

ACCURAY INC  
Form 10-K  
August 29, 2013

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549  
  
**FORM 10-K**

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended June 30, 2013

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
Commission file number 001-33301

**ACCURAY INCORPORATED**

(Exact name of registrant as specified in its charter)

**DELAWARE**

(State or Other Jurisdiction of  
Incorporation or organization)

**20-8370041**

(I.R.S. Employer  
Identification No.)

**1310 Chesapeake Terrace**  
**Sunnyvale, California 94089**

(Address of Principal Executive Offices) (Zip Code)

Registrants' telephone number, including area code: **(408)716-4600**

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, \$.001 par value per share	The NASDAQ Stock Market LLC

Securities registered pursuant to section 12(g) of the Act:

**None**

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

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

## Edgar Filing: ACCURAY INC - Form 10-K

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a  
smaller reporting company)

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant based on the last sale price for such stock on December 31, 2012, the last business day of the registrant's most recently completed second fiscal quarter was: \$247,564,392. Shares of the registrant's common stock held by each executive officer, director and 5% stockholder have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of August 19, 2013, the number of outstanding shares of the registrant's common stock, \$0.001 par value, was 74,705,405.

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Registrant's 2013 Annual Meeting of stockholders are incorporated by reference in Part III of this Form 10-K.

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**ACCURAY INCORPORATED**

**YEAR ENDED JUNE 30, 2013**

**FORM 10-K**

**ANNUAL REPORT**

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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

*This Form 10-K includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including, but not limited to, statements regarding the extent and timing of future revenues and expenses, statements regarding marketing efforts, statements regarding reimbursement rates, statements regarding regulatory requirements, statements regarding future orders, statements regarding the cancer treatment market, statements regarding our strategy, statements regarding our products, statements regarding revenues, statements regarding intellectual property rights, statements regarding TomoTherapy, statements regarding our earnings or other financial results, and other statements using words such as "anticipates," "believes," "could," "estimates," "expects," "forecasts," "intends," "may," "plans," "projects," "should," "will" and "would," and words of similar import and the negatives thereof. Accuray Incorporated ("we," "our," the "Company") has based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. These forward-looking statements speak only as of the date of this Form 10-K and are subject to business and economic risks. Factors that could cause our actual results to differ materially include those discussed under "Risk Factors" in Part I, Item 1A of this report. We undertake no obligation to update or revise any forward-looking statements to reflect any event or circumstance that arises after the date of this report.*

**PART I**

**Item 1. BUSINESS**

**The Company**

We believe we are a leading radiation oncology company with a history of rapid innovations. Our leading edge technologies are designed specifically to deliver highly precise radiosurgery, stereotactic body radiation therapy, intensity modulated radiation therapy, image guided radiation therapy and adaptive radiation therapy tailored to the specific needs of each patient. Our suite of products includes the CyberKnife® Systems and the TomoTherapy® Systems.

The CyberKnife Systems are fully robotic stereotactic radiosurgery systems, or SRS and stereotactic body radiation therapy systems, or SBRT used to treat multiple types of cancer and tumors throughout the body. The CyberKnife Systems automatically track, detect and correct for tumor and patient movement in real-time during the procedure, enabling delivery of precise, high dose radiation with sub-millimeter accuracy while patients breathe normally. Treatment with the CyberKnife Systems requires no anesthesia, and can be performed in one to five staged treatment sessions on an outpatient basis. In addition, the CyberKnife Systems are designed to minimize many of the risks and complications that are associated with other treatment options. The CyberKnife Systems include: the CyberKnife G4, which includes the Fixed collimator; CyberKnife® VSI System, which includes the Fixed and Iris collimators and the new CyberKnife M6 Series System, that comes in configurations that have the option of Fixed collimator, Iris collimator, and a MultiLeaf collimator, or MLC.

The TomoTherapy Systems are used to treat a wide range of cancers and tumors, and enable efficient daily imaging to ensure the accuracy of the patient position before each treatment delivery. The TomoTherapy Systems operate on ring gantries and combine integrated CT imaging with intensity modulated radiation therapy or IMRT, which is designed to deliver radiation treatments with speed and precision while reducing radiation exposure to surrounding healthy tissue. The TomoTherapy Systems include the Hi-Art® System, delivering CT-guided, helical IMRT; the TomoHD System, which includes both our TomoHelicā™ and TomoDirect™ treatment modalities and the Tomo H™ Series Systems that come in configuration options of TomoH™, TomoHD and TomoHDA™ and which includes one

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or more of the following options: TomoHelical™, TomoDirect™, High Performance VoLo™ Planning and TomoEdge Dynamic Jaws.

As of June 30, 2013, 700 CyberKnife and TomoTherapy Systems were installed worldwide, four of which were installed under our shared ownership program.

We were incorporated in California in 1990 and commenced operations in 1992. We reincorporated in Delaware in 2007. Our principal offices are located at 1310 Chesapeake Terrace, Sunnyvale, CA 94089, and our telephone number is (408) 716-4600.

**Market Overview**

Despite significant improvements in cancer diagnosis and treatment, cancer rates continue to increase globally and are a leading cause of death. According to the 2008 World Cancer Report and an update in June 2012, issued by the International Agency for Research on Cancer in the World Health Organization, or WHO, annual cancer rates around the world are projected to increase by over 73% to 22.0 million new cases in the year 2030 from 12.7 million cases in 2008. Since 2010, cancers are estimated to have been the leading cause of death. In the United States, cancer is the second leading cause of death after heart disease.

Cancers can be broadly divided into two groups: solid tumor cancers, which are characterized by the growth of malignant tumors within the body in areas such as the brain, lung, liver, breast or prostate, and hematological, or blood-borne cancers, such as leukemia. The ACS estimates that solid tumor cancers will account for approximately 1.5 million, or approximately 91% of new cancer cases diagnosed and will account for approximately 0.5 million cancer related deaths in the United States.

Traditional methods for the treatment of solid tumor cancers include chemotherapy, surgery and radiation therapy. Currently, the most common type of radiation therapy is external beam radiation therapy, in which patients are treated with high-energy radiation generated by medical equipment external to the patient. Linear accelerators (linacs) have been widely used for radiation therapy for over 30 years. Linacs represent the largest product segment within the global radiation therapy equipment market which was estimated to have a market size of approximately \$2.1 billion in 2011, according to the October 2010 Radiation Therapy Equipment Report by Global Industry Analysts, Inc. While radiation therapy is widely available in the United States and Western Europe, many developing countries currently do not have a sufficient number of linacs to adequately treat their domestic cancer patient populations. We believe increasing demand for advanced medical treatments in many international markets and growth in cancer incidences worldwide will continue to drive demand for advanced linacs in the coming years.

**Radiation Therapy**

Radiation therapy is used to treat a wide range of cancer and tumor types. Radiation therapy works by exposing clusters of cancer cells, or tumors, to a dose of high energy radiation sufficient to cause cell death. When the external beam radiation therapy process begins, the clinician's goal is to target radiation delivery to the tumor as precisely as possible in order to maximize the radiation dose delivered to cancerous tissue and minimize the exposure of healthy tissue. Recent advances in radiation therapy technologies have focused clinicians on further improving the ability to target the radiation dose more precisely at cancer cells while minimizing the exposure of healthy tissue. These advances include the following:

***Intensity modulated radiation therapy.*** Intensity modulated radiation therapy, or IMRT, involves varying, or modulating, the radiation beam intensity across the treatment area. This technique aims to conform the high dose region of the radiation beam more closely with the shape of the tumor,

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enabling the delivery of higher doses of radiation to tumors with a reduced impact on surrounding healthy tissue.

**Image guided radiation therapy.** Image guided radiation therapy, or IGRT, involves delivering radiation guided by images of the treatment area taken shortly before and/or during treatment using CT scan, x-ray, ultrasound or other imaging technologies. By combining imaging with radiation treatment, clinicians can adjust the patient's position relative to the radiation source prior to each treatment to target the tumor more precisely.

**Radiosurgery and Stereotactic Body Radiation Therapy.** Radiosurgery originated for tumors in the brain (intracranial). However, depending on the proximity of normal healthy tissue to the tumor, there was a need for fractionated radiosurgery, even intracranially. The ability to deliver fractionated intracranial radiosurgery (dividing the prescription dose into one to five fractions) has evolved to meet this need. Additionally, the same tumor ablation technique has been extended to the treatment of targets anywhere in the body. To achieve the accuracy and precision required for both radiosurgery and Stereotactic Body Radiation Therapy, image guidance and a wide range of beam angles are critical for treatment.

**Adaptive radiation therapy.** Adaptive radiation therapy involves adjusting a patient's radiation therapy plan during or between fractions to account for changes in the patient's anatomy, the amount and location of the radiation received by the patient, and the size, shape and location of the tumor. While there is no widely accepted definition of adaptive radiation therapy, it has been characterized to include as little as an adjustment to the physical position of the patient relative to the radiation source prior to treatment, as occurs during IGRT, rather than adjustment to the treatment plan. Our approach is based on the belief that adaptive radiation therapy requires monitoring and adjustments to the treatment plan facilitated by both the regular acquisition of updated quantitative images showing the location, size, shape and density of the tumor, and verification of the radiation dose received by the patient throughout the entire course of treatment.

**Dose escalation.** Higher doses of radiation have been shown to yield greater local control of the tumor. The advent of innovative technological features in radiation therapy treatment planning and delivery has allowed the clinical use of dose escalation, increasing the radiation dose administered to tumors in the patient, which has resulted in improved local tumor control and, in some cases, improved patient survival. Hypofractionation is an evolving radiation therapy technique that involves reducing the number of fractions and delivering larger doses of radiation per fraction. The benefits of hypofractionation include patient convenience as a result of fewer treatment visits and more efficient use of radiation therapy systems. Stereotactic radiation therapy and stereotactic radiosurgery procedures, in which treatment is provided in one to five sessions, are extreme examples of hypofractionation. Hypofractionation has been used to date to treat only a limited number of tumor types. These tumors are generally small and are located in a few specific, sensitive regions of the body, such as the head and neck, spinal cord, lung and prostate, where the very high intensity radiation involved in dose escalation increases the need for a radiation delivery system that is capable of locating tumors and delivering radiation with high precision.

Despite advances in radiation therapy techniques, most commercially available radiation therapy systems from other manufacturers still present significant limitations that restrict clinicians' ability to provide the most effective treatment possible. These limitations include:

**Limited versatility and precision.** The C-arm configuration of traditional radiation therapy systems has a limited range and speed of motion due to its size and mechanical structure. Most existing MLCs, which modulate or shape the radiation beams, also have mechanical limitations that reduce their beam-shaping ability and the speed at which they operate. These design elements limit the motion and dynamic range of IMRT intensities capable of being delivered by traditional radiation therapy systems and often make it impractical to deliver radiation from more than five to nine

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treatment angles during a typical treatment session. These limited treatment angles reduce the ability to deliver precisely targeted radiation that minimizes exposure to healthy tissue. Such imprecision may prevent clinicians from treating tumors near sensitive anatomic structures, such as the eye or the spinal cord, or from re-treating patients in an area of the body that was previously exposed to radiation and may be unable to tolerate additional exposure.

***Limited ability to provide frequent, quantitative images.*** Precise radiation therapy requires frequent images that accurately depict the size, shape and location of the tumor. Many traditional radiation therapy systems either do not incorporate CT imaging functionality or use imaging technologies that do not have the ability to generate a quantitative assessment of the patient's and/or target volume's position. In addition, traditional radiation therapy systems measure the amount of radiation emitted by the device based on the system's performance specifications. This calculation does not provide the clinician with data regarding the amount of radiation that was received by the patient or what tissue within the patient's body received any particular amount of radiation. Also, many radiation therapy systems have imaging subsystems that are not suited to use for daily imaging of the patient due to concerns about the additional radiation exposure. Since it is common for internal organs to shift and for the size of the tumor to change during the course of treatment, failure to obtain updated images and adapt the treatment plan throughout the course of treatment may result in a portion, or potentially all, of the radiation dose missing the tumor and instead being absorbed by healthy tissue.

***Failure to integrate multiple functions.*** Many traditional radiation therapy systems were designed solely for the purpose of delivering radiation and therefore do not possess integrated imaging, treatment planning, dose verification or quality assurance capabilities necessary for more advanced treatment protocols. Some systems subsequently have been adapted to include certain elements of this functionality by incorporating modular add-on devices to legacy linac designs. These separate modular components can provide imaging, treatment planning, quality assurance procedures or post-treatment analysis functionality. However, this add-on architectural approach can have safety and accuracy implications because the onus for checking proper data transmission and receipt often falls back to manual methods. This can result in a user reconfiguring and recalibrating the system between patient imaging, treatment planning, radiation delivery and quality assurance.

**Development of Radiosurgery**

Radiosurgery systems differ from traditional radiation therapy systems in that they are designed to deliver a very high cumulative dose of radiation, in a single or a small number of treatments precisely targeted at the tumor rather than at a region that consists of the tumor plus healthy tissue that surrounds the tumor area. The more accurate delivery of radiation allows higher doses to be delivered, increasing the probability of tumor cell death and better local control. In addition, radiosurgery can be used on patients who cannot, because of advanced age or other health reasons, tolerate traditional surgery.

**Our Strategy**

Our goal is to develop equipment and technology that allows physicians to deliver customized leading-edge treatment solutions that help cancer patients live longer, better lives. We endeavor to achieve this goal by expanding clinical opportunities for healthcare providers, helping them offer the best radiation treatment for each patient and by providing patients with treatment tailored to their specific needs. Our vision is a future where the fear, pain and suffering of cancer are a thing of the



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past. We believe our current technologies and our future innovation can help to achieve this. Some of the key elements of our strategy include the following:

***Increase physician adoption and patient awareness to drive utilization.*** We are continually working to increase adoption and awareness of our systems and demonstrate their advantages over more traditional treatment methods. We hold and sponsor symposia and educational meetings and support clinical studies in an effort to demonstrate the clinical benefits of our systems. We regularly meet with clinicians to educate them on the expanded versatility that our systems offer in comparison to more traditional radiation therapy products. To support awareness of all of our product offerings, we assist our customers to increase patient awareness in their communities by helping them develop marketing and educational campaigns.

***Continue to expand the radiosurgery market.*** While radiosurgery has traditionally been used to treat brain tumors, the CyberKnife Systems received U.S. Food and Drug Administration, or FDA, clearance in 2001 to treat tumors anywhere in the body where radiation is indicated. Our system data demonstrate that over 50% of CyberKnife utilization is for cancers and tumors in the body in places other than the brain. There are now hundreds of peer-reviewed publications supporting use of CyberKnife in treatment of various cancer and tumor types.

***Continue to innovate through clinical development and collaboration.*** The clinical success of our products is due in large part to the collaborative partnerships we have developed over the last decade with clinicians, researchers and patients. We proactively seek out and rely on constructive feedback from system users to learn what is needed to enhance the technology. As a result of this collaborative process, we continually refine and upgrade our systems, thereby improving our competitive position in the radiation therapy and radiosurgery markets. Our upgrades are designed to address customer needs in the areas of improving the ease of use and accuracy of treatment, decreasing treatment times, and improving utilization for specific types of tumors.

***Expand sales in international markets.*** We intend to continue to increase our sales and distribution capabilities outside of the United States to take advantage of the large international opportunity for our products. We currently have regional offices in Madison, Wisconsin, Morges, Switzerland, Paris, France, Brussels, Belgium, Hong Kong, China and Tokyo, Japan and direct sales staff in most countries in Western Europe, Japan, India and Canada. Combined with distributors in Eastern Europe, Russia, the Middle East, the Asia Pacific region and Latin America, our sales and distribution channels cover more than 92 countries. However, many of these countries are not highly developed at this time and therefore sales opportunities may be limited. We intend to increase our international revenue by select additions of direct sales and marketing personnel in targeted areas to further penetrate our most promising international markets, as well as additions of distributors.

***Pursue acquisitions, strategic partnerships and joint ventures.*** We intend to actively pursue acquisitions, strategic partnerships and joint ventures we believe will allow us to complement our growth strategy, increase sales in our current markets and expand into adjacent markets, broaden our technology and intellectual property and strengthen our relationships with our customers. For example, in fiscal 2011, we completed the acquisition of TomoTherapy, Inc., a creator of advanced radiation therapy solutions for cancer care. In July 2012, we completed the acquisition of Morphormics, Inc., a privately-held company based in North Carolina, which is a developer of medical imaging software systems.

**Our Products**

Our suite of products includes the CyberKnife® Systems and the TomoTherapy® Systems.

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***The CyberKnife Systems***

Our principal radiosurgery products are the CyberKnife Systems, a robotic radiosurgery system designed to treat tumors anywhere in the body non-invasively, which include the CyberKnife M6 Series with configuration options of Fixed collimators (F), Fixed collimators plus Iris variable aperture collimator (FI), Fixed collimators plus the InCise™ MultiLeaf collimator (FM) and Fixed collimators plus Iris variable aperture collimator plus the InCise MultiLeaf collimator (FIM). The current United States list price for the CyberKnife Systems range from approximately \$4.5 million to \$7 million, depending upon system configuration and options purchased by the customer. The list price typically includes initial training, installation and a one-year warranty. We also offer optional hardware and software, technical enhancements and upgrades to the CyberKnife Systems, as well as service contracts and training to assist customers in realizing the full benefits of the CyberKnife Systems.

Using continual image guidance technology and computer controlled robotic mobility, the CyberKnife Systems are designed to deliver precise radiation from almost any angle and automatically track, detect and correct for tumor and patient movement in real-time throughout the treatment. This design is intended to enable the CyberKnife Systems to deliver high-dose radiation with precision, which minimizes damage to surrounding healthy tissue and eliminates the need for invasive head or body stabilization frames. Our patented image-guidance technology correlates low dose, real-time treatment X-rays with images previously taken with a CT scan of the tumor and surrounding tissue to direct each beam of radiation with increased precision versus treatments without this real-time feedback. This, in turn, enables delivery of a highly conformal, non-isocentric dose of radiation to the tumor, with minimal radiation delivered to surrounding healthy tissue. With its autonomous ability to track, detect and correct for even the slightest tumor and patient movement throughout the entire treatment, the CyberKnife System is intended to provide clinicians with an effective, uninterrupted and accurate treatment

Our newest configurations of CyberKnife Systems include the following:

***The CyberKnife M6 Series with configurations of F, FI, FM and FIM.*** The M6 Series is FDA approved to be used with any of the following options: Fixed collimators (F), an Iris collimator (I) or a Multileaf collimator (M). When the InCise Multileaf collimator (MLC) is available, larger tumors previously thought untreatable with radiosurgery and SBRT will be able to be treated efficiently and with unrivaled accuracy and tissue sparing. The InCise MLC and IMRT planning tools will enable expansion of indications that can be treated with a CyberKnife to include many IMRT indications. The CyberKnife® M6 Series includes disease-specific tracking and treatment delivery solutions for brain, spine, lung and prostate tumors.

***CyberKnife VSI System.*** The CyberKnife VSI System is available with the Fixed collimators or an optional Iris collimator. The VSI System uses an intuitive planning process to enable clinicians to adapt treatment delivery to the distinct characteristics of each patient with continual image guidance.

We believe the CyberKnife Systems offer clinicians and patients the following benefits:

***The only truly robotic system in the market.*** Combining the benefits of continual image guidance and non-isocentric, non-coplanar treatment delivery, the CyberKnife Systems precisely contour radiation delivery to spare healthy tissue while maintaining sub-millimeter accuracy, even for targets that move during treatment. The CyberKnife Systems are the clinical solution to choose when accuracy, flexibility, efficiency and patient comfort are essential.

***Treatment of inoperable or surgically complex tumors.*** The CyberKnife Systems may be used to target tumors that cannot be easily treated with traditional surgical techniques because of their location, number, size, shape or proximity to vital tissues or organs, or because of the age or health of

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the patient. The CyberKnife Systems' intelligent robotics enable the precise targeting of a tumor, while at the same time minimizing damage to surrounding healthy tissue.

***Treatment of tumors throughout the body.*** The CyberKnife Systems have been cleared by the FDA to provide treatment planning and image-guided radiosurgery treatment for tumors anywhere in the body where radiation treatment is indicated. Unlike frame-based radiosurgery systems, which are generally limited to treating brain tumors, the CyberKnife Systems are being used for the treatment of primary and metastatic tumors outside the brain, including tumors on or near the spine and in the lung, liver, prostate and pancreas.

***Real-time tracking of tumor movement.*** The CyberKnife Systems are designed to enable the treatment of tumors that change position due to respiration, tumor or patient movement during treatment. The CyberKnife Systems offer the following features which enhance image guided robotic radiation surgery: Synchrony® Respiratory Tracking System, Xsight® Lung Tracking System, Xsight® Spine Tracking System, InTempo Adaptive Imaging System and Lung Optimized Treatment (optional).

***Significant patient benefits.*** Patients may be treated with the CyberKnife Systems on an outpatient basis without anesthesia and without the risks and complications inherent in traditional surgery. Patients do not require substantial pre-treatment preparation, and typically there is little to no recovery time or hospital stay associated with CyberKnife Systems' treatments. In addition, the CyberKnife Systems eliminate the need for an invasive rigid frame to be screwed into the patient's skull or affixed to other parts of the body, or for artificial breath holding or gating instruments.

***Additional revenue generation through increased patient volumes.*** We believe clinical use of the CyberKnife Systems allows our customers to effectively treat patients where extreme precision and ability to account for motion are important, and patients who otherwise would not have been treated with radiation or who may not have been good candidates for surgery. Therefore, we believe the treatment of these patients generates additional revenue without affecting our customers' traditional radiation therapy practices.

***Upgradeable modular design.*** The CyberKnife Systems have a modular design, which facilitates the implementation of upgrades that generally do not require our customers to purchase an entirely new system to gain the benefits of new features. We continue to work to develop and offer new clinical capabilities enhancing ease of use, reducing treatment times, improving accuracy and improving patient access. The main components and options of the CyberKnife Systems include: the Compact X-brand linear accelerator (linac); Robotic manipulator, the Real-time image-guidance system with continuous target tracking and correction; X-ray sources; Image detectors. Key features of these components include:

***Robotic manipulator.*** The robotic manipulator arm, with six-degrees-of-freedom range of movement, is designed to move around the patient to position the linac and direct the radiation with an extremely high level of precision and repeatability. The manipulator arm provides what we believe to be a unique method of positioning the linac to deliver doses of radiation from nearly any direction and position, without the limitations inherent in gantry-based systems, creating a non-isocentric composite dose pattern with a high level of conformance to the shape of each treated tumor. This flexibility enhances the ability to diversify beam trajectories and beam entrance and exit points, helping to minimize risks of radiation damage to healthy cells near the tumor. Furthermore, the rapid response time of the manipulator arm allows tracking of tumors that move with respiration.

***Real-time image-guidance system with continuous target tracking and correction.*** Without the need for clinician intervention or treatment interruption, the CyberKnife Systems' real-time image-guided robotics is designed to enable continuous monitoring and correction for patient and tumor movements throughout each treatment as it is being delivered.

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***X-ray sources.*** The low-energy X-ray sources generate the X-ray images that help determine the location of bony or other anatomic landmarks, or implanted fiducials, which are used for tracking throughout the entire treatment.

***Image detectors.*** The image detectors capture high-resolution anatomical images throughout the treatment. These live images are continually compared to the patient's CT scan to determine real-time patient positioning. Based on this information, the robotic manipulator automatically corrects for detected movements.

In addition to the main components listed above, we also offer the following components and options: Synchrony Respiratory Tracking System; Xsight Spine Tracking System; Xsight Lung Tracking System; Lung Optimized Treatment; RoboCouch® Patient Positioning System; Xchange Robotic Collimator Changer; Iris Variable Aperture Collimator; 4D Treatment Optimization and Planning System; InTempo Adaptive Imaging System; MultiPlan® Treatment Planning System; MultiPlan MD Suite; CyberKnife Data Management System; MultiPlan Quick Review; Radiosurgery DICOM Interface; Monte Carlo Dose Calculation; Sequential Optimization Treatment Planning; Robotic IMRT™; AutoSegmentation; QuickPlan; PlanTouch™; the InCise™ Multileaf Collimator. Key features of these components are as follow:

***Synchrony Respiratory Tracking System.*** The CyberKnife Systems' proprietary motion tracking system, the Synchrony® Respiratory Tracking System, is used to continuously track tumors that move with respiration as beams are synchronized in real-time to tumor position while adapting to changes in breathing patterns, allowing for the delivery of highly conformed radiation beams while reducing areas of healthy tissue exposed to radiation. The Synchrony system provides what we believe is unsurpassed clinical accuracy of approximately 1.5 millimeters for tumors that move with respiration without the need for implanted fiducials.

***Iris Variable Aperture Collimator,*** which enables delivery of beams in 12 unique sizes with a single collimator, significantly reducing treatment times and the total radiation dose delivered to the patient.

***4D Treatment Optimization and Planning System,*** designed to optimize treatment by taking into account the movement of the tumor and the movement and change in shape of the surrounding tissue, thereby minimizing margins and radiation exposure to healthy tissue.

***MultiPlan Treatment Planning System.*** The MultiPlan System generates a series of beams and calculates the dose that must be delivered from each beam and provides these as a treatment plan. The treatment plan defines the pattern of radiation that meets the physician's dose prescription. The MultiPlan system uses input images from multiple modalities, including computed tomography, or CT, magnetic resonance imaging, or MRI, positron emission tomography, or PET, and 3D angiography.

***CyberKnife Data Management System.*** The results of a patient's treatment delivery, such as dose delivered from each beam, each path and each fraction, and details about the images acquired and corrections applied are recorded and stored in the data management system.

***Radiosurgery DICOM Interface.*** Data management systems, such as the CyberKnife Data Management System, utilize industry-standard interface protocols, such as DICOM, to export patient information to the OIS. With the Radiosurgery DICOM Interface, the CyberKnife Systems complete the Oncology Information System (OIS) electronic medical record with a comprehensive export of the radiosurgery treatment history.

***Monte Carlo Dose Calculation.*** Our Monte Carlo Dose Calculation software uses Monte Carlo simulation algorithms in treatment planning and dose calculation. Our Monte Carlo dose calculation algorithm can perform the necessary treatment planning calculations in a significantly shorter time frame as compared to conventional Monte Carlo dose calculation methods, thereby accelerating the treatment planning process.

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**QuickPlan.** Our QuickPlan® technology allows for a complete treatment plan to be generated automatically, and the results presented to the user for review.

**PlanTouch.** PlanTouch is the first commercially available, fully integrated software application in radiation oncology that allows physicians to remotely review and approve patients' radiation treatment plans on the iPad.

**InCise Multileaf Collimator.** The new InCise Multileaf Collimator is designed specifically for stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) treatments, giving the system the capability to extend its radiosurgical accuracy into a broader field of applications, meeting radiosurgery and radiotherapy needs. With the InCise Multileaf Collimator, the CyberKnife M6 Series can be used to treat large and irregular tumors more efficiently with excellent dose gradients. This added flexibility expands the number of patients eligible for treatment with the CyberKnife M6 Series.

***The TomoTherapy Systems***

The TomoTherapy Systems include the new TomoTherapy H Series with configuration options of TomoH , TomoHD and TomoHDA . The TomoTherapy Systems consist of fully integrated and versatile radiation therapy systems used by healthcare professionals in the treatment of a wide range of cancer types. The current United States list price for the TomoTherapy Systems range from approximately \$3.4 million to \$4.5 million, depending upon system configuration and options purchased by the customer. The list price typically includes initial training, installation and a one-year warranty. We also offer optional hardware and software, technical enhancements and upgrades to the TomoTherapy Systems, as well as service contracts and training to assist customers in realizing the full benefits of the TomoTherapy Systems. We believe the TomoTherapy Systems offer clinicians and patients the following benefits:

**Versatile treatment capabilities.** The TomoTherapy Systems' ring gantry platform enables precise and efficient treatments by eliminating the need for the repeated adjustment and re-calibration steps necessitated by imaging and treating the patient on different systems and mechanically adjusting the C-arm to treat from different angles. The high-speed binary multi-leaf collimator, or MLC, is integrated with the linac and consists of 64 individual low leakage tungsten leaves that move across the beam to either block or allow the passage of radiation, effectively shaping the beam as it is emitted. The combination of the ring gantry and the high-speed MLC (which we refer to as TomoHelical™) allow treatment to be delivered continuously in a 360-degree helical pattern around the patient's body. Moreover, we believe the TomoDirect™ feature provides the TomoTherapy Systems added versatility to provide high quality, fixed angle beams for those cases suited to simple tangential beam radiation delivery. In addition, all TomoTherapy Systems enable an operator to provide non-isocentric three-dimensional conformal image-guided IMRT or stereotactic treatments within a typical cylindrical volume of 80 centimeters in diameter and up to 135 centimeters in length. This expansive treatment field allows large areas of the body to be treated in a single session and the treatment of widely distant tumors. The TomoTherapy Systems' versatility, efficiency and precision offer clinicians an extensive range of effective treatment possibilities.

**Daily, quantitative imaging for better identification of tumors, dose verification and treatment planning.** The TomoTherapy Systems offer integrated quantitative CT imaging capabilities, which depict the density of tumors and healthy tissue more accurately than traditional radiation therapy systems. Our integrated mega-voltage computed tomography, or MVCT, which we market as our CTrue imaging technology, uses a low-intensity, fan beam CT to collect quantitative images prior to each treatment. These images allow lung tissue, fat, muscle and bone to be clearly distinguished. In addition, because of the low radiation dose involved, the clinician can collect daily, quantitative images, which can be used to monitor changes in the patient's internal anatomy and quickly adapt the plan if deemed clinically necessary. We believe daily, quantitative, relatively low dose images are essential to optimizing patient treatment by enabling clinicians to adapt the treatment plan in response to anatomical changes.

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***Integrated treatment system for precise radiation delivery.*** We believe the integration of our CTrue imaging technology, treatment planning and helical delivery mode of radiation beams enables highly accurate and precise radiation delivery. Our adaptive software allows clinicians to establish at the time of treatment the contours of a tumor and any sensitive structures at risk. The TomoTherapy Systems use a highly efficient dose computation algorithm to ensure the radiation beam conforms to the patient's tumor and minimizes exposure to sensitive healthy tissue structures, providing a highly-targeted dose distribution. These features significantly benefit patients by increasing the radiation delivered to cancerous tissues while reducing damage to nearby healthy tissues.

***Efficient clinical workflow for Image Guided Radiation Therapy, or IGRT, and adaptive radiation therapy.*** The TomoTherapy Systems integrate into a single system all of the key elements for radiation therapy, including treatment planning, CT image-guided patient positioning, treatment delivery, quality assurance and adaptive planning. The imaging and treatment planning capabilities of many traditional systems are more modular or require cumbersome add-ons or separate treatment planning systems that result in clinicians taking more steps between scanning, planning and treatment of patients. Conversely, the integrated imaging and treatment features of the TomoTherapy Systems allow clinicians to scan, plan and treat cancer patients efficiently. Daily images can be easily accessed remotely, via our TomoPortal web-enabled interface, to verify patient positioning and collaboratively define patient treatment strategies. Taking advantage of this integration capability, our StatRT software allows the full radiation therapy process CT scanning, treatment planning and treatment delivery to be completed rapidly.

***Low barriers to installation and implementation.*** All external beam radiation systems must be housed in rooms which have special radiation shielding to capture any radiation not absorbed by the patient. The TomoTherapy Systems' size and self-contained design allow customers to retrofit it into existing treatment rooms previously used for legacy radiation therapy systems and avoid, or reduce, the significant construction costs that can be associated with building new, larger treatment rooms, which are often required to install many other radiation therapy systems. With both imaging and radiation delivery capabilities in its ring gantry, the TomoTherapy Systems require less space than other linac systems, which use large moving arms to position the linac or incorporate adjacent imaging equipment used for treatment planning. In addition, because the TomoTherapy Systems have an integrated radiation beam stop, which captures radiation that passes through the patient, it requires less radiation shielding in treatment room walls as compared to the shielding required by a traditional system. We also preassemble, test and commission each TomoTherapy Systems at our manufacturing facility, and ship the system almost fully assembled. This assembly process typically allows radiation "beam on" within four days after delivery and first patient treatments to begin within 30 to 45 days after delivery.

***Platform for further technological advancements in adaptive radiation therapy.*** We believe the TomoTherapy Systems are the only commercially available treatment device that enables truly adaptive radiation therapy because of its unique ability to provide daily, quantitative images, high speed delivery of radiation from fixed beam angles or helically from 360 degrees around the body and real-time verification of the dose received by the patient. We believe the combination of these design features and our integrated treatment planning and optimization software will allow us to continue to enhance the TomoTherapy Systems' adaptive capabilities to enable clinicians to routinely and easily adjust a patient's treatment as needed, thereby remaining true to the intent of the original treatment plan.

In addition to the functionality listed above, the TomoTherapy Systems may be enhanced with the following product options: TomoDirect™ Treatment Mode; Planned Adaptive; OIS Connect ; SharePlan ; TomoTherapy Remote Software Solutions (Remote Planning and TomoPortal);

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TomoQuality Assurance (TQA™) Package; VoLO™ Technology; TomoEdge Dynamic Jaws. Key features of these options are as follow:

***TomoDirect Treatment Mode.*** The TomoDirect mode is a discrete angle, non-rotational delivery mode for the TomoTherapy Systems that allows the user to create a treatment plan that defines up to twelve target-specific gantry angles. Treatment planning is completed rapidly by all beams for each target being delivered sequentially with the couch passing through the bore of the system at an appropriate speed for each gantry angle. The TomoDirect™ mode enables users to plan and treat routine cases with greater efficiency, while achieving the quality of TomoTherapy's unique beamlet-based delivery.

***OIS Connect software option.*** The OIS Connect software option is a DICOM standard-based solution that provides the ability to interface a TomoTherapy Systems to a compatible OIS.

***SharePlan option.*** The SharePlan package provides the ability to automatically convert a treatment plan created for the TomoTherapy Systems to a plan that can be delivered on a conventional linac.

***Tomo Quality Assurance (TQA) package.*** The TQA application offers trending and reporting of many system and dosimetric parameters that allow physicists to monitor the performance of their TomoTherapy Systems.

***VoLO Technology.*** We introduced the VoLO Technology for the TomoTherapy System during fiscal 2012 as a new treatment planning system that leverages advanced graphics processing technology and a new calculation algorithm to increase clinical efficiency, throughput and flexibility in developing even the most complex radiation plans. The new VoLO solution features high-speed parallel processing for both dose calculation and optimization, based on Graphics Processing Unit (GPU) technology a "first" for radiation oncology treatment planning. In addition, VoLO represents the first use of a new Non-Voxel Broad Beam (NVBB) calculation algorithm that takes advantage of both the GPU's unparalleled speed and the TomoTherapy Systems unique beamlet radiation delivery system to develop dose distributions from the perspective of each beamlet (up to tens of thousands in any given plan) as they pass through the patient's body. VoLO technology empowers clinicians to create highly customized treatment plans in less time, with greater flexibility to work interactively and in real time to efficiently develop the best IMRT treatment plans for even the most complex cases.

***TomoEdge Dynamic Jaws.*** We introduced the TomoEdge Dynamic Jaws feature in October 2012 along with the new TomoTherapy H Series. TomoEdge is standard on the TomoTherapy HDA model and is also available on H and HD models. By dynamically varying the width of the collimator jaws during treatment delivery, dose to normal tissues immediately adjacent to the tumor is reduced, contributing to the minimization of radiation side effects. Additionally, overall irradiation time is shortened because the jaws are allowed to open more broadly throughout much of the delivery. The resulting gains in treatment quality and speed expand the TomoTherapy Systems clinical and market reach within the conventional and stereotactic radiotherapy spaces.

## **Sales and Marketing**

We market the CyberKnife and TomoTherapy Systems worldwide through a direct sales force in the United States and Canada, distributors in Latin America, and a combination of direct sales personnel and distributors managed through our regional headquarters in Morges, Switzerland, Hong Kong, China and Tokyo, Japan.

In direct sales markets, we employ a combination of territory sales managers, product specialists, training specialists and marketing managers. Territory sales managers and product specialists are responsible for selling the systems to hospitals and stand-alone treatment facilities. Our marketing managers help market our current products and work with our engineering group to identify and

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develop upgrades and enhancements for our suite of products. Our training specialists train radiation oncologists, surgeons, physicists, dosimetrists and radiation therapists. Additionally, we have sales specialists dedicated to selling upgrades and service to our installed base customers.

In addition to marketing to hospitals and stand-alone treatment facilities, we market to radiation oncologists, neurosurgeons, general surgeons, oncology specialists and other referring physicians. We intend to continue to increase our focus on marketing and education efforts to surgical specialists and oncologists responsible for treating tumors throughout the body. Our marketing activities also include efforts to inform and educate cancer patients about the benefits of the CyberKnife and TomoTherapy Systems.

Under our standard distribution agreement, we generally appoint an exclusive distributor for a specific country. We typically also retains the right to distribute the CyberKnife and TomoTherapy Systems in such territories, though, we remain bound by certain agreements entered into by TomoTherapy prior to our acquisition that did not retain such rights in certain jurisdictions. Our distributors generally provide the full range of service and sales capabilities, although we may provide installation and service support for certain distributors.

From time to time, we may provide our CyberKnife Systems' linac for use in non-medical areas. These areas may include non-destructive testing, visual inspection and other potential applications. We do not currently expect these non-medical uses to represent a significant portion of our revenue in the near term nor have they historically represented a significant portion of our revenues.

**Manufacturing**

We purchase major components for each of our products from outside suppliers, including the robotic manipulator, treatment couches, gantry, magnetrons, imaging detectors and computers. We closely monitor supplier quality, delivery performance and conformance to product specifications, and we also expect suppliers to contribute to our efforts to improve our manufacturing cost and quality.

Some of the components are obtained from single-source suppliers. These components include the gantry, couch, magnetron, solid state modulator and detector for the TomoTherapy Systems and the robot, magnetron and MLC for the CyberKnife Systems. In most cases, if a supplier were unable to deliver these components, we believe we would be able to find other sources for these components subject to any regulatory qualifications, if required. In the event of a disruption in any of these suppliers' ability to deliver a component, we would need to secure a replacement supplier. Additionally, any disruption or interruption of the supply of key subsystems could result in increased costs and delays in deliveries of our treatment systems, which could adversely affect our reputation and results of operations. To help mitigate these risks, we negotiate long-term supply contracts or submit long-term orders and forecasts to our single-source suppliers with the goal that our demand can be satisfied and any capacity problem can be mitigated.

We manufacture certain electrical subsystems, including the linac for our CyberKnife Systems, at our Sunnyvale, California facility, and manufacture TomoTherapy Systems in Madison, Wisconsin. We manufacture the linac for our TomoTherapy Systems at our Chengdu, China facility. Our facilities employ state-of-the-art manufacturing techniques and equipment. Our company-wide quality systems are certified independently and compliant to the internationally recognized quality system standard for medical devices, International Standards Organization, or ISO, 13485:2003, and the Quality System regulations enforced by the FDA. We believe our manufacturing facilities will be adequate for our expected growth and foreseeable future demands for at least the next three years.

The manufacturing processes at our facilities include fabrication, subassembly, assembly, system integration and final testing. Our manufacturing personnel consist of fabricators, assemblers and technicians supported by production engineers as well as planning and supply chain managers. Our



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quality assurance program includes various quality control measures from inspection of raw material, purchased parts and assemblies through on-line inspection. We have also incorporated lean manufacturing techniques to improve manufacturing flow and efficiency. Lean manufacturing techniques include reducing wasteful and extraneous activities, balancing assembly and test flow, as well as better utilizing production assets and resources.

**Intellectual Property**

The proprietary nature of, and protection for, our products, product components, processes and know-how are important to our business. We seek patent protection in the United States and internationally for our product systems and other technology where available and when appropriate. Our policy is to patent or in-license the technology, inventions and improvements that we consider important to the development of our business. In addition, we use license agreements to selectively convey rights to our intellectual property to others. In addition to our patents, we also rely upon trade secrets, know-how, trademarks, copyright protection and continuing technological and licensing opportunities to develop and maintain our competitive position. We require our employees, consultants and outside scientific collaborators to execute confidentiality, invention assignment and, where appropriate, non-competition agreements upon commencing employment or consulting relationships with us.

As of June 30, 2013, we held exclusive field of use licenses or ownership of more than 311 U.S. and foreign patents, and more than 116 U.S. and foreign patent applications. These patents and applications cover various components and techniques incorporated into the CyberKnife and TomoTherapy Systems, or are being incorporated into new technologies under current development, all of which we believe will allow us to maintain a competitive advantage in the field of radiation treatment. We cannot be sure that any patents will be issued from any of our pending patent applications, nor can we assure you that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology.

Patents may provide some degree of protection for preventing others from making, using, selling, or offering for sale a system that shares one or more features of the CyberKnife or TomoTherapy Systems. However, patent protection involves complex legal and factual determinations and is therefore uncertain. The laws governing patentability and the scope of patent coverage continue to evolve, particularly in the areas of technology of interest to us. As a result, we cannot assure you that patents will issue from any of our patent applications. The scope of any of our issued patents may not be sufficiently broad to offer meaningful protection. In addition, our issued patents or patents licensed to us may be successfully challenged, invalidated, circumvented or unenforceable so that our patent rights would not create an effective competitive barrier. Moreover, the laws of some foreign countries may not protect our proprietary rights to the same extent as do the laws of the United States. In view of these factors, our intellectual property positions bear some degree of uncertainty.

We have periodically monitored and continue to monitor the activities of our competitors and other third parties with respect to their use of intellectual property.

In April 2007, we entered into a License and Development Agreement, or Original Agreement, with CyberHeart, Inc., or CyberHeart, and in December 2010, we entered into a License Agreement, or New Agreement, with CyberHeart. As part of these agreements, we have licensed and will continue to license certain intellectual property rights and technologies to CyberHeart, which CyberHeart will use to develop and commercialize new systems and applications in the field of cardiac disease. In the event CyberHeart is able to successfully develop and commercialize such an application, under the agreements, we would be the sole supplier of radiosurgery equipment to CyberHeart and would also be entitled to receive specified payments based on the sale of any CyberHeart products covered by the intellectual property Accuray licenses to CyberHeart. The Original Agreement remains in full force and

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effect until the effective date of the New Agreement, which is the first date of human clinical treatment performed by CyberHeart, using a CyberHeart product together with a CyberKnife System, to affect cardiac tissue ablation with the goal of achieving a therapeutic effect. In December 2010, we also entered into a Patent License Agreement with CyberHeart, pursuant to which CyberHeart granted the Company certain patent rights in the field of non-tumor cardiovascular disease, which rights are exercisable by us only upon the occurrence of certain trigger events specified in the New Agreement. We would pay a specified royalty to CyberHeart for the sale of any our products covered by the licensed CyberHeart patents. Roderick Young, a former member of our Board of Directors, is a founder, officer and director of CyberHeart.

**Research and Development**

Continued innovation is critical to our future success. Our current product development activities include projects expanding clinical applications, driving product differentiation, and continually improving the usability, interoperability, reliability, and performance of our products. We continue to seek to develop innovative technologies so that we can increase our sales. Some of our product improvements have been discussed above under the heading "Products."

Research activities strive to enable new product development opportunities by developing new technologies and advancing areas of existing core technology such as next generation linac, adaptive therapy, patient imaging, motion management, or treatment planning capabilities.

The modular design of our systems supports rapid development for new clinical capabilities and performance enhancements by generally allowing each subsystem to evolve within the overall platform design. Access to regular product upgrades protects customer investment in the system, facilitates the rapid adoption of new features and capabilities among existing installed base customers, and drives increasing value in our multiyear service plans. These upgrades will generally consist of software and hardware enhancements designed to increase the ease of use of our systems, improve the speed and accuracy of patient treatment and meet other customer needs.

As of June 30, 2013, we had 232 employees in our research and development departments. Research and development expenses for the fiscal years ended June 30, 2013, 2012 and 2011 were \$66.2 million, \$81.3 million and \$41.3 million, respectively. We anticipate research and development expenses for fiscal 2014 will be lower than for fiscal 2013 based on the current schedule of our development projects.

A key component of our research and development program is our collaboration with research programs at selected hospitals, cancer treatment centers, academic institutions and research institutions worldwide. Our agreements with these third-party collaborators generally require us to make milestone-based payments during the course of a particular project and often also require that we make up-front payments to fund initial activities. Generally, we obtain non-exclusive worldwide rights to commercialize results from the collaboration with an option to negotiate an exclusive license. For inventions resulting from the collaboration owned or exclusively licensed by Accuray, we generally grant a royalty-free license for the purpose of continuing the institution's research and development, and from time to time, we also grant broader licenses. Our research collaboration programs include work on clinical protocols and hardware and software developments. We also work with suppliers to develop new components in order to increase the reliability and performance of our products and seek opportunities to acquire or invest in the research of other parties where we believe it is likely to benefit our existing or future products.

**Competition**

The medical device industry in general and the non-invasive cancer treatment field in particular, are subject to intense and increasing competition and rapidly evolving technologies. Because our

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products often have long development and regulatory clearance and approval cycles, we must anticipate changes in the marketplace and the direction of technological innovation and customer demands. To compete successfully, we will need to continue to demonstrate the advantages of our products and technologies over well-established alternative procedures, products and technologies, and convince physicians and other healthcare decision makers of the advantages of our products and technologies. Traditional surgery and other forms of minimally invasive procedures, brachytherapy, chemotherapy and other drugs remain alternatives to the CyberKnife and TomoTherapy Systems.

New product sales into this competitive market are primarily dominated by two companies: Elekta AB, or Elekta, and Varian Medical Systems, Inc., or Varian. Some manufacturers of standard linac systems, including Varian and Elekta, have products that can be used in combination with body and/or head frame systems and image-guidance systems to perform both radiosurgical and radiotherapy procedures. Other companies that compete with us to a lesser extent include Mitsubishi Heavy Industries, Ltd., BrainLAB AG, and ViewRay Incorporated.

Furthermore, many government, academic and business entities are investing substantial resources in research and development of cancer treatments, including surgical approaches, radiation treatment, MRI-guided radiotherapy systems, proton therapy systems, drug treatment, gene therapy, and other approaches. Successful developments that result in new approaches for the treatment of cancer could reduce the attractiveness of our products or render them obsolete.

Our future success will depend in large part on our ability to establish and maintain a competitive position in current and future technologies. Rapid technological development may render the CyberKnife and TomoTherapy Systems and their technologies obsolete. Many of our competitors have or may have greater corporate, financial, operational, sales and marketing resources, and more experience in research and development than we have. We cannot assume that our competitors will not succeed in developing or marketing technologies or products that are more effective or commercially attractive than our products or that would render our technologies and products obsolete or less useful. We may not have the financial resources, technical expertise, marketing, distribution or support capabilities to compete successfully in the future. Our competitive position also depends, among other things, on:

Widespread awareness, acceptance and adoption of our products by the radiation oncology and cancer therapy markets;

Innovations that improve the effectiveness and productivity of our systems' treatment processes and enable them to address emerging customer needs;

Availability of reimbursement coverage from third-party payors (including insurance companies, governments, and/or others) for procedures performed using our systems;

Published, peer-reviewed data supporting the efficacy and safety of our systems;

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

Limiting the time period and cost of regulatory approvals or clearances;

The manufacture and delivery of our products in sufficient volumes on time, and accurately predicting and controlling costs associated with manufacturing, installation, warranty and maintenance of the products;

Our ability to attract and retain qualified personnel;

The extent of our intellectual property protection or our ability to otherwise develop proprietary products and processes;

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Securing sufficient capital resources to expand both our continued research and development, and sales and marketing efforts; and

Obtaining and maintaining any necessary United States or foreign regulatory approvals or clearances.

Our customers' equipment purchase considerations typically include reliability, treatment quality, service capabilities, patient throughput, price, payment terms and equipment supplier viability. We believe we compete favorably with our competitors on price and value based upon the technology offered by our treatment systems. We strive to provide a technologically superior product that covers substantially all aspects of radiation therapy to deliver precise treatments with high-quality clinical outcomes that meet or exceed customer expectations.

In addition to competition from technologies performing similar functions as our treatment systems, competition also exists for the limited capital expenditure budgets of our customers. For example, our treatment systems may compete with other equipment required by a radiation therapy department for financing under the same capital expenditure budget, which is typically limited. A purchaser, such as a hospital or cancer treatment center, may be required to select between the two items of capital equipment. Our ability to compete may also be adversely affected when purchase decisions are based solely upon price, since our products are premium-priced systems due to their higher level of functionality and performance.

**US Reimbursement**

In the United States, healthcare providers that purchase capital equipment such as the CyberKnife and TomoTherapy Systems, generally rely on government and private third-party payors for reimbursement for the healthcare treatment and services they provide. Examples of these types of payors include Medicare, Medicaid, private health insurance plans, and health maintenance organizations, which reimburse all or a portion of the cost of treatment, as well as related healthcare services. Reimbursement involves three components: coverage, coding and payment.

***Coverage***

Approximately 60% of patients treated in the United States with the CyberKnife and TomoTherapy Systems are covered through private insurance, rather than through Medicare. There are currently no national coverage determinations in place under Medicare for CyberKnife or TomoTherapy treatment. Coverage criteria for treatment with CyberKnife and TomoTherapy are outlined in local determinations or, in the absence of a formal policy, treatment is covered as long as it is considered reasonable and necessary. The most common indications covered by Medicare in local coverage determinations for robotic radiosurgery are primary and metastatic tumors in the brain, spine, lung, liver, kidney, pancreas, adrenal gland, prostate as well as other cancers that have failed previous treatment. Intensity Modulated Radiation Therapy, or IMRT, is generally covered for cancers of the brain, spine, head and neck, prostate, thoracic, abdominal and retroperitoneal regions, other cancers (e.g. breast) meeting certain criteria, and tumors requiring re-irradiation or where dose tolerance may be exceeded with conventional treatment.

Commercial payor policies vary with most covering robotic radiosurgery for tumors in the brain, spine, and lung. Other indications such as renal, liver, prostate, and pancreatic cancers are also covered by some national and local commercial payors. IMRT is typically covered by commercial payors for the indications covered by Medicare.

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***Coding***

The codes that are used to report robotic radiosurgery treatment delivery are healthcare common procedural codes, or HCPCS, G0339 for the first fraction and G0340 for fractions two through five. For 2014 CMS has proposed to eliminate the G codes for robotic and gantry based SRS/SBRT and replace them with CPT codes 77372 and 77373 in the hospital outpatient setting. The G codes will remain active codes in the freestanding center setting. IMRT delivery is billed under Current Procedural Terminology, or CPT, code 77418. Both HCPCS and CPT codes are valid codes for payment under Medicare and are recognized by commercial payors for use in the hospital outpatient and freestanding center sites of service. Other codes are used to report treatment planning, dosimetry, treatment management, and other procedures routinely performed for treating radiosurgery or radiotherapy patients.

***Payment***

The majority of procedures using the CyberKnife and TomoTherapy Systems are performed in the hospital outpatient department. Medicare payment for CyberKnife and TomoTherapy procedures delivered in the hospital outpatient setting is developed by the Centers for Medicare and Medicaid Services, or CMS, which calculates rates based on costs submitted by hospitals to perform outpatient procedures. Every year, CMS reviews hospital cost data for outpatient procedures, including radiosurgery and radiotherapy, makes adjustments to rates for the following year, and publishes national unadjusted averages for all procedures eligible for payment in this site of service. For calendar year 2013, the national unadjusted average Medicare payment rates for radiosurgery treatment delivered in the hospital outpatient department under codes G0339 and G0340 are \$3,301 and \$2,355 respectively. The 2013 national unadjusted Medicare payment rate for IMRT delivery in the hospital outpatient department under CPT code 77418 is \$484. Imaging is bundled and not separately payable in the hospital outpatient department.

Payment for treatment with CyberKnife and TomoTherapy Systems are also available in the freestanding center settings. In 2013, the primary treatment delivery codes for robotic radiosurgery are carrier priced under Medicare and range from low payment to payment at parity with hospital outpatient departments to slightly above outpatient rates. Medicare payment for IMRT delivery in the freestanding center site of service is calculated by applying a universal multiplier (called a conversion factor) to values set for resource and malpractice costs for the procedure and adjusted to account for geographic variations. The 2013 national unadjusted Medicare payment rate for IMRT delivery in the freestanding center site of service is \$406. Unlike in the hospital outpatient setting, imaging with IMRT is paid separately.

On July 8, 2013, Medicare published its proposed rules for hospital outpatient services, for physicians, and services performed in the freestanding center setting for calendar year 2014. After a 60 day comment period, Medicare will review and analyze the comments. We expect Medicare to complete its review and publish the final rules sometime in early November 2013. For services delivered in the hospital outpatient department CMS has proposed increased payment rates for nearly all radiation oncology codes, while CMS has also proposed bundling of ancillary services (e.g. non-delivery codes). If finalized, the bundling will limit the number of codes and units of codes that can be paid separately; however, the increases in payment rates may mitigate the impact of the cuts, potentially resulting in increases in payment for IMRT treatments, depending on practice patterns. For radiosurgery procedures, the same bundling rules will apply, however, CMS has proposed to replace the G codes (G0339 and G0340) that have historically been used to report robotic treatment delivery and (G0173 and G0251) for non-robotic treatment delivery, with CPT codes that will be used to report gantry and robotic procedures combined. CPT code 77372 will be used for single session intracranial linear accelerator based radiosurgery and CPT code 77373 will be used for multi-session intracranial and multi-session extracranial radiosurgery. If finalized, the payment for single session CyberKnife and

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TomoTherapy radiosurgery treatment delivery in the hospital outpatient setting, will increase significantly up from the current payment rate of \$3,301 for robotic radiosurgery (G0339) and gantry based SRS (G0173) to \$8,576. Payment for multi-session radiosurgery will increase slightly for robotic radiosurgery, up from the 2013 rate of \$2,355 and significantly increase for non-robotic SRS from \$978 to \$2,480 for both. The 2014 proposed national unadjusted payment rate for IMRT delivery under CPT code 77418 in the hospital outpatient department is \$538. Image guidance remains bundled in the hospital outpatient setting and no separate payment is made.

The 2014 proposed payment in the freestanding center setting for robotic radiosurgery delivery for the first and subsequent treatments continues to be set by local Medicare carriers. For delivery of IMRT in the freestanding clinic, Medicare has released its proposed conversion factor, resource and malpractice values and geographic adjustment indices that would be used to calculate payment in 2014. In addition to making adjustment to the conversion factor (the multiplier used to calculate rates for all services priced under the Physician Fee Schedule), CMS has proposed a Medicare Economic Index (MEI) of 5% that could result in smaller cuts to radiation therapy procedures performed in the freestanding center setting, however Congress may wish to capture that savings to offset the Sustainable Growth Rate (SGR). Therefore we have estimated the payment rate for IMRT treatment delivery, conservatively, using the current 2013 conversion factor (which CMS also assumes Congress will keep) but not the 5% MEI. This calculation would result in a payment rate of \$375, an 8% decrease from 2013 for IMRT delivery. Additional payment for image guidance in this site of service remains available. Commercial payors typically base payment on a percentage of billed charges, or on contracted rates, and may benchmark prices based on a percent of Medicare rates. Medicaid develops its own payment policies independently, which vary from state to state.

***Foreign Reimbursement***

Internationally, reimbursement and healthcare payment systems vary from country to country and include single-payor, government-managed systems as well as systems in which private payors and government-managed systems exist side-by-side. In general, the process of obtaining coverage approvals has been slower outside of the United States. Our ability to achieve adoption of our treatment systems, and significant sales volume in international markets, will depend in part on the availability of reimbursement for procedures performed using our products.

**Regulatory Matters**

***Domestic Regulation***

Our products and software are medical devices subject to regulation by the FDA, as well as other regulatory bodies. FDA regulations govern the following activities that we perform and will continue to perform to ensure medical products distributed domestically or exported internationally are safe and effective for their intended uses:

Product design and development;

Document and purchasing controls;

Production and process controls;

Labeling and packaging controls;

Product storage;

Recordkeeping;

Servicing;

Corrective and preventive action and complaint handling;



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Pre-market clearance or approval;

Advertising and promotion; and

Product sales and distribution.

**FDA pre-market clearance and approval requirements.** Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either 510(k) clearance or pre-market approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risks are placed in either class I or II, which requires the manufacturer to submit to the FDA a pre-market notification requesting permission to commercially distribute the device, known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in class III, requiring pre-market approval. All of our current products are class II devices requiring 510(k) clearances.

**510(k) clearance pathway.** When a 510(k) clearance is required, we must submit a pre-market notification demonstrating that our proposed device is substantially equivalent to a previously cleared and legally marketed 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of pre-market approval applications, or PMA. By regulation, the FDA is required to clear or deny a 510(k) pre-market notification within 90 days of submission of the application. Clearance generally takes longer as the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence.

In January 2002, we received 510(k) clearance for the TomoTherapy Hi-Art System intended to be used as an integrated system for the planning and delivery of IMRT for the treatment of cancer. In August 2008, we received 510(k) clearance for our TomoDirect™ System.

In July 1999, we received 510(k) clearance for the CyberKnife System for use in the head and neck regions of the body. In August 2001, we received 510(k) clearance for the CyberKnife System to provide treatment planning and image guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation treatment is indicated. In April 2002, we received 510(k) clearance for the Synchrony Motion Tracking System as an option to the CyberKnife System, intended to enable dynamic image guided stereotactic radiosurgery and precision radiotherapy of lesions, tumors and conditions that move under influence of respiration.

**Pre-market approval (PMA) pathway.** A PMA must be submitted to the FDA if the device is not eligible for the 510(k) clearance process. A PMA must be supported by extensive data, including but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate reasonable evidence of the device's safety and efficacy to the FDA's satisfaction. Currently, no device we have developed and commercialized has required pre-market approval.

**Product modifications.** After a device receives 510(k) clearance or a PMA approval, any modification that could significantly affect its safety or effectiveness, or that would constitute a significant change in its intended use, will require a new clearance or approval. The FDA has issued draft guidance that, if finalized and implemented, will result in manufacturers needing to seek a significant number of new clearances for changes made to legally marketed devices.

We have modified aspects of our CyberKnife and TomoTherapy families of products since receiving regulatory clearance, and we have applied for and obtained additional 510(k) clearances for these modifications when we determined such clearances were required. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with our determination not to seek a new 510(k) clearance or PMA approval, the FDA may require us to seek 510(k) clearance or PMA



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approval. The FDA could also require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or pre-market approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines or penalties. During our fiscal year ended June 30, 2013, we submitted one 510(k) clearance notification for modifications made to the operation of the CyberKnife System and one 510(k) clearance notification for the TomoTherapy System. The CyberKnife submission was cleared on October 26, 2012 and the TomoTherapy submission was cleared on August 29, 2012.

***Pervasive and continuing regulation.*** After a device is placed on the market, numerous regulatory requirements apply. These include:

Quality System Regulation, or QSR, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, documentation and other quality assurance procedures during product design and throughout the manufacturing process;

Labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses; and

Medical device reporting regulations, which require that manufacturers report to the FDA if their device 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.

The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Health Services to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of some of our subcontractors. In June 2012, during an inspection performed by the FDA at our Sunnyvale facility, several minor observations of non-compliance were made. The initial classification of the inspection is considered to be Voluntary Action Indicated. We are undertaking corrective action in response to the FDA's observations and the FDA will reevaluate our correction actions upon reinspection. We believe there were no observations that involved a material violation of regulatory requirements. In July 2012, the FDA completed an inspection at our Madison facility, and no observations were noted. We believe we are in substantial compliance with the QSR. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

Fines, injunctions, consent decrees and civil penalties;

Recall or seizure of our products;

Operating restrictions, partial suspension or total shutdown of production;

Refusing our requests for 510(k) clearance or pre-market approval of new products or new intended uses;

Withdrawing 510(k) clearance or pre-market approvals that are already granted; and

Criminal prosecution.

The FDA also has the authority to require us to repair, replace or refund the cost of any medical device that we have manufactured or distributed. If any of these events were to occur, they could have a material adverse effect on our business.

On June 9 and 10, 2010, the FDA held a public meeting entitled "Device Improvements to Reduce the Number of Under-doses, Over-doses, and Misaligned Exposures from Therapeutic Radiation." The expressed purpose of the meeting was to discuss steps that could be taken by manufacturers of radiation therapy devices to help reduce misadministration and misaligned exposures. In advance of



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and at the meeting, the FDA requested comments in the following areas: features that should be incorporated into radiation therapy devices and their related software, user training, and quality assurance measures. It is likely the FDA will use the information gathered at this meeting to revise the standards and requirements for designing, manufacturing and marketing devices such as ours, creating uncertainty in the current regulatory environment around our current products and development of future products.

***Radiological health.*** Because our CyberKnife and TomoTherapy Systems contain both laser and X-ray components, and because we assemble these components during manufacturing and service activities, we are also regulated under the Electronic Product Radiation Control Provisions of the Federal Food, Drug, and Cosmetic Act. This law requires laser and X-ray products to comply with regulations and applicable performance standards, and manufacturers of these products to certify in product labeling and reports to the FDA that their products comply with all such standards. The law also requires manufacturers to file new product reports, and to file annual reports and maintain manufacturing, testing and sales records, and report product defects. Various warning labels must be affixed. Assemblers of diagnostic X-ray systems are also required to certify in reports to the FDA, equipment purchasers, and where applicable, to state agencies responsible for radiation protection, that diagnostic and/or therapeutic X-ray systems they assemble meet applicable requirements. Failure to comply with these requirements could result in enforcement action by the FDA, which can include injunctions, civil penalties, and the issuance of warning letters.

***Fraud and Abuse Laws***

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Violations of these laws are punishable by significant criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid. Because of the far-reaching nature of these laws, there can be no assurance that we would not be required to alter one or more of our practices to be in compliance with these laws. Evolving interpretations of current laws, or the adoption of new federal or state laws or regulations could adversely affect many of the arrangements we have with customers and physicians. In addition, there can be no assurance that the occurrence of one or more violations of these laws or regulations would not result in a material adverse effect on our financial condition and results of operations.

***Anti-kickback laws.*** Our operations are subject to broad and changing federal and state anti-kickback laws. The Office of the Inspector General of the Department of Health and Human Services, or the OIG, is primarily responsible for enforcing the federal Anti-Kickback Statute and generally for identifying fraud and abuse activities affecting government programs. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration directly or indirectly to induce either the referral of an individual, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. "Remuneration" has been broadly interpreted to include anything of value, including such items as gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments, and providing anything of value at less than fair market value.

Penalties for violating the federal Anti-Kickback Statute include criminal fines of up to \$25,000 and/or imprisonment for up to five years for each violation, civil fines of up to \$50,000 and possible exclusion from participation in federal healthcare programs such as Medicare and Medicaid. Many states have adopted prohibitions similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not only by the Medicare and Medicaid programs, and do not include comparable exceptions.

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The OIG has issued safe harbor regulations which set forth certain activities and business relationships that are deemed safe from prosecution under the federal Anti-Kickback Statute. There are safe harbors for various types of arrangements, including, without limitation, certain investment interests, leases and personal services and management contracts. The failure of a particular activity to comply in all regards with the safe harbor regulations does not mean that the activity violates the federal Anti-Kickback Statute or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG.

The OIG has identified the following arrangements with purchasers and their agents as ones raising potential risk of violation of the federal Anti-Kickback Statute:

Discount and free good arrangements that are not properly disclosed or accurately reported to federal healthcare programs;

Product support services, including billing assistance, reimbursement consultation and other services specifically tied to support of the purchased product, offered in tandem with another service or program (such as a reimbursement guarantee) that confers a benefit to the purchaser;

Educational grants conditioned in whole or in part on the purchase of equipment, or otherwise inappropriately influenced by sales and marketing considerations;

Research funding arrangements, particularly post-marketing research activities, that are linked directly or indirectly to the purchase of products, or otherwise inappropriately influenced by sales and marketing considerations; and

Other offers of remuneration to purchasers that are expressly or impliedly related to a sale or sales volume, such as "prebates" and "upfront payments," other free or reduced-price goods or services, and payments to cover costs of "converting" from a competitor's products, particularly where the selection criteria for such offers vary with the volume or value of business generated.

We have a variety of financial relationships with physicians who are in a position to generate business for us. For example, physicians who own our stock also provide medical advisory and other consulting and personal services. Similarly, we have a variety of different types of arrangements with our customers. For example, our shared ownership program provides a CyberKnife System to customers in exchange for the greater of fixed minimum payments or a portion of the service revenues generated by the customer from use of the CyberKnife. Included in the fee we charge for the shared ownership program are a variety of services, including physician training, educational and marketing support, general reimbursement guidance and technical support. In the case of our former placement program, certain services and upgrades were provided without additional charge based on procedure volume. In the past, we have also provided loans to our customers. We also provide research grants to customers to support customer studies related to, among other things, our CyberKnife Systems.

If our past or present operations are found to be in violation of the federal Anti-Kickback Statute or similar government regulations to which we or our customers are subject, we or our officers may be subject to the applicable penalty associated with the violation, including significant civil and criminal penalties, damages, fines, imprisonment, and exclusion from the Medicare and Medicaid programs. The impact of any such violation may lead to curtailment or restructuring of our operations. Any penalties, damages, fines, or curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that some of these laws are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation. If an enforcement action were to occur, our reputation and our business and financial condition could be harmed, even if we were to prevail or settle the action. Similarly, if the

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physicians or other providers or entities with which we do business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business. Several recently enacted state and federal laws, including laws in Massachusetts and Vermont, and the federal Physician Payment Sunshine Act, now require, among other things, extensive tracking, maintenance of data bases regarding payments to physicians and other designated healthcare providers. These laws require or will require that we 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.

**Physician self-referral laws.** We are also subject to federal and state physician self-referral laws. The federal Ethics in Patient Referrals Act of 1989, commonly known as the Stark Law, prohibits, subject to certain exceptions, physician referrals of Medicare and Medicaid patients to an entity providing certain "designated health services" if the physician or an immediate family member has any financial relationship with the entity. The Stark Law also prohibits the entity receiving the referral from billing any good or service furnished pursuant to an unlawful referral.

In addition, in July 2008, CMS issued a final rule implementing significant amendments to the regulations under the Stark Law. The final rule, which was effective October 1, 2009, imposes additional limitations on the ability of physicians to refer patients to medical facilities in which the physician or an immediate family member has an ownership interest for treatment. Among other things, the rule provides that leases of equipment between physician owners that may refer patients and hospitals must be on a fixed rate, rather than a per use basis. Prior to enactment of the final rule, physician owned entities had increasingly become involved in the acquisition of medical technologies, including the CyberKnife System. In many cases, these entities entered into arrangements with hospitals that billed Medicare for the furnishing of medical services, and the physician owners were among the physicians who referred patients to the entity for services. The rule limits these arrangements and could require the restructuring of existing arrangements between physicians owned entities and hospitals and could discourage physicians from participating in the acquisition and ownership of medical technologies. The final rule also prohibits percentage-based compensation in equipment leases. As a result of the finalization of these regulations, some existing CyberKnife System operators have modified or restructured their corporate or organizational structures. In addition, certain customers that planned to open CyberKnife centers in the United States involving physician ownership have restructured their legal ownership structure. Certain entities were not able to establish viable models for CyberKnife System operation and therefore canceled their CyberKnife System purchase agreements. Accordingly, these regulations have resulted in cancellations of CyberKnife System purchase agreements and could also reduce the attractiveness of medical technology acquisitions, including CyberKnife System purchases, by physician-owned joint ventures or similar entities. As a result, these regulations have had, and could continue to have, an adverse impact on our product sales and therefore on our business and results of operations.

A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to \$100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violations of the Stark Law is subject to civil monetary penalties of up to \$15,000 per bill submission, an assessment of up to three times the amount claimed, and possible exclusion from federal healthcare programs such as Medicare and Medicaid. Various states have corollary laws to the Stark Law, including laws that require physicians to disclose any financial interest they may have with a healthcare provider to their patients when referring patients to that provider. Both the scope and exceptions for such laws vary from state to state.

**Federal False Claims Act.** The federal False Claims Act prohibits the knowing filing or causing the filing of a false claim or the knowing use of false statements to obtain payment from the federal government. When an entity is determined to have violated the False Claims Act, it may be required to

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pay three times the actual damages sustained by the government, plus mandatory civil penalties of between \$5,500 and \$11,000 for each separate false claim. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. In addition, certain states have enacted laws modeled after the federal False Claims Act. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, pay fines or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action. We have retained the services of a reimbursement consultant, for which we pay certain consulting fees, to provide us and facilities that have purchased a CyberKnife or TomoTherapy System or acquired a CyberKnife or TomoTherapy System through our shared ownership program, with general reimbursement advice. While we believe this will assist our customers in filing proper claims for reimbursement, and even though such consultants do not submit claims on behalf of our customers, the fact that we provide these consultant services could expose us to additional scrutiny and possible liability in the event one of our customers is investigated and determined to be in violation of any of these laws.

**HIPAA.** The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

As a participant in the healthcare industry, we are also subject to extensive laws and regulations protecting the privacy and integrity of patient medical information, including privacy and security standards required under HIPAA. The HIPAA privacy standard was recently amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, enacted as part of the American Recovery and Reinvestment Act of 2009. HITECH significantly increases the civil money penalties for violations of patient privacy rights protected under HIPAA. Although we are not a covered entity under HIPAA, we have entered into agreements with certain covered entities under which we are considered to be a "business associate" under HIPAA. As a business associate, we are required to implement policies, procedures and reasonable and appropriate security measures to protect individually identifiable health information we receive from covered entities. Furthermore, as of February 2010, business associates are now directly subject to regulations under HIPAA, including a new enforcement scheme, criminal and civil penalties for certain violations, and inspection requirements.

**Foreign Corrupt Practices Act.** The United States and foreign government regulators have increased regulation, enforcement, inspections and governmental investigations of the medical device industry, including increased United States government oversight and enforcement of the Foreign Corrupt Practices Act. Whenever the United States or another foreign governmental authority concludes that we are not in compliance with applicable laws or regulations, such governmental authority can impose fines, delay or suspend regulatory clearances, institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil penalties against us or our officers or employees, and can recommend criminal prosecution to the Department of Justice. Moreover, governmental authorities can ban or request the recall, repair, replacement or refund of the cost of any device or product we manufacture or distribute. We are also potentially subject to the UK Bribery Act, which could also lead to the imposition of civil and criminal

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finances. Any of the foregoing actions could result in decreased sales as a result of negative publicity and product liability claims, and could have a material adverse effect on our financial condition, results of operations and prospects.

***International Regulation***

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain clearance or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may be different.

The primary regulatory environment in Europe is that of the European Union and the three additional member states of the European Economic Area, or EEA, which have adopted similar laws and regulations with respect to medical devices. The European Union has adopted numerous directives and the European Committee for Standardization has promulgated standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of the relevant directive will be entitled to bear CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directives and, accordingly, may be commercially distributed throughout the member states of the European Economic Area.

The method of assessing conformity to applicable standards and directives depends on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a notified body, an independent and neutral institution appointed by a European Union member state to conduct the conformity assessment. This relevant assessment may consist of an audit of the manufacturer's quality system (currently ISO 13485), provisions of the Medical Devices Directive, and specific testing of the manufacturer's device. In September 2002 and February 2005, Accuray's and TomoTherapy's facilities, respectively, were awarded the ISO 13485 certification, which replaces the ISO 9001 and EN 46001 standards, which have been subsequently maintained through periodic assessments, in accordance with the expiration dates of the standards, and we are currently authorized to affix the CE mark to our products, allowing us to sell our products throughout the European Economic Area.

We are also currently subject to regulations in Japan. A Japanese distributor received the first government approval to market the CyberKnife System from the Ministry of Health and Welfare, or MHLW, in November 1996. In December 2003, we received approval from the MHLW to market the CyberKnife System in Japan for clinical applications in the head and neck, and a new distributor, Chiyoda Technology Corporation, was appointed to distribute the CyberKnife System. In June 2008, we received approval from the MHLW to market the CyberKnife System for treatments throughout the body where radiation treatment is indicated. On June 30, 2009, our subsidiary, Accuray Japan KK, became the Marketing Authorization Holder in Japan, which allowed the Company to directly sell our products in Japan. In August 2010, we received Shonin approval from MHLW to market the CyberKnife G4 System to treat tumors non-invasively anywhere in the body, inclusive of head and neck. Hi-Art Co. Ltd., the original distributor for TomoTherapy in Japan, received the Shonin approval from the MHLW to market the TomoTherapy System for use as an integrated system for the planning and delivery of IMRT for the treatment of cancer in January 2006. The Shonin was transferred to another distributor, Hitachi Medical Corporation in January 2009. During September 2011, Hitachi Medical Corporation received a Shonin approval for the marketing of the TomoHD model. In July 2012, we took over the Shonins and the service operations of the TomoTherapy Systems in Japan from Hitachi Medical Corporation.

We are subject to additional regulations in other foreign countries, including, but not limited to, Canada, Taiwan, China, Korea, and Russia in order to sell our products. We intend that either we or our distributors will receive any necessary approvals or clearance prior to marketing our products in those international markets.

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***State Certificate of Need Laws***

In some states, a certificate of need or similar regulatory approval is required prior to the acquisition of high-cost capital items or the provision of new services. These laws generally require appropriate state agency determination of public need and approval prior to the acquisition of such capital items or addition of new services. Certificate of need regulations may preclude our customers from acquiring one of our systems, whether through purchase or our shared ownership program, and from performing stereotactic radiosurgery procedures using one of our systems. Several of our prospective customers currently are involved in appeals of certificate of need determinations. If these appeals are not resolved in favor of these prospective customers, they may be precluded from purchasing and/or performing services using one of our systems. Certificate of need laws are the subject of continuing legislative activity, and a significant increase in the number of states regulating the acquisition and use of one of our systems through certificate of need or similar programs could adversely affect us.

**Backlog**

For a discussion of the Company's fiscal 2013 backlog, please refer to the section entitled "*Backlog*," in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations.

**Employees**

As of June 30, 2013, we had 989 employees worldwide. None of the employees is represented by a labor union or is covered by a collective bargaining agreement. We have never experienced any employment related work stoppages and we believe our relationship with our employees is good.

**Geographic Information**

For financial reporting purposes, net sales and long-lived assets attributable to significant geographic areas are presented in Note 2, *Summary of Significant Accounting Policies*, in the notes to the consolidated financial statements, which are incorporated herein by reference.

**Available Information**

Our main corporate website address is [www accuray.com](http://www accuray.com). We make available on this web site, free of charge, copies of our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and our proxy statements, and any amendments to those reports, as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the Securities and Exchange Commission, the SEC. All SEC filings are also available at the SEC's website at [www.sec.gov](http://www.sec.gov). In addition, the Corporate Governance Guidelines and the charters of the Audit Committee, Compensation Committee, Nominating and Disclosure Committee of our Board of Directors are also available on the investor relations page of our website. The contents of our web site are not intended to be incorporated by reference into this report or in any other report or document we file or furnish, and any references to our web site are intended to be textual references only.

We operate in a rapidly changing environment that involves significant risks, a number of which are beyond our control. In addition to the other information contained in this Form 10-K, the following discussion highlights some of these risks and the possible impact of these factors on our business, financial condition and future results of operations. If any of the following risks actually occur, our business, financial condition or results of operations may be adversely impacted, causing the trading price of our common stock to decline. In addition, these risks and uncertainties may impact the "forward-looking" statements described elsewhere in this Form 10-K and in the documents incorporated herein by reference. They could affect our actual results of operations, causing them to differ materially from those expressed in "forward-looking" statements.



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**Item 1A. RISK FACTORS**

**Risks Related to Our Business**

*If we do not effectively manage our growth, our business may be significantly harmed.*

In order to implement our business strategy, we expect continued growth in our infrastructure requirements, particularly as we expand our manufacturing capacities and our sales and marketing capabilities. To manage our growth, we must expand our facilities, augment our management, operational and financial systems, hire and train additional qualified personnel, scale-up our manufacturing capacity and expand our marketing and distribution capabilities. Our manufacturing, assembly and installation process is complex and occurs over many months, and we must effectively scale this entire process to satisfy customer expectations and changes in demand. Further, to accommodate our growth and compete effectively, we will be required to improve our information systems. We cannot be certain that our personnel, systems, procedures and internal controls will be adequate to support our future operations. If we cannot manage our growth effectively, our business will suffer.

*We have a large accumulated deficit, may incur future losses and may be unable to achieve profitability.*

As of June 30, 2013, we had an accumulated deficit of \$319.6 million. We may incur net losses in the future, particularly as we resolve manufacturing and supply issues with the MLC option for our new CyberKnife M6 Series and improve our selling and marketing activities. Our ability to achieve and sustain long-term profitability is largely dependent on our ability to successfully market and sell the CyberKnife and TomoTherapy Systems and to control our costs and effectively manage our growth. We cannot assure you that we will be able to achieve profitability. In the event we fail to achieve profitability, our stock price could decline.

*If the CyberKnife or TomoTherapy Systems do not achieve widespread market acceptance, we will not be able to generate the revenue necessary to support our business.*

Achieving physician, patient, hospital administrator and third-party payor acceptance of the CyberKnife and TomoTherapy Systems as preferred methods of tumor treatment will be crucial to our continued success. Physicians will not begin to use or increase the use of the CyberKnife or TomoTherapy Systems unless they determine, based on experience, clinical data and other factors, that the CyberKnife and TomoTherapy Systems are safe and effective alternatives to traditional treatment methods. We often need to educate physicians about the use of stereotactic radiosurgery, IGRT and adaptive radiation therapy, convince healthcare payors that the benefits of the CyberKnife and TomoTherapy Systems and their related treatment processes outweigh their costs and help train qualified physicians in the skilled use of the CyberKnife and TomoTherapy Systems. For example, the complexity and dynamic nature of stereotactic radiosurgery and Robotic IMRT as well as adaptive radiation therapy and IGRT, require significant education of hospital personnel and physicians regarding the benefits of stereotactic radiosurgery and Robotic IMRT, as well as adaptive radiation therapy and IGRT, and require departures from their customary practices. We have expended and will continue to expend significant resources on marketing and educational efforts to create awareness of stereotactic radiosurgery and Robotic IMRT as well as adaptive radiation therapy and IGRT generally and to encourage the acceptance and adoption of our products for these technologies.

The CyberKnife and TomoTherapy Systems are major capital purchases, and purchase decisions are greatly influenced by hospital administrators who are subject to increasing pressures to reduce

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costs. These and other factors, including the following, may affect the rate and level of market acceptance of each of the CyberKnife and TomoTherapy Systems:

The CyberKnife and TomoTherapy Systems' price relative to other products or competing treatments;

Our ability to develop new products and enhancements and receive regulatory clearances and approval, if required, to existing products in a timely manner;

Effectiveness of our sales and marketing efforts;

The impact of the current economic environment on our business and our customers' business, including the postponement by our customers of purchase decisions or required build-outs;

Capital equipment budgets of healthcare institutions;

Increased scrutiny by state boards when evaluating certificates of need requested by purchasing institutions;

Perception by patients, physicians and other members of the healthcare community of the CyberKnife and TomoTherapy Systems' safety, efficacy, efficiency and benefits compared to competing technologies or treatments;

Publication in peer-reviewed medical journals of data regarding the successful use and longer term clinical benefits of the CyberKnife and TomoTherapy Systems;

Willingness of physicians to adopt new techniques and the ability of physicians to acquire the skills necessary to operate the CyberKnife and TomoTherapy Systems;

Extent of third-party coverage and reimbursement rates, particularly from Medicare, for procedures using the CyberKnife and TomoTherapy Systems;

Development of new products and technologies by our competitors or new treatment alternatives;

Regulatory developments related to manufacturing, marketing and selling the CyberKnife and TomoTherapy Systems both within and outside the United States;

Perceived liability risks arising from the use of new products; and

Unfavorable publicity concerning the CyberKnife or TomoTherapy Systems or radiation-based treatment alternatives.

If the CyberKnife or TomoTherapy Systems are unable to achieve or maintain market acceptance, new orders and sales of our systems would be adversely affected, our revenue levels would decrease and our business would be harmed.

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In October 2012, we introduced our new CyberKnife M6 Series Systems that come in configurations that have the option of: fixed collimator, iris collimator, and multi-leaf collimator (MLC). The vendor producing the MLC for our CyberKnife M6 Series Systems has experienced low manufacturing yields and has been able to deliver only a small number of units. Our life-cycle testing revealed that the units did not have the durability that we, and our customers, expect in our products. Therefore, we have decided that we will not release the MLC units produced by our current supplier to the market for commercial use. We are working with additional vendors for key components of our MLC and expect that this will enable us to produce an MLC that meets our standards in the future. The delay in shipment of our MLC may cause a delay in new orders and shipments of CyberKnife M6 Series Systems.

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In October 2012, we introduced our new TomoTherapy H Series Systems which come in configurations of TomoH , TomoHD and TomoHDA . We expect that these new TomoTherapy H Series Systems will drive future orders and revenue growth. If either of these new CyberKnife or TomoTherapy Systems, or any of the CyberKnife or TomoTherapy Systems, is unable to achieve or maintain market acceptance, new orders and sales of our systems would be adversely affected, our revenue levels would decrease and our business would be harmed.

***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 of the CyberKnife and TomoTherapy Systems, we often need to educate physicians about the use of stereotactic radiosurgery and radiation therapy, convince healthcare payers that the benefits of the CyberKnife and TomoTherapy Systems and their related treatment processes outweigh their costs and help train qualified physicians in the skilled use of these systems. For example, the complexity and dynamic nature of stereotactic radiosurgery and Robotic IMRT as well as adaptive radiation therapy and IGRT require significant education of hospital personnel and physicians regarding the benefits of stereotactic radiosurgery and Robotic IMRT as well as adaptive radiation therapy and IGRT and require departures from their customary practices. In addition, we also must educate clinicians regarding the entire functionality of our radiation therapy systems, including techniques using the full quantitative imaging capabilities of our treatment systems, which enable clinicians to adapt a patient's treatment plan in response to anatomical changes and the cumulative amount of radiation received by specific areas within the patient over the course of treatment. We have expended and will continue to expend significant resources on marketing and educational efforts to create awareness of stereotactic radiosurgery, Robotic IMRT as well as adaptive radiation therapy and IGRT and to encourage the acceptance and adoption of our products for these technologies. We cannot be sure that any products we develop will gain significant market acceptance among physicians, patients and healthcare payors, even if we spend significant time and expense on their education. Failure to gain significant market acceptance would adversely affect our product sales and revenues, harming our business, financial condition and results of operations.

***Any failure in our physician training efforts could result in potential liabilities.***

We rely on physicians to devote adequate time to learn to use our products. If physicians are not properly trained, they may misuse or ineffectively use our products. This may result in unsatisfactory patient outcomes, patient injury and related liability or negative publicity which could have an adverse effect on our product sales.

***We depend on key employees, the loss of whom would adversely affect our business. If we fail to attract and retain employees with the expertise required for our business, we may be unable to continue to grow our business.***

We are highly dependent on the members of our senior management, sales, marketing, operations and research and development staff. In January 2013, we underwent a restructuring of our operations, and it may be more difficult to recruit new qualified personnel as a result of that restructuring. Our future success will depend in part on our ability to retain our key employees and to identify, hire and retain additional personnel. Competition for qualified personnel in the medical device industry, particularly in northern California and in Madison, Wisconsin, is intense, and finding and retaining qualified personnel with experience in our industry is very difficult. We believe there are only a limited number of individuals with the requisite skills to serve in many of our key positions and we compete for key personnel with other medical equipment and software manufacturers and technology companies, as well as universities and research institutions. It is increasingly difficult, time consuming and expensive to hire and retain these persons, and we may be unable to replace key persons if they

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leave or fill new positions requiring key persons with appropriate experience. A significant portion of our compensation to our key employees is in the form of stock related grants. A prolonged depression in our stock price could make it difficult for us to retain our employees and recruit additional qualified personnel. We do not maintain, and do not currently intend to obtain, key employee life insurance on any of our personnel. If we fail to hire and retain personnel in key positions, we may be unable to continue to grow our business successfully.

***We may not be able to achieve profitability with respect to our service business relating to TomoTherapy Systems.***

Our overall service operations relating to TomoTherapy Systems currently are modestly profitable. Our ability to increase the profitability of this service business depends in part on reducing warranty and service costs for the TomoTherapy Systems and improving economies of scale in service operations. We may be unable to achieve these reductions in costs or improve the reliability of the TomoTherapy Systems during the time period expected or at all, and this could adversely affect our results of operations, reduce physician confidence in our system, and erode our brand.

***Our ability to achieve profitability depends in part on maintaining or increasing our gross margins on product sales and service, which we may not be able to achieve.***

A number of factors may result in adverse impacts to our gross margins, including:

Actions related to new products, pricing and marketing programs;

Lower than expected manufacturing yields of high cost components leading to increased manufacturing costs;

Low production volume which will result in high levels of overhead cost per unit of production;

The timing of revenue recognition and revenue deferrals;

Sales discounts;

Changes in product configurations;

Increases in material or labor costs;

Increased service or warranty costs or the failure to reduce service or warranty costs, especially with respect to the TomoTherapy Systems;

Excess inventory and inventory holding charges;

Obsolescence charges;

Our ability to reduce production costs;

Increased price competition;

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Variation in the margins across products installed in a particular period; and

How well we execute on our strategic and operating plans.

***We may not realize all of the benefits that we expect from our restructuring of operations that was announced in January 2013 and it may adversely affect our business.***

In January 2013, we announced a restructuring of our operations to focus on improving commercial execution and to position the Company to support sustainable revenue growth and profitability. The restructuring was designed to establish a reduced cost structure and to reallocate resources to commercial sales and marketing initiatives and improve business processes to support

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accelerated revenue growth. The restructuring was designed to generate expense reductions by reducing the number of our employees by approximately 13 percent and reducing program and discretionary spending. We may not be able to implement all of the actions that we intended to take in the restructuring of our operations and we may not realize all of the benefits that were expected from the restructuring. The Company may not be able to successfully establish a cost structure that appropriately reallocates resources to commercial sales and marketing initiatives or may not be able to implement improved business processes to support accelerated revenue growth. The restructuring may not improve commercial execution, and the Company may not be able to support sustainable revenue growth and profitability following the restructuring.

***Our industry is subject to intense competition and rapid technological change, which may result in products or new tumor treatments that are superior to the CyberKnife and TomoTherapy Systems. If we are unable to anticipate or keep pace with changes in the marketplace and the direction of technological innovation and customer demands, our products may become obsolete or less useful and our operating results will suffer.***

The medical device industry in general and the non-invasive cancer treatment field in particular are subject to intense and increasing competition and rapidly evolving technologies. Because our products often have long development and government approval cycles, we must anticipate changes in the marketplace and the direction of technological innovation and customer demands. To compete successfully, we will need to continue to demonstrate the advantages of our products and technologies over well-established alternative procedures, products and technologies, and convince physicians and other healthcare decision makers of the advantages of our products and technologies. Traditional surgery and other forms of minimally invasive procedures, brachytherapy, chemotherapy or other drugs remain alternatives to the CyberKnife and TomoTherapy Systems.

We consider the competition for the TomoTherapy Systems to be existing radiation therapy systems, primarily using C-arm linacs, which are sold by large, well-capitalized companies with significantly greater market share and resources than we have. Several of these competitors are also able to leverage their fixed sales, service and other costs over multiple products or product lines. In particular, we compete with a number of existing radiation therapy equipment companies including Varian Medical Systems, Inc. and Elekta AB, and to a lesser extent, Mitsubishi Heavy Industries, Ltd., BrainLAB AG and ViewRay Incorporated. Varian Medical Systems has been the leader in the external beam radiation therapy market for many years and has the majority market share for radiation therapy systems worldwide. In 2008, Varian began selling and installing RapidArc technology. The RapidArc technology purports to be able to deliver image guided, intensity modulated radiation therapy more rapidly than other similar systems, including the TomoTherapy Systems, and Varian has maintained a strong marketing campaign claiming this technology has the same capabilities as, or better capabilities than, our TomoTherapy Systems. In April, 2010, Varian announced the launch of a new line of TrueBeam systems, which Varian claims are specifically designed for high-precision image guided radiotherapy and radiosurgery. Varian claims this new platform is designed to be versatile and can be used for all forms of advanced external beam radiation therapy. In April 2012, Varian and Siemens announced that they had entered into a strategic global partnership involving mutual marketing and representation of products for imaging and treatment in the global radiation oncology business, the development of software interfaces between Siemens and Varian treatment systems and potential joint development of new products.

The CyberKnife System also competes directly with conventional linac based radiation therapy systems primarily from Elekta AB, BrainLAB AG, Mitsubishi Heavy Industries, Ltd. and Varian Medical Systems, Inc. At least one other company has announced that it is developing a product that, if introduced, would be directly competitive with the CyberKnife System. In general, because of aging demographics and attractive market factors in oncology, we believe that new competitors will enter the radiosurgery and radiation therapy markets in the years ahead. The CyberKnife System has not

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typically been used to perform traditional radiation therapy and therefore competition has been limited with conventional medical linacs that perform traditional radiation therapy. However, the CyberKnife VSI System, which we introduced in November of 2009, may be used to perform Robotic IMRT, an advanced method of traditional radiation therapy, which products of Elekta and Varian are also capable of performing. The new CyberKnife M6 Series, which we introduced in October 2012, includes the option of an MLC which may further the use of the CyberKnife Systems to perform radiation therapy, when this feature is commercially available. In October 2012, Varian announced a new line of C-arm gantries, called the Edge systems, which Varian claims are specifically designed for radiosurgery to compete with our CyberKnife Systems. In addition, some manufacturers of conventional linac based radiation therapy systems, including Varian and Elekta, have products that can be used in combination with body and/or head frames and image guidance systems to perform both radiosurgical and radiotherapy procedures.

Furthermore, many government, academic and business entities are investing substantial resources in research and development of cancer treatments, including surgical approaches, radiation treatment, MRI-guided radiotherapy systems, proton therapy systems, drug treatment, gene therapy (which is the treatment of disease by replacing, manipulating, or supplementing nonfunctional genes), and other approaches. Successful developments that result in new approaches for the treatment of cancer could reduce the attractiveness of our products or render them obsolete.

Our future success will depend in large part on our ability to establish and maintain a competitive position in current and future technologies. Rapid technological development may render the CyberKnife and TomoTherapy Systems and their technologies obsolete. Many of our competitors have or may have greater corporate, financial, operational, sales and marketing resources, and more experience and resources in research and development than we have. We cannot assure you that our competitors will not succeed in developing or marketing technologies or products that are more effective or commercially attractive than our products or that would render our technologies and products obsolete or less useful. We may not have the financial resources, technical expertise, marketing, distribution or support capabilities to compete successfully in the future. Our success will depend in large part on our ability to maintain a competitive position with our technologies.

Our competitive position also depends on:

Widespread awareness, acceptance and adoption by the radiation oncology and cancer therapy markets of our products;

The development of new technologies that improve the effectiveness and productivity of the CyberKnife System radiosurgery process and the TomoTherapy System radiation therapy process;

Product and procedure coverage and reimbursement from third party payors, insurance companies and others;

Availability of adequate coverage and reimbursement from third party payors, insurance companies and others for procedures performed using our systems;

Properly identifying customer needs and delivering new products or product enhancements to address those needs;

Published, peer-reviewed studies supporting the efficacy and safety and long-term clinical benefit of the CyberKnife and TomoTherapy Systems;

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

Limiting the timing and cost of obtaining regulatory approvals or clearances;



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The manufacture and delivery of our products in sufficient volumes on time, and accurately predicting and controlling costs associated with manufacturing, installation, warranty and maintenance of the products;

Our ability to attract and retain qualified personnel;

The extent of our intellectual property protection or our ability to otherwise develop proprietary products and processes;

The ability of our competitors to obtain government funding for the development of intellectual property in foreign jurisdictions;

Securing sufficient capital resources to expand both our continued research and development, and sales and marketing efforts; and

Obtaining and maintaining any necessary United States or foreign market approvals or clearances.

If customers choose not to purchase a CyberKnife or TomoTherapy System or choose to purchase our competitors' products, our revenue and market share would be adversely impacted, and there could be a material adverse effect on our business, financial condition and results of operations. In addition, companies in the pharmaceutical or biotechnology fields may seek to develop methods of cancer treatment that are more effective than radiation therapy and radiosurgery, resulting in decreased demand for the TomoTherapy or CyberKnife Systems. Because the CyberKnife and TomoTherapy Systems have a long development cycle and because it can take significant time to receive government approvals or clearances for changes to the CyberKnife and TomoTherapy Systems, we must anticipate changes in the marketplace and the direction of technological innovation. Accordingly, if we are unable to anticipate and keep pace with new innovations in the cancer treatment market, the CyberKnife or TomoTherapy Systems or an aspect of their functionality may be rendered obsolete, which would have a material adverse effect on our business, financial condition and results of operations. In addition, some of our competitors may compete by changing their pricing model or by lowering the price of their conventional radiation therapy systems or ancillary supplies, or by combining with other competitors. If such pricing strategies are implemented, there could be downward pressure on the price of radiation therapy and radiosurgery systems. If we are unable to maintain or increase our selling prices, our gross margins will decline, and there could be a material adverse effect on our business, financial condition and results of operations.

***Disruption of critical information systems could harm our business and financial condition.***

Information technology helps us operate more efficiently, interface with customers, maintain financial accuracy and efficiency, and accurately produce our financial statements. We implemented and began use of a new Enterprise Resource Planning, or ERP system effective January 1, 2011. Our initial implementation covered the basic elements of our ERP system. We migrated processes and systems used by TomoTherapy to the processes and systems used with our new ERP system, and we plan to implement additional capabilities in the future. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology infrastructure, or if we fail to smoothly manage the new ERP system or its integration with TomoTherapy's processes and systems, we could be subject to transaction errors, processing inefficiencies, the loss of customers, business disruptions, or the loss of or damage to intellectual property through a security breach. In addition, we are considering moving some of our data and information to a cloud computing system, where applications and data are hosted, accessed and processed through a third-party provider over a broadband Internet connection. In a cloud computing environment, we could be subject to outages and security breaches by the third party service provider. If our data management systems do not effectively collect, store, process and report relevant data for the operation of our business, whether due to equipment

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malfunction or constraints, software deficiencies, computer viruses, security breaches, catastrophic events 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 internally and externally report our operating results.

Likewise, data privacy breaches by employees and others with permitted access to our systems may pose a risk that sensitive data may be exposed to unauthorized person or to the public. For example, in May of 2012, an email containing confidential employee information was inadvertently sent to all company employees in our Madison, Wisconsin campus. Immediately upon discovery of this error, Accuray's information technology department took all possible steps to recover this email and to prevent its further distribution. In addition, we offered to pay for up to two years of credit monitoring for any employee desiring such service. There can be no assurance that any efforts we make to prevent against such privacy breaches will prevent breakdowns or breaches in our systems that could adversely affect our business.

***We have limited experience and capability in manufacturing. If we encounter manufacturing problems, or if our manufacturing facilities do not continue to meet federal, state or foreign manufacturing standards, we may be required to temporarily cease all or part of our manufacturing operations, which would result in delays and lost revenue.***

The CyberKnife and TomoTherapy Systems are complex, and require the integration of a number of components from several sources of supply. We must manufacture and assemble these complex systems in commercial quantities in compliance with regulatory requirements and at an acceptable cost. We have a limited history of manufacturing commercial quantities of the CyberKnife and TomoTherapy Systems. In particular, we manufacture compact linacs as a component of the CyberKnife and TomoTherapy Systems. Our linac components are extremely complex devices and require significant expertise to manufacture, and as a result of our limited manufacturing experience we may have difficulty producing needed materials in a commercially viable manner. We may encounter difficulties in scaling up production of the CyberKnife or TomoTherapy Systems, including problems with quality control and assurance, component supply shortages, increased costs, shortages of qualified personnel, the long lead time required to develop additional radiation-shielded facilities for purposes of testing our products and/or difficulties associated with compliance with local, state, federal and foreign regulatory requirements. If our manufacturing capacity does not keep pace with product demand, we will not be able to fulfill orders in a timely manner which in turn may have a negative effect on our financial results and overall business. Conversely, if demand for our products decreases, the fixed costs associated with excess manufacturing capacity may adversely affect our financial results.

In October 2012, we introduced our new CyberKnife M6 Series Systems that come in configurations that have the option of: fixed collimator, iris collimator, and multi-leaf collimator (MLC). The vendor producing the MLC for our CyberKnife M6 Series Systems has experienced low manufacturing yields and has been able to deliver only a small number of units. Our life-cycle testing revealed that the units did not have the durability that we, and our customers, expect in our products. Therefore, we have decided that we will not release the MLC units produced by our current supplier to the market for commercial use. We are working with additional vendors for key components of our MLC and expect that this will enable us to produce an MLC that meets our standards in the future. The delay in shipment of our MLC may cause a delay in new orders and shipments of CyberKnife M6 Series Systems.

Our manufacturing processes and the manufacturing processes of our third-party suppliers are required to comply with the FDA's Quality System Regulation, or QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, production process, controls, manufacturing, labeling, quality assurance, packaging, storage and shipping of our

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products. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality requirements. We are also subject to state licensing and other requirements and licenses applicable to manufacturers of medical devices, and we are required to comply with International Organization for Standardization, or ISO, quality system standards in order to produce products for sale in Europe, as well as various other foreign laws and regulations. Because our manufacturing processes include the production of diagnostic and therapeutic X-ray equipment and laser equipment, we are subject to the electronic product radiation control provisions of the Federal Food, Drug and Cosmetic Act, which requires that we file reports with the FDA, applicable states and our customers regarding the distribution, manufacturing and installation of these types of equipment. The FDA enforces the QSR and the electronic product radiation control provisions through periodic inspections, some of which may be unannounced. We have been, and anticipate in the future being subject to such inspections. FDA inspections usually occur every two to three years. During such inspections, the FDA may issue Inspectional Observations on Form FDA 483, listing instances where the manufacturer has failed to comply with applicable regulations and procedures, or warning letters. Our Sunnyvale facility, where we manufacture the CyberKnife Systems, was most recently inspected by the FDA in June 2012. The 2012 inspection resulted in several observations. The initial classification of the inspection is considered to be Voluntary Action Indicated. We have undertaken corrective actions in response to the FDA's observations. In addition, our Madison facility, where we manufacture the TomoTherapy System, was most recently inspected by the FDA in July 2012. The 2012 inspection resulted in no observations.

If a manufacturer does not adequately address the observations, the FDA may take enforcement action against the manufacturer, including the imposition of fines, restriction of the ability to export product, total shutdown of production facilities and criminal prosecution. If we or a third-party supplier receive a Form FDA 483 with material or major observations that are not promptly corrected, fail to pass a QSR inspection, or fail to comply with these, ISO and other applicable regulatory requirements, our operations could be disrupted and our ability to generate sales could be delayed. Our failure to take prompt and satisfactory corrective action in response to an adverse inspection or our failure to comply with applicable standards could result in enforcement actions, including a public warning letter, a shutdown of our manufacturing operations, a recall of our products, civil or criminal penalties, or other sanctions, which would cause our sales and business to suffer. In addition, because some foreign regulatory approvals are based on approvals or clearances from the FDA, any failure to comply with FDA requirements may also disrupt our sales of products in other countries. We cannot assure you that the FDA or other governmental authorities would agree with our interpretation of applicable regulatory requirements or that we or our third-party suppliers have in all instances fully complied with all applicable requirements. If any of these events occurs, our reputation could be harmed, we could lose customers and there could be a material adverse effect on our business, financial condition and results of operations.

If we cannot achieve the required level and quality of production, we may need to outsource production or rely on licensing and other arrangements with third parties who possess sufficient manufacturing facilities and capabilities in compliance with regulatory requirements. Even if we could outsource needed production or enter into licensing or other third party arrangements, this could reduce our gross margin and expose us to the risks inherent in relying on others. We also cannot assure you that our suppliers will deliver an adequate supply of required components on a timely basis or that they will adequately comply with the QSR. Failure to obtain these components on a timely basis would disrupt our manufacturing processes and increase our costs, which would harm our operating results.

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***The CyberKnife Systems have been in use for a limited period of time for uses outside the brain, and the medical community has not yet developed a large quantity of peer-reviewed literature that supports safe and effective use in those locations in the body.***

The CyberKnife System was initially cleared by a number of regulatory authorities for the treatment of tumors in the brain and neck. More recently, the CyberKnife Systems have been cleared in the United States to treat tumors anywhere in the body where radiation is indicated, and our future growth is dependent in large part on continued growth in full body use of the system. Currently, however, there are a limited number of peer-reviewed medical journal publications regarding the safety and efficacy of the CyberKnife System for treatment of tumors outside the brain or spine. If later studies show that the CyberKnife Systems are less effective or less safe with respect to particular types of solid tumors, or in the event clinical studies do not achieve the results anticipated at the outset of the study, use of the CyberKnife Systems could be negatively affected and our growth and operating results would therefore be harmed.

***Our long-term success, results of operations and the value of our common stock depend on our ability to successfully combine the TomoTherapy business with our pre-existing business, which may be more difficult, costly or time-consuming than expected.***

On June 10, 2011, we acquired TomoTherapy, the business of which we are continuing to integrate with our pre-existing business. While we have made significant progress in integrating the TomoTherapy business into our pre-existing business, we anticipate our integration efforts will continue for the foreseeable future. Our future success, results of operations and the value of our common stock depend, in part, on our ability to realize the anticipated benefits from integrating the TomoTherapy business with our pre-existing business. To realize these anticipated benefits, we must successfully combine our businesses in an efficient and effective manner. If we are not able to achieve these objectives within the anticipated time frame, or at all, the anticipated benefits and cost savings of the acquisition may not be realized fully, or at all, or may take longer to realize than expected, and our results of operations and the value of our common stock may be adversely affected.

The integration process could result in the disruption of existing business, loss of key employees, or inconsistencies in standards, controls, procedures and policies that could adversely affect our ability to maintain relationships with customers, employees, suppliers and other business partners following the acquisition or to achieve the anticipated benefits of the acquisition. Specifically, issues that must be addressed in integrating the operations of TomoTherapy into our pre-existing operations in order to realize the anticipated benefits of the acquisition include, among other things:

Integrating and optimizing the utilization of the properties, equipment, suppliers, distribution channels, manufacturing, service, marketing, promotion and sales activities and information technologies of the combined company;

Consolidating corporate and administrative infrastructures of the combined company, including the consolidation of our European offices into one new location, which occurred in the fall of 2012;

Coordinating geographically dispersed organizations of the combined company;

Retaining existing customers of, and attracting new customers to, the combined company; and

Conforming standards, controls, procedures and policies, business cultures and compensation structures throughout the combined company.

Integration efforts require a significant increase in workload across the organization, and have diverted and will continue to divert management attention and resources. An inability to realize the full extent of the anticipated benefits of the acquisition, as well as any delays encountered in the integration

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process, could have an adverse effect upon our results of operations, which may affect adversely the value of our common stock.

In addition, the actual integration may result in additional and unforeseen expenses, and the anticipated benefits of the integration plan may not be realized. Actual synergies, if achieved at all, may be lower than what we expect and may take longer to achieve than anticipated. If we are not able to adequately address these challenges, we may be unable to successfully integrate the combined company's operations or to realize the anticipated benefits of the integration.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results. As a result, current and potential stockholders could lose confidence in our financial reporting, which could have an adverse effect on our business and our stock price.***

Effective internal controls are necessary for us to provide reliable financial reports and to protect from fraudulent, illegal or unauthorized transactions. If we cannot maintain effective controls and provide reliable financial reports, our business and operating results could be harmed.

A failure to implement and maintain effective internal control over financial reporting could result in a material misstatement of our financial statements or otherwise cause us to fail to meet our financial reporting obligations. This, in turn, could result in a loss of investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our business and operating results and our stock price, and we could be subject to stockholder litigation.

***We may have difficulties in determining the effectiveness of our internal controls due to our complex financial model.***

The complexity of our financial model contributes to our need for effective financial reporting systems and internal controls. We recognize revenue from a range of transactions including CyberKnife and TomoTherapy Systems sales, our shared ownership program and services. The CyberKnife and TomoTherapy Systems are complex products that contain both hardware and software elements. The complexity of the CyberKnife and TomoTherapy Systems and of our financial model pertaining to revenue recognition requires us to process a broader range of financial transactions than would be required by a company with a less complex financial model. Accordingly, deficiencies or weaknesses in our internal controls would likely impact us more significantly than they would impact a company with a less complex financial model. If we were to find that our internal controls were deficient, we could be required to amend or restate historical or pro forma financial statements, which would likely have a negative impact on our stock price.

***If third-party payors do not provide sufficient coverage and reimbursement to healthcare providers for use of the CyberKnife and TomoTherapy Systems, demand for our products and our revenue could be adversely affected.***

Our customers rely significantly on reimbursement for CyberKnife and TomoTherapy procedures. Our ability to commercialize our products successfully will depend in significant part on the extent to which public and private third party payors provide adequate coverage and reimbursement for procedures that are performed with our products. Third-party payors, and in particular managed care organizations, challenge the prices charged for medical products and services and institute cost containment measures to control or significantly influence the purchase of medical products and services. If reimbursement policies or other cost containment measures are instituted in a manner that significantly reduces the coverage for or payment for the procedures that are performed with our products, our existing customers may not continue using our products or may decrease their use of our products, and we may have difficulty obtaining new customers. Such actions would likely have a material adverse effect on our operating results. In November 2012, the centers for Medicare and

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Medicaid Services, or CMS, issued the 2013 Medicare payment rates for hospital outpatient services, for physicians, and services performed in the freestanding center setting for calendar year 2013. While some of the reimbursement rates are modestly higher than in the prior year, others are modestly lower than in the prior year, which could have a negative impact on the continued use of our products by existing customers and our ability to obtain new customers. The final rates for 2013 increase payment in the hospital outpatient setting for many professional and technical codes billed in conjunction with both IMRT and robotic radiosurgery. The payment for robotic radiosurgery delivery decreased slightly while the payment for IMRT delivery increased slightly. CMS reviews such rates annually, and could implement more significant changes in future years.

In calendar year 2013, payment for robotic radiosurgery will continue to be set by local Medicare carriers in the freestanding center setting for robotic radiosurgery delivery. For delivery of IMRT in the freestanding clinic, Medicare has released its conversion factor, resource and malpractice values and geographic adjustment indices that would be used to calculate payment in 2013. In addition to making an adjustment to the conversion factor (the multiplier used to calculate rates for all services priced under the Physician Fee Schedule), CMS made targeted cuts to IMRT based on its belief that shorter treatment times are typically seen in practice, as opposed to the longer times which had previously been used to calculate IMRT payment. While the time-based proposal by CMS was retained in the final rule, CMS considered other direct and indirect inputs that mitigated the overall payment reduction to less than half what it proposed for the reimbursement rate for IMRT.

If in the future CMS significantly decreases reimbursement rates for stereotactic radiosurgery, Robotic IMRT or radiation therapy services, or if other cost containment measures are implemented in the United States or elsewhere, such changes could discourage cancer treatment centers and hospitals from purchasing our products. We have seen our customers' decision making process complicated by the uncertainty surrounding the proposed reduction in Medicare reimbursement rates for radiotherapy and radiosurgery at freestanding clinics in the United States and for physician reimbursement for radiation oncology, which has resulted in delay and sometimes even failure to purchase our products.

***As a strategy to assist our sales efforts, we may offer extended payment terms, which may potentially result in higher Days Sales Outstanding and greater payment defaults.***

We offer longer or extended payment terms for qualified customers in some circumstances. As of June 30, 2013, customer contracts with extended payment terms of more than one year amounted to less than 5% 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, which would affect our revenue, as we recognize revenue on such transactions on a cash basis.

***If we are unable to develop new products or enhance existing products, we may be unable to attract or retain customers.***

Our success depends on the successful development, regulatory clearance or approval, introduction and commercialization of new generations of products, treatment systems, and enhancements to and/or simplification of existing products. The CyberKnife and TomoTherapy Systems, which are currently our principal products, are technologically complex and must keep pace with, among other things, the products of our competitors. We are making significant investments in long-term growth initiatives. Such initiatives require significant capital commitments, involvement of senior management and other investments on our part, which we may be unable to recover. Our timeline for the development of new products or enhancements may not be achieved and price and profitability targets may not prove feasible. Commercialization of new products may prove challenging, and we may be required to invest more time and money than expected to successfully introduce them. Once introduced, new products may adversely impact orders and sales of our existing products, or make them less desirable or even

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obsolete. Compliance with regulations, competitive alternatives, and shifting market preferences may also impact the successful implementation of new products or enhancements. This includes two new versions of our technology platforms: the CyberKnife M6 Series and the TomoTherapy H Series, which we formally introduced in October 2012.

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

Properly identify customer needs;

Prove feasibility of new products;

Educate physicians about the use of new products and procedures;

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 obtaining regulatory approvals or clearances;

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

Price our products competitively;

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

Meet our product development plan and launch timelines;

Improve manufacturing yields of components;

Manage customer acceptance and payment for products;

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

Anticipate and compete successfully with competitors.

Even if customers accept new products or product enhancements, the revenues from these products may not be sufficient to offset the significant costs associated with making them available to customers.

We cannot be sure that we will be able to successfully develop, obtain regulatory approval or clearance for, manufacture or introduce new products, treatment systems or enhancements, the roll-out of which involves compliance with complex quality assurance processes, including the

quality system regulation, or QSR, enforced by the FDA. Failure to obtain regulatory approval or clearance for our products or to complete these processes in a timely and efficient manner 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 backlog, revenues and operating results to suffer.

***The safety and efficacy of our products for certain uses is not yet supported by long-term clinical data, and our products may therefore prove to be less safe and effective than initially thought.***

Although we believe that the CyberKnife and TomoTherapy Systems have advantages over competing products and technologies, we do not have sufficient clinical data demonstrating these advantages for all tumor indications. For example, because our CyberKnife procedures are relatively new, we have limited clinical data relating to the effectiveness of the CyberKnife Systems as a means of controlling the growth of cancer at a particular body site. In addition, we have only limited five-year



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patient survival rate data, which is a common long-term measure of clinical effectiveness in cancer treatment. Further, future patient studies or clinical experience may indicate that treatment with the CyberKnife System does not improve patient survival or outcomes.

Likewise, because the TomoTherapy Systems have only been on the market since 2003, we have limited complication or patient survival rate data with respect to treatment using the system. In addition, while the effectiveness of radiation therapy is well understood, there is a growing but still limited number of peer-reviewed medical journal publications regarding the efficacy of highly conformal treatment such as that delivered by the TomoTherapy System. If future patient studies or clinical experience do not support our beliefs that the TomoTherapy System offers a more advantageous treatment for a wide variety of cancer types, use of the system could fail to increase or could decrease, and our business would therefore be adversely affected.

Such results could reduce the rate of reimbursement by both public and private third-party payors for procedures that are performed with our products, slow the adoption of our products by physicians, significantly reduce our ability to achieve expected revenues and could prevent us from becoming profitable. In addition, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, the FDA could rescind our clearances, our reputation with physicians, patients and others may suffer and we could be subject to significant legal liability.

***We rely on a third party to perform spare parts shipping and other logistics functions on our behalf. A failure or disruption at our logistics provider would adversely impact our business.***

Customer service is a critical element of our sales strategy. As of June 30, 2013 third-party logistics providers stored most of our spare parts inventory in depots around the world and performed a significant portion of our spare parts logistics and shipping activities. If any of our logistics providers suffers an interruption in its business, or experiences delays, disruptions or quality control problems in its operations, or we have to change and qualify alternative logistics providers for our spare parts, shipments of spare parts to our customers may be delayed and our reputation, business, financial condition and results of operations may be adversely affected.

***Our reliance on single-source suppliers for critical components of the CyberKnife and TomoTherapy Systems could harm our ability to meet demand for our products in a timely and cost effective manner.***

We currently depend on single-source suppliers for some of the critical components necessary for the assembly of the CyberKnife and TomoTherapy Systems, including, with respect to the CyberKnife System, the robot and imaging detectors, and, with respect to the TomoTherapy Systems, the ring gantry, the solid state modulator, the radiation detector and the magnetron. If any single-source supplier was to cease delivering components to us or fail to provide the components to our specifications and on a timely basis, we might be required to find alternative sources for these components. In some cases, alternative suppliers may be located in the same geographic area as existing suppliers, and are thus subject to the same economic, political, and geographic factors that may affect existing suppliers to meet our demand. We may have difficulty or be unable to find alternative sources for these components. As a result, we may be unable to meet the demand for the CyberKnife or TomoTherapy Systems, which could harm our ability to generate revenue and damage our reputation. Even if we do find alternate suppliers, we will be required to qualify any such alternate suppliers and we would likely experience a lengthy delay in our manufacturing processes or a cessation in production, which would result in delays of shipment to end users. We cannot assure you that our single-source suppliers will be able or willing to meet our future demands.

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We generally do not maintain large volumes of inventory, which makes us even more susceptible to harm if a single-source supplier fails to deliver components on a timely basis. Furthermore, if we are required to change the manufacturer of a critical component of the CyberKnife or TomoTherapy Systems, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements. We also will be required to assess the new manufacturer's compliance with all applicable regulations and guidelines, which could further impede our ability to manufacture our products in a timely manner. If the change in manufacturer results in a significant change to the product, a new 510(k) clearance would be necessary, which would likely cause substantial delays. The disruption or termination of the supply of key components for the CyberKnife or TomoTherapy Systems could harm our ability to manufacture our products in a timely manner or within budget, harm our ability to generate revenue, lead to customer dissatisfaction and adversely affect our reputation and results of operations.

***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 product.***

The medical device industry is characterized by a substantial amount of litigation over patent and other intellectual property rights. In particular, the field of radiation treatment of cancer is well established and crowded with the intellectual property of competitors and others. We also expect that other participants will enter the field. A number of companies in our market, as well as universities and research institutions, have issued patents and have filed patent applications which relate to the use of radiation therapy and stereotactic radiosurgery to treat cancerous and benign tumors.

Determining whether a product infringes a patent involves complex legal and factual issues, and the outcome of patent litigation actions is often uncertain. We have not conducted an extensive search of patents issued to third parties, and no assurance can be given that third party patents containing claims covering our products, parts of our products, technology or methods do not exist, have not been filed, or could not be filed or issued. Because of the number of patents issued and patent applications filed in our technical areas or fields, our competitors or other third parties may assert that our products and the methods we employ in the use of our products are covered by United States or foreign patents held by them.

In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware, and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. There could also be existing patents that one or more of our products or parts may infringe and of which we are unaware. As the number of competitors in the market for less invasive cancer treatment alternatives grows, and as the number of patents issued in this area grows, the possibility of patent infringement claims against us increases. Regardless of the merit of infringement claims, they can be time-consuming, result in costly litigation and diversion of technical and management personnel. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise funds, if necessary, to continue our operations.

In the event that we become subject to a patent infringement or other intellectual property lawsuit and if the relevant patents or other intellectual property were upheld as valid and enforceable and we were found to infringe or violate the terms of a license to which we are a party, we could be prevented from selling our products unless we could obtain a license or were able to redesign the product to avoid infringement. Required licenses may not be made available to us on acceptable terms or at all. If we were unable to obtain a license or successfully redesign our system, we might be prevented from

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selling our system. If there is an allegation or determination that we have infringed the intellectual property rights of a competitor or other person, we may be required to pay damages, or a settlement or ongoing royalties. In these circumstances, we may be unable to sell our products at competitive prices or at all, and our business and operating results could be harmed.

***We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

As is common in the medical device industry, we employ individuals who were previously employed at other medical equipment or biotechnology companies, including our competitors or potential competitors. We may be subject to claims that we or those employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against claims of this nature, litigation could result in substantial costs and be a distraction to management.

***It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.***

Our success depends significantly on our ability to obtain, maintain and protect our proprietary rights to the technologies used in our products. Patents and other proprietary rights provide uncertain protections, and we may be unable to protect our intellectual property. For example, we may be unsuccessful in defending our patents and other proprietary rights against third party challenges. As key patents expire, our ability to prevent competitors from copying our technology may be limited.

In addition to patents, we rely on a combination of trade secrets, copyright and trademark laws, nondisclosure agreements and other contractual provisions and technical security measures to protect our intellectual property rights. These measures may not be adequate to safeguard the technology underlying our products. If these measures do not protect our rights adequately, third parties could use our technology, and our ability to compete in the market would be reduced. Although we have attempted to obtain patent coverage for our technology where available and appropriate, there are aspects of the technology for which patent coverage was never sought or never received. There are also countries in which we sell or intend to sell the CyberKnife or TomoTherapy Systems but have no patents or pending patent applications. Our ability to prevent others from making or selling duplicate or similar technologies will be impaired in those countries in which we have no patent protection. Although we have several issued patents in the United States and in foreign countries protecting aspects of the CyberKnife and TomoTherapy Systems, our pending United States and foreign patent applications may not issue, may issue only with limited coverage or may issue and be subsequently successfully challenged by others and held invalid or unenforceable.

Similarly, our issued patents and those of our licensors may not provide us with any competitive advantages. Competitors may be able to design around our patents or develop products which provide outcomes comparable or superior to ours. Our patents may be held invalid or unenforceable as a result of legal challenges by third parties, and others may challenge the inventorship or ownership of our patents and pending patent applications. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States. In the event a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be difficult and time consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time consuming and could divert our management's attention from our core business. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against a challenge. In addition, we may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially valuable. Litigation also puts our patents at risk of being invalidated or

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interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us.

We also license patent and other proprietary rights to aspects of our technology to third parties in fields where we currently do not operate as well as in fields where we currently do operate. Disputes with our licensees may arise regarding the scope and content of these licenses. Further, our ability to expand into additional fields with our technologies may be restricted by our existing licenses or licenses we may grant to third parties in the future.

The policies we have in place to protect our trade secrets may not be effective in preventing misappropriation of our trade secrets by others. In addition, confidentiality agreements executed by our employees, consultants and advisors may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure. Litigating a trade secret claim is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge methods and know-how. If we are unable to protect our intellectual property rights, we may be unable to prevent competitors from using our own inventions and intellectual property to compete against us, and our business may be harmed.

***We could become subject to product liability claims, product recalls, other field actions and warranty claims that could be expensive, divert management's attention and harm our business.***

Our business exposes us to potential liability risks that are inherent in the manufacturing, marketing and sale of medical device products. We may be held liable if a CyberKnife or TomoTherapy System causes injury or death or is found otherwise unsuitable during usage. Our products incorporate sophisticated components and computer software. Complex software can contain errors, particularly when first introduced. In addition, new products or enhancements may contain undetected errors or performance problems that, despite testing, are discovered only after installation. Because our products are designed to be used to perform complex surgical and therapeutic procedures involving delivery of radiation to the body, defects, even if small, could result in a number of complications, some of which could be serious and could harm or kill patients. Any weaknesses in training and services associated with our products may also result in product liability lawsuits. It is also possible that defects in the design, manufacture or labeling of our products might necessitate a product recall or other field corrective action, which may result in warranty claims beyond our expectations and may harm our reputation and create adverse publicity. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. We may also be subject to claims for property damage or economic loss related to, or resulting from, any errors or defects in our products, or the installation, servicing and support of our products, or any professional services rendered in conjunction with our products. The coverage limits of our insurance policies may not be adequate to cover future claims. If sales of our products increase or we suffer future product liability claims, we may be unable to maintain product liability insurance in the future at satisfactory rates or with adequate amounts of coverage. A product liability claim, any product recalls or other field actions or excessive warranty claims, whether arising from defects in design or manufacture or labeling, could negatively affect our sales or require a change in the design, manufacturing process or the indications for which the CyberKnife or TomoTherapy Systems may be used, any of which could harm our reputation and business and result in a decline in revenue.

In addition, if a product we designed or manufactured is defective, whether due to design or manufacturing, or labeling defects, improper use of the product or other reasons, we may be required to notify regulatory authorities and/or to recall the product, possibly at our expense. We have voluntarily conducted recalls and product corrections in the past, including four recalls for the CyberKnife System and two recalls for the TomoTherapy System during fiscal year 2012 and two recalls for the CyberKnife System in fiscal year 2013. Accuray initiated each of these recalls. No serious

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adverse health consequences have been reported in connection with these recalls, and the costs associated with each such recall were not material. A required notification of a correction or removal to a regulatory authority or recall could result in an investigation by regulatory authorities of our products, which could in turn result in required recalls, restrictions on the sale of the products or other civil or criminal penalties. The adverse publicity resulting from any of these actions could cause customers to review and potentially terminate their relationships with us. These investigations, corrections or recalls, especially if accompanied by unfavorable publicity, patient injury or termination of customer contracts, could result in our incurring substantial costs, losing revenues and damaging our reputation, each of which would harm our business.

***If we are not able to meet the requirements of our license agreement with the Wisconsin Alumni Research Foundation, or WARF we could lose access to the technologies licensed thereunder and be unable to manufacture, market or sell the TomoTherapy Systems.***

We license patents from WARF covering the multi-leaf collimator and other key technologies incorporated into the TomoTherapy Systems under a license agreement that requires us to pay royalties to WARF. In addition, the license agreement obligates us to pursue an agreed development plan and to submit periodic reports, and restricts our ability to take actions to defend the licensed patents. WARF has the right to unilaterally terminate the agreement if we do not meet certain minimum royalty obligations or satisfy other obligations related to our utilization of the technology. If WARF were to terminate the agreement or if we were to otherwise lose the ability to exploit the licensed patents, our competitive advantage would be reduced and we may not be able to find a source to replace the licensed technology. The license agreement reserves to WARF the initial right to defend or prosecute any claim arising with respect to the licensed technology. If WARF does not vigorously defend the patents, we may be required to engage in expensive patent litigation to enforce our rights, and any competitive advantage we have based on the licensed technology may be hampered. Any of these events could adversely affect our business, financial condition and results of operations.

***Our operations are vulnerable to interruption or loss due to natural disasters, epidemics, terrorist acts and other events beyond our control, which would adversely affect our business.***

We have facilities in countries around the world, including three manufacturing facilities, each of which is equipped to manufacture unique components of our products. The manufacturing facilities are located in Sunnyvale, California, Madison, Wisconsin and Chengdu, China. We do not maintain backup manufacturing facilities for all of our manufacturing facilities or for our IT facilities, so we depend on each of our current facilities for the continued operation of our business. In addition, we conduct a significant portion of other activities, including administration and data processing, at facilities located in the State of California which has experienced major earthquakes in the past, as well as other natural disasters. Chengdu, China, where one of our manufacturing facilities is located, has also experienced major earthquakes in the past. We do not carry earthquake insurance. Unexpected events at any of our facilities, including fires or explosions; natural disasters, such as hurricanes, floods, tornados and earthquakes; war or terrorist activities; unplanned outages; supply disruptions; and failures of equipment or systems, or the failure to take adequate steps to mitigate the likelihood or potential impact of such events, could significantly disrupt our operations, delay or prevent product manufacture and shipment for the time required to repair, rebuild or replace our manufacturing facilities, which could be lengthy, result in large expenses to repair or replace the facilities, and adversely affect our results of operation.

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***We may attempt to acquire new businesses, products or technologies, or enter into strategic collaborations or alliances, and if we are unable to successfully complete these acquisitions or to integrate acquired businesses, products, technologies or employees, we may fail to realize expected benefits or harm our existing business.***

Our success will depend, in part, on our ability to expand our product offerings and grow our business in response to changing technologies, customer demands and competitive pressures. In some circumstances, we may determine to do so through the acquisition of complementary businesses, products or technologies, or through collaborating with complementary businesses, rather than through internal development. The identification of suitable acquisition or alliance candidates can be difficult, time consuming and costly, and we may not be able to successfully complete identified acquisitions or alliances. Other companies may compete with us for these strategic opportunities. In addition, even if we successfully complete an acquisition or alliance, we may not be able to successfully integrate newly acquired organizations, products or technologies into our operations, and the process of integration could be expensive, time consuming and may strain our resources, and we may not realize the expected benefits of any acquisition, collaboration or strategic alliance. Furthermore, the products and technologies that we acquire or with respect to which we collaborate may not be successful, or may require significantly greater resources and investments than we originally anticipated. In addition, we may be unable to retain employees of acquired companies, or retain the acquired company's customers, suppliers, distributors or other partners who are our competitors or who have close relationships with our competitors. Consequently, we may not achieve anticipated benefits of the acquisitions or alliances which could harm our existing business. In addition, future acquisitions or alliances could result in potentially dilutive issuances of equity securities or the incurrence of debt, contingent liabilities or expenses, or other charges such as in-process research and development, any of which could harm our business and affect our financial results or cause a reduction in the price of our common stock.

***Because the majority of our product revenue is derived from sales of the CyberKnife and TomoTherapy Systems, and because we experience a long and variable sales and installation cycle, our quarterly results may be inconsistent from period to period. These fluctuations in revenue may make it difficult to predict our revenue.***

Our primary products are the CyberKnife and TomoTherapy Systems. We expect to generate substantially all of our revenue for the foreseeable future from sales of and service contracts for the CyberKnife and TomoTherapy Systems. The CyberKnife and TomoTherapy Systems have lengthy sales and purchase order cycles because they are major capital equipment items and require the approval of senior management at purchasing institutions. Selling our systems, from first contact with a potential customer to a complete order, generally spans six months to two years and involves personnel with multiple skills. The sales process in the United States typically begins with pre-selling activity followed by sales presentations and other sales related activities. After the customer has expressed an intention to purchase a CyberKnife or TomoTherapy System, we negotiate and enter into a definitive purchase contract with the customer. The negotiation of terms that are not standard for Accuray may require additional time and approvals. Typically, following the execution of the contract, the customer begins the building or renovation of a facility to house the CyberKnife or TomoTherapy System, which together with the subsequent installation of the CyberKnife or TomoTherapy System, can take up to 24 months to complete. During the period prior to installation, the customer must build a radiation-shielded facility to house its CyberKnife or TomoTherapy System. In order to construct this facility, the customer must typically obtain radiation device installation permits, which are granted by state and local government bodies, each of which may have different criteria for permit issuance. If a permit were denied for installation at a specific hospital or treatment center, our CyberKnife or TomoTherapy System could not be installed at that location. In addition, some of our customers are cancer centers or facilities that are new, and in these cases it may be necessary for the entire facility to be completed before the CyberKnife or TomoTherapy System can be installed, which can result in additional

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construction and installation delays. Our sales and installations of CyberKnife and TomoTherapy Systems tend to be heaviest during the third month of each fiscal quarter.

Under our revenue recognition policy, we generally do not recognize revenue attributable to a CyberKnife or TomoTherapy System purchase until after installation has occurred, if we are responsible for providing installation, or delivery. For international sales through distributors, we typically recognize revenue when the system is shipped and we have evidence of a purchase commitment from the end user. Under our current forms of purchase and service contracts, we record a majority of the purchase price as revenue for a CyberKnife or TomoTherapy System upon installation or delivery of the system. Events beyond our control may delay installation and the satisfaction of contingencies required to receive cash inflows and recognize revenue, such as:

Procurement delay;

Customer funding or financing delay;

Delay in or unforeseen difficulties related to customers organizing legal entities and obtaining financing for CyberKnife or TomoTherapy System acquisition;

Construction delay;

Delay pending customer receipt of regulatory approvals, including, for example, certificates of need;

Delay pending customer receipt of a building or radiation device installation permit; and

Delay caused by weather or natural disaster.

In the event that a customer, for any of the reasons above or other reasons, does not proceed with installation of a system after entering into a purchase contract, we would only recognize up to the deposit portion of the purchase price as revenue, unless the deposit was refunded to the customer. Therefore, the long sales cycle together with delays in the shipment and installation of CyberKnife and TomoTherapy Systems or customer cancellations would adversely affect our cash flows and revenue, which would harm our results of operations and may result in significant fluctuations in our reporting of quarterly revenues. Because of these fluctuations, it is likely that in some future quarters, our operating results will fall below the expectations of securities analysts or investors. If that happens, the market price of our stock would likely decrease. These fluctuations also mean that you will not be able to rely upon our operating results in any particular period as an indication of future performance.

***We depend on third-party distributors to market and distribute our products in international markets. If our distributors fail to successfully market and distribute our products, our business will be materially harmed.***

We depend on a number of distributors in our international markets. In some cases, we have maintained both the distributors we had prior to the acquisition of TomoTherapy as well as TomoTherapy's distributors, as product-specific distributors of our systems. We are in the process of consolidating distribution channels in the jurisdictions in which we have multiple distributors. We cannot control the efforts and resources our third-party distributors will devote to marketing the CyberKnife or TomoTherapy Systems. Our distributors may not be able to successfully market and sell the CyberKnife or TomoTherapy Systems, may not devote sufficient time and resources to support the marketing and selling efforts and may not market the CyberKnife or TomoTherapy Systems at prices that will permit the product to develop, achieve or sustain market acceptance. In some jurisdictions, we rely on our distributors to manage the regulatory process, and we are dependent on their ability to do so effectively. In addition, if a distributor is terminated by us or goes out of business, it may take us a period of time to locate an alternative distributor, to seek appropriate regulatory approvals and to train its personnel to market the CyberKnife or TomoTherapy Systems, and our ability to sell and service the CyberKnife or TomoTherapy Systems in the region formerly serviced by such terminated distributor

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could be materially adversely affected. Any of these factors could materially adversely affect our revenue from international markets, increase our costs in those markets or damage our reputation. If we are unable to attract additional international distributors, our international revenue may not grow. If our distributors experience difficulties, do not actively market the CyberKnife or TomoTherapy Systems or do not otherwise perform under our distribution agreements, our potential for revenue and gross margins from international markets may be dramatically reduced, and our business could be harmed. Finally, our efforts to consolidate distributors may not prove to be successful and may adversely affect our business, financial condition and results of operations.

***We face risks related to the current global economic environment, which could delay or prevent our customers from obtaining financing to purchase the CyberKnife and TomoTherapy Systems and implement the required facilities, which would adversely affect our business, financial condition and results of operations.***

The state of the global economy continues to be uncertain. The current global economic conditions and uncertain credit markets and concerns regarding the availability of credit pose a risk that could impact consumer and customer demand for our products, as well as our ability to manage normal commercial relationships with our customers, suppliers and creditors, including financial institutions. If the current situation continues to deteriorate or does not improve, our business could be negatively affected, including such areas as reduced demand for our products resulting from a slow-down in the general economy, supplier or customer disruptions and/or temporary interruptions in our ability to conduct day-to-day transactions through our financial intermediaries involving the payment to or collection of funds from our customers, vendors and suppliers.

For example, in the United States, some of our customers have been delayed in obtaining, or have not been able to obtain, necessary financing for their purchases of the CyberKnife or TomoTherapy Systems. In addition, some of our customers have been delayed in obtaining, or have not been able to obtain, necessary financing for the construction or renovation of facilities to house CyberKnife or TomoTherapy Systems, the cost of which typically range from approximately \$0.3 million for a TomoTherapy System and \$0.5 million for a CyberKnife System, for customers who make only minor renovations to existing facilities, to up to \$2.0 million for a TomoTherapy System and \$2.5 million for a CyberKnife System, for customers who build entirely new facilities that include additional features not necessarily required for the operation of a TomoTherapy or CyberKnife System (e.g., audio visual equipment). This range is based solely on information provided to us by customers and will vary by geography and the needs of a particular customer. To date, these delays have primarily affected customers that were planning to operate freestanding CyberKnife or TomoTherapy Systems centers, rather than hospital-based customers. These delays have in some instances led to our customers postponing the shipment and installation of previously ordered systems or cancelling their system orders, and may cause other customers to postpone their system installation or to cancel their agreements with us. An increase in delays and order cancellations of this nature would adversely affect our product sales, backlog and revenues, and therefore harm our business and results of operations.

***The high unit price of the CyberKnife and TomoTherapy Systems, as well as other factors, may contribute to substantial fluctuations in our operating results, which could adversely affect our stock price.***

Because of the high unit price of the CyberKnife and TomoTherapy Systems and the relatively small number of units installed each quarter, each installation of a CyberKnife or TomoTherapy System can represent a significant percentage of our revenue for a particular quarter. Therefore, if we do not install a CyberKnife or TomoTherapy System when anticipated, our operating results will vary significantly from our expectations. This is of particular concern in the current volatile economic environment, where we have had experiences with customers cancelling or postponing orders for our CyberKnife and TomoTherapy Systems and delaying any required build-outs. These fluctuations and other potential fluctuations mean that you should not rely upon our operating results in any particular



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period as an indication of future performance. In particular, in addition to the other risk factors described above and below, factors which may contribute to these fluctuations include:

Timing of when we are able to recognize revenue associated with sales of the CyberKnife and TomoTherapy Systems, which varies depending upon the terms of the applicable sales and service contracts;

The proportion of revenue attributable to purchases of the CyberKnife and TomoTherapy Systems which are associated with our shared ownership program and our legacy service plans;

Timing and level of expenditures associated with new product development activities;

Regulatory requirements in some states for a certificate of need prior to the installation of a radiation device;

Delays in shipment due, for example, to unanticipated construction delays at customer locations where our products are to be installed, cancellations by customers, natural disasters or labor disturbances;

Delays in our manufacturing processes or unexpected manufacturing difficulties;

Timing of the announcement, introduction and delivery of new products or product upgrades by us and by our competitors;

Timing and level of expenditures associated with expansion of sales and marketing activities such as trade shows and our overall operations;

Fluctuations in our gross margins and the factors that contribute to such fluctuations, as described in the Management's Discussion and Analysis of Financial Condition and Results of Operations;

How well we execute on our strategic and operating plans;

The extent to which our products gain market acceptance;

Actions relating to regulatory matters;

Demand for our products;

Our ability to develop, introduce and market new or enhanced versions of our products on a timely basis;

Our ability to protect our proprietary rights and defend against third party challenges;

Disruptions in the supply or changes in the costs of raw materials, labor, product components or transportation services; and

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Changes in third party coverage and reimbursement, changes in government regulation, or a change in a customer's financial condition or ability to obtain financing.

These factors are difficult to forecast and may contribute to substantial fluctuations in our quarterly revenues and substantial variation from our projections, particularly during the periods in which our sales volume is low. These fluctuations may cause volatility in our stock price.

***If we are unable to maintain existing research collaboration relationships, enter into new collaboration arrangements in the future or enter into license agreements with our collaborators and others, our ability to enhance our products may be adversely affected.***

We have entered into a number of research collaboration arrangements with a range of hospitals, cancer treatment centers and academic institutions. These collaborations support our internal research

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and development capabilities and represent a key element of our ongoing research and development program. Our research collaboration partners may not fulfill all of their obligations under our arrangements with them. If our current research collaborations do not meet our research and development expectations, or if we are unable to enter into additional research collaborations in the future to replace unproductive collaborations or add new collaborations, our ability to enhance our products may be adversely affected. Our inability to successfully collaborate with third parties could increase our development costs, delay new or pending developments and limit the likelihood of successful enhancements to the CyberKnife or TomoTherapy Systems.

Our collaboration agreements generally provide that we either own, in the case of our own developments, have the right to use, in the case of joint developments, or have the right to license, in the case of developments by our collaborator, technology developed pursuant to a collaboration. We cannot provide any assurance that we will successfully enter into license agreements with any of our collaborators concerning technology that is jointly developed or developed by the collaborator, which may prevent us from using that technology. If we are unable to enter into exclusive license agreements with a collaborator over technology that is jointly developed with, or solely developed by, the collaborator, the collaborator may be able to use or license the technology to third parties. Furthermore, if we are unable to enter into license agreements with a collaborator for technology that is jointly developed with, or solely developed by, the collaborator, we may be unable to use that technology. In addition, if we are unable to agree with our collaborators concerning ownership or proper inventorship of technology developed under the collaboration agreement, we may be forced to engage in arbitration or litigation to determine the proper ownership or inventorship. Any of these events could adversely affect our business, financial condition and results of operations.

***International sales of our products account for a significant portion of our revenue, which exposes us to risks inherent in international operations.***

Our international sales, as a percentage of total revenue, have increased over the last four fiscal years. The percentage of our revenue derived from sales outside of the United States was 55% in 2013, 54% in 2012 and 45% in 2011. To accommodate our international sales, we have invested significant financial and management resources to develop an international infrastructure that will meet the needs of our customers. We anticipate that a significant portion of our revenue will continue to be derived from sales of our products in foreign markets and that the percentage of our overall revenue that is derived from these markets may continue to increase. This revenue and related operations will therefore continue to be subject to the risks associated with international operations, including:

Economic or political instability;

Shipping delays;

Changes in foreign regulatory laws governing, among other matters, the clearance, approval and sales of medical devices;

The potential failure to comply with foreign regulatory requirements to market our products on a timely basis or at all;

Difficulties in enforcing agreements with and collecting receivables from customers outside the United States;

Longer payment cycles associated with many customers outside the United States;

Adequate coverage and reimbursement for the CyberKnife and TomoTherapy treatment procedures outside the United States;

Failure of local laws to provide the same degree of protection against infringement of our intellectual property;

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Protectionist laws and business practices that favor local competitors;

The possibility that foreign countries may impose additional taxes, tariffs or other restrictions on foreign trade;

Failure of Accuray employees or distributors to comply with export laws and requirements which may result in civil or criminal penalties and restrictions on our ability to export our products;

The expense and difficulty of establishing and managing facilities and operations in foreign markets;

Building an organization capable of supporting geographically dispersed operations;

Risks relating to foreign currency, including fluctuations in foreign currency exchange rates; and

Contractual provisions governed by foreign laws and various trade restrictions, including U.S. prohibitions and restrictions on exports of certain products and technologies to certain nations.

Our inability to overcome these obstacles could harm our business, financial condition and operating results. Even if we are successful in managing these obstacles, our partners internationally are subject to these same risks and may not be able to manage these obstacles effectively.

Our international operations are also subject to laws regarding the conduct of business overseas, such as the U.S. Foreign Corrupt Practices Act, or FCPA, and the U.K. Bribery Act of 2010. The FCPA prohibits the provision of illegal or improper inducements to foreign government officials in connection with the obtaining of business overseas. Becoming familiar with and implementing the infrastructure necessary to ensure that we and our distributors comply with laws, rules and regulations applicable to new business activities and mitigate and protect against corruption risks could be quite costly, and there can be no assurance that any policies and procedures we do implement will protect us against liability under the FCPA or related laws for actions taken by our agents, employees and intermediaries with respect to our business. Violations of the FCPA or other similar laws by us or any of our employees, executive officers, distributors or other agents could subject us or the individuals involved to criminal or civil liability, cause a loss of reputation in the market, and materially harm our business.

In addition, future imposition of, or significant increases in, the level of customs duties, export quotas, regulatory restrictions or trade restrictions could materially harm our business.

***Multiple factors may adversely affect our ability to fully utilize certain tax loss carryforwards.***

As of June 30, 2013, we had approximately \$288.1 million and \$114.5 million in federal and state net operating loss carry forwards, respectively, which expire in varying amounts beginning in 2019 for federal and 2015 for state purposes. In addition, as of June 30, 2013, we had federal and state research and development tax credit carryforwards of approximately \$9.8 million and \$6.8 million, respectively. The federal research credits will begin to expire in 2019, the California research credits have no expiration date, and the other state research credits will begin to expire in 2014. Utilization of our net operating loss and credit carry forwards is subject to annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code and similar state provisions. However, none of the federal and state net operating loss carryforwards are expected to expire as a result of the ownership change limitation.

***Our results may be impacted by changes in foreign currency exchange rates.***

Currently, the majority of our international sales are denominated in U.S. dollars. As a result, an increase in the value of the U.S. dollar relative to foreign currencies could require us to reduce our sales price or make our products less competitive in international markets. Also, if our international sales increase, we may enter into a greater number of transactions denominated in non-U.S. dollars,

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which would expose us to foreign currency risks, including changes in currency exchange rates. If we are unable to address these risks and challenges effectively, our international operations may not be successful and our business would be materially harmed.

***Changes in interpretation or application of generally accepted accounting principles may adversely affect our operating results.***

We prepare our financial statements to conform with United States Generally Accepted Accounting Principles. These principles are subject to interpretation by the Financial Accounting Standards Board, American Institute of Certified Public Accountants, the Public Company Accounting Oversight Board, the Securities and Exchange Commission and various other regulatory or accounting bodies. A change in interpretations of, or our application of, these principles can have a significant effect on our reported results and may even affect our reporting of transactions completed before a change is announced. Additionally, as we are required to adopt new accounting standards, our methods of accounting for certain items may change, which could cause our results of operations to fluctuate from period to period. For example, due to the significance of the software component in certain of our products, we are currently bound by the software revenue recognition rules for a portion of our business

***Our liquidity could be adversely impacted by adverse conditions in the financial markets.***

At June 30, 2013, we had \$73.3 million in cash and cash equivalents and \$101.1 million in investments. The available cash and cash equivalents are held in accounts managed by third party financial institutions and consist of cash in our operating accounts and cash invested in money market funds and certificates of deposit. The investments are managed by third party financial institutions and consist of U.S. corporate debt securities and commercial paper. To date, we have experienced no realized losses on or lack of access to our invested cash, cash equivalents or investments; however, we can provide no assurances that access to our invested cash and cash equivalents will not be impacted by adverse conditions in the financial markets.

At any point in time, we also have funds in our operating accounts that are with third party financial institutions that exceed the Federal Deposit Insurance Corporation, or FDIC, insurance limits. While we monitor daily the cash balances in our operating accounts and adjust the cash balances as appropriate, these cash balances could be impacted if the underlying financial institutions fail or become subject to other adverse conditions in the financial markets. To date, we have experienced no loss or lack of access to cash in our operating accounts.

***Our ability to raise capital in the future may be limited, and our failure to raise capital when needed could prevent us from executing our growth strategy.***

While we believe that our existing cash, cash equivalents and investments will be sufficient to meet our anticipated cash needs for at least the next twelve months, the timing and amount of our working capital and capital expenditure requirements may vary significantly depending on numerous factors, including the other risk factors described above and below, as well as:

Market acceptance of our products;

The need to adapt to changing technologies and technical requirements;

Our ability to continue to increase orders growth and revenue, manage expenses and integrate the TomoTherapy business;

Our ability to improve service margins;

The existence of opportunities for expansion; and

Access to and availability of sufficient management, technical, marketing and financial personnel.

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If our capital resources are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity securities or debt securities or obtain other debt financing, which could be difficult or impossible in the current economic and capital markets environments. Our debt levels may impair our ability to obtain additional financing in the future. The sale of additional equity securities or convertible debt securities would result in additional dilution to our stockholders. We cannot assure that additional financing, if required, will be available in amounts or on terms acceptable to us, if at all.

**Risks Related to the Regulation of our Products and Business**

***Modifications, upgrades and future products related to the CyberKnife or TomoTherapy Systems or new indications may require new FDA 510(k) clearances or premarket approvals, and such modifications, or any defects in design, manufacture or labeling may require us to recall or cease marketing the CyberKnife or TomoTherapy Systems until approvals or clearances are obtained.***

The CyberKnife and TomoTherapy Systems are medical devices that are subject to extensive regulation in the United States by local, state and the federal government, including by the FDA. The FDA regulates virtually all aspects of a medical device's design, development, testing manufacturing, labeling, storage, record keeping, adverse event reporting, sale, promotion, distribution and shipping. Before a new medical device, or a new intended use or indication of or claim for an existing product, can be marketed in the United States, it must first receive either premarket approval or 510(k) clearance from the FDA, unless an exemption exists. Either process can be expensive, lengthy and unpredictable. The FDA's 510(k) clearance process generally takes from three to twelve months, but it can last longer. The process of obtaining premarket approval is much more costly and uncertain than the 510(k) clearance process and it generally takes from one to three years, or even longer, from the time the application is filed with the FDA. Despite the time, effort and cost, there can be no assurance that a particular device or a modification of a device will be approved or cleared by the FDA in a timely fashion, if at all. 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 those products, and how those products can be promoted.

Medical devices may be marketed only for the indications for which they are approved or cleared. The FDA also may change its policies, adopt additional regulations, or revise existing regulations, each of which could prevent or delay premarket approval or 510(k) clearance of our device, or could impact our ability to market our currently cleared device. We are also subject to medical device reporting regulations which require us to report to the FDA if our products cause or contribute to a death or a serious injury, or malfunction in a way that would likely cause or contribute to a death or a serious injury. We also are subject to Quality System regulations. Our products are also subject to state regulations and various worldwide laws and regulations.

A component of our strategy is to continue to upgrade the CyberKnife and TomoTherapy Systems. Upgrades previously released by us required 510(k) clearance before we were able to offer them for sale. We expect our future upgrades will similarly require 510(k) clearance; however, future upgrades may be subject to the substantially more time consuming data generation requirements and uncertain premarket approval or clearance process. If we were required to use the premarket approval process 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 requires device manufacturers to make their own determination of whether or not a modification requires an approval or clearance; however, the FDA can review a manufacturer's decision not to submit for additional approvals or clearances. Any modification to an FDA approved or cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new premarket approval or 510(k) clearance. The FDA has recently issued a draft guidance that, if finalized, will result in manufacturers needing to seek a significant

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number of new or additional clearances for changes made to legally marketed devices. We cannot assure you that the FDA will agree with our decisions not to seek approvals or clearances for particular device modifications or that we will be successful in obtaining premarket approvals or 510(k) clearances for modifications in a timely fashion, if at all.

We have obtained 510(k) clearance for the CyberKnife Systems for the treatment of tumors anywhere in the body where radiation is indicated, and we have obtained 510(k) clearance for the TomoTherapy Systems to be used as integrated systems for the planning and delivery of IMRT for the treatment of cancer. The TomoTherapy Systems provide precise delivery of radiation to tumors while minimizing the delivery of radiation to vital healthy tissue. The TomoTherapy Systems deliver the radiation therapy, or stereotactic radiotherapy or radiosurgery, treatment in accordance with the physician approved plan using IMRT techniques delivered in a helical tomographic pattern. We have made modifications to the CyberKnife and TomoTherapy Systems in the past and may make additional modifications in the future that we believe do not or will not require additional approvals or clearances. If the FDA disagrees, based on new finalized guidance and requires us to obtain additional premarket approvals or 510(k) clearances for any modifications to the CyberKnife or TomoTherapy Systems and we fail to obtain such approvals or clearances or fail to secure approvals or clearances in a timely manner, we may be required to cease manufacturing and marketing the modified device or to recall such modified device until we obtain FDA approval or clearance and we may be subject to significant regulatory fines or penalties.

The FDA and similar governmental authorities in other countries in which we market and sell our products have the authority to require the recall of our products in the event of material deficiencies or defects in design, manufacture or labeling. A government mandated recall, or a voluntary recall by us, could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling and user manuals. We have voluntarily conducted recalls and product corrections in the past, including four such recalls for the CyberKnife System and two such recalls for the TomoTherapy System during fiscal 2012 and two recalls for the CyberKnife System in fiscal 2013. Accuray voluntarily initiated each of these recalls. To date, no serious health consequences have been reported in connection with these recalls, and the costs associated with each such recall were not material. We cannot ensure that the FDA will not require that we take additional actions to address problems that resulted in previous recalls. Any recall could divert management's attention, cause us to incur significant expenses, generate negative publicity, harm our reputation with customers, negatively affect our future sales and business, require redesign of the CyberKnife or TomoTherapy Systems, and harm our operating results. In these circumstances, we may also be subject to significant enforcement action. If any of these events were to occur, our ability to introduce new or enhanced products in a timely manner would be adversely affected, which in turn would harm our future growth.

***If we are found to have violated laws protecting the confidentiality of patient health information that we possess, we could be subject to contractual liability and civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.***

There are a number of federal and state laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services, or HHS, has promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. These privacy rules protect medical records and other personal health information of patients by limiting their use and disclosure, giving patients the right to access, amend and seek accounting of their own health information and limiting most uses and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. The HIPAA privacy standard was amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, enacted as part of the American Recovery and Reinvestment Act of

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2009. Although we are not a "covered entity" under HIPAA, we are considered a "business associate" of certain covered entities and we have access to patient data, we are directly subject to HIPAA, including its enforcement scheme and inspection requirements, and are required to implement policies, procedures and reasonable and appropriate physical, technical and administrative security measures to protect individually identifiable health information we receive from covered entities.

Our failure to protect health information received from customers in compliance with HIPAA or other laws could subject us to civil and criminal liability to the government and civil liability to the covered entity, could result in adverse publicity, and could harm our business and impair our ability to attract new customers.

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 products 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.

Certain governmental agencies, such as HHS and the Federal Trade Commission, have the authority to protect against the misuse of consumer information by targeting companies that collect, disseminate or maintain personal information in an unfair or deceptive manner. We are also subject to the laws of those foreign jurisdictions in which we sell the CyberKnife and TomoTherapy Systems, some of which currently have more protective privacy laws. If we fail to comply with applicable regulations in this area, our business and prospects could be harmed.

***We are required to comply with federal and state "fraud and abuse" laws, and if we are unable to comply with such laws, we could face substantial penalties and we could be excluded from government healthcare programs, which would adversely affect our business, financial condition and results of operations.***

We are directly or indirectly through our customers, subject to various federal, state and foreign laws pertaining to healthcare fraud and abuse. These laws, which directly or indirectly affect our ability to operate our business primarily include, but are not limited to, the following:

The federal Anti-Kickback Statute, which prohibits persons from soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

State law equivalents to the Anti-Kickback Statute, which may not be limited to government reimbursed items;

The Ethics in Patient Referral Act of 1989, also known as the Stark Law, which prohibits, subject to certain exceptions, physician referrals of Medicare and Medicaid patients to an entity providing certain "designated health services" if the physician or an immediate family member has any financial relationship with the entity. The Stark Law also prohibits the entity receiving the referral from billing for any good or service furnished pursuant to an unlawful referral;

State law equivalents to the Stark Law, which may provide even broader restrictions and require greater disclosures than the federal law;



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The federal False Claims Act, which prohibits the knowing filing or causing the filing of a false claim or the knowing use of false statements to obtain payment from the federal government; and

Similar laws in foreign countries where we conduct business.

The Physician Payment Sunshine Act or the Sunshine Act, which was enacted by Congress as part of the Patient Protection and Affordable Care Act on December 14, 2011, requires medical device companies such as Accuray to track payments and all transfers of value greater than \$10 to licensed physicians and teaching hospitals in the U.S. Final regulations for the tracking and reporting of payments and transfers of value to licensed physicians have been finalized and we must begin tracking such payments beginning August 1, 2013 and must begin reporting payments to the government by March 31, 2014, and annually thereafter. After receiving reports of payments and transfers of value, the government plans to post that data on a public searchable government-maintained website. Failure to comply with the data collection and reporting obligations imposed by the Sunshine Act can result in civil monetary penalties ranging from \$1,000 to \$10,000 for each payment or other transfer of value that is not reported (up to a maximum of \$150,000) and from \$10,000 to \$100,000 for each knowing failure to report (up to a maximum of \$1 million).

The following arrangements with purchasers and their agents have been identified by the Office of the Inspector General of the Department of Health and Human Services as ones raising potential risk of violation of the federal Anti-Kickback Statute:

Discount and free good arrangements that are not properly disclosed or accurately reported to federal healthcare programs;

Product support services, including billing assistance, reimbursement consultation, marketing and other services specifically tied to support of the purchased product, offered in tandem with another service or program (such as reimbursement guarantee) that confers a benefit to the purchaser;

Educational grants conditioned in whole or in part on the purchase of equipment, or otherwise inappropriately influenced by sales and marketing considerations;

Research funding arrangements, particularly post-market research activities, that are linked directly or indirectly to the purchase of products or services, or otherwise inappropriately influenced by sales and marketing considerations; and

Other offers of remuneration to purchasers that are expressly or impliedly related to a sale or sales volume, such as "prebates" and "upfront payment," other free or reduced-price goods or services, and payments to cover costs of "converting" from a competitor's products, particularly where the selection criteria for such offers vary with the volume or value of business generated.

We have various arrangements with physicians, hospitals and other entities which implicate these laws. For example, certain physicians who own our stock also provide medical advisory and other consulting and personal services. Similarly, we have a variety of different types of arrangements with our customers. For example, our shared ownership program entails the provision of our products to our customers under a deferred payment program, where we generally receive the greater of a fixed minimum payment or a portion of the revenues of services. Included in the fee we charge for the placement and shared ownership program are a variety of services, including physician training, educational and marketing support, general reimbursement guidance and technical support. In the past, we have also provided loans to our customers. We also provide research grants to customers to support customer studies related to, among other things, our CyberKnife and TomoTherapy Systems. Certain of these arrangements do not meet Anti-Kickback Statute safe harbor protections, which may result in increased scrutiny by government authorities having responsibility for enforcing these laws.

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If our past or present operations are found to be in violation of any of the laws described above or other similar governmental regulations to which we or our customers are subject, we may be subject to the applicable penalty associated with the violation, including significant civil and criminal penalties, damages, fines, imprisonment and exclusion from the Medicare and Medicaid programs. The impact of any such violations may lead to curtailment or restructuring of our operations, which could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of these laws are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation. If enforcement action were to occur, our reputation and our business and financial condition may be harmed, even if we were to prevail or settle the action. Similarly, if the physicians or other providers or entities with which we do business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

***If we or our distributors do not obtain and maintain the necessary regulatory approvals in a specific country, we will not be able to market and sell our products in that country.***

To be able to market and sell our products in a specific country, we or our distributors must comply with applicable laws and regulations of that country. In jurisdictions where we rely on our distributors to manage the regulatory process, we are dependent on their ability to do so effectively. While the laws and regulations of some countries do not impose barriers to marketing and selling our products or only require notification, others require that we or our distributors obtain the approval of a specified regulatory body. These laws and regulations, including the requirements for approvals, and the time required for regulatory review vary from country to country. The governmental agencies regulating medical devices in some countries, for example, require that the user interface on medical device software be in the local language. We currently provide user guides and manuals, both paper copies and electronically, in the local language but only provide an English language version of the user interface. Obtaining regulatory approvals is expensive and time-consuming, and we cannot be certain that we or our distributors will receive regulatory approvals in each country in which we market or plan to market our products. If we modify our products, we or our distributors may need to apply for additional regulatory approvals before we are permitted to sell them. We may not continue to meet the quality and safety standards required to maintain the authorizations that we or our distributors have received. It can also be costly for us and our distributors to keep up with regulatory changes issued or mandated from time to time. If we change distributors, it may be time-consuming and disruptive to our business to transfer the required regulatory approvals, particularly if such approvals are maintained by our third-party distributors on our behalf. If we or our distributors are unable to maintain our authorizations, or fail to obtain appropriate authorizations in a particular country, we will no longer be able to sell our products in that country, and our ability to generate revenue will be materially adversely affected.

Within the European Union, we are required under the Medical Device Directive to affix the Conformité Européenne, or CE, mark on our products in order to sell the products in member countries of the EU. This conformity to the applicable directives is done through self declaration and is verified by an independent certification body, called a Notified Body, before the CE mark can be placed on the device. Once 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 or directives. CE marking demonstrates that our products comply with the laws and regulations required by the European Union countries to allow free movement of trade within those countries. If we cannot support our performance claims and/or demonstrate or maintain compliance with the applicable European laws and directives, we lose our CE mark, which would prevent us from selling our products within the European Union.

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Under the Pharmaceutical Affairs Law in Japan, a pre-market approval necessary to sell, market and import a product, or shonin, must be obtained from the Ministry of Health, Labor and Welfare, or MHLW, for our products. Before issuing approvals, MHLW examines the application in detail with regard to the quality, efficacy, and safety of the proposed medical device. The shonin is granted once MHLW is content with the safety and effectiveness of the medical device. The time required for approval varies. A delay in approval could prevent us from selling our products in Japan, which could impact our ability to generate revenue and harm our business.

In addition to laws and regulations regarding medical devices, we are subject to a variety of environmental laws and regulations regulating our operations, including those relating to the use, generation, handling, storage, transportation, treatment and disposal of hazardous materials, which laws impose compliance costs on our business and can also result in liability to us. For example, we are in the process of updating the way our products are built such that they will be compliant with the recast Directive on Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment, or the RoHS Directive, which applies to medical devices beginning in July 2014. The recast RoHS Directive bans the placing on the EU market of new electrical and electronic equipment containing more than certain levels of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyl or PBB and polybrominated diphenyl ether, or PBDE. We believe that the RoHS Directive does not impose any restrictions on our products because our products are exempt as large scale fixed installations. The Notified Body which audits our compliance efforts has indicated that they share our view in this respect and that we are and will remain in compliance with the RoHS Directive because the RoHS Directive's restrictions do not apply to our products. Nevertheless, we are considering implementing the restrictions contemplated by RoHS whether or not they apply, albeit possibly not by July 2014.

***Healthcare reform legislation could adversely affect demand for our products, our revenue and our financial condition.***

Healthcare costs have risen significantly over the past decade. There have been and continue to be proposals by legislators, regulators, and third-party payors to keep these costs down. For example, under the sequestration required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, Medicare payments for all items and services under Parts A and B incurred on or after April 1, 2013 have been reduced by up to 2%. In addition, certain proposals, if passed, may impose limitations on the coverage or amounts of reimbursement available for our products from governmental agencies or third-party payors. These limitations could have a negative impact on the demand for our products and services, and therefore on our financial position and results of operations.

In March 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 were signed into law. Together, the two measures made the most sweeping and fundamental changes to the U.S. health care system since the creation of Medicare and Medicaid. The Health Care Reform laws include a large number of health related provisions, some of which have already taken effect and others of which will take effect by 2014, including expanding Medicaid eligibility, requiring most individuals to have health insurance, establishing new regulations on health plans, establishing health insurance exchanges, requiring manufacturers to report payments or other transfers of value made to physicians and teaching hospitals, modifying certain payment systems to encourage more cost-effective care and a reduction of inefficiencies and waste and including new tools to address fraud and abuse. The laws include a decrease in the annual rate of inflation for Medicare payments to hospitals and the establishment of an independent payment advisory board to suggest methods of reducing the rate of growth in Medicare spending. There continue to be many programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impact of the legislation will be. Effective in 2013,

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there is a 2.3% excise tax on U.S. sales of medical devices, including our products. U.S. net sales represented 45% of our worldwide consolidated net sales in fiscal 2013, and therefore, this tax burden may have a material, negative impact on our business, results of operations and cash flow.

In addition, various healthcare reform proposals have also emerged at the state level. We cannot predict the exact effect recently enacted laws or any future legislation or regulation will have on us. However, the implementation of new legislation and regulation may materially lower reimbursements for our products, materially reduce medical procedure volumes and significantly and adversely affect our business.

***Future legislative or regulatory changes to the healthcare system may affect our business.***

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposals to change the healthcare system, and some could involve changes that significantly affect our business.

In April 2008, at the time CMS published final 2009 Medicare inpatient reimbursement rates, CMS issued final rules implementing significant amendments to the regulations under the federal Ethics in Patient Referrals Act, which is more commonly known as the Stark Law, with an effective date of October 1, 2009. These regulations, among other things, impose additional limitations on the ability of physicians to refer patients to medical facilities in which the physician has an ownership interest for treatment. Among other things, the regulations provide that leases of equipment between physician owners that may refer patients and hospitals must be on a fixed rate, rather than on a per use basis. Physician owned entities have increasingly become involved in the acquisition of medical technologies, including the CyberKnife and TomoTherapy Systems. In many cases, these entities enter into arrangements with hospitals that bill Medicare for the furnishing of medical services, and the physician owners are among the physicians who refer patients to the entity for services. The regulations limit these arrangements and could require the restructuring of existing arrangements between physicians owned entities and hospitals and may also discourage physicians from participating in the acquisition and ownership of medical technologies. As a result of the finalization of these regulations, some existing CyberKnife and TomoTherapy System operators may have to modify or restructure their corporate or organizational structures. In addition, certain existing customers that planned to open CyberKnife or TomoTherapy centers in the United States involving physician ownership could also have to restructure. Accordingly, these regulations could reduce the attractiveness of medical technology acquisitions, including CyberKnife and TomoTherapy System purchases, by physician-owned joint ventures or similar entities. As a result, these regulations could have an adverse impact on our product sales and therefore on our business and results of operations.

On June 9 and 10, 2010, the FDA held a public meeting entitled "Device Improvements to Reduce the Number of Under-doses, Over-doses, and Misaligned Exposures from Therapeutic Radiation." The expressed purpose of the meeting was to discuss steps that could be taken by manufacturers of radiation therapy devices to help reduce misadministration and misaligned exposures that have been reported in the press. In advance of and at the meeting, the FDA requested comments in the following areas: features that should be incorporated into radiation therapy devices and their related software, user training, and quality assurance measures. It is likely that the FDA will use the information gleaned at this meeting to significantly revise the standards and requirements for designing, manufacturing and marketing devices such as ours, creating uncertainty in the current regulatory environment around our current products and development of future products. Future legislative or policy initiatives directed at reducing costs could be introduced at either the federal or state level. We cannot predict what healthcare reform legislation or regulations, if any, will be enacted in the United States or elsewhere, what impact any legislation or regulations related to the healthcare system that may be enacted or adopted in the future might have on our business, or the effect of ongoing uncertainty or public perception about these matters will have on the purchasing decisions of our customers.

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**Risks Related to Our Common Stock**

***Our major stockholders own approximately 55% and directors and executive officers own approximately 0.8% of our outstanding common stock as of June 30, 2013, which could limit other stockholders' ability to influence the outcome of key transactions, including changes of control.***

As of June 30, 2013, our current holders of 5% or more of our outstanding common stock held in the aggregate approximately 55% of our outstanding common stock, while our directors and executive officers held in the aggregate approximately 0.8% of our outstanding common stock. This concentration of ownership may delay, deter or prevent a change of control of our company and will make some transactions more difficult or impossible without the support of these stockholders.

***The price of our common stock is volatile and may continue to fluctuate significantly, which could lead to losses for stockholders.***

The trading prices of the stock of high-technology companies of our size can experience extreme price and volume fluctuations. These fluctuations often have been unrelated or out of proportion to the operating performance of these companies. Our stock price has experienced periods of volatility. Broad market fluctuations may also harm our stock price. Any negative change in the public's perception of the prospects of companies that employ similar technology or sell into similar markets could also depress our stock price, regardless of our actual results.

In addition to the other risk factors described above and below, factors affecting the trading price of our common stock include:

Regulatory developments related to manufacturing, marketing or sale of the CyberKnife or TomoTherapy Systems;

Our ability to successfully integrate the TomoTherapy acquisition;

Economic changes and overall market volatility;

Political or social uncertainties;

Changes in product pricing policies;

Variations in our operating results, as well as costs and expenditures;

Changes in our operating results as a result of problems with our internal controls;

Announcements of technological innovations, new services or service enhancements, strategic alliances or significant agreements by us or by our competitors;

Recruitment or departure of key personnel;

Changes in the estimates of our operating results or changes in recommendations by any securities analyst that elects to follow our common stock;

Market conditions in our industry, the industries of our customers and the economy as a whole;

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Sales of large blocks of our common stock; and

Changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results.

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***Future issuances of shares of our common stock or substantial sales of our common stock by our stockholders, including sales pursuant to 10b5-1 plans, could depress our stock price regardless of our operating results.***

Any issuance of equity securities could dilute the interests of our stockholders and could substantially decrease the trading price of our common stock. We may issue equity securities in the future for a number of reasons, including to finance our operations and business strategy (including in connection with acquisitions, strategic collaborations or other transactions), to adjust our ratio of debt to equity, to satisfy our obligations upon the exercise of outstanding warrants or options or for other reasons.

On August 1, 2011, we issued \$100 million aggregate principal amount of our 3.75% Convertible Senior Notes due 2016, which we refer to as the 3.75% Convertible Notes, and in February 2013, we issued \$115 million aggregate principal amount of our 3.50% Convertible Senior Notes due 2018, which we refer to as the 3.50% Convertible Notes, and together with the 3.75% Notes, we refer to them as the Convertible Notes. The price of our common stock could also be affected by possible sales of our common stock by investors who view the Convertible Notes as a more attractive means of equity participation in our company or by any hedging or arbitrage trading activity that involves our common stock. To the extent we issue common stock upon conversion of the Convertible Notes, that conversion would dilute the ownership interests of our stockholders.

Moreover, if our existing stockholders sell a large number of shares of our common stock or the public market perceives that existing stockholders might sell shares of common stock, including sales pursuant to 10b5-1 plans, the market price of our common stock could decline significantly. These sales might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate.

***Increased leverage as a result of the Convertible Notes offering may harm our financial condition and operating results.***

As of June 30, 2013, we had total consolidated long-term liabilities of approximately \$213.2 million, including the liability component of the 3.75% Convertible Notes in the amount of \$83.8 million and the 3.50% Convertible Notes in the amount of \$115.0 million.

Our level of indebtedness could have important consequences to stockholders and note holders, because:

It could affect our ability to satisfy our obligations under the Convertible Notes;

A substantial portion of our cash flows from operations will have to be dedicated to interest and principal payments and may not be available for operations, working capital, capital expenditures, expansion, acquisitions or general corporate or other purposes;

It may impair our ability to obtain additional financing in the future;

It may limit our flexibility in planning for, or reacting to, changes in our business and industry; and

It may make us more vulnerable to downturns in our business, our industry or the economy in general.

***The conditional conversion features of the 3.75% Convertible Notes, if triggered, may adversely affect our financial condition and operating results.***

In the event the conditional conversion features of the 3.75% Convertible Notes are triggered, holders of the 3.75% Convertible Notes will be entitled to convert such notes at any time during

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specified periods at their option. If one or more holders elect to convert their 3.75% Convertible Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying solely cash in lieu of any fractional share), including if we have irrevocably elected full physical settlement upon conversion, we would be required to make cash payments to satisfy all or a portion of our conversion obligation based on the applicable conversion rate, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their 3.75% Convertible Notes, if we have irrevocably elected net share settlement upon conversion we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 3.75% Convertible Notes as a current rather than long-term liability, which could result in a material reduction of our net working capital.

The 3.50% Convertible Notes do not provide for such a conditional conversion feature.

***Provisions in the indenture for the Convertible Notes, our certificate of incorporation and our bylaws could discourage or prevent a takeover, even if an acquisition would be beneficial in the opinion of our stockholders.***

Provisions of our certificate of incorporation and bylaws could make it more difficult for a third party to acquire us, even if doing so would be beneficial in the opinion of our stockholders. These provisions include:

Authorizing the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt;

Establishing a classified board of directors, which could discourage a takeover attempt;

Prohibiting cumulative voting in the election of directors, which would limit the ability of less than a majority of stockholders to elect director candidates;

Limiting the ability of stockholders to call special meetings of stockholders;

Prohibiting stockholder action by written consent and requiring that all stockholder actions be taken at a meeting of our stockholders; and

Establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law may discourage, delay or prevent a change of control of our company. Generally, Section 203 prohibits stockholders who, alone or together with their affiliates and associates, own more than 15% of the subject company from engaging in certain business combinations for a period of three years following the date that the stockholder became an interested stockholder of such subject company without approval of the board or 66<sup>2</sup>/<sub>3</sub>% of the independent stockholders. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.

Furthermore, if a "fundamental change" (as such terms are defined in each the indentures of the Convertible Notes) occurs, holders of the Convertible Notes will have the right, at their option, to require us to repurchase all or a portion of their Convertible Notes. A "fundamental change" generally occurs when there is a change in control of Accuray (acquisition of 50% or more of our voting stock, liquidation or sale of Accuray not for stock) or trading of our stock is terminated. In the event of a "make-whole fundamental change" (as such term is defined in each of the indentures for the Convertible Notes), we may also be required to increase the conversion rate applicable to the Convertible Notes surrendered for conversion in connection with such make-whole fundamental change. A "make-whole fundamental change" is generally a sale of Accuray not for stock in another publicly traded company. In addition, each of the indentures for the Convertible Notes prohibits us



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from engaging in certain mergers or acquisitions unless, among other things, the surviving entity assumes our obligations under the Convertible Notes.

*We have not paid dividends in the past and do not expect to pay dividends in the foreseeable future.*

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all future earnings for the operation and expansion of our business and, therefore, do not anticipate declaring or paying cash dividends in the foreseeable future. The payment of dividends will be at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, and other factors our board of directors may deem relevant. If we do not pay dividends, a return on a stockholders' investment will only occur if our stock price appreciates.

**Item 1B. UNRESOLVED STAFF COMMENTS**

None.

**Item 2. PROPERTIES**

**Facilities**

We currently lease approximately 164,000 square feet of product development, manufacturing and administrative space in three buildings in Sunnyvale, California, as follows:

A manufacturing building, which is approximately 50,000 square feet, which is leased to us until December 2018; and

Two headquarters buildings, which are approximately 74,000 square feet and 40,000 square feet, respectively, which are leased to us until May 31, 2015. We have the right to renew the lease term of our headquarters office buildings for two five-year terms upon prior written notice and the fulfillment of certain conditions.

We also lease approximately 25,000 square feet of development and manufacturing space in Mountain View, California, under a lease expiring in September 2013, which we do not intend to renew.

Our wholly owned subsidiary, TomoTherapy leases approximately 150,000 square feet of product development, manufacturing and administrative space in three buildings in Madison, Wisconsin, as follows:

An office building, which is approximately 61,000 square feet, which is leased to TomoTherapy until June 2018;

A manufacturing facility, which is approximately 56,000 square feet, which is leased to TomoTherapy until May 2018; and