

ACCURAY INC  
Form 10-K  
September 09, 2009

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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 27, 2009**

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:

<b>Title of Each Class</b>	<b>Name of Each Exchange on Which Registered</b>
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

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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 26, 2008: \$263,684,386.

As of August 21, 2009, the number of outstanding shares of the registrant's common stock, \$0.001 par value, was 56,698,022.

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Registrant's 2009 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 27, 2009**

**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. We have 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. 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**

*Historically, our fiscal year has ended on the Saturday closest to June 30th, so that in a 52 week period, each fiscal quarter consisted of 13 weeks. The additional week in a 53 week year was added to the fourth quarter, making such quarter consist of 14 weeks. Fiscal years 2009, 2008, and 2007 are each comprised of 52 weeks. For ease of presentation purposes, we refer to June 30 as the Company's fiscal year end. On June 23, 2009, our board of directors determined to change the Company's fiscal year end to June 30, beginning with fiscal 2010.*

**Item 1. BUSINESS**

**The Company**

We have developed the first and only commercially available intelligent robotic radiosurgery system, the CyberKnife system, designed to treat solid tumors anywhere in the body as an alternative to traditional surgery. For over 30 years, traditional radiosurgery systems, or systems that deliver precise, high dose radiation directly to a tumor, have been used primarily to destroy brain tumors. Our CyberKnife system represents the next generation of radiosurgery systems, combining continuous image-guidance technology with a compact linear accelerator, or linac, that has the ability to move in three dimensions according to a patient's treatment plan. Our image-guidance technology continuously acquires images to track a tumor's location and transmits any position corrections to the robotic arm prior to delivery of each dose of radiation. Our linac is a compact radiation treatment device that uses microwaves to accelerate electrons to create high-energy X-ray beams to destroy the tumor. This combination, which we refer to as intelligent robotics, extends the benefits of radiosurgery to the treatment of tumors anywhere in the body. The CyberKnife system autonomously tracks, detects and corrects for tumor and patient movement in real-time during the procedure, enabling delivery of precise, high dose radiation typically with sub-millimeter accuracy. Traditional radiosurgery systems have limited mobility and generally require the use of a rigid frame attached to a patient's skull to provide a coordinate system to effectively target a tumor, which restricts the ability to effectively treat tumors outside of the brain. The CyberKnife system does not have these limitations and therefore has increased flexibility to treat tumors throughout the body from many different directions, while minimizing the delivery of radiation to healthy tissue and vital organs. The CyberKnife procedure requires no anesthesia, can be performed on an outpatient basis and allows for the treatment of patients who otherwise would not have been treated with radiation or who may not have been good candidates for surgery. In addition, the CyberKnife procedure avoids many of the potential risks and complications that are associated with other treatment options and is more cost effective than traditional surgery.

As of June 30, 2009, 176 CyberKnife systems were installed: 115 in the Americas, two of which are pursuant to our shared ownership program, 43 in Asia and 18 in Europe. Our customers have reported that over 70,000 patients worldwide have been treated with the CyberKnife system since its commercial introduction. Our customers have increasingly used the CyberKnife system for indications outside of the

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brain for tumors on or near the spine and in the lung, liver, prostate and pancreas. Based on customer data, approximately 58% of patients treated with the CyberKnife system in the United States during the year ended June 30, 2009 were treated for tumors outside of the brain.

The CyberKnife system received U.S. Food and Drug Administration, or FDA, 510(k) clearance in July 1999 to provide treatment planning and image-guided robotic radiosurgery for tumors in the head and neck. In August 2001, the CyberKnife system received 510(k) clearance to treat tumors anywhere in the body where radiation treatment is indicated. The CyberKnife system has also received a CE mark for sale in Europe and has been approved for various indications in Japan, Korea, Taiwan, China and other countries. In Europe, Japan, Korea, Taiwan, and China, the CyberKnife system has received approval to provide treatment planning and image-guided robotic radiosurgery for tumors anywhere in the body where radiation treatment is indicated. We received approval for full-body treatment in Japan in June 2008; previously our CyberKnife regulatory approvals in Japan were limited to treatment for indications in the head and neck.

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.

**Cancer Market Overview**

According to the World Health Organization, or WHO, an estimated 7.9 million people died of cancer in 2007, accounting for 13% of all deaths worldwide. Cancer is the second leading cause of death in the United States, after heart disease. The American Cancer Society, or ACS, estimates that approximately 560,000 Americans will die as a result of cancer in 2009. The ACS also estimates that approximately 1.5 million new cases of cancer will be diagnosed in the United States in 2009, with continued increases in the prevalence of cancer forecasted as the U.S. population ages.

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 accounted for approximately 1.4 million, or approximately 95%, of new cancer cases diagnosed and accounted for approximately 500,000 cancer-related deaths in the United States in 2008. In addition, tumors at the original cancer site, called primary tumors, such as in the breast or prostate, even when diagnosed and treated, can lead to the development of tumors in other locations of the body, called secondary tumors. This is referred to as metastatic disease, the movement of cancer cells from one part of the body to another. We are focused on the treatment of solid cancer tumors.

**Traditional Treatments**

Traditional methods for the treatment of solid tumor cancers include surgery, radiation therapy, chemotherapy and other drugs. Surgery and radiation are forms of local control, because the tumor is either directly removed through surgery or irradiated with the objective of destroying the cancer cells comprising the tumor. Chemotherapy is a systemic treatment method which involves the administration of drugs with the objective of killing cancer cells anywhere in the body, including any remaining cancer cells that were not destroyed by local treatment.

***Surgical Removal of Tumors***

A common treatment approach, if applicable to the patient and tumor type, is the removal of the tumor through surgery, with follow-up radiation therapy to kill any remaining cancer cells in the area surrounding the tumor. Surgery is especially appropriate for certain types of cancer, such as breast cancer, where tumors are often well-defined and surgically accessible. However, many types of solid tumors, including those affecting the brain, the spine, the lungs and various other organs, present

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significant challenges to a traditional surgical approach. In many instances, these tumors occur in hard to reach areas or lie within or in close proximity to critical organs. Accordingly, it may be difficult or impossible to surgically access or remove the entire tumor or organ affected. For example, many tumors located near the base of the skull are difficult to treat with traditional surgery without substantial risk of injury to the visual pathways or other critical brain regions.

Traditional surgery is highly invasive because it requires entering the body by incision, is painful and involves significant operative and post-operative risks, including risks associated with anesthesia, infection and other complications. For example, surgery is very difficult to perform on lung tumors because incisions in the sternum are often required to access the lung and because the lung is in motion due to respiration. Lung surgery also entails significant risks of post-surgical complications, including severe bleeding and pneumonia. Traditional surgery also entails significant costs and recovery times, particularly for more complex and difficult surgeries. In addition, for elderly or seriously ill patients, surgery is not typically an alternative, even if the tumor were otherwise operable.

Over the past several years, minimally invasive surgical techniques have been developed to destroy tumors, including cryotherapy, which is the freezing of cancer cells, radiofrequency ablation, a process which heats and destroys tumors, and injection of ethanol directly into tumors; however, these techniques have significant limitations. Cancer cells may not be fully ablated or destroyed and the energy source used in the procedure may damage adjoining healthy tissue or organs. In addition, these techniques are currently only available for a limited range of cancer indications. As a result, these techniques remain in limited use.

***Radiation Therapy***

Radiation therapy has been used for several decades to treat the area around a tumor site, typically as an adjunct to surgery after the tumor has been removed, in an attempt to eliminate remaining cancer cells in that area. Radiation therapy is also used to directly target the tumor in certain instances when surgery is not possible. The goal of radiation therapy is to eliminate all cancer cells in an intended treatment region. However, healthy tissue outside of the intended treatment region also receives substantial radiation. In order to minimize the damage to healthy tissue surrounding the tumor area, a large number of fractions, or staged treatments, are administered daily over multiple weeks. Despite staging treatments over a period of time, radiation therapy can still damage healthy tissue in the treated region, particularly since treatment delivery is relatively imprecise. Besides the potential damage to healthy tissue, radiation therapy may have a number of other adverse side effects including nausea and skin reactions. The nature and severity of these side effects can vary significantly depending on the area of the body treated and on the patient.

Recent advances in radiation therapy have focused on improving the shaping and targeting of the radiation beams to minimize irradiation of healthy tissue. These advances include the development of Intensity Modulated Radiation Therapy, or IMRT, which is designed to vary the intensity and shape of the radiation beam delivered to the tumor, and Image-Guided Radiation Therapy, or IGRT, which is designed to improve targeting accuracy. However, the majority of these treatments are delivered using gantry-based linear accelerator systems that rotate the radiation source on a single axis and therefore have a limited range of motion, which restricts treatment delivery options and generally requires manual repositioning of the patient during treatment. In addition, IMRT and IGRT have a limited ability to accurately target tumors, to conform to the tumor shape, and to detect and compensate for tumor and patient motion during treatment. This results in having a cumulative radiation dose pattern for IMRT and IGRT treatments which generally includes not only the tumor, but also surrounding healthy tissue.

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**Development of Radiosurgery**

Based on the demonstrated principles of radiation as a method of destroying cancer cells, manufacturers have developed radiosurgery systems that have initially shown to be effective in the treatment of brain tumors and there have been various attempts to develop similarly accurate systems to perform radiosurgery elsewhere in the body. By destroying the tumor with a high dose of radiation, radiosurgery systems have been shown to be effective at local control without the risks, costs and other limitations of traditional surgery. 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 small number of treatments specifically targeted at the tumor rather than at a region surrounding the tumor area. The delivery of more accurate 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, due to advanced age or other health reasons, tolerate traditional surgery.

One of the initial radiosurgery techniques was frame-based radiosurgery for the treatment of brain tumors, which requires attaching a rigid frame to the patient's head by screwing it into the skull through the skin to immobilize the patient's head and to aid in targeting the tumor. Besides immobilizing the patient, the frame forms a fixed coordinate system that is used to target a tumor inside the head. Once the frame is attached, the physician then images the head, typically with a computed tomography, or CT, scan, to identify the tumor location relative to the frame. The physician then uses the acquired images to develop a treatment plan, and the patient receives treatment. The entire process usually lasts between four and eight hours.

Although frame-based radiosurgery represents an advancement in cancer treatment, it has significant shortcomings. The necessity for a rigid frame to be screwed into a patient's skull or affixed to the body restricts the area of the body which can be treated. In addition, frame-based radiosurgery systems do not generally succeed in conforming the radiation dose to the tumor, because beam orientations are limited, and therefore it is difficult to match the shape of the treated volume with the shape of the tumors. Further, because it is difficult to precisely reposition the head frame for multiple treatments, these systems are very rarely used when more than one dose of radiation is required. Frame-based radiosurgery approaches have been used for treatment of tumors in other parts of the body, but suffer from significant drawbacks. In particular, it is not practical to attach a frame rigidly to parts of the body other than the head. Tumors in soft tissue organs such as the lung, liver, pancreas and prostate are not rigidly fixed to any external reference points and can move significantly during treatment due to normal bodily functions. Frame-based approaches to delivering radiosurgery for tumors in such locations are rarely as accurate as frame-based systems used to treat brain tumors. This lack of accuracy for tumors located outside the head may compromise the efficacy of traditional radiosurgery and increase the likelihood of delivering significant radiation doses to otherwise healthy tissue.

**The CyberKnife System Solution**

We have developed and commercialized the CyberKnife system, an intelligent robotic radiosurgery system designed to treat solid tumors throughout the body where radiation is indicated as an alternative to traditional surgery. The CyberKnife system combines continuous image-guidance technology with a compact linear accelerator mounted on a computer-controlled manipulator arm to precisely deliver high doses of radiation to a tumor from many different directions. Our system tracks, detects and corrects for tumor and patient movement in real-time during treatment and precisely delivers high doses of radiation to a tumor typically with sub-millimeter accuracy. Key benefits of the CyberKnife system include:

***Treatment of inoperable or surgically complex tumors.*** The CyberKnife system can be used to target tumors that cannot be easily treated with traditional surgical techniques because of their location,



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number, size, shape or proximity to vital tissues or organs, or because of the age or health of the patient. The CyberKnife system's intelligent robotics are designed to enable the delivery of radiation doses that conform closely to the shape of the tumor. This enables the precise targeting of a tumor, while at the same time minimizing damage to surrounding healthy tissue. Treatments performed with the CyberKnife system can also be staged over two to five treatment sessions.

***Treatment of tumors throughout the body.*** The CyberKnife system has been cleared by the FDA to provide treatment planning and image-guided radiosurgery 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 system is 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.*** We believe the CyberKnife system is the first device that is designed to enable the treatment of tumors that may change position due to tumor and patient movement during treatment. That ability is achieved with a level of accuracy typically associated with radiosurgery procedures for brain tumors. In addition, our Synchrony motion tracking system enables highly accurate treatment of tumors that move with respiration.

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

***Facilitates additional revenue generation through increased patient volumes.*** We believe that the CyberKnife system allows our customers to effectively treat 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. In addition, because the CyberKnife treatment is a non-invasive, outpatient procedure requiring little or no recovery time, hospitals can treat more patients than through traditional surgery. In traditional surgery, the time a patient must be at the facility for the procedure and the recovery time tend to be measured in days. With the CyberKnife system, the entire procedure is generally completed within 90 minutes, and the patient often leaves the facility very shortly after treatment. Even if the patient receives four to five treatments, the total time the patient is at the hospital or treatment center is still shorter than with traditional surgery. Furthermore, the more time the patient must be at the hospital, the more resources the hospital must dedicate to the patient. The reduction in overall time and resources required for the CyberKnife procedure, when compared to traditional surgery, leads to an increase in the volume of procedures performed and lower per procedure costs for the hospital. The combination of incremental revenue generation and lower per procedure cost makes the CyberKnife system an attractive addition to our customers' cancer treatment practice.

***Upgradeable modular design.*** Our CyberKnife system has a modular design which facilitates the implementation of upgrades without requiring our customers to purchase an entirely new system. We have a well-established track record of developing and delivering state-of-the-art upgrades to our customers, enabling our customers to take advantage of the continued evolution of our CyberKnife system. We continue to develop and offer new clinical capabilities enhancing ease of use, reducing treatment times, improving accuracy and improving patient access.

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**Our Strategy**

Our goal is to have the CyberKnife system become the standard of care for the treatment of solid tumors, particularly those that are difficult to treat with traditional surgery. We believe our technology can significantly enhance the applications of radiosurgery by increasing the number and type of tumors which can be treated effectively. 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 CyberKnife system and demonstrate its advantages over traditional treatment methods. We intend to increase the number of worldwide sales and marketing personnel in order to increase sales and drive utilization of the CyberKnife system. In addition, we will continue to hold and sponsor symposia and educational meetings and to support clinical studies in an effort to demonstrate the clinical benefits of the CyberKnife system. Finally, we will continue to assist our customers in increasing 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 system has received FDA clearance for and is increasingly being used to treat tumors anywhere in the body where radiation is indicated. Based on customer data, approximately 58% of patients treated with the CyberKnife system in the United States during the year ended June 30, 2009 were treated for tumors outside of the brain. We are facilitating studies to further demonstrate the CyberKnife system's efficacy for treating tumors outside of the brain, and we believe these studies will increase overall utilization of the CyberKnife system and continue to expand the number of patients eligible for radiosurgery. In addition, we have developed and are continuing to develop new upgrades to enable the CyberKnife system to be even better suited for treating tumors anywhere in the body where radiation is indicated.

***Continue to innovate through clinical development and collaboration.*** The clinical success of the CyberKnife system 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 CyberKnife system users to learn what is needed to enhance the technology. Due to this collaborative process, we continually refine and upgrade the CyberKnife system, which ultimately improves our competitive position in the radiosurgery market. Our upgrades are designed to improve the ease of use and accuracy of treatment, decrease the treatment times, and improve the utilization for specific types of tumors. For example, in recent years, we introduced Synchrony, a motion tracking system that is designed to track tumors that move with patient respiration and the Xsight Spine Tracking System, a new target tracking technology, which eliminates the need for surgical implantation of small, inert metal markers, known as fiducials, in the treatment of spinal tumors. In the year ended June 30, 2007, we introduced the Patient Archive and Restore System, the RoboCouch patient positioning system, the Xsight Lung Tracking System, the Xchange robotic collimator changer and the 4D Treatment Optimization and Planning System. In the year ended June 30, 2008, we introduced a higher output linear accelerator, the IRIS Variable Aperture Collimator, MonteCarlo Dose Calculation software, Sequential Optimization treatment planning and a seated RoboCouch, enabling improved patient positioning capabilities. In the year ended June 30, 2009, we introduced the InTempo Adaptive Imaging system, MultiPlan MD Suite, MultiPlan Quick Review, and a Radiosurgery DICOM Interface compatible with the IMPAC MOSAIQ system.

***Leverage our installed base to generate additional recurring revenue.*** We have designed the CyberKnife system so that customers may upgrade their previously purchased systems as we introduce new features. We generate additional revenue by selling multiyear service plans that provide eligibility to receive upgrades, when and if available. These contracts are typically signed prior to the CyberKnife system installation and generate additional revenue throughout the life of the contract. In addition, we sell upgrades to our existing customers who are not covered by service plans or who have exhausted the

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upgrades deliverable pursuant to their service plans. Finally, we offer the shared ownership program, which enables customers to reduce the upfront investment required for the CyberKnife system in exchange for sharing a significant portion of revenue with us that is derived from each procedure.

***Continue to expand international sales and geographic reach.*** We intend 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 Paris, France, Hong Kong, China, Tokyo, Japan, Madrid, Spain, New Delhi, India, Singapore, Moscow, Russia, Munich, Germany, London, UK and Istanbul, Turkey and our sales and distribution channels cover more than 80 countries. We intend to increase our international revenue by increasing the number of distributors and direct sales and support personnel in targeted new international markets, and by further penetrating our established international markets.

***Pursue acquisitions, strategic partnerships and joint ventures.*** We intend to actively pursue acquisitions, strategic partnerships and joint ventures that we believe may allow us to complement our growth strategy, increase market share in our current markets and expand into adjacent markets, broaden our technology and intellectual property and strengthen our relationships with our customers.

### **The CyberKnife System**

Our principal product is the CyberKnife system, an intelligent robotic radiosurgery system that enables the treatment of tumors anywhere in the body where radiation is indicated without the need for invasive surgery or rigid frames. The current United States list price for the CyberKnife system ranges from approximately \$4.2 million to \$5.75 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 system, as well as service contracts and training to assist customers in realizing the full benefits of the CyberKnife system. As of June 30, 2009, we had 176 units installed at customer sites: 115 in the Americas, two of which are pursuant to our shared ownership program, 43 in Asia and 18 in Europe.

The CyberKnife system combines continuous image-guidance technology with a compact linear accelerator mounted on a computer-controlled manipulator arm to precisely deliver high doses of radiation to the tumor from numerous directions during treatment. 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 precisely direct each beam of radiation. This 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 gives clinicians an effective, uninterrupted and accurate treatment alternative.

Key components and technologies of the CyberKnife system include the following:

***Compact X-band linear accelerator.*** This compact linac generates the radiation that destroys the tumor. We believe we are the only commercial manufacturer of a compact X-band linac. This technology allows us to manufacture linacs that are smaller and weigh significantly less than standard medical linacs used in radiation therapy while achieving similar performance. Our linac can provide high energy X-ray beams of different diameters and intensities without the use of radioactive material. In fiscal 2008, we introduced a linac capable of delivering 800 monitor units per minute of energy output, representing the highest output linac we have offered.

***Robotic manipulator.*** The manipulator arm, with six-degrees-of-freedom range of movement, is designed to move and direct the linac with an extremely high level of precision and repeatability. The manipulator arm allows doses of radiation to be delivered from nearly any direction and position,

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without the limitations of gantry-based systems, creating a non-isocentric composite dose pattern that can precisely conform 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 in real time.

***Real-time image-guidance system with continuous target tracking and feedback.*** Without the need for clinician intervention or treatment interruption, the CyberKnife system's revolutionary real-time image-guided robotics enables the CyberKnife system to continuously monitor and correct for patient and tumor movements throughout treatment. The CyberKnife system is able to provide the precise delivery of radiation because of the virtually instantaneous and continuous feedback loop between X-ray-based target localization and automatic correction of the radiation beam throughout the entire treatment. This target tracking and feedback technology uses two digital image detectors to capture low energy X-ray images. The image guidance software carries out an automated comparison of the X-ray images with the patient's CT scan to detect, track and correct for any movement of the tumor or patient before and during the treatment delivery. This allows the CyberKnife system to dynamically target the tumor and adjust the position of the beam to follow the motion of the tumor throughout the treatment, directing the beam to precisely match tumor movement.

***X-ray sources.*** The low-energy X-ray sources generate X-ray images to determine the location of bony landmarks or implanted fiducials throughout the entire treatment.

***Image detectors.*** The image detectors capture high-resolution anatomical images throughout the treatment. These live images are continually compared to previously captured digitally reconstructed radiographs to determine real-time patient positioning. Based on this information, the robotic manipulator instantly corrects for any detected movement.

In addition to the key components listed above, we also offer the following components and features, including:

***Synchrony respiratory tracking system.*** The CyberKnife system employs a proprietary motion tracking system called Synchrony, for targeting tumors that move during respiration. Synchrony software and hardware correlate tumor movement due to respiration with the CyberKnife system treatment beam allowing it to continuously track the tumor as it moves throughout the respiratory cycle. Through this process the CyberKnife system delivers beams 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 exposed to radiation and unprecedented clinical accuracy of approximately 1.5 millimeters.

***Xsight Spine Tracking System.*** For most extracranial tumors, the CyberKnife system uses implanted fiducials to track the position of the tumor throughout treatment. However, the Xsight Spine Tracking System eliminates the need for surgical implantation of fiducials in the delivery of radiosurgery treatments on or near the spine. The Xsight Spine Tracking System utilizes skeletal structures to automatically locate and track tumors with sub-millimeter accuracy. We believe no other commercially available technology today offers this capability.

***Xsight Lung Tracking System.*** The Xsight Lung Tracking System delivers radiosurgical accuracy to some lung tumors without the need for implanted fiducials. The Xsight Lung Tracking System directly tracks the anatomy of the tumor. Integrated with the Synchrony Respiratory Tracking System, treatment margins are significantly minimized by tracking the motion of the tumor as it moves in respiration.

***RoboCouch patient positioning system.*** Fully integrated with the CyberKnife system, the RoboCouch intelligently positions the patient to the planned treatment position with unprecedented accuracy, providing not only greater set up precision, but significantly streamlining the patient set up process.

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The versatility of the RoboCouch allows for automated patient positioning prior to treatment. Additionally, the RoboCouch offers greater positioning flexibility, a lower patient loading height, and a higher patient weight capacity limit when compared to our standard treatment couch.

**Standard treatment couch.** Our standard treatment couch is a computer-controlled treatment couch that is integrated with the image-guidance system. The treatment couch automatically aligns the patient for treatment at the beginning of the procedure. The treatment couch also positions the patient so that the tumor is in the center of the imaging field. When the tumor is correctly positioned, treatment begins and the CyberKnife system tracking software guides the radiation beams to the precise tumor location.

**Xchange robotic collimator changer.** The Xchange robotic collimator changer automatically exchanges secondary collimators, which determine the radiation beam size, during the treatment. The use of multiple collimators can enable faster treatments than the use of a single collimator.

**Iris variable aperture collimator.** The IRIS variable aperture collimator enables delivery of beams in 12 unique sizes with a single collimator. This can significantly reduce treatment times as well as the total radiation dose delivered to the patient. IRIS is offered in conjunction with the Xchange robotic collimator changer.

**4D Treatment Optimization and Planning System.** Our 4D Treatment Optimization and Planning System optimizes treatment by taking into account the movement of the tumor as well as the movement and deformation, or change in shape, of the surrounding tissue, thereby minimizing margins and radiation exposure to healthy tissue.

**InTempo Adaptive Imaging System.** Our InTempo System is a time-based target tracking technology used to compensate for intrafraction prostate motion during treatment delivery. With the InTempo System, our users can utilize adaptive imaging to automatically adjust for large movements in patients during treatment by increasing the X-ray imaging frequency. The user also manages the image age of X-ray images by specifying how long to wait between images.

**MultiPlan treatment planning system.** Our proprietary intuitive planning system called MultiPlan is designed for radiosurgery and includes a standard computer workstation. MultiPlan calculates a treatment plan that produces a pattern of radiation designed to conform to the tumor. 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. After the physician outlines a tumor and critical adjacent tissues on the computer, a radiation scientist uses the MultiPlan system to plan the number, intensity, position and direction of radiation beams. Using unique and patented software algorithms, the system calculates and displays the resultant treatment plan for evaluation, optimization and approval by the physician.

**MultiPlan MD Suite.** Our MultiPlan MD Suite solution allows users to perform pre-planning preparation and post-planning review of treatment plans. MD Suite can be located either local to, or remote from the CyberKnife System. It allows tasks such as contouring, fusion, review and approval of treatment plans, and changing of treatment plan parameters. MultiPlan MD Suite also networks directly to the CyberKnife central database management system (CDMS).

**CyberKnife® Data Management System.** The CyberKnife® Data Management System provides comprehensive storage and processing of the patient data that is generated as the patient progresses through the CyberKnife planning and treatment workflow pre-planning data, such as planning CT images, are imported and stored in the data management system. This information is then available for review by the clinician. The results of a patient's treatment delivery, such as dose delivered from each beam, each path and each fraction, as well as details about the images acquired and corrections applied are recorded and stored in the data management system.

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**MultiPlan Quick Review.** Our MultiPlan Quick Review allows multiple sessions of the MultiPlan Treatment Planning System to be run simultaneously with one primary and up to three secondary sessions being accessible. The primary session has full treatment planning functionality while the secondary sessions can perform all planning functions except for optimization. MultiPlan Quick Review improves clinical workflow by allowing data from multiple patients, or multiple plans from the same patient, to be accessed simultaneously.

**Radiosurgery DICOM Interface.** In a typical oncology department there are many individual systems that play a role in patient diagnosis and treatment delivery. Each of these systems separately manages their own specialized piece of information about a patient. Often a centralized information management system such as an Oncology Information Systems (OIS) is used to minimize the need for the clinical user to access each of these separate systems individually to gather information. Centralization of the patient's oncology treatment record into a single digital record provides clinical benefits that can be realized immediately. 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. Using industry-standard interface protocols, the CyberKnife® Robotic Radiosurgery System completes the OIS electronic medical record with a comprehensive export of the radiosurgery treatment history. Note: The Radiosurgery DICOM Interface requires a compatible version of the Oncology Information System (OIS), a compatible version of the IMPAC MOSAIQ system is required.

**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.

**Sequential Optimization treatment planning.** Sequential optimization treatment planning enables CyberKnife System users to define and prioritize treatment planning objectives for each treatment plan. These objectives can include treatment dose to the targeted tumor, dose minimization in surrounding areas and total radiation delivery throughout the treatment. Sequential optimization enables these objectives to be prioritized and tailored to the unique clinical characteristics of each patient.

**Patient Archive and Restore System.** The Patient Archive and Restore System increases utilization by moving the archive and restore processes from the treatment delivery workstation to an independent archiving system.

**InView remote review system.** The CyberKnife system employs a remote review workstation to allow referring physicians to participate in the treatment process, called InView. InView allows physicians to combine and contour diagnostic images as well as review potential treatment plans as generated by MultiPlan prior to the CyberKnife procedure. By placing InView in physician offices or clinics, we believe that we can expand the number of patients referred for treatment using the CyberKnife system.

### **CyberKnife System Clinical Procedure**

The CyberKnife procedure involves scanning, planning, treatment and follow-up, and may be performed on an outpatient basis.

**Scanning.** Prior to treatment with the CyberKnife system, the patient undergoes imaging procedures to determine the size, shape and location of the tumor. The process begins with a standard high-resolution CT scan. Preparation for the scan may also include the placement of fiducials, in or around the tumor when treating tumors outside the brain. For certain tumors, such as brain and spinal

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tumors, where greater differentiation between different types of soft tissue is required, other imaging techniques, such as MRI, angiography, or PET, may also be used to more accurately differentiate the tumor from surrounding healthy tissue. Our software helps integrate CT scans and other imaging data into the pre-treatment planning process.

**Planning.** Following the scanning, the image data is then digitally transferred to the CyberKnife system's treatment planning workstation, where the treating physician identifies the exact size, shape and location of the tumor to be targeted and the surrounding vital structures to be avoided. A qualified physician and/or radiation scientist or physicist then uses our proprietary software to generate a treatment plan to provide the desired radiation dose to the identified tumor location without exceeding the tolerance of adjacent healthy tissue. As part of the treatment plan, our proprietary planning software automatically determines the number, duration and angles of delivery of the radiation beams.

**Treatment.** During a CyberKnife procedure, a patient lies on the treatment table, which automatically positions the patient. Anesthesia is not required, as the procedure is painless and non-invasive. The treatment, which generally lasts between 30 and 90 minutes, typically involves the administration of between 100 and 200 radiation beams delivered from different directions, each lasting from 10 to 15 seconds. Prior to the delivery of each beam of radiation, the CyberKnife system has the ability to simultaneously take a pair of X-ray images and compare them to the original CT scan. This image guided approach continuously tracks, detects and corrects for any movement of the patient and tumor throughout the treatment to ensure precise targeting. The patient usually leaves the facility immediately upon completion of the procedure.

**Follow-up.** Follow-up imaging, generally with either CT or MRI, is usually performed in the weeks and months following the treatment to confirm the destruction and eventual elimination of the treated tumor.

#### **Shared Ownership Program and Other Services**

We provide a variety of services to support the operation and use of our CyberKnife systems. We expect that these services will enable us to generate a recurring revenue stream that will continue to make up an important portion of our revenue.

#### ***CyberKnife System Shared Ownership Program***

We offer the shared ownership program under which we provide a CyberKnife system to a customer while retaining ownership of that system. In addition, we provide physician training, educational support, general reimbursement guidance and technical support, as well as possible future upgrades to customers under this program. In return, these customers are generally required to pay us the greater of a minimum payment or a portion of the revenue generated through the use of the CyberKnife system. Generally, this minimum monthly payment is equivalent to the revenue generated from treating three to four patients per month, and any revenue received from additional patients is shared between us and the customer. Customers who participate in our shared ownership program are responsible for costs associated with facility preparation and professional and administrative personnel required to operate the CyberKnife system. Our legacy shared ownership program was known as our "placement program."

Agreements under the shared ownership program typically have a term of five years, during which the customer has the option to purchase the system, either at the end of the contractual period or earlier, at the customer's request, at pre-determined prices. Through June 30, 2009, we had installed 18 systems under our shared ownership program, 16 of which had subsequently been sold by that date. During the years ended June 30, 2009, 2008 and 2007, \$3.2 million, \$23.7 million and \$3.0 million, respectively, of revenue was recognized in the consolidated statements of operations for the sale of two,

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twelve, and one CyberKnife systems, respectively, that were formerly under the shared ownership program. At June 30, 2009 and 2008, 747,000 and \$2.3 million, respectively, of amounts for extended warranty and training services related to these sold shared ownership units remained recorded as deferred revenue, and will be recognized over the life of the extended warranty service period and as training service obligations are fulfilled. As of June 30, 2009, two shared ownership units remained active in our installed base.

***Warranty and Support Services***

We generally provide a one-year warranty on the purchase of the CyberKnife system. The warranty period commences on completion of system installation. For the period following the initial one-year warranty, customers can enroll in one of our multiyear service plans for a fee that is fixed at the time of system purchase.

***Diamond Elite multiyear service plan.*** Under our Diamond Elite multiyear service plan, or Diamond plan, our customers have the opportunity to acquire up to two unspecified future upgrades per year, when and if they become available. If we offer more than two upgrades a year, customers can exchange their right to receive future upgrades for the current upgrades available. Currently, the Diamond plan lists for \$495,000 per year and is typically for a term up to five years, cancellable by the customer.

***Emerald multiyear service plans.*** We also offer an Emerald multiyear service plan, or Emerald plan, following the initial one-year warranty period. We provide services under our Emerald agreements during the one-year warranty if the agreement is signed before the start of the warranty period. Under our Emerald plan, customers receive a higher level of support, including a faster response time and coverage for all replacement parts than under our basic service plan. Currently, the list price of our Emerald plan is \$325,000.

***Extended Warranty.*** We now offer our customers the option to purchase an extended warranty for one or two years following the expiration of their initial warranty period. Currently, the list price for the Extended Warranty is \$240,000 per year.

***First Level Maintenance Credit.*** We now offer any customer who purchases the Diamond plan or Emerald plan the option to provide first level maintenance (for example, basic service and troubleshooting assistance) for the CyberKnife System prior to contacting us for support, which currently entitles a customer to a credit, which currently lists for \$85,000 per year, against the Diamond plan or Emerald plan (contingent upon the customer's paying for and receiving appropriate first level maintenance training).

***Legacy multiyear service plans.*** Prior to introducing our Diamond plan, we offered a Platinum Elite multiyear service plan, or Platinum plan, to customers in the United States and our Gold Elite multiyear service plan, or Gold plan, to customers outside the United States. Although these plans are no longer offered, as of June 30, 2009 we were still servicing approximately 24 customers pursuant to both of these legacy multiyear service plans. These multiyear service plans typically have a four year term, including the one-year warranty period, and are cancellable by the customer. Beginning in November 2005, we phased out offering these legacy service plans to new customers. In fiscal year 2009, we also phased out our basic multiyear service plan, which had a list price of \$200,000 per year and was for a term of up to four years.

Under the Platinum plan, in addition to technical support, customers have the opportunity to acquire up to two future upgrades per year for a maximum of eight upgrades over the three or four year term of the arrangement, for an annual fee of approximately \$425,000. If we do not offer at least two upgrades per year, the customer would be entitled to a refund of up to \$100,000 for each upgrade not offered. We have not yet established objective evidence of fair value of those future obligations;



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hence, generally accepted accounting principles in the United States, or GAAP, requires that we cannot begin to recognize any of the revenue derived from the sale of a CyberKnife system or the associated service plan until those specified obligations have been fulfilled. Therefore, the payments made by our customers who have our legacy Platinum plan are categorized as deferred revenue and will be recognized as revenue when we fulfill all obligations to deliver upgrades or the Platinum contract lapses. Once we fulfill all upgrade obligations with respect to a specific Platinum plan or the plan lapses, we will ratably recognize the revenue from the sale of the CyberKnife system and the Platinum plan over the remaining life of the contract.

Under the Gold plan, customers typically have the opportunity to acquire up to two unspecified future software upgrades per year, for an annual fee of approximately \$350,000. If we do not offer an upgrade in any particular year, the customer would be entitled to a refund of up to \$100,000 for each upgrade not offered, except in Japan. Pursuant to the Gold plan customers are required to pay for additional hardware if required for the implementation of new software features.

To date no refunds have been required pursuant to these legacy multiyear service plans.

**Installation and service.** We perform the installation and service of the CyberKnife system in the United States and in selected countries outside the United States. In addition, we have trained third-party service organizations and trained our distributors in Korea, Taiwan, Turkey, India, China, Russia, Ukraine and Italy to perform the CyberKnife system installation and service. We employ service engineers and technical staff with a high degree of expertise, which is required due to the complexity of the CyberKnife system.

**Training.** In addition to the training we offer with the initial installation of the CyberKnife system and the training required when an upgrade is installed, we offer various training sessions for our customers or our distributors for an additional fee.

**Sales and Marketing**

We currently market the CyberKnife system through a direct sales force in the United States and a combination of direct sales personnel and distributors in the rest of the world. Support of our international sales is handled through our European and Asian headquarters in Paris, France, Hong Kong, China and Tokyo, Japan.

In the United States we use a combination of regional sales directors, account specialists, customer account sales executives, product managers and training specialists. Regional sales directors and account specialists are responsible for selling the CyberKnife system to hospitals and stand-alone treatment facilities. Our customer account sales executives sell upgrade products to existing customers. Our product managers help market our current products and work with our engineering group to identify and develop upgrades and enhancements for the CyberKnife system. Our training specialists train radiation oncologists, surgeons, physicists and radiation therapists.

In addition, we recently established a corporate accounts group within the sales organization. This group has responsibility for targeting major national and strategic accounts including hospital groups, operators of multiple radiation oncology centers and group purchasing organizations. We believe that organizations of this nature represent an opportunity for CyberKnife system sales and that they require a different sales focus due to their national or multi-regional scope.

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 will 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 system.

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According to estimates published by the American Society for Therapeutic Radiology and Oncology, or ASTRO, there are over 2,000 hospitals and stand-alone treatment facilities in the United States providing radiation therapy services. Our current United States sales and marketing focus is to target the hospitals and treatment facilities currently providing radiation therapy services, however, in the future we believe that the CyberKnife system will also be marketed to hospitals that do not have radiation therapy facilities.

From time to time, we may provide our linac system 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.

**Manufacturing and Assembly**

We purchase major components of the CyberKnife system, including the robotic manipulator, treatment table or robotic couch, magnetron, which creates the microwaves for use in the linac, imaging cameras and computers, from outside suppliers. We manufacture certain other electronic and electrical subsystems, including the linac, at our Sunnyvale, California and Mountain View, California facilities. We then assemble and integrate these components with our proprietary software for treatment planning and treatment delivery and perform essential testing prior to shipment to customer sites.

Single source suppliers presently provide us with several components, including the magnetron, the treatment couches and the imaging plates. In most cases, if a supplier were unable to deliver these components, we believe that 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 CyberKnife systems, which could adversely affect our reputation and results of operations.

**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. We also rely on trade secrets, know-how and continuing innovation to develop and maintain our competitive position.

We had 13 U.S. patent applications allowed in the fiscal year ended June 30, 2009. As of June 30, 2009, we held 40 U.S. patents, 63 pending U.S. patent applications and are pursuing additional patent applications on additional key inventions to enhance our intellectual property rights. The first of our patents will expire in October 2010 and currently the last of our patents will expire in 2026. As of June 30, 2009, we also held 22 foreign patents, 7 pending published Patent Cooperation Treaty applications and 65 foreign patent applications which correspond to our issued U.S. patents and pending U.S. patent applications. We cannot be sure that any patents will issue 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. An additional key component of our intellectual property is our proprietary software used in planning and delivering the CyberKnife system's therapeutic radiation dose.

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

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execute confidentiality and invention assignment agreements upon commencing employment or consulting relationships with us.

Patents may provide some degree of protection for our intellectual property. However, patent protection involves complex legal and factual determinations and is therefore uncertain. In addition, 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.

In April 2007, we entered into a License and Development Agreement with CyberHeart, Inc., or CyberHeart. As part of this agreement, we will 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 agreement, we would be the sole supplier of radiosurgery equipment to CyberHeart and would also be entitled to receive specified payments based on usage of the CyberHeart system. Roderick Young, a former member of our board of directors, is a founder, officer and director of CyberHeart, Inc.

In December 2004 and in connection with our acquisition of American Science & Engineering's, or AS&E's, High Energy Systems, or HES, business, in January 2005, we entered into a license agreement with AS&E relating to the intellectual property we obtained from the HES acquisition. We granted AS&E an exclusive, worldwide, fully paid license for use of the purchased intellectual property in the national security and non-destructive testing markets, as well as a non-exclusive worldwide, fully paid license of the intellectual property for all uses other than (a) the national security and non-destructive testing markets and (b) medical use or applications. In addition, we received an exclusive, worldwide, fully paid license to any modifications, improvements, enhancements or new developments to the acquired intellectual property by AS&E which are limited to medical uses or applications. We recently began the development of a next-generation linac, using technology developed independently from the intellectual property we obtained from the HES acquisition. We are developing this technology for medical uses and applications and other markets, including national security and non-destructive testing. In October 2006, January 2007 and February 2007, we received correspondence from AS&E expressing concerns that we may be using the intellectual property obtained from the HES acquisition in a manner that breaches, or is intended to breach, our contractual obligations under the license agreement. As of June 30, 2009, we have not received any further correspondence from AS&E regarding this issue. The intellectual property at issue relates to the development of a next-generation linac for use in national security and non-destructive testing areas, as well as medical uses. We are developing the technology used in the next-generation linac independently from the intellectual property we obtained from the HES acquisition. While we do not believe our activities breach or violate the terms of the license agreement, we cannot assure you that AS&E will not assert that we are breaching our obligations under our license agreement with them.

In July 1997, we entered into a license agreement with The Board of Trustees of the Leland Stanford Junior University for technology and patents to develop, manufacture, use and sell products utilizing feature matching technology to align images used in radiosurgery.

Although we are not currently a party to any legal proceedings relating to our intellectual property, in the future, third parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert these claims against

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us or against the licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend against these claims, whether they are with or without any merit, whether they are resolved in favor of or against us or our licensors, we may face costly litigation and diversion of management's attention and resources. As a result of these disputes, we may have to develop costly non-infringing technology, or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, if at all, which could seriously harm our business or financial condition.

**Research and Development**

Continued innovation is critical to our future success. Our current product development activities include projects expanding clinical applications in radiosurgery, driving product differentiation, and continually improving the CyberKnife system's capabilities. Some of our product upgrades include Synchrony, Xsight Spine Tracking System, InView, MultiPlan, RoboCouch, IRIS, MonteCarlo dose calculation, Sequential Optimization treatment planning, InTempo, MultiPlan MD Suite, MultiPlan Quick Review, and Radiosurgery DICOM Interface. Research activities strive to enable new product development opportunities by developing new technologies and advancing areas of existing core technology such as a next generation linac.

The modular design of our products 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 CyberKnife 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 CyberKnife system and improve the speed and accuracy of treatment.

As of June 30, 2009, we had 123 employees in our research and development departments. Research and development expenses for the fiscal years ended June 30, 2009, 2008 and 2007 were \$36.0 million, \$32.9 million and \$26.8 million, respectively. We plan to continue to increase our investment in research and development in future periods.

**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 products often have long development and regulatory 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, minimally invasive procedures, radiation therapy, chemotherapy and other drugs are other means to treat cancer. Also, we compete directly with frame-based radiosurgery systems primarily from Elekta AB (publ), or Elekta, BrainLAB AG, and the Integra Radionics business of Integra Life Sciences Holding Corporation.

The market for standard linacs is dominated by three companies: Elekta, Siemens AG, or Siemens, and Varian Medical Systems, Inc., or Varian. In addition, TomoTherapy Incorporated, or TomoTherapy, markets a radiation therapy product. The CyberKnife system does not perform radiotherapy, which uses low doses of radiation over a long period of time with fractionated treatments to kill cancer cells, and generally does not compete directly with standard medical linacs that perform traditional radiotherapy, although some manufacturers of standard accelerator systems, including Varian and Elekta, have products that can be used in combination with body and/or head frame systems and image-guidance

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systems to perform radiosurgery. In addition, many government, academic and business entities are investing substantial resources in research and development of cancer treatments, including surgical approaches, radiation treatment, 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 system and its 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 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. 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 of our products by the radiation oncology and cancer therapy markets;

the discovery of new technologies that improve the effectiveness and productivity of the CyberKnife system radiosurgery process;

availability of coverage and reimbursement from third-party payors, insurance companies and others for procedures performed using the CyberKnife system;

properly identifying customer needs and delivering new upgrades to address those needs;

published studies supporting the efficacy and safety of the CyberKnife system;

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

limiting the timing and cost of regulatory approvals;

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 patent protection or our ability to otherwise develop proprietary products and processes; and

obtaining any necessary United States or foreign regulatory approvals or clearances.

**Reimbursement**

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In the United States, healthcare providers generally rely on third-party payors; private insurers and governmental payors such as Medicare and Medicaid, to cover and reimburse all or part of the cost of a medical procedure performed with a medical device. Our ability to commercialize our products successfully depends in significant part on the extent to which third-party payors provide and maintain appropriate coverage and reimbursement for our products and related procedures. Medicare coverage and reimbursement policies are particularly significant to our business. If our customers are unable to obtain reimbursement in connection with the use of our products, they may decrease their use of our products or discontinue using them altogether. Not only is Medicare the single largest third-party payor, but many other governmental and commercial payors follow its coverage and reimbursement

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policies. The Medicare coverage and reimbursement policies are developed by the Centers for Medicare and Medicaid Services (CMS), the federal agency responsible for administering the Medicare program and by its contractors. Medicare reimbursement rates for the same or similar procedures vary due to geographic location, type of the facility in which the procedure is performed, and other factors.

Medicare coverage for many procedures using our technology currently exists in the hospital outpatient setting and in the free-standing clinic setting. For hospital outpatient procedures, where most procedures using our CyberKnife system are performed, Medicare payments generally are made under a prospective payment system, which is based on the Ambulatory Payment Classifications, or APCs, under which procedures are categorized.

CMS assigns procedures that are comparable clinically and in terms of resources to the same APC. Hospitals are paid the applicable APC payment rate for the outpatient procedure, regardless of the actual cost for such treatment. For calendar year 2009, the national unadjusted average Medicare payment rate for procedures billed using HCPCS code G0339 (for the first CyberKnife treatment) is \$3,803, and \$2,580 for code G0340 (for each additional CyberKnife treatment). Payment for the free-standing clinic setting is governed by the final Medicare Physician Fee Schedule, and the practice amongst regional Medicare contractors currently varies both in terms of whether they use HCPCS code G0339 and G0340 for CyberKnife procedures, and also in terms of what they pay for CyberKnife procedures.

In addition to Medicare reimbursement to hospitals and clinics, physicians receive reimbursement for their professional services in the hospital outpatient setting and the free-standing clinic setting. Payment to physicians is based on the Medicare Physician Fee Schedule, and payment amounts are updated on an annual basis. For 2009, the American Medical Association, or AMA, issued guidance that deleted Current Procedural Technology, or CPT, code 61793, the Category I CPT code describing the surgeon's role in the delivery of radiosurgery services, and issued the following new CPT codes: 61796, 61797, 61798, 61799, 61800, 63620 and 63621, all relating to neurosurgical procedures that should be used for intracranial and spinal procedures only. Medicare and third-party payors will require the use of these new CPT codes to describe neurosurgeon work for radiosurgery services using our technology for cranial and spinal procedures. Radiosurgery procedures in other anatomies require other surgeons to bill unlisted CPT codes with no assigned payment rates. Payment rates for unlisted codes are set by the local Medicare carrier and rates may vary from no payment to rates equivalent to the comparable CPT rates for the 61796 series of CPT codes. Coding for other physicians (primarily radiation oncologists) involved in the delivery of CyberKnife treatment remains unchanged.

While private third-party payors frequently follow Medicare coverage, coding and payment determinations, we cannot assure you that these payors will adopt coverage and reimbursement policies similar to those established by Medicare or whether they will cover and reimburse the procedures using CyberKnife systems in whole or in part. In the United States, we believe that a majority of private healthcare payors currently provide coverage for some CyberKnife procedures under negotiated contracts with hospitals and clinics.

The current emphasis on cost-containment by third-party payors complicates the task of obtaining appropriate coverage and reimbursement. Often, it is necessary to convince these payors that the new devices or procedures will establish an overall cost savings compared to currently reimbursed devices and procedures. We believe that in many cases the CyberKnife system may offer an opportunity for payors to reduce the cost of treatment for solid tumors; however, we cannot assure you that payors will agree that these advantages exist or that payors will make reimbursement decisions based upon any such advantages. Adequate reimbursement is obviously a key factor for hospitals and physicians considering the purchase of our products, and hence sales by our company.

Reimbursement by third-party payors is often positively influenced by the existence of peer-reviewed publications of long-term safety and efficacy data. Data have been published by leaders

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in the field of radiosurgery on clinical results for patients that have undergone surgical procedures with the CyberKnife system, although we do not yet have long-term safety and efficacy data for a significant patient population size. We cannot assure you that our products will continue to be covered and reimbursed without publication of additional data, including data supporting long-term safety and efficacy of the CyberKnife system.

We have a dedicated health policy, economics and reimbursement group, called "Patient Access". This group provides information to health care stakeholders considering coverage and reimbursement issues for the CyberKnife system, and also provides our customers with copies of relevant coverage, coding and payment policies, including those of the Medicare program, as well as published literature and clinical data supporting clinical safety and efficacy in the device.

To further support appropriate coverage and reimbursement, a group of customers has formally organized into a non-profit organization called CyberKnife Society to pursue patient access to the CyberKnife technology, with a strong emphasis on the United States.

Internationally, reimbursement and healthcare payment systems vary substantially 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 addition, in many international markets, consumers of healthcare services, particularly services involving new or specialized technology, may pay out-of-pocket for such services. Our ability to achieve market acceptance or significant sales volume in international markets we enter will be dependent in large part on the availability of reimbursement for procedures performed using our products under healthcare payment systems in such markets.

**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 that 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;

acceptance controls;

product testing;

product manufacturing;

product safety;

product labeling;



product storage;

recordkeeping;

complaint handling;

pre-market clearance or approval;

advertising and promotion; and

product sales and distribution.

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**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 prior 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. This process is generally 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.

**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 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. As a practical matter, clearance may take longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence.

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 cannot be cleared through the 510(k) process. A PMA must be supported by extensive data, including but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. No device that we have developed has required pre-market approval, nor do we currently expect that any future device or indication will require pre-market approval.

**Product modifications.** After a device receives 510(k) clearance or a PMA, 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. We have modified aspects of our CyberKnife system family 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 for the modifications. 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, the FDA may retroactively require us to seek 510(k) clearance or pre-market 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 27, 2009, we submitted an additional two 510(k) clearances notifications for modifications made to the operation of the CyberKnife system. One application was cleared and one is pending clearance by the FDA.

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***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, control, 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 the past, our prior facility has been inspected, and observations were noted. In August 2008, during routine inspections performed by the FDA, one minor observation was made. We have taken corrective action on the minor observation in response to the FDA's observation. There were no observations that involved a material violation of regulatory requirements. We believe that 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:

fining, 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.

***Radiological health.*** Because our CyberKnife system contains 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. In the past, we failed to submit required reports to the FDA in a timely fashion. To correct our reporting deficiencies, in 2003 we initiated a corrective action plan that



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included, among other things, filing all past due reports with the FDA, applicable state agencies, and customers. We have also developed and implemented procedures to ensure future reports are made in a timely manner. While we believe all past reporting deficiencies have been corrected, we cannot assure you that FDA will deem our corrective actions sufficient or that FDA will not initiate enforcement action against us.

***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.

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;

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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 own our stock who 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 CyberKnife system to our customers under a deferred payment program, where we generally receive the greater of a fixed minimum payment or a portion of the service revenues. 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 physicians or other providers or entities with whom 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.

**Physician self-referral laws.** We are also subject to federal and state physician self-referral laws. The federal Ethics in Patient Referral 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 connection with the release in July 2007 of proposed Medicare reimbursement rates for calendar 2008, CMS proposed significant amendments to the regulations under the federal Ethics in

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Patient Referrals Act, which is more commonly known as the Stark Law. These proposed regulations would, 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 a per use basis. Physician owned entities have increasingly become involved in the acquisition of medical technologies, including the CyberKnife system. 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, as originally proposed, would 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. In July 2008, at the time CMS published final 2008 Medicare in-patient reimbursement rates, CMS issued a final rule essentially implementing the regulations in substantially the manner originally proposed, with an effective date of October 1, 2009. Among other prohibitions, the final rule prohibits percentage-based compensation in equipment leases. As a result of the finalization of these regulations, some existing CyberKnife system operators may have to modify or restructure their corporate or organizational structures. In addition, certain existing customers that planned to open CyberKnife centers in the United States involving physician ownership could also have to restructure prior to the October 2009 effective date of the new regulations. It is possible that some of these entities may not be able to establish viable models for CyberKnife system operation and may therefore cancel their CyberKnife system purchase agreements. Accordingly, these new regulations could result in cancellations of existing 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 could 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 violation 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 must 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 system or acquired a CyberKnife 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 such consultants do not submit claims on behalf of our customers, the fact that we

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provide these consultant services could expose us to additional scrutiny and possible liability in the event one of our customers is investigated as a result 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.

***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, our facility was awarded the ISO 13485 certification, which replaces the ISO 9001 and EN 46001 approvals, which has 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 Technol 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.

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



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our distributors will receive any necessary approvals or clearance prior to marketing our products in those international markets.

**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 the CyberKnife system, whether through purchase or our shared ownership program, and from performing stereotactic radiosurgery procedures using the CyberKnife system. 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 the CyberKnife system. 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 the CyberKnife system through certificate of need or similar programs could adversely affect us.

**Employees**

As of June 30, 2009, we had 458 employees worldwide, including 123 in research and development, 100 in sales and marketing, 106 in installation and service, 30 in manufacturing, and 99 in administration. 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.

**Available Information**

Our web site is located at [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 as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the Securities and Exchange Commission. 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.

**Item 1A. RISK FACTORS**

**Risks Related to Our Business**

*If the CyberKnife system does 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 system as a preferred method of tumor treatment will be crucial to our continued success. Physicians will not begin to use or increase the use of the CyberKnife system unless they determine, based on experience, clinical data and other factors, that the CyberKnife system is a safe and effective alternative to current treatment methods. The CyberKnife system was initially used primarily for the treatment of tumors in the brain, and the broader use of the system to treat tumors elsewhere in the body has been a more recent development. As a result, physician and patient acceptance of the CyberKnife system as a comprehensive tool for treatment of solid tumor cancers anywhere in the body has not yet been fully demonstrated, particularly as compared to products, systems or technologies that have longer histories in the marketplace. The CyberKnife system is a major capital purchase and purchase decisions are greatly influenced by hospital administrators who are subject to increasing

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pressures to reduce costs. These and other factors may affect the rate and level of the CyberKnife system's market acceptance, including:

the CyberKnife system's price relative to other products or competing treatments;

effectiveness of our sales and marketing efforts;

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

capital equipment budgets of healthcare institutions;

perception by physicians and other members of the healthcare community of the CyberKnife system's safety, efficacy 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 system;

willingness of physicians to adopt new techniques and the ability of physicians to acquire the skills necessary to operate the CyberKnife system;

extent of third-party coverage and reimbursement for procedures using the CyberKnife system;

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

regulatory developments related to manufacturing, marketing and selling the CyberKnife system both within and outside the United States;

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

unfavorable publicity concerning the CyberKnife system or radiation-based treatment alternatives.

If the CyberKnife system is unable to achieve or maintain market acceptance, our business would be harmed.

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

We have incurred net losses in every fiscal year since our inception except during the fiscal years ended June 30, 2009 and 2008. As of June 30, 2009, we had an accumulated deficit of \$120.5 million. We may incur net losses in the future, particularly as we increase our manufacturing, sales and marketing and administrative activities and as we continue our research and development activities. Our ability to maintain long-term profitability is largely dependent on our ability to successfully market and sell the CyberKnife system and to control our costs and effectively manage our growth. We cannot assure you that we will be able to maintain profitability. In the event we fail to maintain profitability, our stock price could decline.

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

Current uncertainty in global economic conditions resulting from the recent disruption in credit markets poses a risk to the overall economy 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 deteriorates significantly, our business could be negatively impacted, including such areas as reduced demand for our products resulting from a slow-down in the general economy, supplier or customer disruptions resulting from tighter credit markets 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.

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In addition, due to the recent tightening of credit markets and concerns regarding the availability of credit, particularly in the United States, some of our customers have been delayed in obtaining, or have not be able to obtain, necessary financing for their purchases of the CyberKnife system or for the construction or renovation of facilities to house CyberKnife systems. To date, these delays have primarily affected customers that were planning to operate free-standing CyberKnife systems, 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 and revenues, and therefore harm our business and results of operations.

***The high unit price of the CyberKnife system, as well as other factors may contribute to substantial fluctuations in our operating results.***

Because of the high unit price of the CyberKnife system, and the relatively small number of units installed each quarter, each installation of a CyberKnife system can represent a significant component of our revenue for a particular quarter. Therefore, if we do not install a CyberKnife system when anticipated, our operating results will vary significantly. 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 system and delaying the required build-outs. These fluctuations and other potential fluctuations mean that you should not rely upon our operating results in any particular period as an indication of future performance. In particular, factors which may contribute to these fluctuations may include:

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

the proportion of revenue attributable to purchases of the CyberKnife system, our shared ownership program and installations associated with 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;

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

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.



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*We experience a long and variable sales and installation cycle, which may result in inconsistent quarterly results.*

The CyberKnife system has a lengthy sales and purchase order cycle because it is a major capital equipment item and requires the approval of senior management at purchasing institutions. 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 system, we negotiate and enter into a definitive purchase contract with the customer. This may take the form of a terms agreement setting forth the business and economic terms of the transaction. Typically, following the execution of the contract, the customer begins the building or renovation of a facility to house the CyberKnife system, which together with the subsequent installation of the CyberKnife 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 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 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 system can be installed, which can result in additional construction and installation delays.

Under our revenue recognition policy, we generally do not recognize revenue attributable to a CyberKnife system purchase until after installation has occurred. For international sales through distributors, we typically recognize revenue when the system is sold through to the end user. Therefore the long sales cycle together with the timing of CyberKnife system shipments and installations may result in significant fluctuations in our reporting of quarterly revenues. Under our current forms of purchase and service contracts, we receive a majority of the purchase price for the CyberKnife system upon installation 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 system acquisition;

construction delay;

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 does not, for any of the reasons above or other reasons proceed with installation of the 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, delays in the installation of CyberKnife systems or customer cancellations would adversely affect our cash flows and revenue, which would harm our results of operations.

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

Our customers rely significantly on reimbursement for CyberKnife 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 appropriate coverage and reimbursement for our products and related procedures. If reimbursement policies or other cost containment measures are instituted in a manner that significantly reduces the coverage for or payment of our products, our existing customers



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may not continue using our product or may decrease their use of our product, and we may have difficulty obtaining new customers. Such actions would likely have a material adverse effect on our operating results.

***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 system. If we are unable to anticipate or keep pace with changes in the marketplace and the direction of technological innovation and customer demands, our products may become less useful or obsolete and our operating results will suffer.***

The 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, chemotherapy or other drugs remain alternatives to the CyberKnife system. Also, we compete directly with traditional radiosurgery systems primarily from Elekta AB (publ), or Elekta, BrainLAB AG, the Integra Radionics business of Integra LifeSciences Holdings Corporation, or Radionics, and Varian Medical Systems, Inc., or Varian.

The market for standard linear accelerators is dominated by three companies: Elekta, Siemens AG and Varian. In addition, TomoTherapy Incorporated markets and sells a radiation therapy product. The CyberKnife system is not typically used to perform traditional radiation therapy and therefore does not usually compete directly with standard medical linacs that perform standard radiation therapy. However, some manufacturers of standard 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 radiosurgery. In addition, many government, academic and business entities are investing substantial resources in research and development of cancer treatments, including surgical approaches, radiation treatment, drug treatment, gene therapy, which is the treatment of disease by replacing, manipulating, or supplementing nonfunctional genes, and other approaches. Moreover, at least one other company has announced that it is developing a product that would be directly competitive with the CyberKnife. 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 system and its 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 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. 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 discovery of new technologies that improve the effectiveness and productivity of the CyberKnife system radiosurgery process;

product coverage and reimbursement from third-party payors, insurance companies and others;



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

published studies supporting the efficacy and safety and long-term clinical benefit of the CyberKnife system;

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

limiting the timing and cost of regulatory approvals;

our ability to attract and retain qualified personnel;

the extent of our patent protection or our ability to otherwise develop proprietary products and processes;

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

obtaining any necessary United States or foreign marketing approvals or clearances.

If the CyberKnife system is not competitive based on these or other factors, our business would be harmed.

***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 provide effective controls and reliable financial reports, our business and operating results could be harmed. Our management determined, as of June 30, 2008 and September 30, 2008, that we had material weaknesses in our internal control over financial reporting and that our disclosure controls and procedures were not effective. We began our remediation efforts in the first half of the fiscal year 2009 and management continued to evaluate the effectiveness of our internal controls over financial reporting through June 30, 2009. We concluded that there were no deficiencies in our internal control over financial reporting that would constitute a material weakness as of that date. Although we are making additional improvements in our internal controls over financial reporting, in future periods we may conclude that we have one or more material weaknesses, and remedying these material weaknesses may require significant additional financial and managerial resources and could result in a loss of investor confidence in our internal controls and financial reporting.

***We may have difficulties in determining the effectiveness of our internal control 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 system sales, our shared ownership program and services. The CyberKnife system is a complex product that contains both hardware and software elements. Since the software component is significant in our solution, we are bound by the software revenue recognition rules for our business. The complexity of the CyberKnife system 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 our historical financial statements, which would likely have a negative impact on our stock price.

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***Our reliance on single source suppliers for critical components of the CyberKnife system 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 system, including the robotic manipulator, imaging plates, treatment table, robotic couch and magnetron, which creates the microwaves for use in the linear accelerator. If any single source suppliers were to cease delivering components to us or fail to provide the components on a timely basis, we might be required to qualify an alternate supplier 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.

We generally do not maintain large volumes of inventory. Furthermore, if we are required to change the manufacturer of a critical component of the CyberKnife system, 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 system could harm our ability to generate revenue, lead to customer dissatisfaction and damage our reputation.

***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.

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 system 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 system, 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

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rights or to defend our patents against challenge could be expensive and time consuming and could divert our management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against a challenge.

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.

In October 2006, January 2007 and February 2007, we received correspondence from American Science and Engineering, Inc., or AS&E, expressing concerns that we may be using certain intellectual property we acquired from AS&E through the HES acquisition in a manner that breaches, or may breach, our contractual obligations under a license agreement with them in certain non-medical fields. We have had limited discussions with AS&E regarding their allegations but as of June 30, 2009, we have not received any further written correspondence from AS&E regarding this issue. The intellectual property at issue relates to the development of a next-generation linac that could be used for medical as well as non-medical purposes. We are developing the technology used in the next-generation linac independently from the intellectual property we obtained from the HES acquisition. While we do not believe our activities breach or violate the terms of the license agreement, we cannot assure you that AS&E will not commence litigation on the grounds that we are in breach of our obligations under the license agreement.

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.

***Because the medical device industry is characterized by competing intellectual property, we may be sued for violating the intellectual property rights of others.***

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 in particular, at least one other company has announced that it is developing a product that would be directly competitive with the CyberKnife. 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 stereotactic radiosurgery to treat solid 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

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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. 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 the funds 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. If we were unable to obtain a license or successfully redesign our system, we might be prevented from 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, our business and operating results could 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 the CyberKnife 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 procedures, defects could result in a number of complications, some of which could be serious and could harm or kill patients. 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. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. 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. A product liability claim, any product recalls or other field actions or excessive warranty claims, whether arising from defects in design or manufacture or otherwise, could negatively affect our sales or require a change in the design, manufacturing process or the indications for which the CyberKnife system may be used, any of which could harm our reputation and business, result in a decline in revenue.

In addition, if a product we designed or manufactured is defective, whether due to design or manufacturing 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. In 2002, we were subject to a product recall in Japan, as a result of a failure of our prior distributor to coordinate product modifications and obtain necessary regulatory approvals in a timely manner. In April 2007, we initiated a product correction at twenty different sites related to a software malfunction of the CyberKnife system. As a result of this software malfunction, we provided affected devices with software upgrades designed to correct the

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problems that have been identified. We have notified the FDA regarding these software upgrades and corrections. We cannot ensure that the FDA will not require that we take additional actions to address the software malfunctions. A required notification 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 or recalls, especially if accompanied by unfavorable publicity 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.

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

Although we believe that the CyberKnife system has 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 system as a means of controlling the growth of cancer at a particular body site. In addition, we have only limited five-year 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 outcomes. Such results could 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.

***The CyberKnife system has 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 system has 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 system is 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 system could fail to increase or could decrease and our growth and operating results would therefore be harmed.

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

Our international sales have increased year-over-year for each of the past three fiscal years. We anticipate that a significant portion of our revenue will continue to be derived from sales of the CyberKnife system in foreign markets and that the percentage of our overall revenue that is derived from these markets will 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;

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changes in foreign regulatory laws governing sales of medical devices;

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 reimbursement for the CyberKnife procedure outside the United States;

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

protectionist laws and business practices that favor local competitors;

risks relating to foreign currency; 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 international operations are also subject to United States laws regarding the conduct of business overseas by U.S. companies. In particular, the U.S. Foreign Corrupt Practices Act, or FCPA, prohibits the provision of illegal or improper inducements to foreign government officials in connection with the obtaining of business overseas. Violations of the FCPA by us or any of our employees or executive officers could subject us or the individuals involved to criminal or civil liability and could therefore 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. 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, as our international sales increase, we may enter into a greater number of transactions denominated in non-U.S. dollars, 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.

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

We depend on a limited number of distributors in our international markets. These international distribution relationships are exclusive by geographic region. We cannot control the efforts and resources our third-party distributors will devote to marketing the CyberKnife system. Our distributors may not be able to successfully market and sell the CyberKnife system, may not devote sufficient time and resources to support the marketing and selling efforts and may not market the CyberKnife system at prices that will permit the product to develop, achieve or sustain market acceptance. If we or our distributors terminate our existing agreements, finding new distributors could be an expensive and time-consuming process and sales could decrease during and after any transition period. 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 system or do not otherwise perform under our distribution agreements, our potential for revenue from international markets may be dramatically reduced, and our business could be harmed.

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*We have limited experience and capability in manufacturing and may encounter manufacturing problems or delays that could result in lost revenue.*

The CyberKnife system is complex, and requires 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 system. In particular, we manufacture compact linacs as a component of the CyberKnife system. 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 system, including problems with quality control and assurance, component supply shortages, increased costs, shortages of qualified personnel 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.

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 processes, controls, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. We are also subject to state requirements and licenses applicable to manufacturers of medical devices. Because our manufacturing processes include 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 unannounced inspections. We have been, and anticipate in the future to be, subject to such inspections. Our failure or the failure of a third-party supplier to pass a QSR inspection or to comply with these and other applicable regulatory requirements could result in disruption of our operations and manufacturing delays. 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. 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 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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***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, operations and research and development staff. Our future success will depend in part on our ability to retain these key employees and to identify, hire and retain additional personnel. Competition for qualified personnel in the medical device industry, particularly in northern California, 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 to hire and retain these persons, and we may be unable to replace key persons if they 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 option 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.

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

The number of our employees increased from 194 as of June 30, 2005 to 458 as of June 30, 2009. In order to implement our business strategy, we expect continued growth in our employee and infrastructure requirements, particularly as we expand our manufacturing and sales and marketing capacities. 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. We also expect to increase the number of sales and marketing personnel as we expand our business. 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.

***Any failure in our physician training efforts could result in lower than expected product sales and potential liabilities.***

A critical component of our sales and marketing efforts is the training of a sufficient number of physicians to properly utilize the CyberKnife system. 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.

***As a result of being a public company, we are incurring increased costs.***

As a newly public company, we have incurred and will continue to incur increased legal, accounting and other expenses that we did not incur as a private company as we are now subject to Securities and Exchange Commission, or SEC, NASDAQ Stock Market and other rules focusing on corporate governance and financial reporting. In particular, we were first required to comply with Section 404 of the Sarbanes-Oxley Act regarding management assessment of internal controls during our 2008 fiscal year and we will be required to do so in future years. As a result, we expect to continue to incur substantial fees and costs for future audits. We also expect these rules and regulations to make



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it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers. We continue to monitor developments with respect to these requirements, but we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

***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 and short-term and long-term investments will be sufficient to meet our anticipated cash needs for at least the next 12 months, the timing and amount of our working capital and capital expenditure requirements may vary significantly depending on numerous factors, including:

market acceptance of our products;

the need to adapt to changing technologies and technical requirements;

the existence of opportunities for expansion; and

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

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. The sale of additional equity securities or convertible debt securities would result in additional dilution to our stockholders. Additional debt would result in increased expenses and could result in covenants that would restrict our operations. We have not made arrangements to obtain additional financing, and we cannot assure you that financing, if required, will be available in amounts or on terms acceptable to use, if at all.

***We may attempt to acquire new businesses, products or technologies, and if we are unable to successfully complete these acquisitions or to integrate acquired businesses, products, 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 rather than through internal development. The identification of suitable acquisition candidates can be difficult, time consuming and costly, and we may not be able to successfully complete identified acquisitions. Furthermore, even if we successfully complete an acquisition, 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. 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 which could harm our existing business. In addition, future acquisitions could result in potentially dilutive issuances of equity securities or the incurrence of debt, contingent liabilities or expenses, or other charges such as in-process research and development, any of which could harm our business and affect our financial results or cause a reduction in the price of our common stock.

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

At June 30, 2009 we had cash and cash equivalents of \$36.8 million. These available cash and cash equivalents are held in accounts managed by third party financial institutions and consist of invested cash and cash in our operating accounts. The invested cash is invested in interest bearing funds managed by third party financial institutions. These funds invest in direct obligations of the government of the United States. To date we have experienced no loss or lack of access to our invested cash or cash equivalents; 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 ("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 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.***

Our manufacturing facility is located in a single location in Sunnyvale, California. We do not maintain a backup manufacturing facility, so we depend on our current facility 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. We carry limited earthquake insurance for inventory only. Such coverage may not be adequate or continue to be available at commercially reasonable rates and terms. In the event of a major earthquake or other disaster affecting our facilities, it 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, and result in large expenses to repair or replace the facilities. In addition, concerns about terrorism or an outbreak of epidemic diseases such as avian influenza or severe acute respiratory syndrome, or SARS, especially in our major markets of North America, Europe and Asia could have a negative effect on travel and our business operations, and result in adverse consequences on our revenues and financial performance.

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

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

The CyberKnife system is a medical device that is 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, reporting, sale, promotion, distribution and shipping. Before a new medical device, or a new use 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 and lengthy. The FDA's 510(k) clearance process usually 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

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be no assurance that a particular device will be approved or cleared by the FDA through either the premarket approval process or 510(k) clearance process.

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 and Medical Device Reporting regulations, which regulate the manufacturing and installation and also require us to report to the FDA if our products cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. 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 system. 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 and uncertain premarket approval process.

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. 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 510(k) clearances for modifications.

We have obtained 510(k) clearances for the CyberKnife system for the treatment of tumors anywhere in the body where radiation is indicated. We have made modifications to the CyberKnife system 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 and requires us to obtain additional premarket approvals or 510(k) clearances for any modifications to the CyberKnife system 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.

In addition, even if the CyberKnife system is not modified, 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 or manufacture. 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. There were a number of recalls during the fiscal year ended June 30, 2009. For example, in October 2008, the Company initiated a recall of the RoboCouch Patient Positioning System, a component part to certain CyberKnife System configurations. Thirteen RoboCouch units were affected by the recall and all repairs were made at the affected customer sites in the quarter ended December 31, 2008. A full list of recalls is available on the FDA website. The costs associated with this recall were not material. Any recall could divert management's attention, cause us to incur significant expenses, harm our reputation with customers, negatively affect our future sales and business, require redesign of the CyberKnife system, 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.

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***We must obtain and maintain regulatory approvals in international markets in which we sell, or seek to sell, our products.***

In order for us to market and sell the CyberKnife system internationally, either through direct sales personnel or through distributors, we must obtain and maintain regulatory clearances applicable to the countries and regions in which we are selling, or are seeking to sell, our products. These regulatory approvals and clearances, and the process required to obtain and maintain them, vary substantially among international jurisdictions. In some jurisdictions, we rely on our distributors to manage the regulatory process and we are dependent on their ability to do so effectively. For example, our regulatory approval in Japan was suspended for a period of twelve months during 2003 as a result of a failure of our former distributor to coordinate product modifications and obtain necessary regulatory clearances in a timely manner. As a result, the CyberKnife system was recalled in Japan and our former Japanese distributor was told to stop selling the CyberKnife system. In response, we retained a regulatory consultant who was not affiliated with our former Japanese distributor and worked with the Japanese Ministry of Health, Labor and Welfare and applied for, and received, approval to sell an updated version of the CyberKnife system under the name of CyberKnife II in Japan. By working with a new distributor, Chiyoda Technol Corporation, we were able to begin distributing the CyberKnife II system in 2004 with no probationary period. In the event that we are unable to obtain and maintain regulatory clearances for the CyberKnife system, including new clearances for system upgrades and use of the system anywhere in the body, in international markets we have entered or desire to enter, our international sales could fail to grow or decline.

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

Even if third-party payors provide adequate coverage and reimbursement for the CyberKnife procedure, adverse changes in third-party payors' general policies toward reimbursement could preclude market acceptance for our products and materially harm our sales and revenue growth. 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 addition, certain federal regulatory changes occur at least annually.

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 a per use, basis. Physician owned entities have increasingly become involved in the acquisition of medical technologies, including the CyberKnife system. 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 system operators may have to modify or restructure their corporate or organizational structures. In addition, certain existing customers that planned to open CyberKnife centers in the United States involving physician ownership could also have to restructure prior to the October 2009 effective date of the new regulations. It is possible that some of these entities may not be able to establish viable models for CyberKnife system operation and may therefore cancel their CyberKnife system purchase agreements. Accordingly, these new regulations could result in cancellations of existing CyberKnife system purchase agreements and could also reduce the attractiveness of medical technology

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acquisitions, including CyberKnife 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.

Future legislative or policy initiatives directed at reducing costs could be introduced at either the federal or state level. We cannot predict the impact on our business of any legislation or regulations related to the healthcare system that may be enacted or adopted in the future.

***We are required to comply with federal and state "fraud and abuse" law, 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 and state 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 knowingly and willfully 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; and

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.

The following arrangements with purchasers and their agents have been identified by the Office of the Inspection 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 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 otherwise inappropriately influenced by sales and marketing considerations; and

other offers of remuneration to purchasers that is expressly or impliedly related to a sale or sales volume, such as "prebates" and "upfront payment," other free or reduced-price goods or

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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, 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 placement and shared ownership program entail the provision of our CyberKnife system 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, and, in the case of the placement program, certain services and upgrades are 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. 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.

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.

**Risks Related to Our Common Stock**

*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 newly public companies can experience extreme price and volume fluctuations. These fluctuations often have been unrelated or out of proportion to the operating performance of these companies. Since we became a public company in February 2007, our stock price has been similarly volatile. These broad market fluctuations may continue and could 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.

Factors affecting the trading price of our common stock include:

regulatory developments related to manufacturing the CyberKnife system;

variations in our operating results;

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

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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;

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.

***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.***

Sales of substantial amounts of our common stock in the public market could reduce the prevailing market prices for our common stock. As of August 21, 2009, we have 56,698,022 shares of common stock outstanding. The lockup agreements related to our initial public offering expired with the opening of the securities markets on September 4, 2007, and as a result a large number of shares of our common stock became eligible for sale.

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.

***Our directors, executive officers and major stockholders own approximately 34.2% of our outstanding common stock as of August 21, 2009, which could limit your ability to influence the outcome of key transactions, including changes of control.***

As of August 21, 2009, our directors, executive officers, and current holders of 5% or more of our outstanding common stock, held, in the aggregate, approximately 34.2% of our outstanding common stock. As a result, a small number of stockholders have voting control and may be able to control the election of directors and the approval of significant corporate transactions. This concentration of ownership may also 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.

***We have implemented anti-takeover provisions that 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;



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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;

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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.

*We have not paid dividends in the past and do not expect to pay dividends in the 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 lease approximately 176,000 square feet of product development, manufacturing and administrative space in three buildings in Sunnyvale, California. Our headquarters building, which is approximately 73,000 square feet, is leased to us until December 2009 and an additional office building, which is approximately 53,000 square feet, is leased to us until May 2010. The manufacturing building is approximately 50,000 square feet and is leased to us until December 2011. We have the right to renew the term of our headquarters lease for one three-year term 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. We sublease approximately 1,350 square feet of this space. The sublease term is through March 2010. This facility is leased to us until September 2010. In addition, we maintain offices in: Pittsburgh, Pennsylvania; Miami, Florida; France; China; Japan; Spain; India; Singapore; Russia; Germany; Turkey; and the United Kingdom.

We believe our current facilities are adequate to meet our current needs, but additional space, including additional radiation-shielded areas in which systems can be assembled and tested, will be required in the future to accommodate anticipated increases in manufacturing needs.

**Item 3. LEGAL PROCEEDINGS**

On July 22, 2009, a securities class action lawsuit was filed in the U.S. District Court for the Northern District of California against us and certain of our current and former directors and officers.

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On August 7, 2009 and August 9, 2009, two securities class action complaints, both similar to the one filed on July 22, 2009, were filed against the same defendants in the same court. All of these complaints generally allege that we and the individual defendants made false or misleading public statements regarding our operations and seeks unspecified monetary damages and other relief.

On August 5, 2009, a purported shareholder derivative lawsuit was filed in Santa Clara County Superior Court against certain of our current and former officers and directors. We are named as a nominal defendant. The complaint generally alleges that the defendants breached their fiduciary duties by misrepresenting and/or failing to disclose material information regarding our business and financial performance, and seeks unspecified monetary damages and other relief.

On September 3, 2009, Best Medical International, Inc., or Best Medical, filed a lawsuit against us claiming we induced certain individuals to leave the employment of Best Medical and join us in order to gain access to Best Medical's confidential information and trade secrets. They are seeking monetary damages and other relief.

From time to time we are involved in legal proceedings arising in the ordinary course of our business.

**Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None.

Table of Contents**PART II****Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES*****Stock Information***

Our common stock is traded on the Nasdaq Global Market under the symbol "ARAY." The high and low sale prices for each quarterly period during our fiscal years ended June 30, 2009 and 2008 are as follows:

	<b>High</b>	<b>Low</b>
<b>Year ended June 30, 2009</b>		
First Quarter	\$ 9.08	\$ 6.72
Second Quarter	\$ 9.00	\$ 3.70
Third Quarter	\$ 6.59	\$ 3.78
Fourth Quarter	\$ 8.35	\$ 4.72
<b>Year ended June 30, 2008</b>		
First Quarter	\$22.92	\$12.50
Second Quarter	\$20.99	\$14.12
Third Quarter	\$18.20	\$ 7.82
Fourth Quarter	\$10.19	\$ 6.86

We have never paid cash dividends on our common stock. Our Board of Directors intends to use any future earnings to support operations and reinvest in the growth and development of our business. There are no current plans to pay out cash dividends to common stockholders in the foreseeable future.

As of August 21, 2009, there were 116 registered stockholders of record of our common stock.

**Stock Performance Graph**

The graph set forth below compares the cumulative total stockholder return on our common stock between February 8, 2007 (the date of our initial public offering) and June 30, 2009, with the cumulative total return of (i) the S&P Healthcare Index and (ii) the Nasdaq Composite Index, over the same period. This graph assumes the investment of \$100.00 on February 8, 2007 in our common stock, the S&P Healthcare Index and the Nasdaq Composite Index, and assumes the reinvestment of dividends, if any. The graph assumes the initial value of our common stock on February 8, 2007 was the closing sales price of \$28.47 per share.

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The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock. Information used in the graph was obtained from Research Data Group, a source believed to be reliable, but we are not responsible for any errors or omissions in such information.

**COMPARISON OF 29 MONTH CUMULATIVE TOTAL RETURN\***

Among Accuray Incorporated, The NASDAQ Composite Index  
And The S&P Healthcare Index

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\$100 invested on February 8, 2007 in stock or on January 31, 2007 in index-including reinvestment of dividends.

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The following table sets forth as of June 30, 2009 certain information regarding our equity compensation plans. All of our equity compensation plans have been approved by our security holders.

	A	B	C
Plan category	Number of securities to be issued upon exercise of outstanding options, warrants, and rights	Weighted-average exercise price of outstanding options, warrants, and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in Column A)(1)
Equity compensation plans approved by security holders	8,455,316	\$ 5.70	2,645,757
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>8,455,316</b>	<b>\$ 5.70</b>	<b>2,645,757</b>

- (1) Includes securities to be issued upon vesting of 519,609 restricted stock units at a weighted average grant date fair value of \$18.15.

**Item 6. SELECTED FINANCIAL DATA**

The following selected consolidated financial data should be read in conjunction with, and are qualified by reference to, our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this Form 10-K. The consolidated statements of operations for the years ended June 30, 2009, 2008, and 2007, and the consolidated balance sheet data at June 30, 2009 and 2008, are derived from, and are qualified by reference to, the consolidated financial statements that have been audited by our independent registered public accounting firm, which are included elsewhere in this Form 10-K. The consolidated statements of operations data for the years ended June 30, 2006 and 2005 and the

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consolidated balance sheet data at June 30, 2007, 2006 and 2005 are derived from our audited consolidated financial statements not included in this Form 10-K.

	Years ended June 30,				
	2009	2008	2007	2006	2005
	(in thousands, except per share data)				
<b>Consolidated Statements of Operations Data:</b>					
Net revenue	\$233,598	\$210,381	\$140,452	\$52,897	\$22,377
Cost of revenue(1)	118,308	103,429	60,413	27,492	11,115
Gross profit	115,290	106,952	80,039	25,405	11,262
<b>Operating expenses:</b>					
Selling and marketing(1)	45,493	42,726	37,889	25,186	16,361
Research and development(1)	35,992	32,880	26,775	17,788	11,655
General and administrative(1)	36,223	32,280	23,915	15,923	8,129
Total operating expenses	117,708	107,886	88,579	58,897	36,145
Loss from operations	(2,418)	(934)	(8,540)	(33,492)	(24,883)
Other income (expense), net	3,082	7,184	3,530	56	(238)
Income (loss) before provision for income taxes and cumulative effect of change in accounting principle	664	6,250	(5,010)	(33,436)	(25,121)
Provision for income taxes	55	867	1,444	258	68
Income (loss) before cumulative effect of change in accounting principle	609	5,383	(6,454)	(33,694)	(25,189)
Cumulative effect of change in accounting principle, net of tax of \$0			838		
Net income (loss) attributable to common stockholders	\$ 609	\$ 5,383	\$ (5,616)	\$ (33,694)	\$ (25,189)
<b>Net income (loss) per common share:</b>					
<b>Basic</b>					
Income (loss) before cumulative effect of change in accounting principle	\$ 0.01	\$ 0.10	\$ (0.21)	\$ (2.11)	\$ (1.76)
Cumulative effect of change in accounting principle			0.03		
Basic net income (loss) per share	\$ 0.01	\$ 0.10	\$ (0.18)	\$ (2.11)	\$ (1.76)
<b>Diluted</b>					
Income (loss) before cumulative effect of change in accounting principle	\$ 0.01	\$ 0.09	\$ (0.21)	\$ (2.11)	\$ (1.76)
Cumulative effect of change in accounting principle			0.03		
Diluted net income (loss) per share	\$ 0.01	\$ 0.09	\$ (0.18)	\$ (2.11)	\$ (1.76)
<b>Weighted average common shares outstanding used in computing net income (loss) per share:</b>					
Basic	55,413	54,531	30,764	15,997	14,283

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Diluted 58,729 60,434 30,764 15,997 14,283

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(1)

Includes stock-based compensation expense as follows:

	Years ended June 30,				
	2009	2008	2007	2006	2005
	(in thousands)				
Cost of revenue	\$2,285	\$1,858	\$1,205	\$ 863	\$ 454
Selling and marketing	\$3,441	\$4,197	\$3,958	\$2,569	\$1,903
Research and development	\$3,190	\$3,059	\$2,448	\$1,574	\$1,157
General and administrative	\$6,545	\$7,785	\$5,016	\$3,237	\$2,812

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	Years ended June 30,		
	2009	2008	2007
<b>Selected Operating Data:</b>			
Number of CyberKnife systems installed per year			
Americas	25	19	22
International	11	12	11
<b>Total</b>	<b>36</b>	<b>31</b>	<b>33</b>

	As of June 30,			
	2009	2008	2007	2006
(in thousands)				
<b>Consolidated Balance Sheet Data:</b>				
Cash and cash equivalents	\$ 36,835	\$ 36,936	\$ 204,830	\$ 27,856
Short-term investments	\$ 64,634	\$ 85,536	\$	\$
Long-term investments	\$ 57,252	\$ 37,014	\$	\$
Deferred cost of revenue	\$ 21,917	\$ 43,391	\$ 61,231	\$ 56,588
Total assets	\$ 274,386	\$ 295,004	\$ 332,109	\$ 138,623
Short-term debt	\$	\$	\$	\$
Deferred revenue	\$ 75,882	\$ 114,175	\$ 154,257	\$ 149,664
Working capital (deficit)	\$ 80,083	\$ 87,744	\$ 148,522	\$ (3,783)
Redeemable convertible preferred stock	\$	\$	\$	\$ 27,504
Stockholders' equity (deficiency)	\$ 153,902	\$ 130,763	\$ 125,443	\$ (80,855)

**Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read the following discussion of our consolidated financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this report. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this report on Form 10-K, particularly in "Risk Factors."*

**Overview**

We have developed the first and only commercially available intelligent robotic radiosurgery system, the CyberKnife system, designed to treat solid tumors anywhere in the body as an alternative to traditional surgery. The CyberKnife system combines continuous image-guidance technology with a compact linear accelerator that has the ability to move in three dimensions according to the treatment plan. Our image-guidance technology continuously acquires images to track a tumor's location and transmits any position corrections to the robotic arm prior to delivery of each dose of radiation. Our compact linear accelerator, or linac, is a compact radiation treatment device that uses microwaves to accelerate electrons to create high-energy X-ray beams to destroy the tumor. This combination, which we refer to as intelligent robotics, extends the benefits of radiosurgery to the treatment of tumors anywhere in the body. The CyberKnife system autonomously tracks, detects and corrects for tumor and patient movement in real-time during the procedure, enabling delivery of precise, high dose radiation typically with sub-millimeter accuracy. The CyberKnife procedure requires no anesthesia, can be performed on an outpatient basis and allows for the treatment of patients that otherwise would not have been treated with radiation or who may not have been good candidates for surgery. In addition, the CyberKnife procedure avoids many of the potential risks and complications that are associated with other treatment options and is more cost effective than traditional surgery.

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In July 1999, we obtained 510(k) clearance from the FDA to market the CyberKnife system for the treatment of tumors and certain other conditions in the head, neck and upper spine. In August 2001, we received FDA clearance for the treatment of tumors anywhere in the body where radiation treatment is indicated. In September 2002, we received a CE mark for the sale of the CyberKnife system in Europe. We received approval for full-body treatment in Japan in June 2008; previously our CyberKnife regulatory approvals in Japan were limited to treatment for indications in the head and neck. The CyberKnife system has also been approved for various indications in Korea, Taiwan, China and other countries. Our customers have reported that over 70,000 patients worldwide have been treated with the CyberKnife system since its commercial introduction.

In the United States, we sell to customers, including hospitals and stand-alone treatment facilities, directly through our sales organization. Outside the United States, we sell to customers in over 80 countries directly and through distributors. We have sales and service offices in Paris, France, Hong Kong, China, Tokyo, Japan, Madrid, Spain, New Delhi, India, Singapore, Moscow, Russia, Munich, Germany, Istanbul, Turkey and London, UK. As of June 30, 2009, we had 55 employees in our sales organization.

Our CyberKnife systems are either sold to our customers or placed with our customers pursuant to our shared ownership program. As of June 30, 2009, we had 176 CyberKnife systems installed at customer sites, including 174 sold and two pursuant to our shared ownership program. Of the 176 systems sold and installed, 115 are in the Americas, 43 are in Asia and 18 are in Europe.

In addition to selling the CyberKnife system to customers through direct sales, we offer alternative arrangements to customers who may not have the financial means to purchase a CyberKnife system. For example, under our shared ownership program, we retain title to the CyberKnife system while the customer has use of the system. Our shared ownership contracts generally require a minimum monthly payment from the customer, and we may earn additional revenue through the use of the system at the site. Generally, minimum monthly payments are equivalent to the revenue generated from treating three to four patients per month, and any revenue received from additional patients is shared between us and the customer. We expect to continue to offer our shared ownership program to new customers.

The shared ownership program typically has a term of five years, during which the customer has the option to purchase the system at pre-determined prices. At June 30, 2009, we had two systems installed under our shared ownership program. During the years ended June 30, 2009, 2008 and 2007, \$3.2 million, \$23.7 million and \$3.0 million, respectively, of total revenue was recognized in the consolidated statements of operations for the sale of two, twelve and one CyberKnife system units, respectively, that were formerly under our shared ownership program. At June 30, 2009 and 2008, \$747,000 and \$2.3 million, respectively, of amounts for extended warranty and training services related to these sold shared ownership units remained recorded as deferred revenue, and will be recognized over the life of the extended warranty service period and as training service obligations are fulfilled.

We manufacture and assemble our CyberKnife systems at our manufacturing facility in Sunnyvale, California. We purchase major components, including the robotic manipulator, the treatment table or robotic couch, the magnetron, which creates the microwaves for use in the linear accelerator, the imaging cameras and the computers, from outside suppliers, some of which are single source. Our reliance on single source suppliers could harm our ability to meet demand for our products in a timely and cost effective manner. However, in most cases, if a supplier were unable to deliver these components, we believe that we would be able to find other sources for these components subject to any regulatory qualifications, if required. We manufacture certain other electronic and electrical subsystems, including the linear accelerator. We then assemble and integrate these components with our proprietary software and perform testing prior to shipment to customer sites.

We generate revenue by selling the CyberKnife system and by providing ongoing services and upgrades to customers following installation of the CyberKnife system. The current United States list price for the CyberKnife system ranges from approximately \$4.2 million to \$5.75 million depending

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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 system, as part of our multiyear service plans. Currently, our most comprehensive service plan is our Diamond Elite multiyear service plan, or Diamond plan. Under our Diamond plan, customers are eligible to receive up to two upgrades per year, when and if available. Through June 30, 2008, the Diamond Plan listed for \$460,000 per year and provided for annual renewals for four years including the one-year warranty period. Effective July 1, 2008, the Diamond plan lists for \$495,000 per year and typically provides for annual renewals for up to five years including the one-year warranty period. The customer may cancel the service plan at any time. As of June 30, 2009, 147 of our customers had purchased service plans. Prior to introducing our Diamond plan, we offered legacy service plans, some of which continue to have future upgrade obligations. In these cases, revenue, including Cyberknife product revenue, is recognized ratably over the remaining life of the contract once all upgrade obligations have been satisfied.

The CyberKnife procedure is currently covered and reimbursed by Medicare and other governmental and non-governmental third-party payors. Medicare coverage currently exists in the hospital outpatient setting and in the free-standing clinic setting. For calendar year 2009, the national unadjusted average Medicare payment rates under Healthcare Common Procedure Coding System, or HCPCS, are \$3,803 under code G0339, the billing code for the first treatment, and \$2,580 under code G0340, the billing code for each of the second thru fifth treatments, approximately 3 and 10 percent less than 2008 payment rates, respectively. Payment for the free-standing clinic setting is governed by the final Medicare Physician Fee Schedule. For 2008 and 2009, payment for HCPCS codes G0339 and G0340 in the freestanding clinic settings for first and subsequent treatments were set by the local Medicare carrier and rates may vary from no payment to a payment rate exceeding the hospital outpatient payment rates. We do not anticipate a significant impact of this rule on our business or results of operations.

In addition to Medicare reimbursement to hospitals and clinics, physicians receive reimbursement for their professional services in the hospital outpatient setting and the free-standing clinic setting. Payment to physicians is based on the Medicare Physician Fee Schedule, and payment amounts are updated on an annual basis. For 2009, the American Medical Association, or AMA, issued guidance that deleted Current Procedural Technology, or CPT, code 61793, the Category I CPT code describing physician work delivering radiosurgery services, and issued the following new CPT codes: 61796, 61797, 61798, 61799, 61800, 63620 and 63621, all relating to neurosurgical procedures that should be used for intracranial and spinal procedures only. Medicare and third-party payors will require the use of these new CPT codes to describe physician services for radiosurgery services using our technology for cranial and spinal procedures. Radiosurgery procedures in other anatomies require physicians to bill unlisted CPT codes with no assigned payment rates. Payment rates for unlisted codes are set by the local Medicare carrier and rates may vary from no payment to rates equivalent to the comparable CPT rates for the 61796 series of CPT codes. The inability of physicians to obtain reimbursement under the new CPT codes or any related unlisted or successor CPT codes could result in a material adverse effect on our business.

Our total net revenue was \$233.6 million, \$210.4 million, and \$140.5 million during the years ended June 30, 2009, 2008, and 2007, respectively. Our net income (loss) was \$609,000, \$5.4 million, and (\$5.6) million during the years ended June 30, 2009, 2008, and 2007, respectively. Our net cash provided by (used in) operating activities was (\$8.0) million, (\$18.0) million, and \$11.6 million during the years ended June 30, 2009, 2008, and 2007, respectively. As of June 30, 2009, our backlog (as further discussed under "Backlog" below) was approximately \$555.9 million.

Our future success will depend in large part on our ability to establish and maintain a competitive position in the market. To compete successfully, we will need to continue to demonstrate the advantages of our products and technologies over alternative procedures, products and technologies, and convince physicians and other healthcare decision makers of the advantages of our products and

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technologies. Our business and sales and installation cycle does not immediately create recognizable revenue. As such, we must invest in sales and marketing activities up to 24 months prior to realizing the revenue from those activities. Our ability to achieve and maintain long-term profitability is largely dependent on our ability to successfully market and sell the CyberKnife system and to control our costs and effectively manage our growth.

**Financial Operations**

*Sales and Installation Cycle*

The CyberKnife system has a relatively long sales and installation cycle because it is a major capital item and requires the approval of senior management at purchasing institutions. The typical sales and installation cycle is up to 24 months in duration and involves multiple steps. Initial steps may include pre-selling activity followed by sales presentations and other sales related activities. After the customer has expressed an intention to purchase a CyberKnife system, we typically negotiate and enter into a terms agreement setting forth the business and economic terms for the sale or acquisition of the CyberKnife system and multiyear service plan. After execution of a terms agreement, the customer typically has a specified time window in which to complete final negotiation of legal terms for the sale or acquisition of the CyberKnife system. We bifurcated the process of negotiating agreements on business and legal terms in order to reduce the level of sales force involvement in negotiation of legal terms and improve the efficiency of our customer contracting process. Nevertheless, many customers, particularly in international markets, choose to negotiate a full purchase agreement at the time of sale. The last step in the sales and installation cycle is installation of the CyberKnife system. Prior to installation, a purchasing institution must typically obtain a radiation device installation permit, and in some cases, a certificate of need, or CON, both of which must be granted by state and local government bodies. Recently, as a result of healthcare cost considerations and sensitivity to the cost of major capital equipment items, some state CON boards have become more aggressive in the evaluation of CON applications. This trend, if it continues, may make the CON process more protracted and uncertain. In addition, the purchasing institution must build a radiation shielded facility or upgrade an existing facility to house the CyberKnife system. We typically receive a deposit at the time the terms agreement or full purchase agreement is entered into, or shortly thereafter, and the remaining balance for the sale of the CyberKnife system upon delivery and installation. The customer also typically selects a service plan at the time of signing a CyberKnife system terms agreement and enters into the service plan agreement prior to installation of the system.

Upon installation, we typically recognize the CyberKnife system sale price less the fair value of one year of service. We recognize the fair value of the first year of service as revenue pro rata over the twelve months following installation. In addition, if the customer has purchased our Diamond plan and assuming annual renewals, we would receive payment at the beginning of each of the second, third, fourth and fifth years of the multiyear service plan and recognize that revenue pro rata over each year.

*Legacy Service Plans*

Prior to introducing our Diamond plan, we offered a Platinum Elite multiyear service plan, or Platinum plan. This legacy service plan was structured so that we have an obligation to deliver two upgrades per year over the course of the multiyear service plan. If we fail to deliver the upgrades, our customers are entitled to receive a refund of up to \$100,000 for each upgrade not offered. To date, no refunds have been required pursuant to the Platinum plan. Beginning in November 2005, we phased out offering this legacy service plan to new customers.

The Platinum plan obligates us to deliver up to two upgrades per year during the term of the contract. We have not established fair value for those future obligations; hence, generally accepted accounting principles in the United States, or GAAP, requires that we cannot begin to recognize any of the revenue derived from the sale of the CyberKnife system or the associated service plan until all upgrade obligations have been fulfilled. Therefore, the payments made by our customers who have our

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legacy Platinum plan are categorized as deferred revenue. Once we fulfill all upgrade obligations with respect to a specific Platinum plan, we ratably recognize the revenue from the sale of the CyberKnife system and the Platinum plan over the remaining life of the contract.

***Upgrades***

Customers may purchase additional upgrades as optional extras prior to the delivery of all originally specified upgrade obligations. Such additional upgrades are considered elements of the original arrangement and associated revenues are deferred until the earlier of: (1) delivery of all elements, or (2) establishment of vendor specific objective evidence, or VSOE, of fair value for all undelivered elements. Sales of additional upgrades after delivery of all specified upgrade obligations, as stated in the original contract, are considered separate arrangements and are recognized once all revenue recognition criteria applicable to the separate arrangements are met.

***Warranty***

All customers purchasing a CyberKnife system receive a one-year warranty. In circumstances where we have VSOE of fair value for all undelivered elements, we recognize the CyberKnife system purchase price minus the fair value of one year of support upon installation, and we recognize the value of one year of support ratably over the twelve months following installation.

***Shared Ownership Program Revenue***

As of June 30, 2009, our shared ownership program involved U.S. sites only. We recognize revenue monthly from our shared ownership program that consists of a minimum monthly payment. We also recognize usage-based revenue in excess of the monthly minimum based on usage reports from our customers. We recognized revenue from our shared ownership program of \$3.7 million, \$10.3 million, and \$10.1 million for the years ended June 30, 2009, 2008, and 2007, respectively. In limited cases, we received nonrefundable upfront payments from shared ownership program customers which are treated as deferred revenue and recognized over the term of the contract.

The CyberKnife system shared ownership systems are recorded within property and equipment and are depreciated over their estimated life of seven years. Depreciation and warranty expense attributable to shared ownership systems are recorded within cost of shared ownership program as they are incurred.

***Japan Customized Service Revenue***

In May and December 2003, we entered into separate contractual arrangements to deliver customized upgrade services to our distributor in Japan for 22 CyberKnife systems previously sold. These customized upgrade services consist of two upgrade levels and are being delivered over an extended period concurrent with the distributor's efforts to coordinate delivery with their end user customers. The obligations under the upgrade programs for these 22 systems were completed as of September 30, 2008. We no longer offer this customized service program and instead offer our standard multiyear service plans.

***International Sales Revenue***

For international sales, we recognize revenue once we have met all of our obligations associated with the purchase agreement, other than for undelivered service elements for which we have VSOE of fair value. In most cases, this occurs after the distributor has shipped the unit to the end user or provided evidence of proof of sell-through to end user, assuming all of our remaining obligations have been satisfied. Payments are sometimes secured through letters of credit. In situations where we are directly responsible for installation, we recognize revenue once we have installed the CyberKnife system and have confirmed performance against specification.

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In situations with legacy plans where we have future obligations related to upgrades that are subject to potential refunds, we defer revenue from the sale and service of the CyberKnife system until the final upgrade has been delivered and accepted. After we have delivered all upgrades associated with a service plan and thus eliminated any contractual right to a refund, we ratably recognize the revenue from the sale of the CyberKnife system and the plan over the remaining life of the contract or until we have VSOE of the fair value of remaining undelivered elements. Net revenue from international customers was \$62.0 million, \$67.8 million, and \$49.3 million for the years ended June 30, 2009, 2008, and 2007, respectively.

***Backlog***

Backlog consists of the sum of deferred revenue, future uninvoiced payments that our customers are contractually committed to make and signed contingent contracts that we believe have a substantially high probability of being booked as revenue from CyberKnife system sale agreements, service plans and minimum payment requirements associated with our shared ownership program. Contingencies associated with contingent contracts that are included within backlog may include state or local government approval of a certificate of need for the installation of a radiosurgery system, approval by the board of directors of the hospital or other purchaser of the system and establishment of financing and formation of legal entities by purchasers of systems and, in the case of terms agreements, final negotiation and agreement upon our legal terms for the purchase or acquisition of the CyberKnife system. In addition, in some cases in which customers negotiate full purchase agreements, these agreements are also subject to certain contingencies. We review, on a quarterly basis with respect to each contingent contract included in backlog, whether customer engagement and progress toward satisfaction of contingencies warrant continued inclusion of the contract within backlog.

At June 30, 2009, our non-contingent backlog, which consists of contracts that have satisfied all contingencies, was approximately \$406.6 million, as compared to \$459.7 million at June 30, 2008. Of this non-contingent backlog, \$203.2 million represented CyberKnife system sales at June 30, 2009, as compared to \$259.0 million at June 30, 2008, and \$203.4 million represented revenue from service plans and other recurring revenues at June 30, 2009, as compared to \$200.7 million at June 30, 2008. The contingent portion of backlog was \$149.3 million at June 30, 2009, as compared to \$187.3 million at June 30, 2008. Total backlog was \$555.9 million at June 30, 2009, of which \$284.8 million represented CyberKnife sales and \$271.1 million represented other recurring revenues, as compared to \$647.0 million at June 30, 2008, of which \$358.6 million represented CyberKnife sales and \$288.4 million represented other recurring revenues. We anticipate that this backlog will be recognized over the next five years as installations occur, upgrades are delivered and services are provided. Although backlog includes contractual commitments from our customers, we may be unable to convert this entire backlog, including the entire non-contingent backlog, into recognized revenue due to factors outside our control.

As we have indicated during fiscal 2009, beginning with fiscal year 2010 we will no longer provide information about contingent backlog. We think that such information is of limited use in building financial models. Orders that we consider to be contingent will not be disclosed until all contingencies have been cleared.

For the current quarter, the data that we have provided as to the amounts of both contingent and non-contingent backlog are based on the methodology that we have used throughout fiscal 2009. As part of the transition in our reporting methods, we also plan to refine our definition of backlog in fiscal 2010 to enhance the usefulness of this information in analyzing and building models of our business. Orders that do not meet those refined criteria will not be reported as backlog. In terms of trends, this is likely to lead to a reduction in backlog in the first quarter of fiscal 2010 from what was previously reported in the fourth quarter of fiscal 2009 wholly apart from the amount of new orders received in the first quarter.

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**Results of Operations**

*Overview*

Our results of operations are divided into the following components:

**Net revenue.** Our net revenue consists primarily of product revenue (revenue derived primarily from the sale of CyberKnife systems and the sale of linacs for other uses), shared ownership program revenue (revenue generated from our shared ownership program), services revenue (revenue generated from sales of service plans and training) and other revenue (revenue from specialized upgrade services for units previously sold in Japan and other specialized services).

**Cost of revenue.** Cost of revenue consists primarily of material, labor and overhead costs. In future periods, we expect cost of revenue may fluctuate from quarter to quarter depending on system configurations ordered by our customers and overall revenue mix.

**Selling and marketing expenses.** Selling and marketing expenses consist primarily of costs for personnel and costs associated with participation in medical conferences, physician symposia, and advertising and promotional activities. We expect marketing expenses may fluctuate from quarter to quarter due to the timing of major marketing events, such as significant trade shows.

**Research and development expenses.** Research and development expenses consist primarily of activities associated with our product development, regulatory, and clinical study arrangements.

**General and administrative expenses.** General and administrative expenses consist primarily of compensation and related costs for finance, in-house legal, and human resources, and external expenses related to accounting, legal and other consulting fees.

**Other income, net.** Other income, net consists primarily of interest earned on our cash and cash equivalents and investments, unrealized losses on our long-term trading securities, net of unrealized gains on our put option, foreign currency transaction gains and losses, losses on fixed asset disposals, and state and local sales and use tax fines and penalties. We expect interest income to decrease in the near future in response to the recent decline in interest rates, offset by unrealized gains on our long-term trading securities, net of unrealized losses on our put option.

*Deferred Revenue Platinum Multiyear Service Plans*

We are required to defer all of the revenue associated with our legacy multiyear service plans, including our Platinum plan, until we have satisfied all of the specified obligations related to the delivery of upgrades to the CyberKnife system during the life of the service plan. This includes deferring revenue for the cash received for the purchase of the CyberKnife system and multiyear service plans until we have delivered all upgrades which the customer is eligible to receive. Once we have satisfied our obligations for delivery of upgrades under the plan, we recognize revenue ratably over the remaining life of the service plan. We have not offered the Platinum service plan to new customers since we phased it out when we introduced our Diamond plan in November 2005. Prior to fiscal 2009 we had installed the final upgrades and recognized all revenue on systems sold under Gold agreements. As of the end of June 2009 we had installed the final upgrade on all but one system sold under Platinum agreements. We recognized approximately \$60 million of revenue related to these Platinum agreements in fiscal 2009. We anticipate that we will install final upgrades in the remaining Platinum system and recognize the balance of remaining deferred Platinum revenue over the next two years, with approximately \$24 million in fiscal 2010 and approximately \$4 million in fiscal 2011.

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	Years ended June 30,		
	2009	2008	2007
	(in thousands)		
Net revenue	\$ 233,598	\$ 210,381	\$ 140,452
Products	\$ 159,257	\$ 152,374	\$ 110,320
Shared ownership program	\$ 3,651	\$ 10,262	\$ 10,090
Services	\$ 66,344	\$ 38,808	\$ 16,860
Other	\$ 4,346	\$ 8,937	\$ 3,182

Total net revenue for the year ended June 30, 2009 increased \$23.2 million from the year ended June 30, 2008. During the year ended June 30, 2009, 36 CyberKnife systems were installed, of which 35 were sold and one was attributable to our shared ownership program, compared to 31 systems installed, including 27 units sold and four attributable to our shared ownership program during the year ended June 30, 2008.

Excluding revenue recognized for systems sold under our Platinum plan, we recognized \$123.7 million of product revenue in fiscal 2009, associated with 40 CyberKnife systems, which included 38 units sold and two units purchased out of in our shared ownership program. By comparison, during fiscal 2008, we recognized product revenue of \$130.9 million associated with 46 CyberKnife systems, which included 34 units sold and 12 units purchased out of our shared ownership program. The decrease in fiscal 2009 is due primarily to the sale in fiscal 2008 of twelve CyberKnife systems that had been in our shared ownership program for an aggregate purchase price of \$23.7 million offset partially by the increase from 34 to 38 units sold not related to our shared ownership program.

Excluding revenue recognized for systems sold under our Platinum plan, we recognized non-Platinum service revenue of \$41.9 million for the year ended June 30, 2009, which increased approximately \$15.5 million from the year ended June 30, 2008, due to the continued growth in our installed base under service plans. As of June 30, 2009 and 2008, 123 and 77 of our customers, respectively, had purchased non-Platinum service plans.

We recognized \$60.1 million of revenue in fiscal 2009 from systems sold under our Platinum plan, \$35.6 million for product revenue and \$24.5 million for service revenue. We recognized \$34.0 million of revenue in fiscal 2008 from systems sold under our Platinum plan, \$21.5 million for product revenue and \$12.5 million for service revenue. By the end of June 2009 we had satisfied all upgrade delivery obligations on 29 of the 30 units sold under our Platinum plan. Once all upgrade delivery obligations have been satisfied, revenue is recognized over the remaining term of the contract service term. We anticipate that revenue recognized from systems sold under our Platinum plan will decline to approximately \$24 million in 2010 and \$4 million in 2011.

Shared ownership program revenue for the year ended June 30, 2009 decreased approximately \$6.6 million from the year ended June 30, 2008, primarily due to the sale of 16 CyberKnife systems through the year ended June 30, 2009 that had been in our shared ownership program. We anticipate revenue from our shared ownership program will decrease in future periods due to the sale of the shared ownership systems through June 30, 2009.

Revenue from upgrade services in Japan, classified as "Other revenue" in our consolidated statements of operations for the year ended June 30, 2009, decreased approximately \$4.6 million from the year ended June 30, 2008 due to a decrease in upgrade services provided to our installed systems in Japan.

Total net revenue for the year ended June 30, 2008 increased \$69.9 million from the year ended June 30, 2007. During the year ended June 30, 2008, we installed 31 CyberKnife systems, including 27



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units sold and four attributable to our shared ownership program. During the year ended June 30, 2007, 33 CyberKnife systems were installed, of which 31 units were sold and two units were attributable to our shared ownership program.

Excluding revenue recognized under our Platinum plan during the year ended June 30, 2008, we recognized product revenue of \$130.9 million associated with 46 CyberKnife systems, which included 34 units sold and twelve units sold that had been in our shared ownership program. During the year ended June 30, 2007, we recognized product revenue of \$104.0 million associated with 32 CyberKnife systems, which included 31 units sold and one unit that had been in our shared ownership program. The increase in product revenue was primarily attributable to the sale of twelve CyberKnife systems that had been in our shared ownership program for an aggregate purchase price of \$23.7 million during the year ended June 30, 2008. Also, during the year ended June 30, 2008, we satisfied all revenue recognition criteria for seven units previously sold to a distributor in China and recognized \$13.1 million of product revenue related to these units.

We recognized non-Platinum service revenue of \$26.3 million for the year ended June 30, 2008 which increased approximately \$11.8 million from the year ended June 30, 2007, primarily due to the continued growth in our installed base under service plans. As of June 30, 2008 and 2007, 77 and 45 of our customers, respectively, had purchased non-Platinum service plans.

For system units attributable to our Platinum plan, we recognized revenue of \$34.0 million of revenue recognized from 20 system units, of which \$21.5 million was attributable to product revenue and \$12.5 million was attributable to service revenue. During the year ended June 30, 2007, we recognized revenue of \$8.6 million from 12 system units attributable to our Platinum plan, of which \$6.3 million was attributable to product revenue and \$2.3 million was attributable to service revenue.

Shared ownership program revenue for the year ended June 30, 2008 remained relatively consistent from the year ended June 30, 2007.

Revenue from upgrade services in Japan, classified as "Other revenue" in our consolidated statements of operations for the year ended June 30, 2008, increased approximately \$5.8 million from the year ended June 30, 2007 due to an increase in upgrade services provided to our installed systems in Japan.

**Gross profit**

	Years ended June 30,					
	2009		2008		2007	
	(Dollars in thousands)	(% of net revenue)	(Dollars in thousands)	(% of net revenue)	(Dollars in thousands)	(% of net revenue)
Gross profit	\$ 115,290	49.4%	\$ 106,952	50.8%	\$ 80,039	57.0%
Products	\$ 90,353	56.7%	\$ 85,191	55.9%	\$ 66,957	60.7%
Shared ownership program	\$ 2,876	78.8%	\$ 7,745	75.5%	\$ 7,453	73.9%
Services	\$ 21,753	32.8%	\$ 11,943	30.8%	\$ 4,591	27.2%
Other	\$ 308	7.1%	\$ 2,073	23.2%	\$ 1,038	32.6%

Gross profit as a percentage of net revenue for the year ended June 30, 2009 decreased slightly from the year ended June 30, 2008. This decrease is attributable to increases in the mix of the proportion of services revenue as a percentage of total net revenues, which have higher costs of revenue as compared to product revenue and decrease in shared ownership revenues as a percentage of total net revenues, which have lower costs of revenue as compared to product revenue. The increase in service revenue margins was attributable mainly to an increase in platinum service margins due to high margins on five Platinum systems that were fully recognized during the year ended June 30, 2009, in accordance with the final upgrades being installed at these sites during the final period of the service contract term, compared to one site that was fully recognized during the year ended June 30, 2008.

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Shared ownership program revenue as a percentage of net revenues for the year ended June 30, 2009 decreased primarily due to the sale of two CyberKnife systems that had been in our shared ownership program during the year ended June 30, 2009 compared to the sale of 12 CyberKnife systems that had been in our shared ownership program during the year ended June 30, 2008.

Gross profit as a percentage of net revenue for the year ended June 30, 2008 decreased from the year ended June 30, 2007 due mainly to a decrease in margins for product revenues plus an increase in service revenues, which have high costs of revenue. The decrease in products revenue margins was attributable mainly to an increase in sales of CyberKnife systems that were previously in our shared ownership program and an increase in CyberKnife system shipments through our distributor channel during the year ended June 30, 2008, both of which typically have lower gross margins than conventional CyberKnife system sales. We recognized revenue associated with the sale of 12 and one CyberKnife systems that had been in our shared ownership program during the years ended June 30, 2008 and 2007, respectively. Also during the year ended June 30, 2008, we satisfied all revenue recognition criteria for seven systems previously sold to a distributor in China and recognized \$13.1 million of non-recurring product revenue related to these systems. No such systems were sold during the year ended June 30, 2007.

**Selling and marketing expenses**

	Years ended June 30,		
	2009	2008	2007
	(Dollars in thousands)		
Sales and marketing	\$45,493	\$42,726	\$37,889
<i>% of net revenue</i>	19.5%	20.3%	27.0%

Selling and marketing expenses for the year ended June 30, 2009 increased \$2.8 million from the year ended June 30, 2008. The increase was primarily attributable to an increase of \$1.8 million in sales commissions due to an increase in sales and previously paid amounts that were expensed for employees terminated during the year ended June 30, 2009, an increase of \$468,000 in expenses primarily related to contribution made to the CyberKnife Society, and an increase of \$462,000 in severance related charges recorded under the Plan.

Selling and marketing expenses for the year ended June 30, 2008 increased \$4.8 million from the year ended June 30, 2007. The increase was primarily attributable to an increase of \$3.1 million in salary and related costs, including stock-based compensation, largely due to increased headcount and an increase of \$1.7 million in facility and operational costs as a result of the continuing expansion of our international sales presence.

**Research and development expenses**

	Years ended June 30,		
	2009	2008	2007
	(Dollars in thousands)		
Research and development	\$35,992	\$32,880	\$26,775
<i>% of net revenue</i>	15.4%	15.6%	19.1%

Research and development expenses for the year ended June 30, 2009 increased \$3.1 million from the year ended June 30, 2008. The increase was primarily attributable to an increase of \$1.4 million in spending on clinical development studies primarily for lung and prostate, an increase of \$1.4 million in costs related to additional quality assurance and technical publications activities, and an increase of \$287,000 in severance related charges recorded under the Plan.

Research and development expenses for the year ended June 30, 2008 increased \$6.1 million from the year ended June 30, 2007. The increase was primarily attributable to an increase of \$5.2 million in salary and related costs, including stock-based compensation, largely due to increased headcount, an

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increase of \$1.3 million in consulting and outside services related to increased research and development activity for various CyberKnife projects, and an increase of \$819,000 in non-inventory materials and other operational costs as a result of increasing our research and development activity for various CyberKnife projects.

**General and administrative expenses**

	<b>Years ended June 30,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
	<b>(Dollars in thousands)</b>		
General and administrative	\$36,223	\$32,280	\$23,915
<i>% of net revenue</i>	<i>15.5%</i>	<i>15.3%</i>	<i>17.0%</i>

General and administrative expenses for the year ended June 30, 2009 increased \$3.9 million from the year ended June 30, 2008. The increase was primarily attributable to an increase of \$2.4 million in severance benefits due to employee separation costs and costs recorded under the Plan, an increase of \$428,000 in outside consulting services related mainly to expenses recorded for Morphormics, Inc. ("Morphormics"), our variable interest entity which we are required to consolidate in our financial results subsequent to the acquisition in July 2008, an increase of \$883,000 in legal fees and accounting, audit and tax fees mainly as a result of the investigation of the handling and accounting for certain inventory items conducted during the year ended June 30, 2009, and an increase of \$444,000 in bad debt expense.

General and administrative expenses for the year ended June 30, 2008 increased \$8.4 million from the year ended June 30, 2007. The increase was primarily attributable to an increase of \$6.9 million in salary and related costs, including stock-based compensation, largely due to increased headcount and an increase in stock-based compensation charges associated with option grants to purchase common stock, and an increase of \$1.5 million in other corporate administration costs from being a public company for all of fiscal 2008 compared to five months in fiscal 2007.

Table of Contents**Other income, net**

	Years ended June 30,		
	2009	2008	2007
	(Dollars in thousands)		
Other income, net	\$3,082	\$7,184	\$3,530
<i>% of net revenue</i>	<i>1.3%</i>	<i>3.4%</i>	<i>2.5%</i>

Other income, net for the year ended June 30, 2009 decreased \$4.1 million from the year ended June 30, 2008 primarily due to a decrease of \$3.8 million in interest income due to a decrease in both the average daily balances kept in interest bearing accounts and the interest rates earned on amounts kept in those accounts during the year ended June 30, 2009 compared to the year ended June 30, 2008 and net unrealized losses of \$319,000 related to the change in fair value of our trading securities.

Other income, net for the year ended June 30, 2008 increased \$3.6 million from the year ended June 30, 2007. The increase was primarily due to higher average daily balances kept in interest bearing accounts, as a result of receiving proceeds from our initial public offering, or IPO, in February 2007, for 12 months during the year ended June 30, 2008 compared to only five months during the year ended June 30, 2007.

**Cumulative effect of change in accounting principle.** For the year ended June 30, 2007, we recorded the cumulative effect of a change in accounting principle of \$838,000 related to our adoption effective July 1, 2006, of Statement of Financial Accounting Standards, or SFAS No. 123R, *Share-Based Payment, an amendment of FASB Statements Nos. 123 and 95*, ("SFAS 123R"), related to our accounting for stock-based compensation. We had previously accounted for our stock-based compensation expense in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation*, ("SFAS 123"), which permitted us to either estimate forfeitures in determining our stock-based compensation expense or to adjust the expense at the time forfeitures occurred. SFAS 123R requires that we estimate forfeitures. Since we had previously adjusted our stock-based compensation expense at the time forfeitures occurred, we have included in our consolidated statement of operations for the year ended June 30, 2007 the cumulative effect of a change in accounting principle for the adjustment to reflect forfeitures related to compensation expense recorded in prior periods.

**Provision for income taxes**

	Years ended June 30,		
	2009	2008	2007
	(Dollars in thousands)		
Provision for income taxes	\$ 55	\$867	\$1,444
<i>% of net revenue</i>	<i>0.02%</i>	<i>0.4%</i>	<i>1.0%</i>

The provision for income taxes for the year ended June 30, 2009 decreased \$812,000 from the year ended June 30, 2008. In fiscal 2009, we recorded a decrease in foreign taxes of \$142,000 as compared to the prior year as the result of changes in our jurisdictional mix of income. We also recorded a decrease in federal and state taxes of \$670,000 as compared to the prior year due to the carryback of a current year net operating loss to the prior year.

The provision for income taxes for the year ended June 30, 2008, decreased \$577,000 from the year ended June 30, 2007. In fiscal 2008, we recorded a decrease in foreign taxes of \$58,000 as compared to the prior year as the result of the recognition of tax benefits associated with the utilization of foreign net operating losses. We also recorded a decrease in federal and state alternative minimum taxes, or AMT, of \$519,000 primarily due to a decrease in taxable income resulting from an increase in stock option deductions available under SFAS 123R in the current year.

As of June 30, 2009, we had federal and state net operating loss carryforwards of \$49.4 million and \$32.4 million, respectively. These federal and state net operating loss carryforwards are available to

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offset against future taxable income, if any, in varying amounts and will begin to expire beginning in 2019 and 2015 for federal and state purposes, respectively. Such net operating loss carryforwards include tax benefits from employee option exercises in excess of the stock-based compensation expense that has been recognized for those awards in accordance with SFAS 123R. We will record approximately \$7.3 million as a credit to additional paid in capital if and when such excess benefits are ultimately realized. We also had federal and state research and development tax credit carryforwards of approximately \$3.3 million and \$4.1 million, respectively. If not utilized, the federal tax credit carryforwards will begin to expire in 2019, while the state tax credits have no expiration date. In addition, among other matters, realization of the entire deferred tax asset is dependent on our ability to generate sufficient taxable income prior to the expiration of the carryforwards. Due to the inconsistent history of net operating income as adjusted for permanent differences, we cannot conclude that the net domestic deferred tax assets will more likely than not be realized. Accordingly, we have recorded a valuation allowance against our domestic net deferred tax assets.

At June 30, 2009, there was no provision for U.S. income tax for undistributed earnings as it is currently our intention to reinvest these earnings indefinitely in operations outside the U.S. If repatriated, these earnings could result in a tax expense at the current U.S. Federal statutory tax rate of 35%, subject to available net operating losses and other factors. Subject to limitation, tax on undistributed earnings may also be reduced by foreign tax credits that may be generated in connection with the repatriation of earnings.

We adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109*, ("FIN 48"), on July 1, 2007. See Note 9 to the Consolidated Financial Statements for a detail description.

**Stock-Based Compensation Expense**

Effective July 1, 2006, we adopted SFAS 123R using the modified prospective method under which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123R for all share-based payments granted or modified after the effective date and (b) based on the previous requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date. SFAS 123R also requires the benefits of tax deductions in excess of recognized compensation cost be reported as a financing cash flow, rather than as an operating cash flow as required under previous literature.

SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary in subsequent periods if actual forfeitures differ from initial estimates. Stock-based compensation expense was recorded net of estimated forfeitures for the years ended June 30, 2009, 2008 and 2007 such that expense was recorded only for those stock-based awards that are expected to vest. For the years ended June 30, 2009, 2008 and 2007, we recorded \$15.5 million, \$16.9 million and \$12.6 million, respectively, of stock-based compensation expense, net of estimated forfeitures, for stock options, 2007 Employee Stock Purchase Plan, or ESPP, options and restricted stock units granted to employees. During the years ended June 30, 2009, we recognized \$929,000 of stock-based compensation expense related to accelerated vesting of stock options and RSUs in conjunction with non-recurring employee separation costs, included in the total compensation amounts above. No such expenses were recognized during the years ended June 30, 2008 and 2007.

For the year ended June 30, 2007, we recorded the cumulative effect of a change in accounting principle of \$838,000 related to the adoption of SFAS 123R since we had previously adjusted stock-based compensation expense at the time forfeitures occurred in accordance with SFAS 123. The cumulative effect of this change in accounting principle reflects estimated forfeitures related to periods prior to July 1, 2006.

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As of June 30, 2009, there was approximately \$30.9 million, net of estimated forfeitures, of unrecognized compensation cost related to unvested stock options, ESPP options and restricted stock units which we expect to be recognized over a weighted average period of 2.00 years.

During the years ended June 30, 2009, 2008, and 2007, we recognized \$0, \$114,000, and \$171,000, respectively, of stock-based compensation expense for stock options granted to non-employees. For certain stock option grants, we made modifications to the option terms. These modifications included extensions of the vesting period and acceleration of vesting.

**Liquidity and Capital Resources**

At June 30, 2009, we had \$36.8 million in cash and cash equivalents. During the year ended June 30, 2009, cash and cash equivalents decreased by \$101,000. This decrease was primarily attributable to cash used in operating activities of \$8.0 million, and was partially offset by cash provided by investing activities of \$1.9 million and cash provided by financing activities of \$5.8 million. In November 2008, we obtained a line of credit with UBS. The line of credit is due on demand and allows for borrowings of up to 75% of par value of ARS. No borrowings were outstanding as of June 30, 2009. We believe that we have sufficient cash resources and anticipated cash flows to continue in operation for at least the next 12 months.

*Years ended June 30, 2009, 2008, and 2007*

**Cash Flows From Operating Activities.** Net cash used in operating activities was \$8.0 million for the year ended June 30, 2009. Our net income of \$609,000 during fiscal year 2009 was offset by an increase in accounts receivable of \$2.8 million, a decrease in deferred revenue, net of deferred cost of revenue, of \$16.5 million, and an increase in inventories of \$9.7 million. The increase in accounts receivable was primarily a result of the timing difference between the shipment of products and the receipt of customer payment. The decrease in deferred revenue, net of deferred cost of revenue, was primarily a result of the recognition of revenue previously deferred for systems sold under our Platinum plan offset partially by differences between invoicing customers for products and services and the recognition of the invoicing as revenue. The increase in inventories was due primarily to an increase in our business volume and the increase in our worldwide installed base and associated service inventory requirements. Positive cash flow from working capital changes include an increase in accrued liabilities of \$4.9 million of which \$1.3 million was related to the inventory investigation in the first quarter and the balance was due to the timing differences between the receipt of goods and service and vendor payments. Non-cash charges included \$15.5 million of stock-based compensation, \$2.7 million of charges for write-downs of inventory and \$6.7 million of depreciation and amortization expense.

Net cash used in operating activities was \$18.0 million for the year ended June 30, 2008. Our net income of \$5.4 million during fiscal year 2008 was offset by an increase in accounts receivable of \$23.9 million, a decrease in deferred revenue, net of deferred cost of revenue, of \$13.8 million, and an increase in inventories of \$10.4 million. The increase in accounts receivable was primarily a result of the timing difference between the shipment of products and the receipt of customer payment. The decrease in deferred revenue, net of deferred cost of revenue, was primarily a result of the timing of differences between invoicing customers under service contracts and the recognition of revenue over the contractual service period, the continued satisfaction of specified obligations to begin revenue recognition for units covered by our Platinum plans and the recognition of revenue and cost of revenue for units previously shipped to a distributor in China. The increase in inventories was due primarily to an increase in our business volume. Non-cash charges included \$16.9 million of stock-based compensation and \$7.7 million of depreciation and amortization expense.

Net cash provided by operating activities was \$11.6 million for the year ended June 30, 2007. Our net loss of \$5.6 million during fiscal year 2007 was offset by non-cash charges of \$6.2 million of depreciation and amortization expense, and \$12.6 million of stock-based compensation offset by the cumulative effect of a change in accounting principle of \$838,000 due to the adoption of SFAS 123R.

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Other significant working capital changes that contributed to positive cash flows provided by operations in fiscal 2007 included an increase in accounts payables of \$9.5 million, an increase in accrued liabilities of \$3.1 million and an increase in deferred revenue, net of deferred cost of revenue of \$1.9 million. The increase in accounts payable was due to increases in the volume of our business and the increase in accrued liabilities was due to increases in compensation related accruals due to increased headcount. The increase in deferred revenue, net of deferred cost of revenue, was primarily a result of the timing differences between invoicing customers under service contracts and the recognition of revenue over the contractual service period, and the continued satisfaction of specified obligations to begin revenue recognition for units covered by our Platinum service plans. Offsets to positive cashflow included an increase in inventories of \$8.8 million, an increase in prepaid expenses and other current assets of \$5.1 million, and a decrease in customer advances of \$1.5 million due to an increase in the number of systems shipped.

**Cash Flows From Investing Activities.** Net cash provided by investing activities was \$1.9 million for the year ended June 30, 2009 and was attributable to a decrease in restricted cash of \$4.3 million and net marketable security activities of \$1.8 million, which consisted of \$157.7 million of sales and maturities of marketable securities offset by \$155.9 million in purchases. We also used \$4.2 million of cash for purchases of property and equipment. The decrease in restricted cash is due to the release of amounts related to contracts with customers requiring that deposited cash amounts be secured via letter of credit until delivery of the CyberKnife unit occurs.

Net cash used in investing activities was \$133.4 million for the year ended June 30, 2008 and was attributable to net investment of our excess cash and cash equivalents in higher yielding investment accounts of \$123.6 million, which consisted of \$177.7 million of purchases and \$54.1 million of sales and maturities of marketable securities, \$5.0 million of purchases of property and equipment, and \$4.8 million of restricted cash activity. The increase in investment activity during the year ended June 30, 2008 is due primarily to the January 2008 investment of proceeds from our initial public offering in February 2007. The increase in restricted cash is due to arrangements in contracts with customers requiring that deposited cash amounts be secured via letter of credit until delivery of the CyberKnife unit occurs.

Net cash used in investing activities was \$7.5 million for the year ended June 30, 2007, which was primarily due to purchases of property and equipment of \$7.2 million.

Purchases of property and equipment in all periods were due to the expansion of our facilities and operations.

**Cash Flows From Financing Activities.** Net cash provided by financing activities was \$5.8 million for the year ended June 30, 2009 and was primarily attributable to proceeds from the exercise of common stock options and the purchase of common stock under our ESPP.

Net cash used in financing activities was \$16.2 million for the year ended June 30, 2008 and was primarily attributable to stock repurchases of \$24.0 million, partially offset by proceeds from the exercise of common stock options of \$4.4 million and proceeds from our ESPP of \$3.0 million.

Net cash provided by financing activities was \$172.9 million for the year ended June 30, 2007 and was primarily attributable to net proceeds from our initial public offering of \$170.6 million and proceeds from the exercise of common stock options of \$1.7 million.

***Operating Capital and Capital Expenditure Requirements***

Our future capital requirements depend on numerous factors. These factors include but are not limited to the following:

revenue generated by sales of the CyberKnife system, our shared ownership program and service plans;

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costs associated with our sales and marketing initiatives and manufacturing activities;

rate of progress and cost of our research and development activities;

costs of obtaining and maintaining FDA and other regulatory clearances of the CyberKnife system;

effects of competing technological and market developments; and

number and timing of acquisitions and other strategic transactions.

We believe that our current cash and cash equivalents will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least 12 months. If these sources of cash and cash equivalents are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain additional credit facilities. The sale of additional equity or convertible debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock and could contain covenants that would restrict our operations. Additional financing may not be available at all, or in amounts or on terms acceptable to us. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned product development and marketing efforts.

**Contractual Obligations and Commitments**

The following table is a summary of our non-cancelable contractual cash obligations, net of sublease income as of June 30, 2009:

	Total	Less than 1 year	Payments due by period		More than 5 years
			1 - 3 years	3 - 5 years	
			(in thousands)		
Operating leases	\$ 7,507	\$ 4,012	\$ 2,964	\$ 531	\$
Sublease income	\$ (167)	\$ (167)	\$	\$	\$
<b>Total</b>	<b>\$ 7,340</b>	<b>\$ 3,845</b>	<b>\$ 2,964</b>	<b>\$ 531</b>	<b>\$</b>

**Off Balance Sheet Arrangements**

We do not have any off balance sheet arrangements.

**Inflation**

We do not believe that inflation has had a material impact on our business and operating results during the periods presented.

**Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as revenue and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from those estimates under different assumptions or conditions.





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Our significant accounting policies are more fully described in the notes to our consolidated financial statements included elsewhere in this report. We believe the following are our critical accounting policies including the more significant estimates and assumptions used in preparation of our consolidated financial statements.

***Revenue Recognition***

We earn revenue from the sale of our products, our shared ownership program, and the provision of related services, which can include installation services, post-contract customer support, or PCS, training and consulting. Our products and upgrades to those products include software that is essential to the functionality of the products and accordingly, we account for the sale of our products pursuant to Statement of Position No. 97-2, *Software Revenue Recognition*, or SOP 97-2, as amended. We record our revenues net of any value added or sales tax. From time to time, we introduce customers to third party financing organizations. No amounts received from these third party financing organizations are at risk.

We recognize product revenues for sales of the CyberKnife system, replacement parts and accessories when there is persuasive evidence of an arrangement, the fee is fixed or determinable, collection of the fee is probable and delivery has occurred as prescribed by SOP 97-2. Payments received in advance of product shipment are recorded as customer advances and are recognized as revenue or deferred revenue upon product shipment or installation.

For arrangements with multiple elements, we allocate arrangement consideration to services and PCS based upon VSOE of fair value of the respective elements. VSOE of fair value for the services element is based upon our standard rates charged for the products or services when such products or services are sold separately or based upon the price established by management having the relevant authority when that service is not yet being sold separately. When contracts contain multiple elements, and VSOE of fair value exists for all undelivered elements, we account for the delivered elements, principally the CyberKnife system, based upon the "residual method" as prescribed by SOP No. 98-9, *Modification of SOP No. 97-2 with Respect to Certain Transactions*, or SOP 98-9. If VSOE of fair value does not exist for all the undelivered elements, all revenue is deferred until the earlier of: (1) delivery of all elements, or (2) establishment of VSOE of fair value for all undelivered elements.

*CyberKnife Sales with Legacy Service Plans*

For sales of CyberKnife systems with PCS arrangements that include specified or committed upgrades for which we have not established VSOE of fair value, all revenue is deferred until the specified or committed upgrades are delivered. In such cases, once all upgrade obligations have been delivered, all deferred revenue is recognized ratably over the remaining life of the PCS arrangement.

Sales of additional upgrades as optional extras prior to the delivery of all originally specified upgrade obligations are considered additional elements of the original arrangement and associated revenues are deferred and accounted for as described above. Sales of additional upgrades after delivery of all specified upgrade obligations, as stated in the original contract, are recognized once all revenue recognition criteria applicable to those arrangements are met.

*CyberKnife Sales with Nonlegacy Service Plans*

In fiscal year 2006, we began selling CyberKnife systems with PCS contracts that only provide for upgrades when and if they become available. We have established VSOE of the fair value of PCS in these circumstances. For arrangements with multiple elements that include the CyberKnife system, installation services, training services and a PCS service agreement, we recognize the CyberKnife system and installation services revenue following installation and acceptance of the system by application of the residual method as prescribed in SOP No. 98-9 when VSOE of fair value exists for all undelivered elements in the arrangement, including PCS.

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*Other Revenue-Japan Upgrade Services*

Other revenue primarily consists of upgrade revenues related to the sale of specialized services specifically contracted to provide current technology capabilities for units previously sold through a distributor into the Japan market. The upgrade programs include elements where VSOE of fair value has not been established for the PCS. As a result, associated revenues are deferred and recognized ratably over the term of the PCS arrangement, generally four years.

*PCS and Maintenance Services*

Service revenue for providing PCS, which includes warranty services, extended warranty services, unspecified when and if available product updates and technical support is deferred and recognized ratably over the service period, generally one year, until no further obligation exists. At the time of sale, we provide for the estimated incremental costs of meeting product warranty if the incremental warranty costs are expected to exceed the related service revenues. Training and consulting service revenues, that are not deemed essential to the functionality of the CyberKnife system, are recognized as such services are performed.

Costs associated with providing PCS and maintenance services are expensed when incurred, except when those costs are related to units where revenue recognition has been deferred. In those cases, the costs are deferred until the recognition of the related revenue and are expensed over the period of revenue recognition.

*Distributor Sales*

Sales to third party distributors are evidenced by distribution agreements governing the relationships together with binding purchase orders or signed quotations on a transaction-by-transaction basis. We record revenues from sales of CyberKnife systems to distributors based on a sell-through method where revenue is only recognized upon shipment of the product to the end user customer or we are provided evidence of proof of sell-through to the end user, and once all revenue recognition criteria are met including completion of all our obligations under the terms of the purchase order. For sales of upgrades and accessories to distributors, revenue is recognized on either a sell-through or sell-in basis, depending upon the terms of the purchase order and once all revenue recognition criteria are met. These criteria require that persuasive evidence of an arrangement exists, the fees are fixed or determinable, collection of the resulting receivable is probable and there is no right of return.

Our agreements with customers and distributors generally do not contain product return rights.

We assess the probability of collection based on a number of factors, including past transaction history with the customer and the credit-worthiness of the customer. We generally do not request collateral from our customers. If we determine that collection of a fee is not probable, we will defer the fee and recognize revenue upon receipt of cash.

*Shared Ownership Program*

We also enter into arrangements under our shared ownership program with certain customers. Under the terms of such program, we retain title to our CyberKnife system, while the customer has use of the product. We generally receive a minimum monthly payment and earn additional revenues from the customer based upon their use of the product. We may provide unspecified upgrades to the product during the term of each program when and if available. Upfront, non-refundable payments from the customer are deferred and recognized as revenue over the contractual period. Revenues from our shared ownership program are recorded as they become earned and receivable and are included within shared ownership program revenues in the consolidated statements of operations.

The CyberKnife systems associated with our shared ownership program are recorded within property and equipment and are depreciated over their estimated useful life of seven years.

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Depreciation and warranty expense attributable to the CyberKnife shared ownership systems are recorded within cost of our shared ownership program.

*Long-Term Manufacturing Contracts*

We also recognize revenue and cost of revenue related to long-term manufacturing contracts using contract accounting on the percentage-of-completion method in accordance with SOP No. 81-1, Accounting for Performance of Construction-Type and Certain Production-Type Contracts. During the years ended June 30, 2009, 2008, and 2007, contract revenue of \$2.4 million, \$1.0 million, and \$0, respectively, was recorded with related costs of \$2.4 million, \$943,000, and \$0, respectively. We recognize any loss provisions from the total contract in the period such loss is identified. During the year ended June 30, 2009, increases in projected costs to complete were sufficient to create a loss position for certain projects. As such, an estimated loss provision of \$97,000 was recognized during the year ended June 30, 2009. No loss provision was recognized during the years ended June 30, 2008 or 2007. As of June 30, 2009 and 2008, costs of \$0 and \$1.0 million, respectively, were recorded in deferred cost of revenue related to long-term manufacturing contracts.

*Deferred Revenue and Deferred Cost of Revenue*

Deferred revenue consists of deferred product revenue, deferred shared ownership revenue, deferred service revenue and deferred other revenue. Deferred product revenue arises from the timing differences between the shipment of products and satisfaction of all revenue recognition criteria consistent with our revenue recognition policy. Deferred shared ownership revenue results from the receipt of advance payments of monthly minimum lease payments, which will be recognized ratably over the term of the shared ownership program. Deferred service revenue results from the advance payment for services to be delivered over a period of time, usually one year. Service revenue is recognized ratably over the service period. Deferred other revenue results primarily from the Japan upgrade services programs and is due to timing difference between the receipt of cash payments for those upgrades and final delivery to the end user customer. Deferred cost of revenue consists of the direct costs associated with the manufacture of units, direct service costs and deferred costs associated with the Japan upgrade services for which the revenue has been deferred in accordance with our revenue recognition policies. Deferred revenue, and associated deferred cost of revenue, expected to be realized within one year are classified as current liabilities and current assets, respectively.

*Stock-Based Compensation*

Effective July 1, 2006, we adopted SFAS 123R using the modified prospective method under which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123R for all share-based payments granted or modified after the effective date and (b) based on the previous requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date. SFAS 123R also requires the benefits of tax deductions in excess of recognized compensation cost be reported as a financing cash flow, rather than as an operating cash flow as required under previous guidance.

SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary in subsequent periods if actual forfeitures differ from initial estimates. For the year ended June 30, 2007, we recorded a cumulative effect of a change in accounting principle of \$838,000, net of tax of \$0, related to the adoption of SFAS 123R since we had previously adjusted stock-based compensation expense at the time forfeitures occurred in accordance with SFAS 123. The cumulative effect of this change in accounting reflects estimated forfeitures related to periods prior to July 1, 2006.

Under SFAS 123R, we estimated the fair value of each option award on the date of grant using the Black-Scholes option-pricing model using the assumptions noted in the table below. Expected volatility is based on the historical volatility of a peer group of publicly traded companies. The expected term of options is based upon the vesting term (i.e., 25% on the first anniversary of the vesting start

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date and 36 equal monthly installments thereafter) and on its partial life history. The risk-free rate for the expected term of the option is based on the U.S. Treasury Constant Maturity rate. During the years ended June 30, 2009, 2008 and 2007, the estimated fair values of the stock options granted were calculated at each date of grant using the Black-Scholes option pricing model, using fair values of common stock between \$4.67 and \$28.47 per share. Following our IPO, the fair value of our common stock is determined by its closing market price as published by the Nasdaq Global Market. During the years ended June 30, 2009, 2008 and 2007, we recognized \$10.3 million, \$12.2 million and \$10.5 million, respectively, of stock-based compensation expense for stock options granted to employees. The weighted-average assumptions used to value options granted during the years ended June 30, 2009, 2008 and 2007 were as follows:

	Year ended June 30,		
	2009	2008	2007
Risk-free interest rate	2.58%	3.65%	4.89%
Dividend yield			
Expected life	6.25	6.25	6.25
Expected volatility	64.3%	60.3%	74.8%

Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned in accordance with SFAS 123 and Emerging Issues Task Force No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. We believe that the fair value of the stock options is more reliably measurable than the fair value of the services received. The estimated fair value of the stock options granted is calculated using the Black-Scholes option pricing model, as prescribed by SFAS 123, using fair values of common stock and weighted-average assumptions during the year of grant. We recognized \$0, \$114,000, and \$171,000 during the years ended June 30, 2009, 2008, and 2007, respectively, of stock-based compensation expense for stock options granted to non-employees.

In January 2007, in connection with our IPO, the Board of Directors approved the 2007 Incentive Award Plan, or 2007 Plan, and the ESPP. The ESPP is deemed compensatory and compensation costs are accounted for under SFAS 123R.

Under the ESPP, qualified employees are entitled to purchase common stock at 85% of the fair market value on specified dates. During the years ended June 30, 2009, 2008 and 2007 the estimated fair value of ESPP shares was calculated at the date of grant using the Black-Scholes option pricing model, using fair values of common stock between \$4.06 per share and \$18.00 per share. Expected volatility is based on the historical volatility of a peer group of publicly traded companies. The expected term is based upon the offering period of the ESPP. The risk-free rate for the expected term of the ESPP option is based on the U.S. Treasury Constant Maturity rate. For the years ended June 30, 2009, 2008 and 2007, we recognized \$998,000, \$1.0 million and \$441,000 of compensation expense related to our ESPP, respectively. The following weighted-average assumptions were used during the years ended June 30, 2009, 2008 and 2007:

	Year ended June 30,		
	2009	2008	2007
Risk-free interest rate	0.42%	3.07%	5.16%
Dividend yield			
Expected life	0.50	0.50	0.75
Expected volatility	84.2%	59.8%	49.9%

In connection with the 2007 Plan, we issued restricted stock units, or RSUs, and recognized \$4.1 million, \$4.0 million and \$1.5 million of stock-based compensation expense, net of forfeitures for restricted stock units granted during the years ended June 30, 2009, 2008 and 2007, at a weighted-average grant date fair value of \$6.49, \$14.55 and \$28.17, respectively.

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Excess tax benefits from tax deductions for exercised options and disqualifying dispositions, in excess of the deferred tax asset attributable to stock compensation costs for such options are credited to additional paid-in-capital. Realized excess tax benefits for the years ended June 30, 2009, 2008 and 2007 were \$0, \$419,000 and \$0, respectively.

At June 30, 2009 and 2008, \$456,000 and \$489,000 of capitalized stock-based compensation costs were included as components of inventory and deferred cost of revenue.

***Inventories***

Inventories are stated at the lower of cost (on a first-in, first-out basis) or market. Excess and obsolete inventories are written down based on historical sales and forecasted demand, as judged by management. We determine inventory and product costs, which include allocated production overheads, through use of standard costs.

***Investments***

We account for certain assets in accordance with SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* ("SFAS 159"). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value, with changes in fair value recognized in earnings each reporting period. The election, called the fair value option, will enable entities to achieve an offset accounting effect for changes in fair value of certain related assets and liabilities without having to apply complex hedge accounting provisions. In November 2008, we entered into an agreement ("Rights Agreement") with UBS, which provides us with ARS Rights ("Rights") to sell our ARS at par value to UBS at any time during the period June 30, 2010 through July 2, 2012. These Rights are a separate freestanding instrument accounted for separately from the ARS, and are registered, nontransferable securities accounted for as a put option initially recorded at fair value. Under the Rights Agreement, UBS may, at its discretion, purchase or sell the ARS at any time through July 2, 2012 without prior notice to us and must pay us par value for the ARS within one day of the sale transaction settlement. We agreed to release UBS from certain potential claims related to its marketing and sale of ARS. Additionally, UBS offered us a "no net cost" loan up to the par value of the ARS as determined by UBS until June 30, 2010 and we agreed to release UBS from certain potential claims related to the collateralized ARS in certain specified circumstances. During the three months ended December 31, 2008, we elected fair value accounting for the put option recorded in connection with the Rights Agreement. This election was made in order to mitigate volatility in earnings caused by accounting for the purchased put option and underlying ARS under different methods. The initial election of fair value led to a \$3.3 million gain included in "Other income, net" for the put option asset, which is recorded in long-term trading securities.

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Due to our entering into this Rights Agreement with UBS and enabling UBS to sell the ARS at any time, the ARS previously reported as available-for-sale have been transferred to trading securities and are classified as long-term trading securities on the condensed consolidated balance sheet as of June 30, 2009. Due to the change in classification to trading securities at the time of entering into the Rights Agreement, we transferred the previously accumulated unrealized loss of \$3.8 million from "Accumulated other comprehensive income (loss)" to "Other income, net" and recorded additional unrealized gains of \$2.1 million relating to the change in fair value of the trading securities from November 2008 through June 30, 2009. At June 30, 2009, the total fair value of the ARS was \$20.7 million, net of \$1.7 million of unrealized losses.

Additionally, we recorded unrealized gains of \$3.3 million related to the fair value of the put option at the time we entered into the Rights Agreement and recorded additional unrealized losses relating to the change in fair value of the put option from November 2008 through June 30, 2009 of \$2.0 million, for a total fair value of the put option of \$1.3 million as of June 30, 2009. During the year ended June 30, 2009, the \$1.7 million unrealized loss in fair value of the ARS and the \$2.0 million of unrealized loss on the put option, partially offset by the \$3.3 million gain recognized on the put option, resulted in a net \$319,000 decrease to "Other income, net".

We account for investments in accordance with SFAS 157, *Fair Value Measurements* ("SFAS 157"). In February 2008, the FASB issued FSP FAS 157 *Effective Date of FASB Statement 157* ("FSP FAS 157-2"), which provided a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, we adopted the provisions of SFAS 157 with respect to its financial assets and liabilities only. SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under SFAS 157 as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

*Level 1* Unadjusted quoted prices that are available in active markets for the identical assets or liabilities at the measurement date.

*Level 2* Other observable inputs available at the measurement date, other than quoted prices included in Level 1, either directly or indirectly, including:

Quoted prices for similar assets or liabilities in active markets;

Quoted prices for identical or similar assets in non-active markets;

Inputs other than quoted prices that are observable for the asset or liability; and

Inputs that are derived principally from or corroborated by other observable market data.

*Level 3* Unobservable inputs that cannot be corroborated by observable market data and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

The adoption of SFAS 157 did not have a material impact on our results of operations and financial condition.

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***Provision for Income Taxes***

Estimates and significant management judgment are required in the calculation of certain tax liabilities and in the determination of the recoverability of certain deferred tax assets, which arise from temporary differences and carryforwards. Due to uncertainties related to our ability to realize our deferred tax assets, we record a valuation allowance equal to the amount of our net domestic deferred tax assets. If we subsequently determine that it is more likely than not we will be able to realize a portion or the full amount of deferred tax assets, we will record an adjustment to the deferred tax asset valuation allowance as a credit to earnings in the period such determination is made.

**Recent Accounting Pronouncements**

In June 2009, the FASB issued SFAS No. 166, *Accounting for Transfers of Financial Assets, an amendment to SFAS No. 140*. The new standard eliminates the concept of a "qualifying special-purpose entity," changes the requirements for derecognizing financial assets, and requires additional disclosures in order to enhance information reported to users of financial statements by providing greater transparency about transfers of financial assets, including securitization transactions, and an entity's continuing involvement in and exposure to the risks related to transferred financial assets. SFAS No. 166 is effective for fiscal years beginning after November 15, 2009. We will adopt SFAS No. 166 in fiscal 2011 and are evaluating the impact it will have to our consolidated financial statements.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events*. This standard is intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. Specifically, this standard sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. SFAS No. 165 is effective for fiscal years and interim periods ending after June 15, 2009 and applied prospectively. The adoption of SFAS No. 165 did not have a material impact on our consolidated financial statements.

In April 2009, the FASB issued FASB Staff Position ("FSP") FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly* ("FSP FAS 157-4"). FSP FAS 157-4 provides guidance on (1) estimating the fair value of an asset or liability when the volume and level of activity for the asset or liability have significantly decreased and (2) identifying transactions that are not orderly. This FSP is effective for the first reporting period (interim or annual) ending after June 15, 2009, with earlier application permitted. The adoption of FSP FAS 157-4 did not have a material impact on our consolidated financial statements.

Also in April 2009, the FASB issued FSP FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments* ("FSP FAS 115-2"). FSP FAS 115-2 requires entities to initially apply the provisions of the standard to previously other than temporarily impaired debt securities (debt securities that the Company does not intend to sell and that the Company is not more likely than not required to sell before recovery), existing as of the date of initial adoption, by making a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. This FSP is effective for the first reporting period (interim or annual) ending after June 15, 2009, with earlier application permitted. The adoption of FSP FAS 115-2 did not have a material impact on our consolidated financial statements.

Also in April 2009, the FASB issued FSP FAS 107-1 and APB 28-1, *Interim Disclosures About Fair Value of Financial Instruments* ("FSP FAS 107-1"). FSP FAS 107-1 expands the fair value disclosures required for all financial instruments within the scope of FASB Statement No. 107, *Disclosures About Fair Value of Financial Instruments* ("FAS 107"), to interim periods. It also requires entities to disclose



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the method(s) and significant assumptions used to estimate the fair value of financial instruments in financial statements on an interim and annual basis and to highlight any changes from prior periods. This FSP is effective for the first reporting period (interim or annual) ending after June 15, 2009, with earlier application permitted. The adoption of FSP FAS 107-1 did not have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "*Business Combinations*" ("*SFAS 141R*"). SFAS 141R establishes principles and requirements for recognizing and measuring assets acquired, liabilities assumed and any noncontrolling interests in the acquiree in a business combination. SFAS 141R also provides guidance for recognizing and measuring goodwill acquired in a business combination; requires purchased in-process research and development ("*IPR&D*") to be capitalized at fair value as intangible assets at the time of acquisition; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination; expands the definition of what constitutes a business; and requires the acquirer to disclose information that users may need to evaluate and understand the financial effect of the business combination. SFAS 141R was effective on a prospective basis and will impact business combination transactions for which the acquisition date occurs after December 15, 2008. Depending on the nature and magnitude of our future business combination transactions, SFAS 141R may have a material impact on our consolidated financial position and/or results of operations.

The FASB also issued FSP FAS 141(R)-1, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise From Contingencies* ("*FSP FAS 141(R)-1*") in April 2009. Under the FSP, an acquirer is required to recognize at fair value an asset acquired or a liability assumed in a business combination that arises from a contingency if the acquisition-date fair value of that asset or liability can be determined during the measurement period. If the acquisition-date fair value cannot be determined, then the acquirer follows the recognition criteria in FASB Statement No. 5, *Accounting for Contingencies*, and FASB Interpretation No. 14, *Reasonable Estimation of the Amount of a Loss* an interpretation of FASB Statement No. 5, to determine whether the contingency should be recognized as of the acquisition date or after it. This FSP is effective for business combinations whose acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Depending on the nature and magnitude of our future business combination transactions, SFAS 141(R)-1 may have a material impact on our consolidated financial statements.

In December 2008, the FASB issued FASB Staff Position ("*FSP*") FAS 140-4 and Financial Interpretations ("*FIN*") 46(R)-8, *Disclosures by Public Entities (Enterprises) about Transfers of Financial Assets and Interest in Variable Interest Entities* ("*FSP FAS 140-4*"). This disclosure-only FSP improves the transparency of transfers of financial assets and an enterprise's involvement with variable interest entities, including qualifying special-purpose entities. This FSP is effective for the first reporting period (interim or annual) ending after December 15, 2008, with earlier application encouraged. The adoption of FSP FAS 140-4 and FIN 46(R)-8 did not have a material impact on our consolidated financial statements.

In October 2008, the FASB issued FSP No. FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active* ("*FSP FAS 157-3*"). FSP FAS 157-3 provides examples to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP FAS 157-3 was effective upon issuance and did not have a material impact on our consolidated financial statements.

In April 2008, the FASB issued FSP FAS 142-3, *Determination of the Useful Life of Intangible Assets* ("*FSP FAS 142-3*"), which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of intangible assets under SFAS No. 142, *Goodwill and Other Intangible Assets* ("*SFAS 142*"). The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of the expected cash flows used to measure the fair value of the asset under SFAS No. 141 (revised 2007), *Business*

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*Combinations* ("SFAS 141R"), and other U.S. generally accepted accounting principles. FSP FAS 142-3 is effective for financial statements issued for fiscal years and interim periods beginning after December 15, 2008. The adoption of FSP FAS 142-3 did not have a material impact on our consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities - an amendment of FASB Statement No. 133* ("SFAS 161"). SFAS 161 requires enhanced disclosures regarding derivatives and hedging activities, including: (a) the manner in which an entity uses derivative instruments; (b) the manner in which derivative instruments and related hedged items are accounted for under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*; and (c) the effect of derivative instruments and related hedged items on an entity's financial position, financial performance, and cash flows. SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The adoption of SFAS 161 did not have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements - An Amendment of ARB No. 51* ("SFAS 160"). SFAS 160 amends Accounting Research Bulletin No. 51, *Consolidated Financial Statements* ("ARB 51"), to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. This statement also amends certain of ARB 51's consolidation procedures for consistency with the requirements of SFAS 141R. In addition, SFAS 160 also includes expanded disclosure requirements regarding the interests of the parent and its noncontrolling interest. The provisions of SFAS 160 are effective for fiscal years beginning after December 15, 2008. Earlier adoption is prohibited. We determined that the adoption of SFAS 160 will not have a material impact on our consolidated financial statements.

**Item 7A. QUANTITATIVE & QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions.

For the year ended June 30, 2009, all of our executed sales contracts were denominated in U.S. dollars, with the exception of three sales contracts: one denominated in Euros, one in British Pounds and one in Swiss Francs. Future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products outside the United States. For direct sales outside the United States it is likely we will sell in the local currency, which could expose us to additional foreign currency risks, including changes in currency exchange rates. Some of our commissions related to sales of the CyberKnife system are payable in Euros. To the extent that management can predict the timing of payments under these or contracts we enter into that are denominated in foreign currencies, we may engage in hedging transactions to mitigate such risks in the future.

***Interest Rate Risk***

At June 30, 2009, we had \$36.8 million of cash and cash equivalents and \$121.9 million invested in other financial instruments. Our earnings are affected by changes in interest rates due to the impact those changes have on interest income generated from our cash and investment balances. We believe that while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, and except as described below, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments. However, should interest rates increase, the market value of our investments may decline, which could result in a realized loss if we are forced to sell before scheduled maturity. If overall interest rates had risen by 100 basis points, the fair value of our net investment position at June 30, 2009 would have decreased by approximately \$803,000, assuming consistent levels.

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***Credit Risk***

The \$22.4 million of ARS we held as of June 30, 2009 failed at auction and have continued to fail at auction due to sell orders exceeding buy orders. As of June 30, 2009, we have written down our ARS from their par value of \$22.4 million to the estimated fair value of approximately \$20.7 million. The \$1.7 million decline in market value was recorded to other expense during the year ended June 30, 2009 in conjunction with our decision to reclassify the ARS from the available-for-sale category to the trading category. In addition, we entered into a settlement agreement with UBS whereby we have the option to sell the ARS at par value to UBS between June 30, 2010 and July 1, 2012. As part of the settlement with UBS, we have entered into a "no net cost" secured line of credit agreement with UBS. The secured line of credit allows borrowings as determined by UBS. The available borrowings afford us additional cash liquidity until we exercise our option to sell at par value, expected to be on or about June 30, 2010. As of June 30, 2009, no borrowings are outstanding on this line of credit. Based on our ability to access our cash and cash equivalents, our expected operating cash flows and our other sources of cash, we do not anticipate the current lack of liquidity on these investments to have a material impact on our financial condition or results of operations.

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**Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**ACCURAY INCORPORATED**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders  
Accuray Incorporated

We have audited the accompanying consolidated balance sheets of Accuray Incorporated and subsidiaries (collectively, "the Company") as of June 30, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity (deficiency), and cash flows for each of the three years in the period ended June 30, 2009. Our audits of the basic financial statements included the financial statement schedule listed in the index appearing under Item 15(a)(2). These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Accuray Incorporated and subsidiaries as of June 30, 2009 and 2008, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2009 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Accuray Incorporated's internal control over financial reporting as of June 30, 2009, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated September 8, 2009 expressed an unqualified opinion thereon.

/s/ GRANT THORNTON LLP  
San Francisco, California  
September 8, 2009

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**Accuray Incorporated**  
**Consolidated Balance Sheets**

(in thousands, except share and per share amounts)

	June 30,	
	2009	2008
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 36,835	\$ 36,936
Restricted cash	527	4,830
Short-term available-for-sale securities	64,634	85,536
Accounts receivable, net of allowance for doubtful accounts of \$484 and \$27 at June 30, 2009 and 2008, respectively	36,427	33,918
Inventories	28,909	23,047
Prepaid expenses and other current assets	6,186	6,431
Deferred cost of revenue - current	18,984	31,667
<b>Total current assets</b>	<b>192,502</b>	<b>222,365</b>
Long-term available-for-sale securities	35,245	37,014
Long-term trading securities	22,007	
Deferred cost of revenue - noncurrent	2,933	11,724
Property and equipment, net	15,066	17,140
Goodwill	4,495	4,495
Intangible assets, net	668	926
Other assets	1,470	1,340
<b>Total assets</b>	<b>\$ 274,386</b>	<b>\$ 295,004</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 14,941	\$ 12,962
Accrued compensation	10,119	7,504
Other accrued liabilities	6,069	4,369
Customer advances - current	13,185	22,331
Deferred revenue - current	68,105	87,455
<b>Total current liabilities</b>	<b>112,419</b>	<b>134,621</b>
Long-term other liabilities	288	
Customer advances - noncurrent		2,900
Deferred revenue - noncurrent	7,777	26,720
<b>Total liabilities</b>	<b>120,484</b>	<b>164,241</b>
Commitments and contingencies (Note 8)		
<b>Stockholders' equity</b>		
Preferred stock, \$0.001 par value; authorized: 5,000,000 shares; no shares issued and outstanding		
Common stock, \$0.001 par value; authorized: 100,000,000 shares; issued: 58,783,547 and 56,719,864 shares at June 30, 2009 and 2008, respectively; outstanding: 56,643,529 and 54,579,846 shares at June 30, 2009 and 2008, respectively	57	55
Additional paid-in capital	273,946	252,901
Accumulated other comprehensive income (loss)	416	(1,067)
Accumulated deficit	(120,517)	(121,126)

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Total stockholders' equity	153,902	130,763
Total liabilities and stockholders' equity	\$ 274,386	\$ 295,004

Assets and liabilities include related party transaction amounts as follows:

Accounts receivable	\$ 9	\$
Deferred cost of revenue current	\$	\$ 11
Deferred revenue current	\$ 209	\$ 231

The accompanying notes are an integral part of these consolidated financial statements.