agencies may place large orders with our OEM customers in a short time period and then may not place any orders for a long time period thereafter. In April 2008, we added a new manufacturing facility for the production of SIP products in Las Vegas.

Our ACCEL Proton Therapy business develops, designs, manufactures and services products and systems for delivering proton therapy, another form of external beam radiation therapy using proton beams for the treatment of cancer. Proton therapy, as a clinical treatment modality, is still not wide-spread and the technology is still developing. We are investing substantial resources to commercialize ACCEL s advanced proton technology and to build this new business. Proton therapy facilities, nevertheless, are large scale construction projects that can take three years or more to complete. With the cost of a multiple-gantry system in excess of \$60 million and the total cost for a center approaching \$100 million, significant customer investment and perhaps complex project financing will be required. Consequently, the customers decision-making cycle is very long and orders for proton therapy systems generally involve many contingencies. Since we currently will not book these orders until contingencies are eliminated, we do not expect to book any orders for proton therapy systems in the short term and do not expect to start generating significant proton therapy systems revenues until fiscal year 2010 at the earliest. Given the heavy reliance of customers of this business on credit and large-scale project financing, this business may be the most vulnerable to general economic turmoil and contraction in the credit markets.

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.

Compared to fiscal year 2007, net orders in the Other category were down 7% in fiscal year 2008 due primarily to a reduction in the proton therapy service business. Revenue grew by 62% in fiscal year 2008 over the year-ago period due to growth in SIP product revenues.

This discussion and analysis of our financial condition and results of operations is based upon and should be read in conjunction with the Consolidated Financial Statements and the notes included elsewhere in this Annual Report on Form 10-K, as well as the information contained under Risk Factors contained in Item 1A. We discuss our results of operations below.

58

#### **Critical Accounting Estimates**

The preparation of our financial statements and related disclosures in conformity with accounting principles generally accepted in the United States, or GAAP, requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. These estimates and assumptions are based on historical experience and on various other factors that we believe are reasonable under the circumstances. We periodically review our accounting policies and estimates and make adjustments when facts and circumstances dictate. In addition to the accounting policies that are more fully described in the Notes to the Consolidated Financial Statements included in this Annual Report on Form 10-K, we consider the critical accounting policies described below to be affected by critical accounting estimates. Our critical accounting policies that are affected by accounting estimates include share-based compensation expense, revenue recognition, valuation of allowance for doubtful accounts, valuation of inventories, assessment of recoverability of goodwill and intangible assets, valuation of warranty obligations, assessment of environmental remediation liabilities, valuation of defined benefit and post-retirement benefit plans and taxes on earnings. Such accounting policies are impacted significantly by judgments, assumptions and estimates used in the preparation of our Consolidated Financial Statements, and actual results could differ materially from these estimates. For a discussion of how these estimates and other factors may affect our business, also refer to the Risk Factors in Item 1A.

#### Share-based Compensation Expense

Effective October 1, 2005, we adopted Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123(R), using the modified prospective transition method. We have valued our share-based payment awards granted beginning in fiscal year 2006 using the Black-Scholes option-pricing model. The determination of fair value of share-based payment awards on the date of grant using the Black-Scholes option-pricing model is affected by VMS s stock price, as well as the input of other subjective assumptions, including the expected term of stock awards and the expected price volatility of VMS stock over the expected term of the awards.

The expected term is based on the observed and expected time to post-vesting exercise and post-vesting cancellations of stock options by our employees. Upon the adoption of SFAS 123(R), we determined the expected term of stock options based on the demographic grouping of employees and retirement eligibility. Upon the adoption of SFAS 123(R), we used a combination of historical and implied volatility, or blended volatility, in deriving the expected volatility assumption. Blended volatility represents the weighted average of implied volatility and historical volatility. Implied volatility was derived based on six-month traded options on VMS common stock. Implied volatility is weighted in the calculation of blended volatility based on the ratio of the six-month term of the exchange-traded options to the expected lives of the employee stock options. Historical volatility represents the remainder of the weighting. Our decision to incorporate implied volatility was based on our assessment that implied volatility of publicly traded options in VMS common stock is reflective of market conditions and is generally reflective of both historical volatility and expectations of how future volatility will differ from historical volatility. In determining the extent of use of implied volatility, we considered: (i) the volume of market activity of traded options; (ii) the ability to reasonably match the input variables of traded options to those of stock options granted by us, including the date of grant; (iii) the similarity of the exercise prices; and (iv) the length of term of traded options. After considering the above factors, we determined that we cannot rely exclusively on implied volatility based on the fact that the term of VMS six-month exchange-traded options is less than one year and that it is different from the expected lives of the stock options we granted. Therefore, we believe a combination of the historical volatility over the expected lives of the stock options granted by us and the implied volatility of six-month exchange-traded options best reflects the expected volatility of VMS common stock going forward. The risk-free interest rate assumption is based upon observed interest rates appropriate for the term of our stock options. The dividend yield assumption is based on our history and expectation of dividend payouts. If factors change

59

and we employ different assumptions in the application of SFAS 123(R) in future periods, the compensation expense that we record under SFAS 123(R) may differ significantly from what we have recorded in the current period. In addition, we are required to estimate the expected forfeiture rate and recognize expense only for those shares expected to vest. If our actual forfeiture rate is materially different from our estimate, the stock-based compensation expense could be significantly different from what we have recorded in the current period.

#### Revenue Recognition

We frequently enter into sales arrangements with customers that contain multiple elements or deliverables such as hardware, software and services. Judgments as to the allocation of the proceeds received from an arrangement to the multiple elements of the arrangement, the determination of whether any undelivered elements are essential to the functionality of the delivered elements and the appropriate timing of revenue recognition are critical in respect to these arrangements to ensure compliance with GAAP. In addition, the amount of product revenues recognized is affected by our judgments as to whether objective and reliable evidence of fair value exists for hardware products and vendor-specific objective evidence of the fair value for software products in arrangements with multiple elements. Changes to the elements in an arrangement and the ability to establish objective and reliable evidence of fair value or vendor-specific objective evidence of the fair value for those elements could affect the timing of revenue recognition. Revenue recognition also depends on the timing of shipment and is subject to customer acceptance and the readiness of customers facilities. If shipments are not made on scheduled timelines or if the products are not accepted by the customer in a timely manner, our reported revenues may differ materially from expectations. In addition, revenues related to certain highly customized scientific research instrument products and proton therapy commissioning service contracts, as well as highly customized image detection systems, are recognized under the percentage of completion method. Under the percentage-of-completion method of accounting, sales and gross profit are recognized as work is performed based on the relationship between actual costs incurred and total estimated costs at the completion of the contract. If a loss is expected on a contract, the estimated loss would be charged to cost of sales in the period the loss is identified. Because the percentage-of-completion method involves considerable use of estimates in determining revenues, costs and profits and in assigning the amounts to accounting periods, and because the estimates must be periodically reviewed and appropriately adjusted, if our estimates prove to be inaccurate, we may be forced to adjust revenues or even record a contract loss in later periods.

#### Allowance for Doubtful Accounts

Credit evaluations are undertaken for all major sale transactions before shipment is authorized. Normal payment terms usually require payment of a small portion of the total amount due upon signing of the purchase order, a significant amount upon transfer of risk of loss and the remaining amount upon completion of the installation. On a quarterly basis, we evaluate aged items in the accounts receivable aging report and provide an allowance in an amount we deem adequate for doubtful accounts. If our evaluation of our customers financial conditions does not reflect the future ability to collect outstanding receivables, additional provisions may be needed and our operating results could be negatively impacted.

#### **Inventories**

Our inventories include high technology parts and components that are specialized in nature or subject to rapid technological obsolescence. We have programs to minimize the required inventories on hand and we regularly review inventory quantities on hand and adjust for excess and obsolete inventory based primarily on historical usage rates and our estimates of product demand and production. Actual demand may differ from our estimates, in which case we may have understated or overstated the provision required for obsolete and excess inventory, which would have an impact on our operating results.

60

#### Goodwill and Intangible Assets

Goodwill is initially recorded when the purchase price paid for a business acquisition exceeds the estimated fair value of the net identified tangible and intangible assets acquired. The majority of companies that we have acquired have not had significant identified tangible assets and, as a result, a significant portion of the purchase price has been typically allocated to intangible assets and goodwill. Our future operating performance will be impacted by the future amortization of these acquired intangible assets and potential impairment charges related to goodwill if indicators of impairment exist. As a result of business acquisitions, the allocation of the purchase price to goodwill and intangible assets could have a significant impact on our future operating results. The allocation of the purchase price of the acquired companies to goodwill and intangible assets requires us to make significant estimates and assumptions, including estimates of future cash flows expected to be generated by the acquired assets and the appropriate discount rate for these cash flows. Should conditions differ from management s estimates at the time of the acquisition, material write-downs of intangible assets and/or goodwill may be required, which would adversely affect our operating results.

We annually evaluate goodwill and purchased assets with indefinite lives for impairment in accordance with SFAS 142 *Goodwill and Other Intangible Assets*. The impairment test for goodwill is a two-step process. Step one consists of a comparison of the fair value of a reporting unit with its carrying amount, including the goodwill allocated to each reporting unit. We determine the fair value of our reporting units based on the present value of estimated future cash flows of the reporting units. If the carrying amount is in excess of the fair value, step two requires the comparison of the implied fair value of the reporting unit s goodwill with the carrying amount of the reporting unit s goodwill. Any excess of the carrying value of the reporting unit s goodwill over the implied fair value of the reporting unit s goodwill is recorded as an impairment loss. The impairment test for intangible assets with indefinite useful lives, if any, consists of a comparison of fair value to carrying value, with any excess of carrying value over fair value being recorded as an impairment loss. We will continue to make assessments of impairment on an annual basis in the fourth quarter of our fiscal years or more frequently if indicators of potential impairment arise.

#### Warranty Obligations

We warrant most of our products for a specific period of time, usually twelve months, against material defects. We provide for the estimated future costs of warranty obligations in cost of revenues when the related revenues are recognized. The accrued warranty costs represent our best estimate at the time of sale of the total costs that we will incur to repair or replace product parts that fail while still under warranty. The amount of accrued estimated warranty costs obligation for established products is primarily based on historical experience as to product failures adjusted for current information on repair costs. For new products, estimates will include historical experience of similar products, as well as reasonable allowance for start-up expenses. Actual warranty costs could differ from the estimated amounts. On a quarterly basis, we review the accrued balances of our warranty obligations and update the historical warranty cost trends, if required. If we were required to accrue additional warranty costs in the future, it would negatively impact our operating results.

#### **Environmental Matters**

We are subject to a variety of environmental laws around the world regulating the handling, storage, transport and disposal of hazardous substances that do or may create increased costs for some of our operations. Environmental remediation liabilities are recorded when environmental assessments and/or remediation efforts are probable and the costs of these assessments or remediation efforts can be reasonably estimated, in accordance with SFAS No. 5, *Accounting for Contingencies*, and the American Institute of Certified Public Accountants, Statement of Position 96-1, *Environmental Remediation Liabilities*. The accrued environmental costs represent our best estimate as to the total costs of remediation and the time period over which these costs will be incurred. On a quarterly basis, we review

61

these accrued balances. If we were required to accrue additional environmental remediation costs in the future, it would negatively impact our operating results.

#### Defined Benefit and Post-Retirement Benefit Plans

We sponsor six defined benefit pension plans in Germany, Japan, Switzerland and the United Kingdom covering the employees who meet the applicable eligibility requirements. In July 2007, we made changes to the defined benefit plan in the United Kingdom by terminating the accrual of additional benefits for existing participants and suspending the enrollment of new participants. We also sponsor a post-retirement benefit plan that provides healthcare benefits to certain eligible retirees in the United States. We do not have any defined benefit pension plans in the United States. Several statistical and other factors that attempt to anticipate future events are used in calculating the expense and liability related to those plans for which the benefit is actuarially determined. These factors include assumptions about the discount rate, expected return on plan assets, rate of future compensation increases and healthcare cost increases, which we determine within certain guidelines. In addition, we also use subjective factors, such as withdrawal and mortality rates, to calculate the expense and liability. The actuarial assumptions we use are long-term assumptions and may differ materially from actual experience particularly in the short term due to changing market and economic conditions and changing participant demographics. These differences may have a significant impact on the amount of pension expense we record.

The expected rates of return on the various defined benefit pension plans assets are based on the asset allocation of each plan and the long-term projected return of those assets. The discount rate enables us to state expected future cash flows at a present value on the measurement date. The discount rates used for defined benefit plans in all countries are primarily based on the yields of a universe of high of quality corporate bonds in each country or the spot rate on high quality AA-rated corporate bonds, with durations corresponding to the expected durations of the benefit obligations. In countries where the corporate bond market is not sufficiently representative at longer durations, the discount rate also takes into account the yield of long-term government bonds corresponding to the duration of the benefit obligations and the difference between the yield curve on high quality corporate fixed-income investments and government fixed-income investment. A lower discount rate increases the present value of benefit obligations. See Note 9 Retirement Plans of Notes to Consolidated Financial Statements for a detailed discussion of our defined benefit and post-retirement benefit plans.

#### Taxes on Earnings

We are subject to taxes on earnings in both the United States and numerous foreign jurisdictions. As a global taxpayer, significant judgments and estimates are required in evaluating our tax positions and determining our provision for taxes on earnings.

Effective as of the beginning of fiscal year 2008, we adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*, or FIN 48. FIN 48 contains a two-step approach to recognizing, derecognizing and measuring uncertain tax positions accounted for in accordance with SFAS No. 109, *Accounting for Income Taxes*. The first step is to evaluate the tax position for recognition by determining whether the weight of available evidence indicates that it is more likely than not that, based on the technical merits, the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. Recognition, derecognition, and measurement are based on management s best judgment given the facts, circumstances and information available at the end of the accounting period. A tax benefit should be recognized in the first period in which it meets the more likely than not recognition threshold, and conversely, a tax benefit previously recognized should be derecognized in the first period in which new information results in a change in judgment in which the position fails to meet the recognition threshold. A benefit not previously recognized would be recognized when the tax position is effectively settled through examination, negotiation or litigation with tax authorities, or when the statute

62

of limitations for the relevant taxing authority to examine and challenge the position has expired. Our policy to include interest and penalties related to unrecognized tax benefits within the provision for taxes on earnings did not change as a result of the adoption of FIN 48.

In addition, the carrying value of our net deferred tax assets assumes that we will be able to generate sufficient future taxable earnings in certain tax jurisdictions to utilize these deferred tax assets. Should we conclude it is more likely than not that we will be unable to recover our net deferred tax assets in these tax jurisdictions, we would increase our valuation allowance and our tax provision would increase in the period in which we make such a determination.

Earnings derived from our international regions are generally taxed at rates lower than U.S. rates. Our effective tax rate is impacted by existing tax laws in both the United States and in the respective countries in which our international subsidiaries do business. In addition, a decrease in the percentage of our total earnings from our international regions, or a change in the mix of international regions among particular tax jurisdictions, could increase our effective tax rate. Also, our current effective tax rate does not assume U.S. taxes on certain undistributed profits 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.

#### **Results of Operations**

#### Fiscal Year

Our fiscal year is the 52- or 53-week period ending on the Friday nearest September 30. Fiscal year 2008 comprised the 52-week period ended on September 26, 2008. Fiscal year 2007 comprised the 52-week period ended on September 28, 2007 and fiscal year 2006 was the 52-week period ended on September 29, 2006. Set forth below is a discussion of our results of operations for the fiscal years 2008, 2007 and 2006. As indicated above, the operating results of Research Instruments have been segregated and presented as a discontinued operation for all periods.

#### Discussion of Results of Operations for Fiscal Years 2008, 2007 and 2006

#### Total Revenues

Revenues by sales classification			Fiscal Years		
(Dollars in millions)	2008	% Change	2007	% Change	2006
Product	\$ 1,690	17%	\$ 1,448	8%	\$ 1,342
Service Contracts and Other	380	24%	307	20%	256
Total Revenues	\$ 2,070	18%	\$ 1,755	10%	\$ 1,598
Product as a percentage of total revenues	82%		82%		84%
Service Contracts and Other as a percentage of total					
revenues	18%		18%		16%
Revenues by region					
North America	\$ 1,003	16%	\$ 865	7%	\$ 807
Europe	619	17%	529	18%	450
Asia	349	24%	281	10%	255
Rest of world	99	24%	80	(7%)	86
Total International(1)	1,067	20%	890	13%	791
Total	\$ 2,070	18%	\$ 1,755	10%	\$ 1,598
	,		•		
North America as a percentage of total revenues	48%		49%		51%
International as a percentage of total revenues	52%		51%		49%

(1) We consider international revenues to be revenues outside of North America.

63

Total revenues increased in fiscal year 2008 over fiscal year 2007 and increased in fiscal year 2007 over fiscal year 2006 primarily due to increases in Oncology Systems revenues in each year, as well as contributions from the X-ray Products business segment and the Other category. The foregoing increase in total revenues in each year was also primarily due to the growth in product revenues, and to a lesser extent, an increase in service contracts and other revenues.

Growth in product revenues in fiscal year 2008 over fiscal year 2007 and in fiscal year 2007 over fiscal year 2006 was due to contributions from Oncology Systems, X-ray Products and SIP. Product revenues grew at a higher rate in fiscal year 2008 than in fiscal year 2007 over year-ago periods primarily due to higher growth in Oncology Systems product revenues. The rate of growth in total service contracts and other revenues was higher in fiscal year 2008 over fiscal year 2007 than the growth rate in fiscal year 2007 over fiscal year 2006 primarily due to growth in Oncology Systems service contracts revenues in each of those fiscal years.

International revenue growth exceeded the North American revenue growth in fiscal year 2008 over fiscal year 2007 and in fiscal year 2007 over fiscal year 2006 due in part to the weaker U.S. dollar against foreign currencies. Since fiscal year 2007, international revenues have represented more than half of our worldwide revenues. In fiscal year 2008, both business segments and SIP contributed to the revenue growth over fiscal year 2007 in all geographic regions. In fiscal year 2007, both business segments and our businesses in the Other category contributed to the revenue growth over the prior fiscal year in all geographic regions, except for the rest of the world region where Oncology Systems revenues declined.

#### **Oncology Systems Revenues**

Revenues by sales classification			Fiscal Years		
(Dollars in millions)	2008	% Change	2007	% Change	2006
Product	\$ 1,302	14%	\$ 1,145	5%	\$ 1,088
Service Contracts(1)	370	26%	295	19%	248
Total Oncology Systems	\$ 1,672	16%	\$ 1,440	8%	\$ 1,336
Product as a percentage of Oncology Systems revenues	78%		80%		81%
Service Contracts as a percentage of Oncology Systems					
revenues	22%		20%		19%
Oncology Systems revenues as a percentage of total revenues	81%		82%		84%

(1) Revenues from service contracts represent revenues from fixed-term service contracts and labor cost services. This excludes revenues from spare parts sold by our service department.

The increases in Oncology Systems product revenues for fiscal year 2008 over fiscal year 2007 were primarily driven by increased revenues from sales of our high energy linear accelerators, our treatment planning and information management software products and our accessory products that enable IGRT (including our OBI). However, these revenue increases in fiscal year 2008 over fiscal year 2007 were partially offset by a decline in revenues from sales of IMRT-upgrades, reflecting the continued slowdown in demand for IMRT-upgrade products after several years of rapid adoption of IMRT technology. The U.S. dollar s weakness against foreign currencies in fiscal year 2008 compared to that of fiscal year 2007 also contributed to the increase in Oncology Systems revenues. In fiscal year 2007, the increase in Oncology Systems product revenues over fiscal year 2006 was driven by higher sales volume of accessory products that enable IGRT; partially offset by lower sales volume of our high-energy linear accelerators and other non-IGRT products such as IMRT upgrades, simulators and brachytherapy products. The higher rate of product revenue growth in fiscal year 2008 over fiscal year 2007 compared to fiscal year 2007 over fiscal year 2006 was due primarily to the weak first half net orders in fiscal year 2007. Because a portion of our orders for products are shipped within one year of the placement of such order from the

customer, our fiscal year 2007 product revenues were adversely impacted since there were less product orders to ship within the fiscal year. During fiscal year 2007, Oncology Systems revenues were also negatively impacted by the timing of product shipments in accordance with planned customer-requested delivery dates.

The increase in service contract revenues in fiscal year 2008 over fiscal year 2007 and in fiscal year 2007 over fiscal year 2006 was primarily driven by increased customer adoption of service contracts as the sophistication of our products and installed base of software products increased and was also favorably impacted by the U.S. dollar s weakness against foreign currencies. Since service contract revenues grew faster than product revenues from fiscal year 2006 to fiscal year 2007 and from fiscal year 2007 to fiscal year 2008, service contract revenues also increased as a percentage of total Oncology Systems revenues in the same time periods.

Revenues by region (Dollars in millions)	2008	% Change	Fiscal Years 2007	% Change	2006
North America	\$ 866	15%	\$ 754	7%	\$ 705
Europe	517	14%	454	12%	404
Asia	200	25%	160	8%	148
Rest of world	89	24%	72	(9%)	79
Total International	806	18%	686	9%	631
Total Oncology Systems	\$ 1,672	16%	\$ 1,440	8%	\$ 1,336
	,				
North America as a percentage of Oncology Systems					
revenues	52%		52%		53%
International as a percentage of Oncology Systems					
revenues	48%		48%		47%

All of our geographic regions contributed to the Oncology Systems revenues growth in fiscal year 2008 over fiscal year 2007. The higher revenue growth rate in fiscal year 2008 over fiscal year 2007 in both the North American and international regions, as compared with the growth rate in fiscal year 2007 over fiscal year 2006, was primarily due to the weak net orders growth in the first half of fiscal year 2007 which resulted in lower shipment volumes and revenues in the second half of fiscal year 2007. For fiscal year 2008, the growth in international revenues over fiscal year 2007 was due to increases in product revenues in all international regions from sales of our high energy linear accelerators, our accessory products that enable IGRT (including our OBI) and our treatment planning and information management software products, as well as an increase in service contracts revenues. The U.S. dollar s weakness against foreign currencies in fiscal year 2008 compared to most of fiscal year 2007 also contributed to the increase in Oncology Systems international revenues. These increases in international revenues were partially offset by decreases in product revenues from sales of IMRT-upgrades, primarily in Europe, reflecting the continued slowdown in demand for IMRT-upgrade products after several years of rapid adoption of IMRT technology. North American revenues grew in fiscal year 2008 over fiscal year 2007 primarily due to increases in product revenues from sales of our high energy linear accelerators, our treatment planning and information management software products and our accessory products that enable IGRT (including our OBI), as well as an increase in service contracts revenues. A decrease in product revenues from IMRT-upgrades partially offset these increases in North American revenues.

All of our geographic regions, except the rest of the world region, contributed to the Oncology Systems revenues growth in fiscal year 2007 over fiscal year 2006. The growth in North American revenues in fiscal year 2007 over the year-ago period was primarily due to the higher sales volume of our accessory products that enable IGRT (including our OBI), as well as increase in service contracts revenues, partially offset by lower sales volume of our high-energy linear accelerators. The increase in international revenues in fiscal year 2007 over the prior year was primarily due to the increase in international service contract revenues and the increase in sales volume of our accessory products that

enable IGRT and our high-energy linear accelerators in Europe and Asia, which was partially offset by lower sales volume of other non-IGRT products such as, simulators and brachytherapy products in Europe, and the decrease in sales volume of our high-energy linear accelerators in the rest of world region.

Varying cycles of higher and lower revenues between the international and North American regions is a historical pattern reflecting different technology adoption cycles and demand cycles that is consistent with the net order patterns discussed more fully under Net Orders. Oncology Systems revenues also continued to be influenced by the timing of product shipments in accordance with planned customer-requested delivery dates.

#### X-ray Products Revenues

Revenues by region			Fiscal Years		
(Dollars in millions)	2008	% Change	2007	% Change	2006
North America	\$ 107	12%	\$ 96	9%	\$ 88
Europe	45	28%	35	24%	28
Asia	143	21%	119	13%	105
Rest of world	10	21%	8	11%	7
Total International	198	22%	162	15%	140
Total X-ray Products	\$ 305	19%	\$ 258	13%	\$ 228
North America as a percentage of X-ray Products revenues	35%		37%		38%
International as a percentage of X-ray Products revenues	65%		63%		62%
X-ray Products revenues as a percentage of total revenues	15%		15%		14%

X-ray Products higher revenue growth in fiscal year 2008 over fiscal year 2007 as compared to the growth in fiscal year 2007 over fiscal year 2006 was the result of significant revenue growth in our flat panel detector product line in fiscal year 2008. All of our geographic regions contributed to the increase in X-ray Products revenues for fiscal years 2008 and 2007. The growth in X-ray Products revenues in both the international and in North American regions in fiscal year 2008 over fiscal year 2007 similarly reflects increased revenues from sales of our flat panel detectors and, to a lesser extent, increased revenues from sales of our x-ray tubes in international regions.

The growth in X-ray Products revenues in North America in fiscal year 2007 over fiscal year 2006 was primarily driven by increased revenues from sales of our flat panel detectors, whereas the growth in international revenues in fiscal year 2007 over fiscal year 2006 was primarily driven by increased revenues from sales of our high power, anode grounded CT scanning tubes and our flat panel detectors.

We believe the flat panel detector product line will continue to contribute to our growth in X-ray Products revenues as flat panel detectors, which enable filmless x-ray, replace traditional film and image-intensifier x-ray products in many medical applications.

#### Other Revenues

Revenues by sales classification		F	iscal Years		
(Dollars in millions)	2008	% Change	2007	% Change	2006
Product	\$ 83	84%	\$ 45	76%	\$ 26
Service Contracts and Other	10	(21%)	12	53%	8
Total Other	\$ 93	62%	\$ 57	71%	\$ 34
Other revenues as a percentage of total revenues	4%		3%		2%

66

For our Other category, which includes SIP, ACCEL Proton Therapy and GTC, revenues in fiscal year 2008 increased over the prior fiscal year primarily due to growth in product revenues in our SIP business. The higher product revenues from SIP were attributable to increased sales of our Linatron x-ray accelerators and image detection products to OEM customers for cargo screening and border protection. Revenues in the Other category in fiscal year 2007 increased over fiscal year 2006 primarily due to the higher sales volume of our Linatron x-ray accelerators to our OEM customers for cargo screening and border protection.

#### Gross Margin

			Fiscal Years		
(Dollars in millions)	2008	% Change	2007	% Change	2006
Dollar by segment					
Oncology Systems	\$ 723	19%	\$ 609	6%	\$ 573
X-ray Products	120	16%	104	30%	80
Other	35	71%	20	97%	10
Gross margin	\$ 878	20%	\$ 733	10%	\$ 663
Percentage by segment					
Oncology Systems	43.2%		42.3%		42.9%
X-ray Products	39.3%		40.2%		34.9%
Total Company	42.4%		41.8%		41.5%

In fiscal year 2008, total gross margin improved by 0.6 percentage points compared with fiscal year 2007, primarily due to the increase in gross margin for Oncology Systems and SIP, partially offset by the decline in gross margin for X-ray Products. In fiscal year 2007, total gross margin increased by 0.3 percentage points from fiscal year 2006 primarily due to significant improvement in gross margin of X-ray Products and SIP, which was partially offset by a decrease in Oncology Systems gross margin.

Product gross margin was 41.7% in fiscal year 2008, compared to 41.1% and 41.2% in fiscal years 2007 and 2006, respectively. Service contracts and other gross margin was 45.5% in fiscal year 2008, compared to 44.9% and 43.4% in fiscal years 2007 and 2006, respectively. Improvements in both product and service contracts gross margins contributed to the higher gross margin achieved in Oncology Systems in fiscal year 2008 compared to fiscal year 2007. Product gross margin in Oncology Systems increased from 41.4% in fiscal year 2007 to 42.4% in fiscal year 2008 primarily due to higher sales volume and product mix shift toward higher margin products. Service contracts gross margin in Oncology Systems increased from 45.7% in fiscal year 2007 to 46.1% in fiscal year 2008 primarily due to higher contract volumes and growth in higher margin software maintenance contracts.

Oncology Systems gross margin decreased 0.6 percentage points in fiscal year 2007 over fiscal year 2006. In fiscal year 2007, Oncology Systems gross margin benefited from increases in service contracts gross margin but was unfavorably impacted by decreases in product gross margins over the prior year, which more than offset the service contract gross margin increase. Service gross margin increased from 44.1% in fiscal year 2006 to 45.7% in fiscal year 2007 due primarily to higher volume and the continued growth in higher margin software maintenance contracts. The 0.6 percentage points decrease in Oncology Systems product gross margin in fiscal year 2007 from the prior year was primarily due to the effect of hedging foreign currency denominated sales contracts when the orders were booked. While the weakening of the U.S. dollar positively affected our revenues in fiscal year 2007, it had a negative impact on our Oncology Systems gross margin percentage.

The X-ray Products gross margin decrease of 0.9 percentage points in fiscal year 2008 from fiscal year 2007 was primarily due to increased raw material costs and quality costs for x-ray tube products and increased raw material costs for flat panel products, although these increases were partially offset by the

product mix shift toward a greater proportion of flat panel detectors which generally carry higher margin than x-ray tube products. X-ray Products gross margin in fiscal year 2007 increased by 5.3 percentage points from the fiscal year 2006 as a result of (i) product mix shift towards sales of higher margin high power, anode grounded CT scanning tubes and flat panel detectors, (ii) cost reduction efforts and (iii) leverage from higher sales volume. X-ray Products gross margin will continue to be impacted by factors such as sales mix between and among flat panel detectors and x-ray tube products, product pricing, timing of new product introduction, cost reduction efforts and material costs. Rising costs of raw materials due to increased worldwide demand, which we have seen over the last two years, continued through most of fiscal year 2008 and primarily affected our X-ray Products business. With the recent worldwide economic downturn, global demand for such commodities has lessened and we have seen decreases in some commodity prices for our materials.

#### Research and Development

			Fiscal Years		
(Dollars in millions)	2008	% Change	2007	% Change	2006
Research and development	\$ 136	16%	\$ 117	17%	\$ 100
As a percentage of total revenues	7%		7%		6%

The \$19 million increase in research and development expense for fiscal year 2008 over fiscal year 2007 was driven by a \$14 million increase in Oncology Systems and a \$5 million increase in the Other category. The \$14 million increase in research and development expenses in Oncology Systems for fiscal year 2008 compared to fiscal year 2007 was attributable primarily to a \$15 million increase in employee headcount, materials costs and consulting expenses for development of our next generation linear accelerator products, as well as a \$5 million unfavorable currency impact as the research and development expenses in our foreign operations are translated into U.S. dollars. A reduction in \$5 million in expenses related to other product development projects partially offset these effects. The \$5 million increase in the Other category primarily reflected a \$3 million increase in research and development expenses for x-ray accelerator products in SIP.

The \$17 million increase in research and development expenses in fiscal year 2007 resulted from increased spending of \$10 million in Oncology Systems, \$5 million in X-ray Products and \$2 million in the Other category. The \$10 million increase in research and development expenses in Oncology Systems in fiscal year 2007 compared to the year-ago period was attributable primarily to: (a) a \$5 million increase in employee headcount, materials costs and consulting expenses for development of our next generation linear accelerator products, (b) a \$2 million increase in expenses for development of software products, (c) a \$2 million unfavorable foreign currency impact resulting from the relatively weak U.S. dollar as the research and development expenses incurred by our foreign operations was translated into U.S. dollars and (d) an increase in development expenses for radiosurgery products of \$1 million. The \$5 million increase in X-ray Products was primarily due to increased expenses for development projects related to flat panel detectors and X-ray tube products. The \$2 million increase in the Other category was primarily due to an increase of \$1 million associated with research and development at ACCEL, which was acquired in the second quarter of fiscal year 2007 and an increase of \$1 million associated with the expenses incurred by BIR, which was acquired by us in the third quarter of fiscal year 2007.

## Selling, General and Administrative

			Fiscal Years		
(Dollars in millions)	2008	% Change	2007	% Change	2006
Selling, general and administrative	\$ 323	16%	\$ 277	9%	\$ 254
As a percentage of total revenues	16%		16%		16%

68

Our selling, general and administrative expenses as a percentage of revenues has remained flat from fiscal year 2006 to fiscal year 2008. The \$46 million increase in selling, general and administrative expenses for fiscal year 2008 compared to the same period in fiscal year 2007 was primarily attributable to: (a) a \$16 million increase in expenses resulting from an increase in employee-related costs and headcount to support our growing business activities; (b) a \$7 million unfavorable foreign currency impact as the selling, general and administrative expenses of our foreign operations are translated into U.S. dollars; (c) a \$7 million increase in fees for certain commission arrangements and product promotions which were tied to growth in Oncology Systems revenues; (d) a \$7 million increase in expenses primarily related to accruals for contingent legal liabilities and (e) a \$6 million increase in operating expenses associated with ACCEL Proton Therapy, BIR and Pan-Pacific and (f) a loss of \$1 million for hedging balance sheet exposures from our various foreign subsidiaries and business units compared to a gain of \$4 million in fiscal year 2007. These increases were partially offset by the receipt of a \$5 million payment related to resolution of a gain contingency.

The \$23 million increase in selling, general and administrative expenses for fiscal year 2007 compared to fiscal year 2006 was primarily attributable to: (a) operating expenses of \$8 million associated with ACCEL Proton Therapy and BIR, (b) a \$5 million increase in employee-related and other operating expenses associated with required corporate, regulatory and information technology infrastructure improvements to support our growing businesses, (c) a \$4 million increase in fees related to certain commission arrangements, (d) a \$3 million unfavorable foreign currency translation impact resulting from the relatively weak U.S. dollar for our foreign operations as the selling, general and administrative expenses are translated into U.S. dollars, (e) a \$3 million increase in employee-related and other operating expenses related to the expansion of our operations into China and (f) a \$2 million decrease in income on equity investment in dpiX Holding LLC, or dpiX Holding, from the year-ago period (see Note 4 Related Party Transactions in Notes to the Consolidated Financial Statements). These increases were partially offset by \$1.0 million in additional gains recognized for hedging balance sheet exposures from our various foreign subsidiaries and business units.

Interest Income, Net

	Fiscal Years							
(Dollars in millions)	2008	% Change	2007	% Change	2006			
Interest income, net	\$ 6.6	(10%)	\$7.4	(21%)	\$ 9.3			

The decrease in interest income, net, in fiscal year 2008 over fiscal year 2007 was attributable to increased borrowings in fiscal year 2008 and lower average interest rate earned on our cash and cash equivalents in fiscal year 2008. The decrease in interest income, net in fiscal year 2007 over fiscal year 2006 was due to lower balances of cash, cash equivalents and marketable securities and increased borrowings in fiscal year 2007.

## Taxes on Earnings

	Fiscal Years				
	2008	Change	2007	Change	2006
Effective tax rate	31%	1%	30%	6%	24%

The increase in the effective tax rate in fiscal year 2008 compared to fiscal year 2007 primarily because the earlier period included a greater tax benefit realized from the federal research and development credit. The effective tax rate for fiscal year 2007 included the benefit of the federal research and development credit for the full year plus the benefit of a retroactive reinstatement of the credit, which had previously expired on December 31, 2005. By comparison, the federal research and development credit was in effect for only one quarter during fiscal year 2008.

The increase in the effective tax rates in fiscal year 2007 from fiscal year 2006 was primarily due to tax benefits recorded in the prior fiscal year related to (i) the repatriation of foreign earnings under the American Jobs Creation of 2004, or the Job Creation Act, which resulted in a decrease in our effective tax rate of approximately four percentage points in fiscal year 2006, (ii) a deferred tax asset adjustment for certain prior years state and federal temporary differences, which resulted a decrease in our effective tax rate of approximately two percentage points in fiscal year 2006.

In general, our effective income tax rate differs from the U.S. federal statutory rate primarily because our foreign earnings are taxed at rates that are, on average, lower than the U.S. federal rate, and our domestic earnings are subject to state income taxes. Our future effective tax rate could be adversely affected by having lower earnings than anticipated in countries where we have lower statutory rates and higher earnings than anticipated in countries where we have higher statutory rates, by changes in the valuation of our deferred tax assets or liabilities, and by changes in tax laws or interpretations of those laws. We also expect that our effective tax rate may experience increased fluctuation from period to period under the provisions of FIN 48. Please refer to further discussion of the adoption of FIN 48 in Note 12 Income Taxes of the Notes to the Consolidated Financial Statements.

## Net Earnings Per Diluted Share

		Fiscal Years			
	2008	% Change	2007	% Change	2006
Net earnings per diluted share	\$ 2.31	24%	\$ 1.86	3%	\$ 1.80

The increase in earnings per diluted share in fiscal year 2008 over fiscal year 2007 resulted from the increase in total revenues, the improvement in our gross margin, the leverage in our operating expenses, as well as the reduction in outstanding shares of common stock due to stock repurchases. The increase in net earnings per diluted share in fiscal year 2007 over fiscal year 2006 can be attributed to the increase in total revenues and the reduction in outstanding shares of common stock due to stock repurchases, partially offset by the increase in effective tax rate and the decline in profitability due to our planned investments in growth initiatives, including our ACCEL acquisition, research and development, and our expansion into China.

#### **Net Orders**

Total Net Orders (by segment and region) (Dollars in millions)	2008	% Change	Fiscal Years 2007	% Change	2006
Oncology Systems:					
North America	\$ 1,020	13%	\$ 905	5%	\$ 861
Total International	851	16%	731	9%	674
Total Oncology Systems	\$ 1,871	14%	\$ 1,636	7%	\$ 1,535
X-ray Products:					
North America	\$ 131	28%	\$ 102	(8%)	\$ 111
Total International	206	21%	171	30%	131
Total X-ray Products	\$ 337	24%	\$ 273	13%	\$ 242
Other:	\$ 94	(7%)	\$ 101	139%	\$ 43
Total Net Orders	\$ 2,302	15%	\$ 2,010	10%	\$ 1,820

Our total net orders grew in fiscal year 2008 from fiscal year 2007 primarily due to the net order growth in Oncology Systems and, to a lesser extent, net order growth in X-ray Products and SIP, partially offset by a decline in ACCEL Proton Therapy net orders. For fiscal year 2007, all of our businesses contributed to the net order growth over fiscal year 2006.

70

Oncology Systems net orders for fiscal year 2008 grew 14% over fiscal year 2007, compared to 7% growth in fiscal year 2007 over fiscal year 2006. The single digit net order growth in fiscal year 2007 over fiscal year 2006 was the result of a weak net order growth in the first half of the fiscal year, which impacted both the North American and the international regions.

North American Oncology Systems net orders grew 13% in fiscal year 2008 from fiscal year 2007, compared to 5% in fiscal year 2007 from fiscal year 2006. The growth in Oncology Systems North American net orders in fiscal year 2008 over fiscal year 2007 was primarily driven by demand for our new RapidArc products and growth in demand for our high energy linear accelerators, as well as growth in demand for our service contracts. The growth in North American net orders in fiscal year 2007 over fiscal year 2006 reflect continued growth in demand for our products that enable IGRT (including our OBI), our high energy linear accelerators and service contracts, partially offset by declines in demand for non-IGRT products including IMRT upgrades and brachytherapy products.

International net orders for Oncology Systems grew 16% in fiscal year 2008 over the prior year compared to 9% in fiscal year 2007 over fiscal year 2006. All international regions contributed to the international net order growth in fiscal year 2008 over fiscal year 2007. The increase in international net orders in fiscal year 2008 over the prior fiscal year was primarily due to demand for our new RapidArc products and growth in demand for our high energy linear accelerators, as well as growth in demand for our accessory products that enable IGRT (including our OBI). Growth in demand for our service contracts also contributed to Oncology Systems net order growth in the international region. In addition, international Oncology Systems net orders in fiscal year 2008 were favorably impacted by the U.S. dollar s weakness against foreign currencies compared to most of fiscal year 2007. When measured in constant currency, the international Oncology Systems growth rate for fiscal year 2008 was 8%, with increases in all regions. In fiscal year 2007, all geographic regions contributed to the increase in international orders. The growth in international net orders also reflects increased demand for our products that enable IGRT (including our OBI), our high energy linear accelerators and service contracts, partially offset by decrease in demand for other product lines, including IMRT upgrades and brachytherapy products. When measured in constant currency, fiscal year 2007 international Oncology Systems net orders grew 4% with increases in all regions but Europe.

Oncology Systems trailing twelve months net order growth for the last three fiscal quarters were: as of June 27, 2008, 13% total increase, with an 8% increase for North America and an 18% increase for international regions; as of March 28, 2008, 12% total increase, with a 9% increase for North America and a 16% increase for international regions; and as of December 28, 2007, 10% total increase, with a 3% increase for North America and a 19% increase for international regions. Consistent with the historical pattern, we expect that Oncology Systems net orders will continue to experience regional fluctuations.

The increase in X-ray Products net orders in fiscal year 2008 over fiscal year 2007 was primarily due to increased demand for our flat panel detectors and, to a lesser extent, increased demand for our x-ray tube products. The increase in X-ray Products net orders in fiscal year 2007 over fiscal year 2006 was due to increased demand for our high power, anode grounded CT scanning tubes and, to a lesser extent, increased demand for our flat panel detectors. The flat panel detector product line has become a significant contributor to our X-ray Products business segment, and we believe this product line will continue to contribute to our growth as flat panel detectors replace traditional film and image-intensifier x-ray products in many medical, dental and veterinary applications.

Net orders in the Other category, comprised of SIP, ACCEL Proton Therapy business and GTC, decreased 7% in fiscal year 2008 over fiscal year 2007, primarily due to a decrease in net orders for ACCEL proton therapy services partially offset by an increase in SIP net orders. The 139% growth in net orders in fiscal year 2007 over fiscal year 2006 in the Other category was driven by (i) the strong growth in net orders for our SIP Linatron x-ray accelerators for cargo screening and border protection

71

# Edgar Filing: VARIAN MEDICAL SYSTEMS INC - Form 10-K

#### **Table of Contents**

and for replacements of older products for industrial inspection and non-destructive testing and (ii) new orders received for ACCEL proton therapy services.

We are now seeing wider deployment of our Linatron x-ray accelerators for cargo screening and border protection and are optimistic about the long-term potential of our SIP business. However, orders for our SIP products may be unpredictable as governmental agencies may place large orders with our OEM customers in a short period and then may not place any orders for a long time thereafter.

Also, while we believe there is a promising market for proton therapy systems, the market for proton therapy treatment is still developing, and we expect great variability in the demand for these products due to the large scale of the related construction projects, the complexity of project financing and the resulting longer customer decision cycles when compared with our Oncology Systems business. Since we currently will not book these orders until contingencies are eliminated, we do not expect to book an order for a proton therapy system in the short term. Given the heavy reliance of customers of this business on credit and large-scale project financing, this business may be the most vulnerable to general economic turmoil and contraction in credit markets.

In any given period, orders growth in either North America or international regions, or both, could fluctuate because of the high dollar amount of individual orders. The timing of sales and revenue recognition will vary significantly based on the delivery requirements of individual orders, acceptance schedules and the readiness of individual customer sites for installation of our products although the sales and revenue recognition cycles are usually shorter for some types of orders, such as upgrades (*i.e.*, the addition of new features or accessories to existing equipment). Thus, orders in any quarter or period may not be directly correlated to the level of sales or revenues in any particular future quarter or period. Moreover, as the overall mix of net orders includes a greater proportion of software products and newly introduced Oncology Systems products, which typically take more time from order to completion of installation and acceptance, the average time period within which orders convert into sales could lengthen and our revenue in a specific period could be lower as a result.

## **Discontinued Operations**

In the fourth quarter of fiscal year 2008, we approved a plan to sell Research Instruments to focus exclusively on the development of our ACCEL Proton Therapy business. In accordance with the provisions of SFAS 144, Research Instruments became an asset group held for sale in the fourth quarter of fiscal year 2008. Accordingly, we have segregated the net assets and operating results of Research Instrument from continuing operations on our Consolidated Balance Sheets and in our Consolidated Statement of Earnings for all periods presented. Research Instruments was previously included in the Other category. Revenues from Research Instruments were \$35 million and \$22 million for fiscal years 2008 and 2007, respectively. Net loss from Research Instruments increased from \$3 million in fiscal year 2007 to \$16 million in fiscal years 2008, which included a charge of \$3 million for the impairment of long-lived assets and goodwill impairment. See Note 15 Discontinued Operations and Assets Held for Sale to the Consolidated Financial Statements for detailed discussion.

#### Backlog

At September 26, 2008, we had a backlog of \$1.9 billion, an increase of 14% compared to September 28, 2007. Our Oncology Systems backlog at September 26, 2008 increased by 13% from September 28, 2007, including a 16% increase for North America and a 9% increase for international regions.

## **Liquidity and Capital Resources**

Liquidity is the measurement of our ability to meet potential cash requirements, including ongoing commitments to repay borrowings, acquire businesses and fund continuing operations. Our sources of cash include operations, stock option exercises and employee stock purchases, borrowings and interest

72

income. Our cash usage is actively managed on a daily basis to ensure the maintenance of sufficient funds to meet our needs. Because the Research Instruments business s cash flows were not material for any period presented, we have not segregated them from continuing operations on our statements of cash flows and the discussion herein.

#### Cash and Cash Equivalents

The following table summarizes our cash and cash equivalents:

	Septen	nber 26,	Septer	nber 28,			
(In millions)	20	2008		2007		Increase	
Cash and cash equivalents	\$	397	\$	263	\$	134	

Our cash and cash equivalents increased \$134 million from \$263 million at September 28, 2007 to \$397 million at September 26, 2008. The increase in cash and cash equivalents in fiscal year 2008 was primarily due to \$372 million of cash generated from operating activities, \$129 million of cash provided by stock option exercises and employee stock purchases, and \$42 million of cash provided by the excess tax benefits from share-based compensation. These increases were partially offset by cash used for the repurchase of VMS common stock of \$262 million, capital expenditures of \$81 million, net repayments under line of credit agreements of \$41 million and the repayment of bank borrowings of \$9 million. In addition, the effects of exchange rate changes in fiscal year 2008 resulted in a decrease in cash and cash equivalents of \$8 million.

At September 26, 2008, we had approximately \$24 million or 6% of total cash and cash equivalents in the United States. Approximately \$373 million or 94% of total cash and cash equivalents was held abroad and could be subject to additional taxation if it were repatriated to the United States. As of September 26, 2008, most of our cash and cash equivalents that were held abroad were in U.S. dollars. Because our cash levels in the United States are relatively low, we have used our credit facilities to meet our cash needs from time to time and expect to continue to do so in the future. Borrowings under our credit facilities may be used for working capital, capital expenditures, acquisitions and other corporate purposes.

#### Cash Flows

		Fiscal Years	
(In millions)	2008	2007	2006
Net cash flow provided by (used in):			
Operating activities	\$ 372	\$ 300	\$ 202
Investing activities	(88)	(56)	(12)
Financing activities	(142)	(240)	(156)
Effects of exchange rate changes on cash and cash equivalents	(8)	(13)	(5)
Net increase (decrease) in cash and cash equivalents	\$ 134	\$ (9)	\$ 29

Our primary cash inflows and outflows for fiscal years 2008, 2007 and 2006 were as follows:

• We generated net cash from operating activities of \$372 million in fiscal year 2008, compared to \$300 million and \$202 million in fiscal years 2007 and 2006, respectively.

The \$72 million increase in net cash from operating activities during fiscal year 2008 compared to fiscal year 2007 was primarily driven by an increase of \$40 million in net earnings, a net change of \$22 million in operating assets and liabilities (working capital items) and an increase in non-cash items of \$10 million.

# Edgar Filing: VARIAN MEDICAL SYSTEMS INC - Form 10-K

#### **Table of Contents**

The major contributors to the net change in working capital items in fiscal year 2008 were deferred revenues, advance payments from customers, accounts receivable, inventories and prepaid expenses and other current assets as follows:

- Deferred revenues increased by \$40 million primarily due to timing of revenue recognized based on customer acceptance of our Oncology Systems products and the increase in Oncology Systems product revenues.
- Advance payments from customers increased \$23 million due to increased orders.
- Accounts receivables decreased by \$22 million due to strong collection performance in fiscal year 2008.
- Inventories increased by \$56 million due to anticipated customer demands for products in fiscal year 2009 in all of our businesses.
- Prepaid expenses and other current assets increased by \$37 million primarily due to estimated tax payments made during fiscal year 2008 and the overall growth of our business operations.

The \$98 million increase in net cash from operating activities in fiscal year 2007 from fiscal year 2006 was driven by a net change of \$35 million in operating assets and liabilities (working capital items) and a net increase in non-cash items of \$68 million and non-cash net earnings from discontinued operations in fiscal year 2006 of \$1 million, partially offset by a decrease in net earnings of \$6 million.

The major contributors to the net change in working capital items in fiscal year 2007 were inventories, prepaid expenses and other current assets, deferred revenues and advance payments from customers.

- Inventories increased by \$30 million primarily due to higher productions to meet anticipated customer demands for products in all of our businesses.
- Prepaid expenses and other current assets increased by \$13 million due to overall growth of our business operations.
- Deferred revenues decreased by \$16 million due to higher amount of revenues recognized based on customer acceptance of our Oncology Systems products and the recognition of a portion of revenues associated with certain products that enable IGRT upon shipment beginning in the second quarter of fiscal year 2007, rather than deferring 100% of the revenues until customer acceptance.
- Advance payments from customers increased by \$35 million due to increased orders and lower revenue growth in Oncology Systems.

We expect that cash provided by operating activities may fluctuate in future periods as a result of a number of factors, including fluctuations in our operating results, timing of product shipments and customer acceptance, accounts receivable collections, inventory management, and the timing of tax and other payments. For additional discussion, please refer to Risk Factors in Item 1A.

• Investing activities used \$88 million of net cash in fiscal year 2008, \$56 million in fiscal year 2007 and \$12 million in fiscal year 2006. Cash used for purchases of property, plant and equipment was \$81 million in fiscal year 2008, compared to \$64 million and \$41 million in fiscal years 2007 and 2006, respectively. In fiscal year 2008, we also invested \$8 million in a privately held company. In fiscal year

# Edgar Filing: VARIAN MEDICAL SYSTEMS INC - Form 10-K

2007, we used cash of \$27 million to acquire ACCEL and \$21 million to acquire BIR. We also made a \$4 million earn-out payment to Mitsubishi Electric Co., or MELCO, in fiscal year 2007. In fiscal years 2007 and 2006, we invested \$25 million and \$12 million, respectively, in dpiX Holding for the construction of a manufacturing facility in Colorado. Our net proceeds from maturities of marketable securities were \$94 million and \$45 million during fiscal years 2007 and 2006, respectively. We did not hold any marketable securities in fiscal year 2008.

74

• Financing activities used net cash of \$142 million in fiscal year 2008 compared to \$240 million and \$156 million in fiscal years 2007 and 2006, respectively. In fiscal year 2008, we used \$262 million for the repurchases of common stock, compared to \$319 million in fiscal year 2007 and \$271 million in fiscal year 2006. We used \$41 million to repay borrowings under our credit facilities in fiscal year 2008. In fiscal years 2008, 2007 and 2006, we used \$9 million, \$15 million and \$3 million, respectively, in the repayment of bank borrowings. In fiscal year 2007, we also used \$12 million to repurchase the 35% ownership interest in our Japanese subsidiary from MELCO. Cash used for financing activities in fiscal years 2008 and 2006 also includes \$1 million and \$8 million (the value of withheld shares), respectively, used to satisfy employee tax withholding obligations when restricted performance share awards and restricted common stock vested. These uses were partially offset by cash proceeds from employee stock option exercises and employee stock purchases of \$129 million, \$45 million and \$74 million in fiscal years 2008, 2007 and 2006, respectively, as well as cash provided by excess tax benefits from share-based compensation of \$42 million in fiscal year 2008, \$20 million in fiscal year 2007 and \$52 million in fiscal year 2006. In fiscal year 2007, we also borrowed \$41 million in net cash from our credit facility.

We expect our capital expenditures, which typically represent construction and/or purchases of facilities, manufacturing equipment, office equipment and furniture and fixtures, as well as capitalized costs related to the implementation of software applications, will be approximately 3.4% of revenues in fiscal year 2009.

During fiscal year 2008, we had a \$100 million unsecured revolving credit facility with Bank of America, N.A., or the BofA Credit Facility, to support general corporate purposes, including working capital, capital expenditures, permitted acquisitions and other lawful corporate purposes. The BofA Credit Facility would have expired, on July 27, 2009 but was amended and restated subsequent to the end of fiscal year 2008 (see below discussion regarding the amended and restated \$150 million revolving credit facility with Bank of America, N.A.). Borrowings under the BofA Credit Facility accrued interest either (i) based on the London InterBank Offered Rate, or LIBOR, plus a margin of 0.45% to 0.70% based on a leverage ratio involving funded indebtedness and earnings before interest, tax and depreciation and amortization, or EBITDA, or (ii) based upon a base rate of either the federal funds rate plus 0.5% or BofA s announced prime rate, whichever is greater, plus a margin of 1.75% to 2.25% based on a leverage ratio involving funded indebtedness and EBITDA, depending upon our instructions to BofA. The BofA Credit Facility contained customary affirmative and negative covenants for facilities of this type. We also agreed to maintain certain financial covenants relating to (i) leverage ratios involving funded indebtedness and EBITDA, (ii) liquidity and (iii) consolidated assets. As of September 26, 2008, we were in compliance with all covenants and there were no outstanding balances under the BofA Credit Facility.

In May 2008, our Japanese subsidiary, or VMS KK, entered into an agreement with BofA, or the Japanese BofA Credit Facility, providing for a revolving credit facility that enabled VMS KK to borrow in Japanese Yen up to a maximum amount equivalent to \$30 million. On November 10, 2008, the Japanese BofA Credit Facility was terminated. Borrowings under the Japanese BofA Credit Facility could be used by VMS KK for working capital, capital expenditures and other lawful corporate purposes. VMS guaranteed the payment of the outstanding balance under the Japanese BofA Credit Facility. Borrowings under the Japanese BofA Credit Facility accrued interest based on the basic loan rate announced by the Bank of Japan plus a margin customary for this type of facility based on a leverage ratio involving funded indebtedness and EBITDA. Interest rates on advances were adjustable daily. As of September 26, 2008, there was no outstanding balance under the Japanese BofA Credit Facility.

On November 10, 2008, we amended and restated our revolving credit facility with Bank of America, N.A., the Amended BofA Credit Facility. We increased the line of credit to \$150 million and secured a portion of the facility with a pledge of stock issued by certain of our present and future subsidiaries that are deemed to be material subsidiaries under the terms of the Amended BofA Credit Facility. As of November 10, 2008, we have pledged to BofA 65% of the voting shares that we hold in Varian Medical

75

Systems Nederland B.V., a wholly-owned subsidiary. The Amended BofA Credit Facility may be used for working capital, capital expenditures, permitted acquisitions and other lawful corporate purposes. The Amended BofA Credit Facility will expire, if not extended by mutual agreement of us and Bank of America, N.A., on November 10, 2011. Borrowings under the Amended BofA Credit Facility accrue interest either (i) based on LIBOR plus a margin of 1.25% to 1.50% based on a leverage ratio involving funded indebtedness and EBITDA, or (ii) based upon a base rate of either the federal funds rate plus 0.5% or BofA s announced prime rate, whichever is greater, minus a margin of 0.5% to 0% based on a leverage ratio involving funded indebtedness and EBITDA, depending upon our instructions to BofA. We may select borrowing periods of one, two, three or six months for advances based on the LIBOR rate. Interest rates on advances based on the base rate are adjustable daily. As of November 11, 2008, there was no outstanding balance under the Amended BofA Credit Facility. The Amended BofA Credit Facility contains customary affirmative and negative covenants for facilities of this type. We have also agreed to maintain certain financial covenants relating to (i) leverage ratios involving funded indebtedness and EBITDA, (ii) liquidity and (iii) consolidated assets.

For further discussion regarding our credit facilities, please refer to Note 6 Credit Facilities of the Notes to the Consolidated Financial Statements.

Total debt as a percentage of total capital decreased to 3.8% at September 26, 2008 compared to 9.9% at September 28, 2007 largely due to the repayments of outstanding balances under the credit facilities during fiscal year 2008. The ratio of current assets to current liabilities increased to 1.81 to 1 at September 26, 2007 from 1.50 to 1 at September 28, 2007 primarily due to the increase in cash and cash equivalents in fiscal year 2008.

Our liquidity is affected by many factors, some of which result from the normal ongoing operations of our business and some of which arise from uncertainties and conditions in the United States and global economies. Although our cash requirements will fluctuate as a result of the shifting influences of these factors, we believe that existing cash and cash equivalents and cash to be generated from operations and current or future credit facilities will be sufficient to satisfy anticipated commitments for capital expenditures and other cash requirements through fiscal year 2009. We currently anticipate that we will continue to utilize our available liquidity and cash flows from operations, as well as borrowed funds, to repurchase our common stock, make strategic acquisitions, invest in the growth of our business and invest in advancing our systems and processes.

#### Days Sales Outstanding

Trade accounts receivable days sales outstanding, or DSO, were 74 days at September 26, 2008 compared to 88 days at September 28, 2007. Our accounts receivable and DSO are primarily impacted by timing of product shipments, collections performance, payment terms and mix of revenues from different regions. As of September 26, 2008, less than 1% of our accounts receivable balance was related to customer contracts with extended payment terms with more than one year.

#### Stock Repurchase Program

During fiscal years 2008, 2007 and 2006, we paid \$262 million, \$319 million and \$271 million, respectively, to repurchase 5,110,000 shares, 7,000,000 shares and 5,395,100 shares, respectively, of VMS common stock under various Board of Directors authorizations. All shares that have been repurchased have been retired. As of September 26, 2008, 5,890,000 shares of VMS common stock remained available for repurchase under an authorization that expires on December 31, 2008. On November 17, 2008, we announced that our Board of Directors had authorized the repurchase of an additional 8,000,000 shares of our common stock from January 1, 2009 through December 31, 2009.

76

#### **Contractual Obligations**

The following summarizes our contractual obligations as of September 26, 2008 and the effect such obligations are expected to have on our liquidity and cash flows in future periods:

		Payments Due By Period						
	Fiscal	Fiscal Years	Fiscal Years					
(In millions)	Year 2009	2010 - 2011	2012 - 2013	Beyond	Total			
Long term debt(1)	\$ 8.0	\$ 14.5	\$ 11.6	\$ 6.3	\$ 40.4			
Interest obligation on long term debt	2.6	3.6	1.3	0.3	7.8			
Operating Leases(2)	15.2	20.0	11.2	9.6	56.0			
Total(3)	\$ 25.8	\$ 38.1	\$ 24.1	\$ 16.2	\$ 104.2			

(1) At September 26, 2008, we had long-term debt of \$40.4 million. Long-term debt, including current maturities, decreased \$9 million from September 28, 2007 due to principal repayments. The fixed interest rates on the outstanding debt on this date ranged from 6.70% to 7.58% with a weighted average interest rate of 6.88%. As of September 26, 2008, land and buildings with a carrying amount of \$14.4 million were pledged as collateral against certain loans we assumed related to purchases of land and buildings in Las Vegas.

The remaining unsecured loan agreements contain certain covenants relating to loan prepayment, future borrowings and dividend payments. We have also agreed to maintain covenants relating to working capital and operations results. During fiscal years 2008, 2007 and 2006, the Company was in compliance with all restrictive covenants of the unsecured term loan agreements. For further discussion regarding long-term debt, see Note 5 Long-term Debt of the Notes to the Consolidated Financial Statements.

- (2) We lease office space and have entered into other lease commitments in North America as well as various locations in Europe, Asia, Australia and South America. Operating leases include future minimum lease payments under all our noncancelable operating leases as of September 26, 2008.
- (3) As a result of the adoption of FIN 48, we reclassified unrecognized tax benefits to long-term income taxes payable, which is included in Other long-term liabilities in fiscal year 2008. Long-term income taxes payable includes the liability for uncertain tax positions, including interest and penalties, and may also include other long-term tax liabilities. As of September 26, 2008, our liability for uncertain tax positions was \$89.5 million and we do not anticipate payment of these amounts in the next twelve months. We are unable to reliably estimate the timing of future payments related to uncertain tax positions; therefore, the liability for uncertain tax positions has been excluded from the table above.

We have also excluded obligations connected with our pension and post-retirement plans as they are not contractually fixed as to timing and amount. See Note 9 Retirement Plans of Notes to Consolidated Financial Statements for a detailed discussion of these benefit plans.

In October 2008, to support the growth in our operations and our longer term objective of co-locating our operations, we consummated an agreement with VI for their surrender to us, for \$21 million to be paid over a two-year period, of their sublease of a building containing approximately 210,000 square feet of floor space and the related leasehold interest for the land, which extends to 2056, located adjacent to our corporate headquarter in Palo Alto, California.

## Contingencies

We are subject to a variety of environmental laws around the world regulating the handling, storage, transport and disposal of hazardous substances that do or may create increased costs for some of our operations. Although we follow procedures that we consider appropriate under existing regulations,

77

these procedures can be costly and we cannot completely eliminate the risk of contamination or injury from these materials, and, in the event of such an incident, we could be held liable for any damages that result. In addition, we could be assessed fines or penalties for failure to comply with environmental laws and regulations. These costs and any future violations or liability under environmental laws or regulations could have a material adverse effect on our business.

In addition, we may be required to incur significant additional costs to comply with future changes in existing environmental laws and regulations or new laws and regulations. For example, several countries, including many in the European Union, or EU, are requiring medical equipment manufacturers to bear some or all of the cost of product disposal at the end of a product s useful life, thus creating increased costs for our operations. The EU has also adopted a directive that may require the adoption of restrictions on the use of some hazardous substances in certain of our products sold in the EU as well as providing material content information to customers and requested parties. This directive could increase costs for our operations.

From the time we began operating, we handled and disposed of hazardous materials and wastes following procedures that were considered appropriate under regulations, if any, existing at the time. We also hired companies to dispose of wastes generated by our operations. The U.S. Environmental Protection Agency, or EPA, or third parties have named us as a potentially responsible party, or PRP, under the Comprehensive Environmental Response Compensation and Liability Act of 1980, as amended, or CERCLA, at nine sites where we, as Varian Associates, Inc., are alleged to have shipped manufacturing waste for recycling or disposal and, as a PRP we may have an obligation to reimburse the EPA or other third parties for cleanup costs at these sites. In addition, we are overseeing environmental cleanup projects and, as applicable, reimbursing third parties for cleanup activities under the direction of, or in consultation with, federal, state and/or local agencies at certain current VMS or former Varian Associates, Inc. facilities (including facilities disposed of in connection with our sale of our Electron Devices business during 1995 and the sale of our thin film systems business during 1997). Under the terms of the agreement governing the distribution of the shares, or the spin-offs, of Varian, Inc., or VI and Varian Semiconductor Equipment Associates, Inc., or VSEA, by us in 1999, VI and VSEA are each obligated to indemnify us for one-third of these environmental cleanup costs (after adjusting for any insurance proceeds realized or tax benefits recognized by us).

As described below, we have accrued a total of \$14.7 million at September 26, 2008 to cover our liabilities for these cleanup projects.

- Various uncertainties make it difficult to estimate, or determine the likelihood within a range of estimates of, the project management costs, legal costs and costs of certain third-party claims at all of the sites and facilities. In addition, for the nine sites and one of the facilities, various uncertainties make it difficult to assess the likelihood and scope of further cleanup activities or to estimate the future cost of such activities. As of September 26, 2008, we nonetheless estimated that our future exposure (net of VI s and VSEA s indemnification obligations) for the cleanup costs for these ten locations, as well as project management costs, legal costs and the costs of certain third party-claims for all locations ranged in the aggregate from \$3.3 million to \$7.3 million. Management believes that no amount in the range of estimated future costs is more probable of being incurred than any other amount in the range and therefore we have accrued \$3.3 million for these cleanup projects as of September 26, 2008. The amount accrued has not been discounted to present value due to the uncertainties that make it difficult to develop a best estimate of future costs.
- As to all other facilities, we have gained sufficient knowledge to better estimate the scope and costs of future cleanup activities based upon formal agreements with other parties defining our future liabilities or formal cleanup plans that have either been approved by or completed in accordance with the requirements of the state or federal environmental agency with jurisdiction over the facility. As of September 26, 2008, we estimated that our future exposure (net of VI s and

78

VSEA s indemnification obligations) for the cleanup costs at these facilities, and reimbursements of third party s claims for these facilities, ranged in the aggregate from \$6.4 million to \$37.2 million. The time frames over which these cleanup project costs are estimated vary, ranging from 1 year to 30 years as of September 26, 2008. As to each of these facilities, management determined that a particular amount within the range of estimated costs was a better estimate of the future environmental liability than any other amount within the range, and that the amount and timing of these future costs were reliably determinable. The best estimate within the range was \$16.3 million at September 26, 2008. We accordingly accrued \$11.4 million, which represents our best estimate of the future costs of \$16.3 million discounted at 4%, net of inflation.

At September 26, 2008, our reserve for environmental liabilities, based upon future environmental related costs estimated as of that date, was calculated as follows:

(In millions)	Recurring Costs		Non-Recurring Costs		nticipated re Costs
Fiscal Years:					
2009	\$ 0.9	\$	0.9	\$	1.8
2010	0.6		0.7		1.3
2011	0.7		0.7		1.4
2012	0.7		1.2		1.9
2013	0.8		0.5		1.3
Thereafter	10.1		1.8		11.9
Total costs	\$ 13.8	\$	5.8		19.6
Less imputed interest					(4.9)
Reserve amount				\$	14.7

Recurring costs include expenses for such tasks as ongoing operation, maintenance and monitoring of cleanup while non-recurring costs include expenses for such tasks as soil excavation and treatment, injection/monitoring well installation and other costs for soil and groundwater *in situ* treatment by injection, ground and surface water treatment system construction, soil and groundwater investigation, certain governmental agency costs required to be reimbursed by us, governmental agency response costs (including agency costs required to be reimbursed by the responding company), treatment system and monitoring well removal and closure, and costs to defend against and settle pending and anticipated third-party claims.

When we developed the estimates above, we considered the financial strength of other potentially responsible parties. These amounts are, however, only estimates and may be revised in the future as we get more information on these projects. We may also spend more or less than these estimates. Based on current information, we believe that our reserves are adequate, but as the scope of our obligations becomes more clearly defined, these reserves (and the associated indemnification obligations of VI and VSEA) may be modified and related charges/credits against earnings may be made.

We receive certain cash payments in the form of settlements and judgments from defendants, our insurers and other third parties from time to time. We have also reached an agreement with an insurance company under which the insurance company has agreed to pay a portion of our past and future environmental-related expenditures, and we, therefore, had included a \$2.9 million receivable in Other assets at September 26, 2008. We believe that this receivable is recoverable because it is based on a binding, written settlement agreement with a solvent and financially viable insurance company and the insurance company has paid the claims that we have made in the past.

Our present and past facilities have been in operation for many years, and over that time in the course of those operations, these facilities have used substances, that are or might be considered hazardous, and

we have generated and disposed of wastes, that are or might be considered hazardous. Therefore, it is possible that additional environmental issues may arise in the future that we cannot now predict.

#### Acquisition-Related Commitments/Obligations

When we acquired ACCEL in January 2007, ACCEL was involved in a contract-related lawsuit. Subsequent to the acquisition, we settled this lawsuit and agreed to perform under a new contract for a fixed price. From January to September 2007, we gathered information related to the expected cost of satisfying our contract commitment and completed our assessment as of September 28, 2007. As a result, the final purchase price allocation of ACCEL included a loss accrual related to this contingency of 28.3 million. If the actual costs related to the contingency exceed the estimated amount or if the estimated loss increases, the variances will be recognized in the Consolidated Statement of Earnings in the periods these variances arise. As of September 26, 2008, the actual costs incurred had been consistent with the estimated costs for the contract and the balance of the loss accrual related to this contingency was 13.0 million. We are currently engaged in arbitration to resolve a dispute under the new contract.

#### Other Matters

We are involved, from time to time, in legal proceedings, claims and government inspections or investigations, arising in the ordinary course of our business. Such matters are subject to many uncertainties and outcomes are not predictable with assurance. We accrue amounts that we believe are adequate to address any liabilities related to legal proceedings and other loss contingencies that we believe will result in a probable loss. While we cannot assure you as to the ultimate outcome of any legal proceeding or other loss contingency involving us, management does not believe any pending matter will be resolved in a manner that would have a material adverse effect on our consolidated financial position, results of operations or cash flows. However, it is possible that a legal or other proceeding brought against us could have an impact of this

#### **Off-Balance Sheet Arrangements**

In conjunction with the sale of our products in the ordinary course of business, we provide standard indemnification of business partners and customers for losses suffered or incurred for property damages, death and injury and for patent, copyright or any other intellectual property infringement claims by any third parties with respect to our products. The term of these indemnification arrangements is generally perpetual. Except for losses related to property damages, the maximum potential amount of future payments we could be required to make under these agreements is unlimited. As of September 26, 2008, we have not incurred any significant costs since the spin-offs to defend lawsuits or settle claims related to these indemnification arrangements.

We have entered into indemnification agreements with our directors and officers and certain of our employees that serve as officers or directors of our foreign subsidiaries that may require us to indemnify our directors and officers and those certain employees against liabilities that may arise by reason of their status or service as directors or officers, and to advance their expenses incurred as a result of any legal proceeding against them as to which they could be indemnified. Generally, the maximum obligation under such indemnifications is not explicitly stated and, as a result, the overall amount of these obligations cannot be reasonably estimated.

## **Recent Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 157, *Fair Value Measurements*, or SFAS 157. SFAS 157 defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. In February 2008, the FASB issued FASB Staff Position, or FSP, No. FAS 157-1, or FSP No. 157-1, and FSP No. FAS 157-2, or FSP No. 157-2. FSP No. 157-1 amends SFAS 157 to exclude

80

from its scope SFAS No. 13, *Accounting for Leases*, or SFAS 13, and other accounting pronouncements that address fair value measurements for purposes of lease classification or measurement under SFAS 13. FSP No. 157-2 delays the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis, to our first quarter of fiscal year 2010. The measurement and disclosure requirements of SFAS 157 related to financial assets and financial liabilities are effective for us in the first quarter of fiscal year 2009. The adoption of SFAS 157 for financial assets and financial liabilities is not expected to have a material impact on our consolidated financial position, results of operations and cash flows. We are currently assessing the impact that SFAS 157 will have on our consolidated financial position, results of operations and cash flows when SFAS 157 is applied to nonfinancial assets and nonfinancial liabilities beginning in the first quarter of fiscal 2010.

In September 2006, the FASB issued SFAS No. 158, *Employer s Accounting for Defined Benefit Pension and Other Postretirement Plans an amendment of FASB Statements No. 87, 88, 106 and 132(R)*, or SFAS 158. SFAS 158 requires us to (a) recognize a plan s funded status in our statement of financial position, (b) measure a plan s assets and the obligations that determine its funded status as of the end of our fiscal year and (c) recognize changes in the funded status of a defined benefit plan in the year in which the changes occur through other comprehensive income. We adopted the requirement to recognize the funded status of a defined benefit plan and the disclosure requirements in the fourth quarter of fiscal year 2007. Please refer to Note 9 Retirement Plans for a discussion of the effects of adopting the recognition provisions and disclosure requirements of SFAS 158. We are not required to adopt the measurement date provisions until fiscal year 2009. Based on the evaluation to date, we do not believe the adoption of the measurement date provisions of SFAS 158 will have a material impact on our consolidated financial position, results of operations and cash flows.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities -Including an Amendment of FASB Statement No. 115*, or SFAS 159. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 is effective for us beginning in the first quarter of fiscal year 2009, and it is not expected to have a material impact on our consolidated results of operations, financial position or cash flows.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations*, or SFAS 141(R). SFAS 141(R) establishes principles and requirements for how an acquirer recognizes and measures in our financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. SFAS 141(R) also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141(R) is effective for us in the first quarter of fiscal year 2010. The impact of the adoption of SFAS 141(R) will depend on the nature and extent of business combinations occurring on or after the beginning of fiscal year 2010.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of Accounting Research Bulletin No. 51*, or SFAS 160. SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent s, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent s ownership interest, and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective for us in the first quarter of fiscal year 2010. We are currently assessing the potential impact, if any, SFAS 160 may have on our consolidated financial position, results of operations and cash flows.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities*, or SFAS 161, which is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their

81

## Edgar Filing: VARIAN MEDICAL SYSTEMS INC - Form 10-K

#### **Table of Contents**

effects on an entity s financial position, financial performance and cash flows. SFAS 161 is effective for us in the second quarter of fiscal year 2009. We are currently assessing the potential impact, if any, SFAS 161 may have on our consolidated financial position, results of operations and cash flows.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS 162, which identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP (the GAAP hierarchy). SFAS 162 will become effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. We do not expect the adoption of SFAS 162 to have a material effect on our consolidated financial position, results of operations or cash flows.

#### Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to two primary types of market risks: foreign currency exchange rate risk and interest rate risk.

## Foreign Currency Exchange Rate Risk

As a global entity, we are exposed to movements in foreign currency exchange rates. These exposures may change over time as business practices evolve. Adverse movements could have a material negative impact on our financial results. Our primary exposures related to foreign currency denominated sales and purchases are in Europe, Asia, Australia and Canada.

We have many transactions denominated in foreign currencies and address certain of those financial exposures through a program of risk management that includes the use of derivative financial instruments. We sell products throughout the world, often in the currency of the customer's country, and typically hedge certain of these larger foreign currency transactions when they are not in the subsidiaries functional currency. These foreign currency sales transactions that fit our risk management policy criteria, are hedged with forward contracts. We may use other derivative instruments in the future. We enter into foreign currency forward contracts primarily to reduce the effects of fluctuating foreign currency exchange rates. We do not enter into forward contracts for speculative or trading purposes. The forward contracts range from one to twelve months in maturity.

We also hedge the balance sheet exposures from our various foreign subsidiaries and business units. We enter into foreign currency forward contracts to minimize the short-term impact of currency fluctuations on assets and liabilities denominated in currencies other than the U.S. dollar functional currency.

The notional amounts of forward contracts are not a measure of our exposure. The fair value of forward contracts generally reflects the estimated amounts that we would receive or pay to terminate the contracts at the reporting date, thereby taking into account and approximating the current unrealized and realized gains or losses of the open contracts. A move in foreign currency exchange rates would change the fair value of the contracts, and the fair value of the underlying exposures hedged by the contracts would change in a similar offsetting manner.

82

The notional values and the weighted average contractual foreign currency exchange rates of our sold and purchased forward exchange contracts outstanding at September 26, 2008 were as follows:

(In millions)	otional lue Sold	nal Value rchased	Weighted Average Contract Rate
Australian dollar	\$ 14.9	\$	0.8399
British pound	1.8	10.7	1.8677
Canadian dollar	13.9	2.7	1.0303
Danish krone	6.1		5.0825
Euro	219.6	9.8	1.4591
Indian Rupee	2.6		47.2700
Japanese yen	14.4		105.5800
Swedish krona	7.6		6.5966
Swiss franc		39.5	1.0853
Totals	\$ 280.9	\$ 62.7	

#### **Interest Rate Risk**

Our market risk exposure to changes in interest rates depends primarily on our investment portfolio and short-term borrowings. Our investment portfolio consists of cash and cash equivalents and we did not have any marketable securities as of September 26, 2008. The principal amount of cash and cash equivalents at September 26, 2008 totaled \$397 million with a weighted average interest rate of 2.53%. In the event that interest rates were to decrease substantially, we might reinvest a substantial portion of our investment portfolio at lower interest rates.

As of September 26, 2008, we had the \$100 million BofA Credit Facility. Borrowings under the BofA Credit Facility accrued interest based on the LIBOR, the federal funds rate or the bank s prime rate plus a margin. In addition, the Japanese BofA Credit Facility allowed us to borrow in Japanese Yen up to a maximum amount equivalent to \$30 million. Borrowings under this credit facility accrue interest based on the Bank of Japan basic loan rate. As of September 26, 2008, there were no outstanding balances under these credit facilities.

On November 10, 2008, we amended and restated our revolving credit facility with BofA, the Amended BofA Credit Facility. We increased the line of credit to \$150 million and secured a portion of the facility with a pledge of stock issued by certain of our present and future subsidiaries that are deemed to be material subsidiaries under the terms of the Amended BofA Credit Facility. As of November 10, 2008, we have pledged to BofA 65% of the voting shares that we hold in Varian Medical Systems Nederland B.V., a wholly-owned subsidiary. Similar to the BofA Credit Facility, borrowings under the Amended BofA Credit Facility accrue interest based on the LIBOR or the federal funds rate or the bank s prime rate plus a margin.

We are affected by market risk exposure primarily through the effect of changes in interest rates on amounts payable under these credit facilities. See detailed discussion of our credit facilities in Liquidity and Capital Resources section in Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations.

In addition, we had \$40.4 million of long-term debt outstanding at September 26, 2008 carried at a weighted average fixed interest rate of 6.88% with principal payments due in various installments over a six-year period. To date, we have not used derivative financial instruments to hedge the interest rate of our investment portfolio, short-term borrowings or long-term debt, but may consider the use of derivative instruments in the future

The table below presents principal amounts and related weighted average interest rates by year for our cash and cash equivalents and long term debts.

(Dollars in millions)	2009	2010	2011	Fiscal Years 2012	2013	Thereafter	Total
Assets:							
Cash and cash equivalents	\$ 397.3	\$	\$	\$	\$	\$	\$ 397.3
Average interest rate	2.53%						2.53%
Liabilities:							
Long-term debt	\$ 8.0	\$ 9.0	\$ 5.5	\$ 11.6	\$	\$ 6.3	\$ 40.4
Average interest rate	6.90%	6.85%	6.80%	7.03%		6.70%	6.88%

The estimated fair value of our cash and cash equivalents (94% of which was held abroad at September 26, 2008 and could be subject to additional taxation if it was repatriated to the United States) approximated the principal amounts reflected above based on the maturities of these financial instruments.

The fair value of our long-term debt is estimated based on the current rates available to us for debt of similar terms and remaining maturities. Under this method, the fair value of our debt was estimated to be \$42.2 million at September 26, 2008. We determined the estimated fair value amount by using available market information and commonly accepted valuation methodologies. However, it requires considerable judgment in interpreting market data to develop estimates of fair value. Accordingly, the fair value estimate presented is not necessarily indicative of the amount that we or holders of the instrument could realize in a current market exchange. The use of different assumptions and/or estimation methodologies may have a material effect on the estimated fair value.

Although payments under certain of our operating leases for our facilities are tied to market indices, these operating leases do not expose us to material interest rate risk.

84

# Item 8. Financial Statements and Supplementary Data

# VARIAN MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF EARNINGS

(In thousands, except per share amounts)	2008	Fiscal	Years Ended 2007		2006
Revenues:					
Product	\$ 1,689,724	\$ 1	1,447,746	\$ 1.	,342,047
Service contracts and other	380,006		307,326		255,773
Total revenues	2,069,730		1,755,072	1	,597,820
Cost of revenues:					
Product	985,133		852,980		789,674
Service contracts and other	207,065		169,229		144,819
Total cost of revenues	1,192,198		1,022,209		934,493
Gross margin	877,532		732,863		663,327
Operating expenses:					
Research and development	135,599		117,320		100,408
Selling, general and administrative	322,529		276,918		253,563
Total operating expenses	458,128		394,238		353,971
Operating earnings	419,404		338,625		309,356
Interest income	11,498		12,165		13,974
Interest expense	(4,879)	)	(4,791)		(4,648)
Earnings from continuing operations before taxes	426,023		345,999		318,682
Taxes on earnings	130,767		103,083		75,120
Earnings from continuing operations	295,256		242,916		243,562
Earnings (loss) from discontinued operations, net of taxes	(15,772)	)	(3,460)		1,529
Net Earnings	\$ 279,484	\$	239,456	\$	245,091
Net earnings (loss) per share basic:					
Continuing operations	\$ 2.37	\$	1.91	\$	1.86
Discontinued operations	(0.13)		(0.03)		0.01
Net earnings per share	\$ 2.24	\$	1.88	\$	1.87
Net earnings (loss) per share diluted:					
Continuing operations	\$ 2.31	\$	1.86	\$	1.80
Discontinued operations	(0.12)		(0.03)	ψ	0.01
Net earnings per share	\$ 2.19	\$	1.83	\$	1.81

Shares used in the calculation of net earnings per share:

# Edgar Filing: VARIAN MEDICAL SYSTEMS INC - Form 10-K

Weighted average shares outstanding Basic	124,800	127,407	130,964
Weighted average shares outstanding Diluted	127,604	130,622	135,439

See accompanying notes to the consolidated financial statements.

# VARIAN MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

# CONSOLIDATED BALANCE SHEETS

(In thousands, except par values)	Sep	September 26, 2008		September 28, 2007	
Assets					
Current assets:					
Cash and cash equivalents	\$	397,306	\$	263,246	
Accounts receivable, net of allowance for doubtful accounts of \$3,110 at September 26, 2008 and					
\$3,859 at September 28, 2007		486,310		499,330	
Inventories		282,980		213,095	
Prepaid expenses and other current assets		78,018		48,150	
Deferred tax assets	&nb				