

ANCHEL EDWARD
Form 4
May 21, 2007

FORM 4

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

OMB APPROVAL

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Check this box if no longer subject to Section 16. Form 4 or Form 5 obligations may continue. See Instruction 1(b).

STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP OF SECURITIES

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section 30(h) of the Investment Company Act of 1940

(Print or Type Responses)

1. Name and Address of Reporting Person *
ANCHEL EDWARD

2. Issuer Name and Ticker or Trading Symbol
OCEAN BIO CHEM INC [OBCI]

5. Relationship of Reporting Person(s) to Issuer

(Check all applicable)

(Last) (First) (Middle)
7566 VIA GRANDE
(Street)

3. Date of Earliest Transaction
(Month/Day/Year)
05/17/2007

Director 10% Owner
 Officer (give title below) Other (specify below)

BOYNTON BEACH, FL 33437
(City) (State) (Zip)

4. If Amendment, Date Original Filed(Month/Day/Year)

6. Individual or Joint/Group Filing(Check Applicable Line)
 Form filed by One Reporting Person
 Form filed by More than One Reporting Person

Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned

1. Title of Security (Instr. 3)	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if any (Month/Day/Year)	3. Transaction Code (Instr. 8)	4. Securities Acquired (A) or Disposed of (D) (Instr. 3, 4 and 5)	5. Amount of Securities Beneficially Owned Following Reported Transaction(s) (Instr. 3 and 4)	6. Ownership Form: Direct (D) or Indirect (I) (Instr. 4)	7. Nature of Ownership (Instr. 4)	
				(A) or (D)	Price			
			Code	V	Amount			
Common stock	05/17/2007	05/17/2007	A		\$ 15,000	A	252,579	D
					1.66			

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

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(9-02)

Table II - Derivative Securities Acquired, Disposed of, or Beneficially Owned (e.g., puts, calls, warrants, options, convertible securities)

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1. Title of Derivative Security (Instr. 3)	2. Conversion or Exercise Price of Derivative Security	3. Transaction Date (Month/Day/Year)	3A. Deemed Execution Date, if any (Month/Day/Year)	4. Transaction Code (Instr. 8)	5. Number of Derivative Securities Acquired (A) or Disposed of (D) (Instr. 3, 4, and 5)	6. Date Exercisable and Expiration Date (Month/Day/Year)		7. Title and Amount of Underlying Securities (Instr. 3 and 4)			
				Code	V	(A)	(D)	Date Exercisable	Expiration Date	Title	Amount or Number of Shares
Common stock options	\$ 1.66	05/17/2007	05/17/2007	A		15,000		05/17/2008	05/16/2012	Common stock	15,000

Reporting Owners

Reporting Owner Name / Address	Relationships			
	Director	10% Owner	Officer	Other
ANCHEL EDWARD 7566 VIA GRANDE BOYNTON BEACH, FL 33437		X		

Signatures

Edward Anchel 05/21/2007

**Signature of Reporting Person Date

Explanation of Responses:

* If the form is filed by more than one reporting person, *see* Instruction 4(b)(v).

** Intentional misstatements or omissions of facts constitute Federal Criminal Violations. *See* 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).

Remarks:

Shares were awarded as a component of compensation in lieu of a cash bonus.

Note: File three copies of this Form, one of which must be manually signed. If space is insufficient, *see* Instruction 6 for procedure.

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

properly identify customer needs;

prove the feasibility of new products;

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limit the time required from proof of feasibility to routine production;

comply with internal quality assurance systems and processes timely and efficiently;

limit the timing and cost of regulatory approvals;

accurately predict and control costs associated with inventory overruns caused by phase-in of new products and phase-out of old products;

price our products competitively and profitably;

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

appropriately manage our supply chain;

manage customer acceptance and payment for products;

manage customer demands for retrofits of both new and old products; and

anticipate and compete successfully with competitors.

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

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

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

We conduct business globally. Our international revenues accounted for approximately 54% and 62% of revenues from continuing operations during the first quarter of fiscal years 2012 and 2011, respectively. As a result, we must provide significant service and support globally. We intend to continue to expand our presence in international markets and expect to expend significant resources in doing so, although we cannot be sure we will be able to meet our sales, service and support objectives or obligations, or recover our investments. Accordingly, our future results could be harmed by a variety of factors, including:

the difficulties in enforcing agreements and collecting receivables through many foreign country's legal systems;

the longer payment cycles associated with many foreign customers;

currency fluctuations;

changes in the political, regulatory, safety or economic conditions in a country or region;

the imposition by foreign countries of additional taxes, tariffs or other restrictions on foreign trade;

the lower sales prices and gross margins usually associated with sales of our products in the international region;

the longer period in the international region from shipment to revenue recognition that generally results in greater revenue recognition deferrals and higher backlog;

any inability to obtain export licenses and other required export or import licenses or approvals;

failure to comply with export laws and requirements which may result in civil or criminal penalties and restrictions on our ability to export our products, particularly our industrial linear accelerator products;

failure to obtain proper business licenses or other documentation, or to otherwise comply with local laws and requirements regarding marketing, sales, service or any other business we conduct in a foreign jurisdiction, which may result in civil or criminal penalties and restrictions on our ability to conduct business in that jurisdiction; and

the possibility that it may be more difficult to protect our intellectual property in foreign countries.

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

As of December 30, 2011, 97% of our cash and cash equivalents were held abroad. If these funds were repatriated to the United States, they could be subject to additional taxation and our overall tax rate and our results of operations could suffer.

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Our effective tax rate is impacted by tax laws in both the United States and in the respective countries in which our international subsidiaries do business. Earnings from our international region are generally taxed at rates lower than U.S. rates. A change in the percentage of our total earnings from the international region, or a change in the mix of particular tax jurisdictions within the international region could cause our effective tax rate to increase or decrease. Also, we are not currently taxed in the United States on certain undistributed earnings of certain foreign subsidiaries. These earnings could become subject to incremental foreign withholding or U.S. federal and state taxes should they either be deemed or actually remitted to the United States, or if tax laws change, in which case our financial results could be adversely affected. In addition, Congress has considered proposals that would significantly change U.S. taxation of U.S.-based multinational corporations. Although we cannot predict whether or in what form Congress would enact any such proposals, legislation of this type could negatively impact our effective tax rate and adversely affect our financial results.

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

Since fiscal year 2008, the global economy has been impacted by the sequential effects of the subprime lending crisis; the credit market crisis; collateral effects on the finance and banking industries; volatile currency exchange rates and energy costs; concerns about inflation (deflation), slower economic activity, consumer confidence, corporate profits and capital spending, adverse business conditions, liquidity and unemployment; concerns over the downgrade of the sovereign debt of the United States and several European countries; and continued sovereign debt and recession uncertainties in Europe and other foreign countries. These conditions have shrunk capital equipment budgets, slowed decision-making, made financing for large equipment purchases more expensive and more time consuming to obtain, and made it difficult for our customers and our vendors to accurately forecast and plan future business activities and reduced their confidence. This, in turn, has caused our customers to freeze, delay or dramatically reduce purchases and capital project expenditures. Even though economic activity has shown some improvement, recovery has been sluggish and we cannot predict the strength or sustainability of an economic recovery, in general or specifically in the healthcare industry. It has taken time for our customers to establish new budgets and may take more time for them to fully return to normal purchasing patterns. Project delays may continue, particularly as they relate to large scale or government projects, which may be affected by austerity measures. Alternatively, in the past, some countries, including Japan, have adopted and may in the future adopt government stimulus programs to revitalize their economies and improve healthcare and medical services. The availability of stimulus programs in the future could positively affect our results in one period and adversely affect our results in other periods, making it difficult for investors to compare our financial results between fiscal periods. Weak economic recovery may also disrupt supply if vendors consolidate or go out of business. As with our customers and vendors, these economic conditions make it more difficult for us to accurately forecast and plan our future business activities. Historically, our business has felt the effects of market trends later than other sectors in the healthcare industry, such as diagnostic radiology, and we may experience the effects of any economic recovery later than others in the healthcare industry. A continued weak or deteriorating healthcare market would inevitably adversely affect our business, financial conditions and results of operations.

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

Our products and those of OEMs that incorporate our products are subject to extensive and rigorous government regulation in the United States. Compliance with these laws and regulations is expensive and time-consuming, and failure to comply with these laws and regulations could adversely affect our business. Furthermore, public media reports on misadministrations of radiotherapy in patients and focus on the role of the FDA in regulating medical devices has led to increased scrutiny of medical device companies and an increased likelihood of enforcement actions.

U.S. laws governing marketing a medical device. In the United States, as a manufacturer and seller of medical devices and devices emitting radiation or utilizing radioactive by-product material, we and some of our suppliers and distributors are subject to extensive regulation by federal governmental authorities, such as the FDA, NRC and state and local regulatory agencies, such as the State of California, to ensure the devices are safe and effective and comply with laws governing products which emit, produce or control radiation. These regulations govern, among other things, the design, development, testing, manufacturing, packaging, labeling, distribution, import/export, sale and marketing and disposal of our products.

Unless an exception applies, the FDA requires that the manufacturer of a new medical device or a new indication for use of, or other significant change in, existing currently marketed medical device obtain either 510(k) pre-market notification clearance or PMA before it can market or sell those products in the United States. Modifications or enhancements to a product that could significantly affect its safety or effectiveness, or that would constitute a major change in the intended use of the device, technology, materials, labeling, packaging, or manufacturing process may also require a new 510(k) clearance. The FDA has recently issued a draft guidance that, if finalized and implemented, will result in manufacturers needing to seek a significant number of new clearances for changes made to legally marketed devices. Although manufacturers make the initial determination whether a change to a cleared device requires a new 510(k) clearance, we cannot assure you that the FDA will agree with our decisions not to seek additional approvals or clearances for particular modifications to our products or that we will be successful in obtaining new 510(k) clearances for modifications. Obtaining clearances or approvals is time-consuming, expensive and uncertain. We may not be able to obtain the necessary clearances or approvals or may be unduly

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

Further, as we enter new businesses or pursue new business opportunities, such as opportunities that require clinical trials, we may become subject to additional laws, rules and regulations, including FDA rules and regulations that are applicable to the clinical trial process and protection of study subjects. Becoming familiar with and implementing the infrastructure necessary to comply with these laws, rules and regulations could be quite costly. In addition, failure to comply with these laws, rules and regulations could delay the introduction of new products and could adversely affect our business.

Quality systems, audits and failure to comply. Our manufacturing operations for medical devices, and those of our third-party manufacturers, are required to comply with the FDA's QSR, as well as other federal and state regulations for medical devices and radiation emitting products. The FDA makes announced and unannounced periodic and on-going inspections of medical device manufacturers to determine compliance with QSR and in connection with these inspections issues reports, known as Form FDA 483 reports when the FDA believes the manufacturer has failed to comply with applicable regulations and/or procedures. If observations from the FDA issued on Form FDA 483 reports are not addressed and/or corrective action taken in a timely manner and to the FDA's satisfaction, the FDA may issue a Warning Letter and/or proceed directly to other forms of enforcement action. Similarly, if a Warning Letter were issued, prompt corrective action to come into compliance would be required. Failure to respond timely to Form FDA 483 observations, a Warning Letter or other notice of noncompliance and to promptly come into compliance could result in the FDA bringing enforcement action against us, which could include the total shutdown of our production facilities, denial of importation rights to the U.S. for products manufactured in overseas locations, adverse publicity and criminal and civil fines. The expense and costs of any corrective actions that we may take, which may include products recalls, correction and removal of products from customer sites and/or changes to our product manufacturing and quality systems, could adversely impact our financial results and may also divert management resources, attention and time. Additionally, if a Warning Letter were issued, customers could delay purchasing decisions or cancel orders, and we could face increased pressure from our competitors who could use the Warning Letter against us in competitive sales situations, either of which could adversely affect our reputation, business and stock price. Currently, we are responding to and working with the FDA to fully resolve Form FDA 483 observations issued in May 2011 related to the inspections of our Oncology Systems manufacturing facilities located in Helsinki, Finland and Haan, Germany. These observations generally include issues with complaint investigations, corrective actions and preventive actions, filings required under medical device reporting regulations and purchasing controls. While in the past, we have received Form 483 observations that we successfully resolved with the FDA, we cannot be certain that we will have similar success in promptly resolving these observations.

In addition, we are required to timely file various reports with the FDA, including reports required by the medical device reporting regulations (MDRs), that require that we report to regulatory authorities if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business.

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

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Our medical devices utilizing radioactive material are subject to the NRC clearance and approval requirements, and the manufacture and sale of these products are subject to extensive federal and state regulation that varies from state to state and among regions. Our manufacture, distribution, installation and service of medical devices utilizing radioactive material or emitting radiation also requires us to obtain a number of licenses and certifications for these devices and materials. Service of these products must also be in accordance with a specific radioactive materials license. Obtaining licenses and certifications may be time consuming, expensive and uncertain. In addition, we are subject to a variety of environmental laws regulating our manufacturing operations and the handling, storage, transport and disposal of hazardous materials, and which impose liability for the cleanup of any contamination from these materials. In particular, the handling and disposal of radioactive materials resulting from the manufacture, use or disposal of our products may impose significant costs and requirements. Disposal sites for the lawful disposal of materials generated by the manufacture, use or decommissioning of our products may no longer accept these materials in the future, or may accept them on unfavorable terms.

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

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

adverse publicity affecting both us and our customers;

increased pressures from our competitors;

investigations by governmental authorities or Warning Letters;

finances, injunctions, and civil penalties;

partial suspensions or total shutdown of production facilities, or the imposition of operating restrictions;

increased difficulty in obtaining required FDA clearances or approvals;

losses of clearances or approvals already granted;

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

delays in purchasing decisions by customers or cancellation of existing orders;

the inability to sell our products;

difficulty in obtaining product liability or operating insurance at a reasonable cost, or at all; and

civil fines and criminal prosecutions.

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

The laws and regulations and their enforcement are constantly undergoing change, and we cannot predict what effect, if any, changes to these laws and regulations may have on our business. For example, HIPAA was amended by the HITECH Act, enacted as part of the American Recovery and Reinvestment Act of 2009. The HITECH Act significantly increases the civil money penalties for violations of patient privacy rights protected under HIPAA. Furthermore, business associates who have access to patient health information provided by hospitals and healthcare providers are now directly subject to HIPAA, including the new enforcement scheme and inspection requirements. Moreover, there has been a trend in recent years toward more stringent regulation and enforcement of requirements applicable to medical device manufacturers who receive or have access to patient health information.

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

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

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

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

Within the EEA, we must affix a CE mark, a European marking of conformity that indicates that a product meets the essential requirements of the Medical Device Directive. This conformity to the Medical Device Directive is done through self-declaration and is verified by an independent certification body, called a Notified Body. Once clearance is obtained and the CE mark is affixed to the device, the Notified Body will regularly audit us to ensure that we remain in compliance with the applicable European laws and Medical Device Directive. By affixing the CE mark marking to our product, we are certifying that our products comply with the laws and regulations required by the EEA countries, thereby allowing the free movement of our products within these countries and others that accept CE mark standards. If we cannot support our performance claims and demonstrate compliance with the applicable European laws and Medical Device Directive, we would lose our right to affix the CE mark to our products, which would prevent us from selling our products within the EU/EEA/Switzerland territory. Significant revisions to some of the applicable regulations governing requirements for medical devices in the EU/EEA/Switzerland went into effect in March 2010. These revisions have introduced additional uncertainty into the marketing authorization process for medical devices in Europe. Until medical device manufacturers and European regulatory agencies, including Notified Bodies and competent authorities, have greater experience with interpreting and applying the revised regulations, we may be subject to risks associated with additional testing, modification, certification or amendment of our existing market authorizations, or we may be required to modify products already installed at our customers facilities in order to comply with the official interpretations of these revised regulations.

In addition, we are required to timely file various reports with international regulatory authorities, including reports required by international adverse event reporting regulations, that require that we report to regulatory authorities if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not timely filed, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business.

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

Manufacturing and selling a device internationally. We are also subject to laws and regulations that apply to manufacturers of radiation emitting devices and products utilizing radioactive materials, as well as laws and regulations of general

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applicability relating to matters such as environmental protection, safe working conditions, manufacturing practices and other matters. These are often comparable to, if not more stringent than, the equivalent regulations in the United States. Sales overseas are also affected by regulation of matters such as product standards, packaging, labeling, environmental and product recycling requirements, import and export restrictions, tariffs, duties and taxes.

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

adverse publicity affecting both us and our customers;

investigations by governmental authorities;

fines, injunctions, civil penalties and criminal prosecutions;

increased difficulty in obtaining required approvals in foreign countries;

losses of clearances or approvals already granted;

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

delays in purchasing decisions by customers or cancellation of existing orders; and

the inability to sell our products in or to import our products into such countries.

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

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

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

On March 23, 2010, President Obama signed into law the Affordable Health Care for America Act. While we are continuing to evaluate this legislation and its potential impact on our business, and many of its provisions are yet to be implemented, it may adversely affect the demand for

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our products and services, and therefore our financial position and results of operations, possibly materially.

Specifically, one of the components of the new law is a 2.3% excise tax on sales of most medical devices, which include our Oncology Systems products, starting in 2013. The Congressional Budget Office estimates that the total cost to the medical device industry could exceed \$20 billion over ten years. This tax may put increased pressure on medical device manufacturers and purchasers, and may lead our customers to reduce their orders for products we produce or to request that we reduce the prices we charge for our products in order to offset the tax. Other elements of this new legislation, including comparative effectiveness research, an independent payment advisory board, payment system reforms (including shared savings pilots) and the reporting of certain payments by us to healthcare professionals and hospitals (the Physician Payment Sunshine Act), could meaningfully change the way healthcare is developed and delivered, and may materially impact numerous aspects of our business, including the demand and availability of our products, the reimbursement available for our products from governmental and third-party payors, and reduced medical procedure volumes.

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Various healthcare reform proposals have also emerged at the state level, and we are unable to predict which, if any of these proposals will be enacted. We believe that the uncertainty created by healthcare reform in the United States has complicated our customers' decision-making process and impacted our Oncology Systems business, and we expect that this uncertainty will persist until there is greater clarity on how the Affordable Health Care for America Act and state proposals will affect healthcare providers. We are unable to predict what effect ongoing uncertainty surrounding these matters will have on our customers' purchasing decisions. However, an expansion in government's role in the U.S. healthcare industry may adversely affect our business, possibly materially.

CHANGES TO RADIATION ONCOLOGY REIMBURSEMENTS MAY AFFECT DEMAND FOR OUR PRODUCTS

Sales of our healthcare products indirectly depend on whether adequate reimbursement is available to our customers from a variety of sources, such as government healthcare insurance programs, including the Medicare and Medicaid programs; private insurance plans; health maintenance organizations; and preferred provider organizations. In general, third-party payors in the United States are increasingly cost-conscious, and we cannot be sure that they will reimburse our customers at levels sufficient to enable us to achieve or maintain sales and price levels for our products in this market. Without adequate support from third-party payors, the market for our products may be limited. There is no uniform policy on reimbursement among third-party payors, nor can we be sure that procedures using our products will qualify for appropriate levels of reimbursement from third-party payors. Once Medicare has made a decision to provide reimbursement for a given treatment, these reimbursement rates are generally reviewed and adjusted by Medicare annually. Private third-party payors, although independent from Medicare, sometimes use portions of Medicare reimbursement policies and payment amounts in making their own reimbursement decisions. As a result, decisions by CMS to reimburse for a treatment, or changes to Medicare's reimbursement policies or reductions in payment amounts with respect to a treatment sometimes extend to third-party payor reimbursement policies and amounts for that treatment. We have seen our customers' decision-making process complicated by the uncertainty surrounding Medicare reimbursement rates for radiotherapy and radiosurgery in the United States. From time to time, CMS and third party payors may review and modify the factors upon which they rely to determine appropriate levels of reimbursement for cancer treatments. For example, CMS and third-party payors have begun to focus on the comparative effectiveness of radiation therapy versus other methods of cancer treatment, including surgery, and could modify reimbursement rates based on the results of comparative effectiveness studies. If comparative effectiveness studies are not available, or if available studies show that other cancer treatments are more effective than radiotherapy or radiosurgery, reimbursement rates for radiotherapy or radiosurgery could be reduced. Any significant cuts in reimbursement rates for radiotherapy, radiosurgery, proton therapy or brachytherapy, or concerns or proposals regarding further cuts, could further increase uncertainty, influence our customers' decisions, reduce demand for our products, cause customers to cancel orders and have a material adverse effect on our revenues and stock price.

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

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

Because our business is global and payments are generally made in local currency, fluctuations in foreign currency exchange rates can impact our results by affecting product demand or our expenses and/or the profitability in U.S. dollars of products and services that we provide in foreign markets.

While we use hedging strategies to help offset the effect of fluctuations in foreign currency exchange rates, the protection these strategies provide is affected by the timing of transactions, and the effectiveness of those strategies, the number of transactions that are hedged, forecast volatility and the extent to which exchange rates change. If our hedging strategies do not offset these fluctuations, our revenues and other operating results may be harmed. In addition, movement in foreign currency exchange rates could impact our financial results positively or negatively in one period and not another, making it more difficult to compare our financial results from period to period. Furthermore, on July 21, 2010, President Obama signed into law the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act). The Dodd-Frank Act contains provisions which may impact our existing hedging strategies, but we cannot predict those effects at this time.

In addition, long-term movements in foreign currency exchange rates can also affect the competitiveness of our products in the local currencies of our international customers. Even though our international sales are mostly in local currencies, our

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cost structure is weighted towards the U.S. dollar. The volatility of the U.S. dollar that we have experienced over the last several years has affected the competitiveness of our pricing against our foreign competitors, some of which may have cost structures based in other currencies, either helping or hindering our international order and revenue growth, thereby affecting our overall financial performance and results. Changes in monetary or other policies here and abroad, including as a result of economic instability or concerns about the downgrade and levels of sovereign debt, or in reaction thereto, would also likely affect foreign currency exchange rates. For example, the Euro has been impacted by the sovereign debt crisis in Greece and other European countries. In the event that one or more European countries were to replace the Euro with another currency, our sales into these countries, or into Europe generally, would likely be adversely affected until stable exchange rates are established.

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

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

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

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

Anti-corruption laws and regulations. We are also subject to the U.S. Foreign Corrupt Practices Act and anti-corruption laws, and similar laws in foreign countries, such as the U.K. Bribery Act of 2010, which became effective on July 1, 2011. In general, there is a worldwide trend to strengthen anticorruption laws and their enforcement. Any violation of these laws could create a substantial liability for us, subject our officers and directors to personal liability and also cause a loss of reputation in the market. Transparency International's 2010 Corruption Perceptions Index measured the degree to which public sector corruption is perceived to exist in 178 countries around the world, and found that nearly three quarters of the countries in the index, including many that we consider to be high growth areas for our products, such as China, India, Russia and Brazil, scored below five, on a scale from 10 (very clean) to 0 (highly corrupt). We currently operate in many countries where the public sector is perceived as being more or highly corrupt. Our strategic business plans include expanding our business in regions and countries that are rated as higher risk for corruption activity by Transparency International.

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Becoming familiar with and implementing the infrastructure necessary to comply with laws, rules and regulations applicable to new business activities and mitigate and protect against corruption risks could be quite costly. In addition, failure to comply with these laws, rules and regulations could delay our expansion into high-growth markets and could adversely affect our business. This notwithstanding, we will inevitably do more business in countries where the public sector is perceived to be more or highly corrupt and be engaging in business in more countries perceived to be more or highly corrupt. Increased business in higher risk countries could subject us and our officers and directors to increased scrutiny and increased liability. In addition, from time to time, we may conduct internal investigations or face audits or investigations by one or more domestic or foreign government agencies, which could be costly and time-consuming, and could divert our management and key personnel from our business operations. An adverse outcome under any such investigation or audit could subject us to fines or criminal or other penalties, which could adversely affect our business and financial results.

PRODUCT DEFECTS OR MISUSE MAY RESULT IN MATERIAL PRODUCT LIABILITY OR PROFESSIONAL ERRORS AND OMISSIONS CLAIMS, LITIGATION, INVESTIGATION BY REGULATORY AUTHORITIES OR PRODUCT RECALLS THAT COULD HARM 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 operate within our customers' facilities and network systems, and under quality assurance procedures established by the facility that ultimately result in the delivery of radiation to patients. Human and other errors or accidents may arise from the operation of our products in complex environments, particularly with products from other vendors, where interoperability or data sharing protocol may not be optimized even though the equipment or system operates according to specifications. As a result, we may face substantial liability to patients, our customers and others for damages resulting from the faulty, or allegedly faulty, design, manufacture, installation, servicing, support, testing or interoperability of our products with other products, or their misuse or failure, as well as liability related to the loss or misuse of private patient data. We may also be subject to claims for property damages or economic loss related to or resulting from any errors or defects in our products, or the installation, servicing and support of our products. Any accident or mistreatment could subject us to legal costs, litigation, adverse publicity and damage to our reputation, whether or not our products or services were a factor. Litigation and other legal proceedings can be costly and can divert management's time and resources. An unfavorable outcome in litigation or proceedings against us could adversely affect our financial results. Adverse publicity regarding any accidents or mistreatments, even ones that do not involve our products, could cause patients to be less receptive to radiotherapy treatments, causing them to question the efficacy of radiation therapy and seek other methods of treatment and adversely impacting our business. Adverse publicity could also result in additional regulation of radiation therapy, medical devices or the healthcare industry in general. Increased regulatory activities could adversely affect our ability to promote, manufacture and sell our products, and therefore negatively impact our business and results of operations.

In addition, if a product we design or manufacture were defective (whether due to design, labeling or manufacturing defects, improper use of the product or other reasons), we may be required to correct or recall the product and notify regulatory authorities. The adverse publicity resulting from a correction or recall could damage our reputation and cause customers to review and potentially terminate their relationships with us. A product correction or recall could consume management time and have an adverse financial impact on our business, including incurring substantial costs, losing revenues and accruing losses under accounting principles generally accepted in the United States (GAAP).

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

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

Rapidly evolving technology, intense competition and pricing pressure characterize the markets for radiation therapy equipment and software. Some of our competitors have greater financial, marketing and other resources than we have. Also, we believe that new competitors will enter our markets, as we have encountered new competitors as we have entered new markets such as radiosurgery, volumetric modulated arc therapy and proton therapy. To compete successfully, we must provide technically superior, clinically proven products that deliver more precise, cost-effective, high quality clinical outcomes, in a complete package of products and services, and to do so ahead of our competitors. As our Oncology Systems products are generally sold on a basis of total value to the customer, our business may suffer when purchase decisions are based solely upon price, which can happen if hospitals and clinics give purchasing decision authority to group purchasing organizations. In addition, additional competitors may delay customer purchasing decisions as customers evaluate the products of these competitors along with ours, potentially extending our sales cycle and adversely affecting our net orders.

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

In our SIP business, we compete with other OEM suppliers, primarily outside of the United States. The market for our SIP products used for nondestructive testing in industrial applications is small and highly fragmented.

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

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

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

As radiation oncology treatment becomes more complex, our customers are increasingly focusing on ease-of-use and interconnectivity. Our equipment and software are highly sophisticated and require a high level of training and education to use them competently and safely, requirements made even more important because they work together within integrated environments. We have directed substantial product development efforts into (i) increasing the interconnectivity of our products for more seamless operation within a system, (ii) enhancing the ease of use of our software products and (iii)

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reducing setup and treatment times and increasing patient throughput. We have emphasized maintaining an open systems approach that allows customers to mix and match our various individual products, incorporate products from other manufacturers, share information with other systems or products and use the equipment for offering various methods of radiation therapy treatment. We have done this based on our belief that such interconnectivity will increase the acceptance and adoption of IMRT, IGRT and volumetric modulated arc therapy and will stimulate demand for our products. There are competitive closed-ended dedicated-use systems, however, that place simplicity of use ahead of flexibility. If we have misjudged the importance to our customers of maintaining an open systems approach, or if we are unsuccessful in our efforts to increase interconnectivity, enhance ease-of-use and reduce setup and treatment times, our revenues could suffer.

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

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

We file applications as appropriate for patents covering new products and manufacturing processes. We cannot be sure, however, that our current patents, the claims allowed under our current patents, or patents for technologies licensed to us will be sufficiently broad to protect our technology position against competitors. Issued patents owned by, or licensed to, us may be challenged, invalidated or circumvented, or the rights granted under the patents may not provide us with competitive advantages. We also cannot be sure that patents will be issued from any of our pending or future patent applications. Asserting our patent rights against others in litigation or other legal proceedings is costly and diverts managerial resources. 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. These protections may prove inadequate, since agreements may still be breached and we may not have adequate remedies for a breach, and our trade secrets may otherwise become known to or be independently developed by others. We have trademarks, both registered and unregistered, that are maintained and enforced to provide customer recognition for our products in the marketplace, but unauthorized third parties may still use them. We also have agreements with third parties that license to us certain patented or proprietary technologies. In some cases products with substantial revenues may depend on these license rights. If we were to lose the rights to license these technologies, or our costs to license these technologies were to materially increase, our business would suffer.

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

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' activities for possible conflicts with their own intellectual property rights. In addition, non-practicing entities may review our activities for conflicts with their patent rights. Determining whether a product infringes a third party's intellectual property rights involves complex legal and factual issues, and the outcome of this type of litigation is often uncertain. Third parties may claim that we are infringing their intellectual property rights, and we may be found to infringe those intellectual property

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rights. We may not be aware of intellectual property rights of others that relate to our products, services or technologies. From time to time, we have received notices from third parties asserting infringement and we have been subject to lawsuits alleging infringement of third-party patent or other intellectual property rights. For example, we are currently involved in a patent infringement lawsuit relating to our Real-time Position Management technology. 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, and we may not prevail in a dispute. We do not maintain insurance for intellectual property infringement, so costs of defense, whether or not we are successful in defending an infringement claim, will be borne by us and could be significant. If we are unsuccessful in defending or appealing an infringement claim, we may be subject to significant damages. If actual damages significantly exceed our estimates, our consolidated financial position, results of operations or cash flows could be materially adversely affected. We may also be subject to injunctions against development and sale of our products, which could be material. If a third party rights holder is willing to license rights, we may be required to enter into costly royalty or license agreements.

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

We obtain some of the components included in our products from a limited group of suppliers or from a single-source supplier, such as the radioactive sources for high dose afterloaders, klystrons for linear accelerators; transistor arrays and cesium iodide coatings for flat panel detectors, and specialized integrated circuits, x-ray tube targets, housings, glassframes and various other x-ray tube components; and radiofrequency components, magnets and gantry hardware for proton therapy systems. 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 insurance to protect against business interruption loss, this insurance coverage may not be adequate or continue to remain available on acceptable terms, if at all. Additionally, some of our single-source suppliers supply components for certain of our rapidly growing product lines. Manufacturing capacity limitations of any of our suppliers or other inability of these suppliers to meet increasing demand could adversely affect us, resulting in curtailed growth opportunities for 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, could adversely affect our business and financial results and could damage our customer relationships.

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

We rely upon the supplies of certain raw materials such as tungsten, lead and copper for Oncology Systems and SIP; copper, lead, tungsten, rhenium, molybdenum zirconium, and various high grades of steel alloy for x-ray tubes, and high-grade steel, high-grade copper and iron for VPT. Demand for these raw materials both within the United States and from foreign countries, such as China, has increased over the last few years, resulting in limited supplies and higher prices. Worldwide demand, availability and pricing of these raw materials have been volatile, and we expect that availability and pricing will continue to fluctuate in the future. If supplies are restricted and prices increase, 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

We have seen and may continue to see some consolidation among our customers in our Oncology Systems business, as hospitals and clinics combine through mergers and acquisitions, and as they join group purchasing organizations or affiliated enterprises. 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 customer approvals. Both increased order size and extended purchasing cycles could cause our net orders 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.

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WE SELL OUR X-RAY PRODUCTS TO A LIMITED NUMBER OF OEM CUSTOMERS, MANY OF WHICH ARE ALSO OUR COMPETITORS, AND A REDUCTION IN BUSINESS OR INABILITY TO PROPERLY FORECAST SALES BY ONE OR MORE OF THESE CUSTOMERS COULD REDUCE OUR SALES

We sell our x-ray tube products to a limited number of OEM customers, many of which are also our competitors with in-house x-ray tube manufacturing operations. If these customers manufacture a greater percentage of their components in-house or otherwise lower external sourcing costs, we could experience the loss of, or reduction in purchasing volume by, one or more of these customers. Such a loss or reduction could have a material adverse effect on our X-ray Products business. In addition, economic concerns, such as concerns over a sluggish economic recovery, levels of sovereign debt or restrictions in government spending, as well as the effects of natural disasters (such as power outages and facility closures), have made it difficult for our OEM customers to accurately forecast and plan future business activities, and our x-ray business has in the past been impacted by inventory reduction efforts and a slowdown in sales at some of these customers. For example, we believe the weak X-ray Products revenue growth we experienced in the first quarter of fiscal year 2012 was related to inventory adjustments by several customers in Japan who appear to have overstocked tubes and panels in order to maintain normal production schedules despite the blackouts that followed the March 2011 earthquake and tsunami. Similar inventory adjustments could occur in the future. Our agreements for x-ray components may contain purchasing estimates that are based on our customers' historical purchasing patterns, and actual purchasing volumes under the agreements may vary significantly from our estimates.

ORDERS FOR OUR SECURITY AND INSPECTION PRODUCTS COULD 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 organizations 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 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 as governmental agencies may place large orders with us or our OEM customers in a short time period, and then may not place any orders for a long time period thereafter. Because it is difficult to predict our OEM customer delivery and acceptance schedules, the actual timing of sales and revenue recognition will vary significantly.

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, which depend upon government budgets and appropriations that are subject to political changes. We have seen customers freeze or dramatically reduce purchases and capital project expenditures, delay projects, or act cautiously as governments around the world wrestle with spending priorities. As economic recovery remains sluggish and concerns about levels of government employment and government debt continue, we expect that these effects will also continue. Furthermore, bid awards in this business may be subject to challenge by third parties, as we have previously encountered with a large government project, which can make the certainty and timing of some SIP orders unpredictable. As a result, this business is subject to unpredictability in the timing of orders, sales and revenue that could cause volatility in our revenues and earnings, and therefore the price of VMS common stock.

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

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

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OUR BUSINESS MAY SUFFER IF WE ARE NOT ABLE TO HIRE AND RETAIN 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, and service, sales, marketing and other qualified staff. We compete for key personnel with other medical equipment and software manufacturers and technology companies, as well as universities and research institutions. Because this competition is intense, compensation-related costs could increase significantly if the supply of qualified personnel decreases or demand increases. If we are unable to hire, train or retain qualified personnel, we will not be able to maintain and expand our business, and our business would suffer.

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

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

IF WE FAIL TO SUCCESSFULLY ACQUIRE OR INTEGRATE NEW BUSINESSES, PRODUCTS AND TECHNOLOGY, WE MAY NOT REALIZE EXPECTED BENEFITS OR MAY HARM OUR BUSINESS

We need to grow our businesses in response to changing technologies, customer demands and competitive pressures. In some circumstances, we may decide to grow our business through the acquisition of complementary businesses, products or technologies rather than through internal development. For example, in March 2011 we acquired all of the outstanding equity of a privately-held supplier of devices for delivery of brachytherapy treatment of cancer and in October 2011 acquired Calypso. Identifying suitable acquisition candidates can be difficult, time-consuming and costly, and we may not be able to identify suitable candidates or successfully complete identified acquisitions. In addition, completing an acquisition can divert our management and key personnel from our business operations, which could harm our business and affect our financial results. Even if we complete an acquisition, we may not be able to successfully integrate newly acquired organizations, products, technologies or employees into our operations, or may not fully realize some of the expected synergies.

Integrating an acquisition can also be expensive and time-consuming, and may strain our resources. It may cost us more to commercialize new products than we originally anticipated, as we are experiencing with our proton therapy systems, which could impact our results of operations. In many instances, integrating a new business will also involve implementing or improving internal controls appropriate for a public company 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 divest acquired businesses, or assets of those businesses. Even if we do so, an acquisition may not produce the full efficiencies, growth or benefits we expected. If we decide to sell assets or a business, as we did in fiscal year 2008 with the scientific research instruments business that we acquired as part of our acquisition of ACCEL, it may be difficult to identify buyers or alternative exit strategies on acceptable terms, in a timely manner, or at all, which could delay the accomplishment of our strategic objectives. Additionally, we may be required to dispose of a business at a lower price or on less advantageous terms, or to recognize greater losses, than we had anticipated.

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 decide to sell assets or a business, we may be required to recognize an impairment loss on the write down of our assets and goodwill, which could adversely affect our financial results. In addition, acquisitions can result in potentially dilutive issuances of equity securities or the incurrence of debt, contingent liabilities or expenses, or other charges, any of which could harm our business and affect our financial results.

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

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

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

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

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

We have experienced and expect in the future to experience fluctuations in our operating results, including net orders, revenues and margins. Drivers of orders include timing of announcement of and introduction of new products or product enhancements by us and our competitors, as well as changes or anticipated changes in third party reimbursement amounts or policies applicable to treatments using our products. The availability of economic stimulus packages or other government funding may also affect timing of customer purchases. Many of our products require significant capital expenditures by our customers. Accordingly, individual product orders can be quite large in dollar amounts, which can extend the customer purchasing cycle. We have experienced this with our IGRT products, and with our proton therapy products because of the high cost of the proton therapy equipment and the complexity of project financing. In addition, the budgeting cycles of hospitals and clinics for capital equipment purchases are frequently fixed well in advance. As a result of the sluggish recovery from the 2008 worldwide economic downturn and contraction in credit markets, as well as continued uncertainty regarding global economic conditions, the purchasing cycle has extended and may extend even further as potential customers more closely scrutinize and prioritize their capital spending budgets, and analyze appropriate financing alternatives. In addition, some of our more sophisticated equipment, such as IGRT and proton therapy products, requires greater site preparation and longer construction cycles, which can delay customer decision cycles even further. The timing of when individual orders are placed, installation is accomplished and the revenues recognized affect our quarterly results.

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

delay in shipment due, for example, to unanticipated construction delays at customer locations where our products are to be installed, cancellations or rescheduling by customers, extreme weather conditions, natural disasters or port strikes;

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

for proton therapy systems, failure to satisfy contingencies associated with an order;

the method of accounting used to recognize revenue;

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

timing of appropriate regulatory approvals or authorizations.

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

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

changes in foreign currency exchange rates;

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

changes in the relative portion of our revenues represented by the international region;

fluctuation in our effective tax rate, 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;

the impact of changing levels of sales on sole purchasers of certain of our x-ray products;

the unfavorable outcome of any litigation or administrative proceeding or inquiry; and

accounting changes and adoption of new accounting pronouncements.

Because many of our operating expenses are based on anticipated capacity levels and a high percentage of these expenses are fixed for the short term, a small variation in the timing of revenue recognition can cause significant variations in operating results from quarter to quarter. Our overall gross margin may also be impacted by the gross margin of our proton therapy products, which are presently 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 GAAP, and are not within the scope of the audit or reviews conducted by our independent registered 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. High levels of order cancellation 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, revenues and net earnings in one or more future periods may fall below the expectations of securities analysts and investors. In that event, the trading price of VMS common stock would almost certainly decline.

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

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

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Since proton therapy projects are highly customized and are generally large and more complex, 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. Consequently, this business is vulnerable to general economic and market conditions. The worldwide economic downturn resulted in a contraction in credit markets. This has made and may continue to make it more difficult for potential customers of this business to find appropriate financing for large proton therapy projects, which could cause them to delay or cancel their projects, or request that we participate in financing arrangements (such as we recently did for the Scripps Proton Therapy Center) or payment concessions in their agreements with us, which could impact our operating results. 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, and therefore our operating results for this business, may vary significantly from period to period.

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We expect that a limited number of customers will account for a substantial portion of VPT's business for the foreseeable future. Because an order for a proton therapy system can be relatively large, an order in one fiscal period will cause our net orders to vary significantly, making comparisons between fiscal periods more difficult. Further, the award of a proton therapy system order may be subject to challenge by third parties, which can make these orders more unpredictable than other products. If a customer cancels an order for a proton therapy system, such as occurred with the order for a proton therapy system for Skandion Kliniken in Sweden, it would negatively impact our orders in the fiscal period in which the order is cancelled and we would lose the opportunity for the product and services revenues that the order represents.

In addition, many of the components used in proton therapy equipment require a long lead time, which may require an increase in our levels of inventory. This may cause fluctuations in the operating results of VPT that may make it difficult to predict our results and to compare our results from period to period.

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. Additionally, 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, as well as in some situations participate in or provide project financing for the project. Providing financing for one or more proton therapy centers, such as the Scripps Proton Therapy Center, could adversely affect our financial results, since we cannot provide any assurance that a center will be completed on time or within budget, that the center can or will generate sufficient patient volumes and revenues to support scheduled loan payments or to provide incremental revenue to us, that a loan commitment may be syndicated to third parties or refinanced at maturity, or that the borrower will have the financial means to pay off any financing at maturity. If a borrower does not have the financial means to pay off its debts and if we cannot recover our investment from the sale of any collateral, we may be required to write off the debt investment, which would adversely affect our financial results. If we must establish special purpose entities to finance and manage a proton therapy project, we may be required to consolidate these special purpose entities in our financial statements. Since the cost of each proton therapy center project will generally exceed \$100 million, the amount of potential liability and potential for financial loss may be higher than the levels historically assumed by us for our traditional radiation therapy business and may also exceed the project's value. Insurance covering these contingencies may be unobtainable. If we cannot reasonably mitigate or eliminate these contingencies or risks, our ability to competitively bid upon proton center projects will be negatively impacted or we may be required to assume material amounts of potential liability, all of which may have adverse consequences to us. In addition, we have encountered and may encounter additional challenges in the commercialization of the proton therapy products, which may increase our research and development costs and delay the introduction of our products. This and other unanticipated events could adversely affect our business and make our results of operations unpredictable.

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

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

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

We prepare our financial statements to conform to GAAP. These principles are subject to interpretation by the FASB, 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

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of, these principles can have a significant effect on our reported results and may even affect our reporting of transactions completed before a change is announced. In addition, when we are required to adopt new accounting standards, our methods of accounting for certain items may change, which could cause our results of operations to fluctuate from period to period and make it more difficult to compare our financial results to prior periods.

As our operations evolve over time, we may introduce new products or new technologies that require us to apply different accounting principles, including that regarding revenue recognition, than we have applied in past periods. Additionally, we recognize revenues for our proton therapy systems and proton therapy commissioning contracts and for certain highly customized image detection systems in our SIP business under the percentage-of-completion method, which affects the timing of revenue recognition. We could be required to apply these methods to other businesses in the future. 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 which must be periodically reviewed and appropriately adjusted. For example, revenues recognized under the percentage-of-completion method are based on contract costs incurred to date compared with total estimated contract costs. In circumstances in which the final outcome of a contract cannot be precisely estimated but a loss on the contract is not expected, we recognize revenues under the percentage-of-completion method based on a zero profit margin until more precise estimates can be made. Recognizing revenues using the percentage-of-completion method based on a zero profit margin, as we are doing with the revenues associated with the Scripps Proton Therapy Center, will lower our gross margins and make it more difficult to compare our financial results from quarter to quarter.

If our estimates prove to be inaccurate or circumstances change over time, we would be required to adjust revenues or even record a contract loss in later periods, and our financial results could suffer. In addition, if a loss is expected on a contract under the percentage-of-completion method, the estimated loss would be charged to cost of sales in the period the loss is identified. The application of different types of accounting principles and related potential changes 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.

ENVIRONMENTAL LAWS IMPOSE COMPLIANCE COSTS ON OUR BUSINESS AND CAN ALSO RESULT IN LIABILITY

We are subject to environmental laws around the world. These laws regulate many aspects of our operations, including our handling, storage, transport and disposal of hazardous materials. They can also impose cleanup liabilities, including with respect to discontinued operations. As a consequence, we can incur significant environmental costs and liabilities, some recurring and others not recurring. Although we follow procedures intended to comply with existing environmental laws, we, like other businesses, can never completely eliminate the risk of contamination or injury from certain materials that we use in our business and, therefore, the prospect of resulting claims and damage payments. We may also be assessed fines or penalties for failure to comply with environmental laws and regulations. Although insurance has provided coverage for portions of cleanup costs resulting from historical occurrences, we maintain only limited insurance coverage for costs or claims that might result from any future contamination.

Future changes in environmental laws could also increase our costs of doing business, perhaps significantly. Several countries, including some in the EU, now require medical equipment manufacturers to bear certain disposal costs of products at the end of the product's useful life, increasing our costs. The EU has also adopted a directive that may lead to restrictions on the use of certain hazardous substances in some of our products sold there. This directive, along with another that requires material disclosure information to be provided upon request, could increase our operating costs. All of these costs, and any future violations or liabilities under environmental laws or regulations, could have a material adverse effect on our business.

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

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

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If a legal proceeding were finally resolved against us, it could result in significant compensatory damages, and in certain circumstances punitive or trebled damages, disgorgement of revenue or profits, remedial corporate measures or injunctive relief imposed on us. If any final amounts owed were in excess of the amounts accrued or if other resolution or actions taken as a result of the legal proceeding were to restrain our ability to market one or more of our material products or services, our consolidated financial position, results of operations or cash flows could be materially adversely affected.

AS A STRATEGY TO ASSIST OUR SALES EFFORTS, WE MAY PARTICIPATE IN PROJECT FINANCING OR OFFER EXTENDED PAYMENT TERMS, WHICH MAY ADVERSELY AFFECT OUR FINANCIAL RESULTS

We have provided financing for the construction and start-up operations of the Scripps Proton Therapy Center, and we may be requested to provide financing to other potential VPT customers in the future. Some of this financing may be secured by assets of the borrower. Providing such financing could adversely affect our financial results, since we cannot provide any assurance that a center will be completed on time or within budget, that the center can or will generate sufficient patient volumes and revenues to support scheduled loan payments or to provide incremental revenue to us, or that the borrower will have the financial means to pay off any financing at maturity. In addition, in connection with our financing of the Scripps Proton Therapy Center, we cannot provide any assurance that any portion of our loan commitment can be syndicated to third parties by ORIX Capital Markets LLC, the agent for the lenders, or that the loan facility can be successfully refinanced upon the maturity of the loan, which has a maximum term of six years. If a borrower does not have the financial means to pay off its debts and if we cannot recover our investment from the sale of any collateral, we may be required to write off the debt investment, which would adversely affect our financial results.

In addition, in some circumstances we offer longer or extended payment terms for qualified customers in our other businesses. Many of the areas where we offer such longer or extended payment terms have under-developed legal systems for securing debt and enforcing collection of debt. As of December 30, 2011, customer contracts with remaining terms of more than one year amounted to approximately 3% of our accounts receivable balance. While we qualify customers to whom we offer longer or extended payment terms, their financial positions may change adversely over the longer time period given for payment. This may result in an increase in payment defaults and uncollectible accounts, which would affect our net earnings. In addition, longer or extended payment terms could impact the timing of our revenue recognition, and they have in the past and may in the future result in an increase in our days sales outstanding.

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

Information technology helps us operate efficiently, interface with and support our customers, maintain financial accuracy and efficiency, and accurately produce our financial statements. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology infrastructure, we could be subject to, among other things, transaction errors, processing inefficiencies, the loss of customers, business disruptions, or the loss of or damage to intellectual property through a security breach. If our data management systems do not effectively collect, secure, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, or human error, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations will be impaired, perhaps materially. Any such impairment could materially and adversely affect our financial condition, results of operations, cash flows and the timeliness with which we report our operating results internally and externally.

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Moreover, we manufacture and sell products that allow our customers to store confidential information about their patients. While we have implemented security measures to protect our systems from unauthorized access, these measures do not secure our customers' equipment or any information stored in our customers' systems or at their locations. A breach of network security and systems or other events that cause the loss or public disclosure of, or access by third parties to, our customers' stored information could have serious negative consequences for our business, including possible fines, penalties and damages, reduced demand for our solutions, an unwillingness of our customers to use our solutions, harm to our reputation and brand, and time-consuming and expensive litigation, any of which could have an adverse effect on our financial results.

OUR OPERATIONS ARE VULNERABLE TO INTERRUPTION OR LOSS DUE TO NATURAL OR OTHER DISASTERS, POWER LOSS, STRIKES AND OTHER EVENTS BEYOND OUR CONTROL

We conduct a significant portion of our activities, including manufacturing, administration and data processing at facilities located in the State of California and other seismically active areas that have experienced major earthquakes and other natural disasters. We carry limited earthquake insurance that may not be adequate or continue to be available at commercially reasonable rates and terms. A major earthquake or other disaster (such as a major fire, flood, tsunami, volcanic eruption or terrorist attack) affecting our facilities, or those of our suppliers, could significantly disrupt our operations, and delay or prevent product manufacture and shipment during the time required to repair, rebuild or replace our or our suppliers' damaged manufacturing facilities; these delays could be lengthy and costly. If any of our customers' facilities are adversely affected by a disaster, shipments of our products could be delayed. Additionally, customers may delay purchases of our products until operations return to normal. Even if we are able to quickly respond to a disaster, the ongoing effects of the disaster could create some uncertainty in the operations of our businesses, such as the recent catastrophe in Japan has created. In addition, our facilities may be subject to a shortage of available electrical power and other energy supplies. Any shortages may increase our costs for power and energy supplies or could result in blackouts, which could disrupt the operations of our affected facilities and harm our business. Further, 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. In addition, concerns about terrorism, the effects of a terrorist attack, political turmoil or an outbreak of epidemic diseases, such as the swine flu, 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.

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(a) Not applicable

(b) Not applicable

(c) The following table provides information with respect to the shares of common stock repurchased by us during the first quarter of fiscal year 2012.

Period	Total Number of Shares Purchased	Average Price Paid 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 (1)
October 1, 2011 - October 28, 2011	85(2)	\$ 56.95		7,433,718
October 29, 2011 - November 25, 2011	481(3)	\$ 57.29		7,433,718
November 26, 2011 - December 30, 2011		\$		7,433,718
Total	566	\$		

- (1) In February 2011, VMS's Board of Directors authorized the repurchase of 12,000,000 shares of VMS common stock through the end of our fiscal year 2012. We expect remaining repurchases under this authorization, if any, will be made in open market purchases, in privately negotiated transactions (including accelerated share repurchase programs) or under Rule 10b5-1 share repurchase plans, and may be made from time to time or in one or more blocks. Shares will be retired upon repurchase.
- (2) Consists of 85 shares of VMS common stock that were tendered to VMS in satisfaction of tax withholding obligations upon the vesting of restricted common stock granted under the Company's employee stock plans.
- (3) Consists of 481 shares of VMS common stock that were tendered to VMS in satisfaction of tax withholding obligations upon the vesting of restricted common stock and restricted stock units granted under the Company's employee stock plans.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

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(a) Exhibits required to be filed by Item 601 of Regulation S-K:

Exhibit No.	Description
15.1	Letter Regarding Unaudited Interim Financial Information.
31.1	Chief Executive Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act.
31.2	Chief Financial Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act.
32.1	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

Attached as Exhibit 101 to this Quarterly Report on Form 10-Q are the following formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Statements of Earnings for the three months ended December 30, 2011 and December 31, 2010; (ii) Condensed Consolidated Statements of Earnings for the three months ended December 30, 2011 and December 31, 2010; (iii) Condensed Consolidated Balance Sheets at December 30, 2011 and December 31, 2010; (iv) Condensed Consolidated Statements of Cash Flows for the three months ended December 30, 2011 and December 31, 2010; and (v) Notes to Condensed Consolidated Financial Statements for the three months ended December 30, 2011 and.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

VARIAN MEDICAL SYSTEMS, INC.
(Registrant)

Dated: February 7, 2012

By: */s/* **ELISHA W. FINNEY**
Elisha W. Finney
Senior Vice President, Finance and
Chief Financial Officer
*(Duly Authorized Officer and
Principal Financial Officer)*

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