

ACCURAY INC  
Form 10-K  
September 04, 2007

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 10-K

(Mark One)

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

For the fiscal year ended **June 30, 2007**

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number **001-33301**

## ACCURAY INCORPORATED

(Exact Name of Registrant as Specified in Its Charter)

**DELAWARE**  
(State or Other Jurisdiction of  
Incorporation or organization)

**20-8370041**  
(I.R.S. Employer  
Identification No.)

**1310 Chesapeake Terrace  
Sunnyvale, California 94089**

(Address of Principal Executive Offices) (Zip Code)

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

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

Title of Each Class
Common stock, \$.001 Par Value Per Share

Name of Each Exchange on Which Registered
The NASDAQ Stock Market LLC

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

**None**

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

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

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

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

Indicate by check mark 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, or a non-accelerated filer in Rule 12-b2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant based on the last sale price for such stock on December 31, 2006: Not applicable because trading of the registrant's common stock on the NASDAQ Global Market commenced on February 8, 2007.

As of August 17, 2007, the number of outstanding shares of the registrant's common stock, \$0.001 par value, was 53,851,781.

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ACCURAY INCORPORATED

YEAR ENDED JUNE 30, 2007

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 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**

**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 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. 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.

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, 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. In Japan, the CyberKnife system is currently approved to provide treatment for indications in the head and neck. As of June 30, 2007, 109 CyberKnife systems were installed and are in use: 71 in the Americas, 10 of which are pursuant to our shared ownership programs, 26 in Asia and 12 in Europe. Our customers have reported that over 35,000 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 brain for tumors on or near the spine and in the lung, liver, prostate and pancreas. Based on customer data, approximately 54% of patients treated with the CyberKnife system in the United States during the year ended June 30, 2007 were treated for tumors outside of the brain.

We were incorporated in 1990 and commenced operations in 1992. Initially we funded our operations through individual private investors, as well as from the sale of a prototype system to Stanford University Hospital. After 1992, we sold additional prototype systems which helped fund our operations. These prototype systems were granted an Investigational Device Exemption, or IDE, by the FDA and treatment with the CyberKnife system began in 1994. We also were able to secure regulatory approval in Japan, and the subsequent sales of systems in Japan helped to fund our continued operations and development. While the CyberKnife system was refined and upgraded, additional funding was obtained through private investors, bridge loans and several rounds of financing.

### **Cancer Market Overview**

According to the World Health Organization, or WHO, an estimated 7.6 million people died of cancer in 2005, accounting for 13% of all deaths worldwide. The WHO estimates that there are 24.6 million people living with cancer worldwide, with approximately 10.9 million new cases being diagnosed every year. 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 2007. The ACS also estimates that approximately 1.4 million new cases of cancer will be diagnosed in the United States in 2007, with continued increases in the prevalence of cancer forecasted as the U.S. population ages. The National Institutes of Health estimates that the treatment of cancer accounted for more than \$74.0 billion in direct medical costs in 2005.

Cancers can be divided broadly into two groups: solid tumor cancers, which are characterized by the growth of malignant tumors within the body in areas such as the brain, lung, liver, breast or prostate, and hematological, or blood-borne, cancers, such as leukemia. The ACS estimates that solid tumor cancers will account for approximately 1.34 million, or approximately 92%, of new cancer cases diagnosed and will account for approximately 500,000 cancer-related deaths in the United States in 2007. 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.

### **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 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, or fractionation, 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 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.

## 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 skull to immobilize the patient's head and to aid in targeting the tumor. This procedure begins by attaching a rigid frame to the patient's head by screwing it into the skull through the skin. 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, 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 with a level of accuracy 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 that 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 additional 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.

## **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 54% of patients treated with the CyberKnife system in the United States during the year ended June 30, 2007 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 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 fiscal 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. We also maintain close relationships with our customers through our shared ownership programs and service plans. This further enables us to understand their needs and allows us to develop new technologies and upgrades that improve and expand clinical applications and drive increased utilization of our CyberKnife 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 at the time of CyberKnife system purchase 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 upgrades deliverable pursuant to their service plans. Finally, we offer shared ownership programs, which enable 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, and



Tokyo, Japan, and our sales and distribution channels cover more than 45 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.

In an effort to streamline our sales efforts in Japan, our former distributor Meditec Corporation, transferred all of its inventory to our existing distributor Chiyoda Technol Corporation in fiscal year 2006. As part of that inventory transfer our former distributor, Meditec paid us a lump sum payment for such inventory. Such payment was over 10% of our total net revenue for the fiscal year ended June 30, 2006. Meditec was a subsidiary of Marubeni Corporation, one of our stockholders.

***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 list price for the CyberKnife system is approximately \$4.2 million, which 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, 2007, we had 109 units installed at customer sites: 71 in the Americas, 10 of which are pursuant to our shared ownership programs, 26 in Asia and 12 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.

***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, 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 October 2005, we introduced larger, in-floor X-ray image detectors, which provide greater treatment access.

In addition to the key components listed above, we also offer the following components and features, several of which have been introduced as upgrades since 2004, 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.

**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. 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 AXUM treatment couch.

**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.



**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.

**In-Room CT System.** The In-Room CT System enables diagnostic quality 3D and 4D patient imaging just prior to treatment. Combined with the RoboCouch patient positioning system, the In-Room CT System provides a smooth and efficient scan-to-treatment transition without having to re-enter the treatment room or manually move the patient.

**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.

**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.

**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.

**AXUM treatment couch.** AXUM is a computer-controlled treatment couch integrated with the image-guidance system that automatically aligns the patient for treatment at the beginning of the procedure. AXUM moves the treatment couch to position 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.

#### **CyberKnife System Clinical Workflow**

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 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 Programs 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 Programs***

We offer shared ownership programs 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 programs are responsible for costs associated with facility preparation and professional and administrative personnel required to operate the CyberKnife system. Our legacy shared ownership programs were known as our placement programs.

The shared ownership programs typically have a term of five years, during which the customer has the option to purchase the system at pre-determined prices. As of June 30, 2007, we had installed 10 systems under our shared ownership programs.

##### ***Warranty and Support Services***

We provide a one-year warranty on the purchase of the CyberKnife system. In addition, for a fee that is fixed at the time of purchase, customers can enroll in one of our multiyear service plans:

***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. The Diamond plan currently lists in the United States for \$460,000 per year, and provides for annual renewals for four years.

**Ruby multiyear service plan.** Under our Ruby multiyear service plan, or Ruby plan, customers outside the United States have the opportunity to acquire up to two unspecified future software upgrades per year when and if they become available. The Ruby multiyear service plan currently lists for \$380,000 per year and provides for annual renewals for four years.

**Basic and Emerald multiyear service plans.** We also offer a basic multiyear service plan, and our Emerald multiyear service plan, or Emerald plan, following the initial one-year warranty period. Under our Emerald plan, customers receive a higher level of support, including a faster response time and coverage for all replacement parts. The current annual prices of our basic and Emerald service plans are \$220,000 and \$275,000, respectively.

**Legacy multiyear service plans.** Prior to November 2005, we offered our Platinum 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. While these plans are no longer offered, as of June 30, 2007 we were still servicing approximately 46 customers pursuant to these legacy multiyear service plans. These multiyear service plans typically provide for annual renewals for four years, including the one-year warranty period.

Under our Platinum plan, in addition to technical support, customers have the opportunity to acquire at least 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 \$100,000 for each upgrade not offered. To date no refunds have been required or are due pursuant to these multiyear service plans.

Under our Gold plan, customers typically have the opportunity to acquire up to two unspecified future software upgrades per year, for an annual fee of \$350,000. If we do not offer an upgrade in any particular year, the customer would be entitled to a refund of \$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 or are due pursuant to these 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 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. As of June 30, 2007, we had 79 engineers, technicians and support personnel in our installations, service and support group. We intend to increase the number of our installation and service personnel as our sales increase.

**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 and in Hong Kong, China. As of June 30, 2007, we had a total of 107 employees in our worldwide sales and marketing group. We expect to continue to increase the number of sales and marketing personnel as we expand our business.



In the United States we use a combination of sales directors, sales specialists, customer account sales executives, product managers, account managers and training specialists. Sales directors and sales specialists are responsible for selling the CyberKnife system to hospitals and stand-alone treatment facilities. 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 account managers are primarily responsible for supporting the CyberKnife systems with marketing and education after installation is completed. Our training specialists train radiation oncologists, surgeons, physicists and radiation therapists.

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.

According to the American Society for Therapeutic Radiology and Oncology, or ASTRO, as of 2004 there were approximately 2,010 hospitals and stand-alone treatment facilities in the United States providing radiation therapy services. There are a total of 5,756 hospitals in the United States registered with the American Hospital Organization as of 2004. Our sales and marketing strategy is to target the hospitals and treatment facilities currently providing radiation therapy services, however, in the future we believe that the CyberKnife system will be marketed to hospitals that do not have radiation therapy facilities. In addition, we believe that free-standing cancer centers present a future opportunity to market the CyberKnife system within the United States.

On April 3, 2007, we entered into a Distribution and Remarketing Agreement with Siemens Medical Solutions Inc. USA, acting through its Oncology Care Systems Group, or OCS, pursuant to which we are authorized to purchase, license, sell, and sublicense certain OCS products directly from OCS. OCS granted us the right to purchase and license certain models of CT scanners from OCS, and to promote, market, lease, resell and sublicense the CT scanners to end users, either directly or through its channels of distribution, in the United States and other territories, and to market the CT scanners in conjunction with our CyberKnife and/or RoboCouch products.

From time to time, we may provide our linac system for use in non-medical areas. For example, we are in discussions with a third party to develop and provide two prototype units of our next generation X-ray source system for non-destructive testing uses.

#### **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 facility. 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. Approximately 50,000 square feet in our Sunnyvale facilities are presently dedicated to these manufacturing and assembly activities.

In January 2005, we acquired American Science and Engineering s, or AS&E, High Energy Systems, or HES, business for \$8.4 million. This acquisition provided us with the sole ownership of the intellectual property associated with our X-band linac, trade secrets and know-how used in the manufacturing process and included the hiring of key technologists previously employed by AS&E. HES had been the sole source manufacturer of the linac used in the CyberKnife system.

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.

As of June 30, 2007, we held 16 U.S. patents, three allowed U.S. patent applications, 68 pending U.S. patent applications, and are pursuing additional U.S. patent applications on additional key inventions to enhance our intellectual property rights. The first of our patents will expire in 2010 and currently the last of our patents will expire in 2024. As of June 30, 2007, we also held 21 foreign patents, 15 pending published Patent Cooperation Treaty applications and 38 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. Through the HES acquisition, we acquired certain intellectual property rights for the compact linac used in current versions of the CyberKnife system.

In addition to our patents, we also rely upon trade secrets, know-how, trademarks, copyright protection and continuing technological and licensing opportunities to develop and maintain our competitive position. We require our employees, consultants and outside scientific collaborators to execute confidentiality 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.

We have also entered into licensing agreements with third parties relating to rights and technologies. On January 30, 1991, we entered into a Manufacturing License and Technology Transfer Agreement with Schonberg Radiation Corporation under which Schonberg granted us a perpetual exclusive license to use and manufacture products utilizing some of Schonberg's patent and other intellectual property rights relating to the design, engineering and manufacturing of the compact linacs that may be used in the

CyberKnife system for medical applications. On November 29, 2006, we entered into a Patent and Trademark License Agreement with Forte Automation Systems, Inc., or Forte, under which we granted Forte a license, exclusive with respect to one customer for patent rights and trademark rights related to our patient positioning system.

On April 27, 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, who resigned from our board of directors in January 2007, is a founder, officer and director of CyberHeart, Inc.

In December 2004 and in connection with the HES acquisition, 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 may intend to breach, our contractual obligations under the license agreement. 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.

On July 9, 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 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 AXUM, Express, Synchrony, Xsight Spine Tracking System, InView, MultiPlan and RoboCouch. 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, 2007, we had 127 employees in our research and development departments. Research and development expenses for the fiscal years ended June 30, 2007, 2006 and 2005 were \$26.8 million, \$17.8 million and \$11.7 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 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, 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, a more recent entrant, 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 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 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;
- 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;
- 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.

#### **Reimbursement**

In the United States, healthcare providers generally rely on third-party payors, principally 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 appropriate coverage and reimbursement for our products and related procedures are obtained from third-party payors. We cannot assure you that government or private third-party payors will cover and reimburse the procedures using our technology in whole or in part in the future or that payment rates will be adequate.

Medicare coverage and reimbursement policies are particularly significant to our business. Not only is Medicare the single largest third-party payor, but many other governmental and commercial payors follow its coverage and reimbursement policies. The Medicare coverage and reimbursement policies are developed by the Centers for Medicare and Medicaid Services, or CMS, the federal agency responsible for administering the Medicare program and its contractors. Medicare reimbursement rates for the same or





similar procedures vary due to geographic location, nature of the facility in which the procedure is performed (e.g., teaching or community hospital) and other factors.

Medicare coverage for procedures using our technology currently exists in the hospital outpatient setting and in the free-standing clinic setting. For hospital outpatient procedures, where currently the vast majority of 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. CMS will frequently categorize a procedure or service in a new technology APC where the procedure does not have sufficient claims data to be placed in an existing APC that is appropriate in terms of clinical characteristics and resource costs. Once CMS has collected sufficient claims data on the procedure being paid under a new technology APC, the agency will assign the procedure to an existing APC group. Procedures generally are reimbursed under new technology APCs for two to three years. Beginning in 2004, both planning and treatment using our CyberKnife system were assigned to new technology APCs. Medicare accomplished this through certain temporary billing codes: Healthcare Common Procedure Coding System, or HCPCS, code G0338 ( Linear-accelerator-based stereotactic radiosurgery planning ), HCPCS code G0339 ( Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session, or first session of fractionated treatment ) for the first or single treatment, and HCPCS code G0340 ( Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment ) for any subsequent treatments.

CMS has determined that planning for stereotactic radiosurgery procedures using our technology should be reported using several Category I Current Procedure Terminology, or CPT, codes. The CPT planning codes are assigned to clinical APCs with payment levels that resulted in a slight increase in payment in 2006 and 2007 as compared to prior years. For calendar 2008, CMS has proposed increases in payment rates for certain CPT codes applicable to treatment planning resulting in a cumulative increase for treatment planning reimbursement in 2008 as compared to 2007, assuming the proposed increases are implemented.

For 2004 to 2006, placement of HCPCS codes G0339 and G0340 in the new technology APCs resulted in a national payment rate of \$5,250 for the first treatment and \$3,750 for each treatment thereafter, up to a maximum of five treatments. For 2007, CMS determined that procedures performed in the hospital outpatient department using our technology be transitioned from the new technology APCs to two clinical APCs. Under the finalized payment rules, the national payment rate for procedures billed using HCPCS code G0339 is \$3,896, and procedures billed under HCPCS code G0340 are paid \$2,645. For 2008, CMS has proposed HCPCS codes G0339 and G0440 remain in clinical APCs assigned in 2007 at increased payment rates as compared to 2007. The proposed payment rates for 2008 for HCPCS codes G0339 and G0440 are \$3,918 and \$3,017, respectively. We cannot assure you that these proposed payment rates will be implemented as proposed.

Medicare payment to free-standing clinics generally is based on the physician fee schedule. There are no national payment rates for HCPCS codes G0339 and G0340, and Medicare contractors determine the payment rates for their jurisdiction. We understand that some Medicare contractors may require the use of other billing codes for the 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 is based on the physician fee schedule, and payment amounts are updated on an annual basis. Beginning in

2007, CMS changed how it determines payment levels under the physician fee schedule. Specifically, CMS revised the methodology for calculating the physician work component, which reflects physician time and intensity of effort in performing a procedure or service. CMS also changed its methodology for calculating the practice expense component, which reflects the overhead expenses that a physician incurs, such as rent, equipment and salaries. We do not expect that these changes will result in any significant change in reimbursement for physician professional services performed in connection with the CyberKnife procedure. At this time, we cannot predict the full impact of these changes on our operations. Under proposed guidelines for 2008 Medicare reimbursements, CMS has proposed changes in payment rates for certain CPT codes applicable to physician services that may result in increases in some areas and decreases in others. We expect that the net effect of these changes will not result in significant changes in reimbursement for physician professional services performed in connection with the CyberKnife procedure.

We also cannot assure you that Medicare will continue to cover and reimburse the procedures using the CyberKnife system, or that the amounts reimbursed under applicable codes will be adequate. 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 provide coverage for CyberKnife procedures under negotiated contracts with hospitals and clinics.

The American Medical Association, or AMA, established four new Category I CPT codes relating to stereotactic radiosurgery, which became effective January 1, 2007. Third-party payors may decide to use three of these codes to describe treatment (CPT codes 77372 and 77373) and treatment management (CPT code 77435) using our technology. CMS has announced that these codes are not to be used for our technology for Medicare payments for hospital outpatient services under the prospective payment system in 2007. These codes were assigned values for payments under the Medicare physician fee schedule for 2007 and may be required by Medicare contractors for use in other settings. CMS has again proposed that these codes are not to be used for our technology for Medicare payments for hospital outpatient services under the prospective payment system in 2008. Instead, CMS has again proposed that the G-codes be retained for use in these settings in 2008. At this time, most freestanding clinics seeking reimbursement for services using our technology have not yet begun to use these new codes. The extent to which any of these new codes would be required in the future by Medicare contractors for services using our technology and performed in free-standing clinics or by other third-party payors is unclear. It is also unclear at this time whether or for how long the new codes will continue to coexist with or replace the existing codes for treatment using our technology (HCPCS codes G0339 and G0340) and how the level of reimbursement would be impacted by the new codes. If Medicare contractors begin to require the use of the new codes for 2007 or 2008, the reimbursement rates for CPT codes 77372 and 77373 under the 2007 and proposed 2008 Medicare physician fee schedule could result in a material adverse effect on our business.

The current emphasis on cost-containment by third-party payors makes it exceedingly difficult for new medical devices and surgical procedures to obtain adequate 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 the CyberKnife system may offer an opportunity for payors to reduce the cost of treatment for solid tumors as compared with surgical removal; 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. Hospitals would be less likely to purchase our products if they do not receive sufficient levels of reimbursement. In addition, if physicians or hospital administrators believe that our system will add cost to a procedure but will not add sufficient offsetting economic or clinical benefits, physician adoption could be impaired. Any reduction or limitation in use of our products could cause our sales to suffer.

Reimbursement by third-party payors is often positively influenced by the existence of peer-reviewed publications of long-term safety and efficacy data. We have collected and published data on clinical results for patients that have undergone surgical procedures involving use of 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 hired a director of reimbursement and have established a dedicated reimbursement group that seeks to provide education to physicians and facilities in working with payors on coverage and reimbursement issues for procedures involving the use of the CyberKnife system. This group participates in reimbursement application processes worldwide, assists our customers in obtaining pre-approval from third-party payors for patients who will be undergoing treatment using the CyberKnife system and 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 adequate coverage and reimbursement, a group of customers has formally organized into a non-profit organization to pursue patient access to the CyberKnife technology, adequate reimbursement, coverage and payment of our product worldwide, with a strong emphasis on the United States. This group, the CyberKnife Coalition, has a charter to promote patient access to CyberKnife system technology and treatment, and realize adequate coverage and reimbursement to support that treatment. The Coalition seeks to assure and advocate that procedures using the CyberKnife system continue to be reimbursed at appropriate levels by Medicare and other third-party payors.

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 health care payment systems in such markets. To date, healthcare providers in Europe and in Asian markets with installed CyberKnife systems have been able to successfully negotiate coverage contracts with their local payors at adequate payment rates.

## **Regulatory Matters**

### ***Domestic Regulation***

Our products and software are medical devices subject to regulation by the U.S. Food and Drug Administration, or 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.

**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

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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. From January 1, 2003 to June 30, 2007, we submitted an additional eight 510(k) clearances notifications for modifications made to the operation of the CyberKnife system. These applications were cleared by the FDA.

***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 May 2004 and April 2006, during routine inspections performed by the FDA, two minor observations were made in each inspection. We have taken corrective action on the minor observations in response to the FDA's observations. There were no observations that involved a material violation of regulatory requirements. We believe that we are in substantial compliance with the QSR. In February 2007, during routine inspections performed by the FDA of one of our manufacturing facilities, no observations were made.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- fines, injunctions, consent decrees and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or pre-market approval of new products or new intended uses;
- withdrawing 510(k) clearance or pre-market approvals that are already granted; and
- criminal prosecution.

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

**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 we initiated in 2003, a corrective action plan that 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 health care 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 health care 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 Office of the Inspector General of the Department of Health and Human Services, or 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 health care programs;
- Product support services, including billing assistance, reimbursement consultation and other services specifically tied to support of the purchased product, offered in tandem with another service or program (such as a reimbursement guarantee) that confers a benefit to the purchaser;
- Educational grants conditioned in whole or in part on the purchase of equipment, or otherwise inappropriately influenced by sales and marketing considerations;
- Research funding arrangements, particularly post-marketing research activities, that are linked directly or indirectly to the purchase of products, or otherwise inappropriately influenced by sales and marketing considerations; and
- Other offers of remuneration to purchasers that are expressly or impliedly related to a sale or sales volume, such as prebates and upfront payments, other free or reduced-price goods or services, and payments to cover costs of converting from a competitor's products, particularly where the selection criteria for such offers vary with the volume or value of business generated.

We have a variety of financial relationships with physicians who are in a position to generate business for us. For example, physicians 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 placement and shared ownership programs 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 programs 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.

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 of proposed Medicare reimbursement rates for calendar 2008, CMS has also proposed significant amendments to the regulations under the federal Ethics in 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. Physician owned entities have increasingly become involved in the acquisition of medical technologies, including the CyberKnife. 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 proposed regulations, if adopted, would limit these arrangements and could require the restructuring of existing arrangements between physician owned entities and hospitals and may also discourage physicians from participating in the acquisition and ownership of medical technologies. As a result, these proposed regulations, if enacted, 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 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 in November 1996. In December, 2003, we received approval from the Ministry of Health, Labour and Welfare to market the CyberKnife system in Japan and a new distributor, Chiyoda Technol Corporation, was appointed to distribute the CyberKnife system. Current clinical use in Japan is limited to head and neck applications. Although we and our distributor have applied for approval of broader clinical use of the CyberKnife system in Japan, it is not possible to accurately predict the timing of this approval.

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

#### **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 programs, 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, 2007, we had 449 employees worldwide, including 127 in research and development, 107 in sales and marketing, 79 in installation and service, 58 in manufacturing, and 78 in administration. None of the employees are 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.

## Item 1A. Risk Factors

### Risks Related to Our Business

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

We have incurred net losses in every fiscal year since our inception. As of June 30, 2007, we had an accumulated deficit of \$126.3 million. We may continue to 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 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. We are required to defer revenue associated with our legacy multiyear service plans due to specified obligations related to the delivery of upgrades to the CyberKnife system. Although we anticipate our deferred revenue will begin to decline in future periods, we may not be able to recognize some portions of our deferred revenue until we have satisfied all obligations for delivery of upgrades. We cannot assure you that we will be able to achieve or maintain profitability. In the event we fail to achieve and maintain profitability, our stock price could decline.

*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 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;
- 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 and our stock price would decline.

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

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 may vary significantly and our stock price may be materially harmed. 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, shared ownership programs 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;

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- 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. Any failure to meet investor expectations regarding our operating results may cause our stock price to decline.

*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 often begins with a letter of intent between us and the customer. After the letter of intent is signed, we enter into a definitive purchase contract with the customer. Generally 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 approximately 12 months or longer to complete. During this period, the customer must build a radiation-shielded facility to house their 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.

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 delivered to the end user's site. 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;
- organizational delay caused by customer personnel;
- 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 and could cause our stock price to decline.

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

Our ability to commercialize our products successfully will depend in significant part on the extent to which appropriate coverage and reimbursement for our products and related procedures are obtained from third-party payors, including governmental payors such as Medicare. Third-party payors, and in particular managed care organizations, are increasingly challenging the prices charged for medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services. These cost containment measures, if instituted in a manner affecting the coverage for or payment of our products, could have a material adverse effect on our operating results.

Uncertainty exists as to the coverage and reimbursement status of new medical products and services and new indications for existing products. The CyberKnife procedure is currently covered and reimbursed by Medicare and other governmental and non-governmental third-party payors. However, we cannot assure you that the CyberKnife procedure will continue to be reimbursed at current rates or that third-party payors will continue to consider our products cost-effective relative to other treatments and provide coverage and reimbursement for our products, in whole or in part. For 2007, CMS issued a final rule that resulted in a downward adjustment to the reimbursement rates for treatments using our technology in the hospital outpatient department. For 2007, under the finalized Medicare payment rules, the national payment rates for procedures billed using these codes are \$3,896 and \$2,645, respectively. For 2004 to 2006, the Medicare billing codes for treatments using the CyberKnife system in the hospital outpatient department were assigned a national payment rate of \$5,250 for the first treatment and \$3,750 for each treatment thereafter, up to a maximum of five treatments. For 2008, CMS has proposed increasing the payment rates for procedures billed using these codes to \$3,918 and \$3,017, respectively. However, we cannot assure you that these reimbursement rates will be implemented as proposed.

In addition, new billing codes for stereotactic radiosurgery have been established by the American Medical Association, effective 2007. CMS has determined that the new codes are not to be used for hospital outpatient claims under the prospective payment system for 2007 and, instead, existing billing codes for our technology continue to be in effect. It appears that the new billing codes established by the American Medical Association generally are not being used for treatments using the CyberKnife system in non-hospital settings, or free-standing clinic settings, as well. It remains unclear how these new billing codes will be used for procedures in other settings for Medicare purposes or how they will be used by non-Medicare payors in the future. Payment amounts for 2007 under the Medicare physician fee schedule for freestanding clinic settings may result in a decrease from current payment amounts if these codes are required for billing our technology. Physicians, hospitals and other healthcare providers may be reluctant to purchase the CyberKnife system or may decline to do so entirely if they determine there is not sufficient coverage and reimbursement from third-party payors for the cost of the CyberKnife procedure. In addition, if physicians or hospital administrators believe that our CyberKnife system will add costs to a procedure, but will not add sufficient offsetting economic or clinical benefits, adoption could be impaired. Any reduction or limitation in use of the CyberKnife system could have an adverse impact on our sales.

Our success in international markets also depends upon the eligibility of reimbursement for the CyberKnife procedure through government-sponsored healthcare payment systems and third-party payors. Reimbursement and healthcare payment systems in international markets vary significantly by country and, within some countries, by region. In many international markets, payment systems may control reimbursement for procedures performed using new products as well as procurement of these products. In addition, as economies of emerging markets develop, these countries may implement changes in their healthcare delivery and payment systems. Furthermore, healthcare cost containment efforts similar to those underway in the United States are prevalent in many of the other countries in which we intend to sell our products and these efforts are expected to continue. Market acceptance of our products in a particular



country may depend on the availability and level of reimbursement in that country. In the event that our customers are unable to obtain adequate reimbursement for the CyberKnife procedures in international markets in which we are selling, or are seeking to sell, CyberKnife systems, market acceptance of our products would be adversely affected.

***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, which could cause our stock price to decline. 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. For instance, on December 8, 2003, President George W. Bush signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which, among other things, established a new prescription drug benefit and changed reimbursement methodologies for drugs and devices used in hospital outpatient departments and in the home. In addition, certain federal regulatory changes occur at least annually. CMS has determined that, beginning in 2007, treatments in hospital outpatient departments using our technology will no longer be assigned a new technology classification and, instead, will be transitioned to a classification that would result in a reduction in Medicare payments to hospitals. Further, new billing codes that went into effect in 2007 may be required by third-party payors in the future and may result in a decrease in payments for services using our technology. A downward adjustment in reimbursement could have a material adverse effect on our operations.

In addition, in connection with the release of proposed Medicare reimbursement rates for calendar 2008, CMS has also proposed significant amendments to the regulations under the federal Ethics in 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. Physician owned entities have increasingly become involved in the acquisition of medical technologies, including the CyberKnife. 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 proposed regulations, if adopted, would limit these arrangements and could require the restructuring of existing arrangements between physician owned entities and hospitals and may also discourage physicians from participating in the acquisition and ownership of medical technologies. As a result, these proposed regulations, if enacted, 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 laws, and, if we are unable to comply with such laws, we could face substantial penalties and we could be excluded from government healthcare programs, which would adversely affect our business, financial condition and results of operations.***

We are directly, or indirectly through our customers, subject to various federal 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; and

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

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 health care 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 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 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 placement and shared ownership programs 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 programs 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 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. See [Business Regulatory Matters](#) for further information regarding federal and state fraud and abuse laws.

***Modifications, upgrades and future products related to the CyberKnife system or new indications may require new U.S. Food and Drug Administration, or 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 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 a 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. 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, harm our operating results, and result in a decline in our stock price. 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.

***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, 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 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 and cause the price of our common stock to decline.

***Our accountants have identified and reported to us material weaknesses for the years ended June 30, 2007, 2006 and 2005, relating to our internal controls over financial reporting. If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements could be impaired, which could adversely affect our operating results, our ability to operate our business and our stock price.***

In connection with the audit of our consolidated financial statements for the years ended June 30, 2007, 2006 and 2005, our independent registered public accounting firm identified material weaknesses and significant deficiencies in our internal controls over financial reporting. Material weaknesses and significant deficiencies relate to a lack of segregation of duties, inadequate review procedures and the misapplication of accounting policies related to revenue recognition and stock-based compensation.

Our independent registered public accounting firm has not yet audited the effectiveness of our internal controls over financial reporting. Accordingly, our independent registered public accounting firm has not rendered an opinion on our internal controls over financial reporting. Beginning with our annual report on Form 10-K for the fiscal year ending June 30, 2008, we will become subject to the rules

promulgated under Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, which requires publicly-held companies to include in its annual report on Form 10-K an assessment by management of the effectiveness of our internal controls over financial reporting. We have begun the process of evaluating internal controls over financial reporting, and in the process of conducting this evaluation additional material weaknesses, significant deficiencies and other control deficiencies may be identified. To comply with our Section 404 obligations, we are incurring additional expenses including hiring additional personnel and outside consultants, and we may experience a diversion on management's time and attention. Ensuring that we have adequate internal financial and accounting controls and procedures in place to help ensure that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be evaluated frequently.

Even after any corrective actions are implemented, the effectiveness of our controls and procedures may be limited by a variety of risks including:

- faulty judgment, omissions or mistakes;
- circumvention of our internal controls and procedures;
- inappropriate management override of internal controls and procedures; and
- risk that enhanced internal controls and procedures may still not be adequate to assure timely and reliable financial information, processing and reporting.

Although we have taken measures to remediate the material weaknesses as well as the other significant deficiencies and control deficiencies, we cannot assure you that we have identified all, or that we will not in the future have additional material weaknesses, significant deficiencies and control deficiencies.

Our independent registered public accounting firm has not evaluated any of the measures we have taken, or that we propose to take, to address the material weaknesses and the significant deficiencies and control deficiencies discussed above. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in implementation, could cause us to fail to meet our periodic reporting obligations or result in material misstatements in our consolidated financial statements, which in turn could cause investors to lose confidence in our reported financial information, leading to a decline in our stock price. Any such failure could also adversely affect management's assessment of our disclosure controls and procedures, required with the filing of our quarterly and annual reports and the results of periodic management evaluations and annual auditor attestation reports regarding the effectiveness of our internal controls over financial reporting that will be required when the Securities and Exchange Commission's, or SEC's, rules under Section 404 become applicable to us beginning with our Annual Report on Form 10-K for the year ending June 30, 2008.

In addition, 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, shared ownership programs and services. The CyberKnife system is a complex product that contains both hardware and software elements. The complexity of the CyberKnife system and of our financial model 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.

*We are subject to numerous risks in connection with Section 404 of the Sarbanes-Oxley Act.*

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the Securities and Exchange Commission adopted rules requiring public companies to include in annual reports on Form 10-K an assessment by management of the effectiveness of internal controls over financial reporting. In addition, our independent auditors must attest to and report on management's assessment of the effectiveness of our internal controls over financial reporting. We will need to comply with this requirement commencing with our Annual Report on Form 10-K for the fiscal year ending June 30, 2008. To comply with this requirement, we are incurring additional expenses and a diversion of management's time. While we currently anticipate completion of testing and evaluation of our internal control over financial reporting with respect to the requirements of Section 404 of Sarbanes-Oxley in a timely fashion, we may not be able to accomplish this because the applicable requirements are complex and time-consuming. In addition, as a result of our evaluation of internal control over financial reporting and related systems, we and our auditors had identified one or more material weaknesses in our internal control over financial reporting as described above.

If we fail to evaluate our internal control over financial reporting and related systems in compliance with the requirements of Section 404, if we or our auditors determine that we have material weakness in our internal controls, if we fail to maintain the adequacy of our internal controls (including any failure to implement required new or improved controls), or if we experience difficulties in their implementation, our business and results of operations could be harmed, and we could fail to meet our reporting obligations which would negatively impact the market price of our shares and increase the volatility of our stock price.

***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. 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;
- 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.

***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, in Japan, our clearances are currently limited to use of the CyberKnife system in the head and neck. In addition, our regulatory approval in Japan was suspended for a period of twelve months during 2003 as a result of a failure of our 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. These events would harm our business and could cause our stock price to decline.

***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 they 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 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 nonmedical fields. 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 use 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. 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 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 and our stock price may decline.

***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 and cause our stock price to fall.

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. Most recently, 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 are providing affected devices with software upgrades designed to correct the 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, 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.***

We anticipate that a significant portion of our revenue will continue to be derived from sales of the CyberKnife system in foreign markets. This revenue and related operations will therefore continue to be subject to the risks associated with international operations, including:

- economic or political instability;
- shipping delays;
- changes in foreign regulatory laws governing 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; 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.

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. 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. In certain cases our distributors are responsible for the service and support of our CyberKnife systems.

***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 have recently begun manufacturing 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.

***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 cannot grow or achieve profitability.***

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 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 449 as of June 30, 2007. In addition, we have significantly expanded our development and operational facilities, including our recent

acquisition of a linac manufacturing facility and our new manufacturing site. 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 recently public company, we are incurring increased legal, accounting and other expenses that we did not incur as a private company as we are now subject to SEC, the NASDAQ Stock Market and other rules focusing on corporate governance and financial reporting. In particular, as a public company we will be required to comply with Section 404 regarding management assessment of internal controls. We will first become subject to Section 404 in connection with the audit of our consolidated financial statements for the fiscal year ending June 30, 2008, and we expect to continue to incur substantial additional audit fees and costs for that year's audit as well as for future audits. We also expect these new rules and regulations to make 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 are currently evaluating and monitoring developments with respect to these new rules, and 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. 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.

***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 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;
- 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 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 17, 2007, we have 53,851,781 shares of common stock outstanding. The lockup agreements related to our initial public offering will expire with the opening of the securities markets on September 4, 2007, and as a result a large number of shares of our common stock will become 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, 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 32.6% of our outstanding common stock as of August 17, 2007, which could limit your ability to influence the outcome of key transactions, including changes of control.***

As of August 17, 2007, our directors, executive officers, and current holders of 5% or more of our outstanding common stock, held, in the aggregate, approximately 32.6% 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;
- prohibiting cumulative voting in the election of directors, which would limit the ability of less than a majority of stockholders to elect director candidates;
- limiting the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent and requiring that all stockholder actions be taken at a meeting of our stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law may discourage, delay or prevent a change of control of our company. Generally, Section 203 prohibits stockholders who, alone or together with their affiliates and associates, own more than 15% of the subject company from engaging in certain business combinations for a period of three years following the date that the stockholder became an interested stockholder of such subject company without approval of the board or 66 $\frac{2}{3}$ % 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.

***An active trading market for our common stock may not be sustained.***

Prior to the initial public offering of our common stock in February 2007, there had been no public market for our common stock. Although our common stock is listed on the NASDAQ Global Market, an active trading market for our shares may not be sustained. Accordingly, you may not be able to sell your shares quickly or at the market price if trading in our stock is not active.

***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, any limitations on payments of dividends present in our current and future debt agreements, and other factors our board of directors may deem relevant. We are subject to several covenants under our debt arrangements that place restrictions on our ability to pay dividends. If we do not pay dividends, a return on your 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, and approximately 25,000 square feet of development and manufacturing space in Mountain View, California. Our headquarters building, which is approximately 73,000 square feet, is leased to us until February 2008 and an additional office building, which is approximately 53,000 square feet, is leased to us until May 2010. Our manufacturing facility in Sunnyvale is approximately 50,000 square feet and is leased to us until July 2011. The Mountain View facility is leased to us until October 2010. 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 maintain offices in France, China and Japan. 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**

From time to time we are involved in legal proceedings arising in the ordinary course of our business. We believe that there is no litigation pending that could have a material adverse effect on our results of operations and financial condition.

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

None.

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**PART II****Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDERS 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 of the quarters ended are as follows:

	<b>2007</b>	
	<b>High</b>	<b>Low</b>
First Quarter	N/A	N/A
Second Quarter	N/A	N/A
Third Quarter (beginning February 8, 2007)	\$ 31.09	\$ 19.66
Fourth Quarter	\$ 27.58	\$ 21.50

We have never paid cash dividends on our common stock. Our Board of Directors intend 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 17, 2007, there were 209 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, 2007, with the cumulative total return of (i) the S&P Health Care 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 Health Care 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.

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 5 MONTH CUMULATIVE TOTAL RETURN\***

Among Accuray Incorporated, The NASDAQ Composite Index

And The S&P Health Care Index

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

***Sale of Unregistered Securities***

During the fiscal year ended June 30, 2007, the Registrant made sales of the following unregistered securities:

1. The Registrant sold an aggregate of 1,175,824 shares of common stock to employees, directors and consultants for consideration in the form of cash and forfeited shares in the aggregate amount of \$1,176,189 upon the exercise of stock options and stock awards, no shares of which have been repurchased.
2. The Registrant granted stock options and stock awards to employees, directors and consultants under its 1998 Equity Incentive Plan covering an aggregate of 1,504,280 shares of common stock, with exercise prices ranging from \$9.00 to \$13.05 per share. Of these, options covering an aggregate of 56,156 were cancelled without being exercised.
3. The Registrant sold an aggregate of 495,833 shares of common stock to an individual investor upon the cashless exercise of a warrant.
4. In connection with the Registrant's initial public offering of shares of its common stock, the outstanding preferred stock of the Registrant converted into shares of common stock in accordance with the Registrant's certificate of incorporation immediately prior to the initial public offering.



5. In connection with the reincorporation of Registrant's predecessor, Accuray Incorporated, a California corporation, or Accuray-CA, into Delaware, shareholders, optionholders and a warrant holder of Accuray-CA exchanged securities held in Accuray-CA for corresponding securities of the Registrant.

6. The Registrant claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraphs (1) and (2) above under Section 4(2) of the Securities Act in that such sales and issuances did not involve a public offering or under Rule 701 promulgated under the Securities Act, in that they were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701.

7. The Registrant claimed exemption from registration under the Securities Act for the sale and issuance of securities in the transactions described in paragraphs (3) through (6) by virtue of Section 4(2) and/or Regulation D promulgated thereunder as transactions not involving any public offering. All of the purchasers of unregistered securities for which the Registrant relied on Section 4(2) and/or Regulation D represented that they were accredited investors as defined under the Securities Act. The Registrant claimed such exemption on the basis that (a) the purchasers in each case represented that they intended to acquire the securities for investment only and not with a view to the distribution thereof and that they either received adequate information about the registrant or had access, through employment or other relationships, to such information and (b) appropriate legends were affixed to the stock certificates issued in such transactions.

#### *Use of Proceeds from Public Offering of Common Stock*

Our initial public offering of 18,399,998 shares of our common stock, par value \$0.001, by us and certain stockholders was effected through a Registration Statement on Form S-1 (Reg. No. 333-138622) which was declared effective by the Securities and Exchange Commission on February 7, 2007. We issued 10,399,998 shares on February 13, 2007 for gross proceeds of \$187.2 million. We paid the underwriters a commission of \$13.1 million and incurred additional offering expenses of approximately \$3.5 million. After deducting the underwriters commission and the offering expenses, we received net proceeds of approximately \$170.6 million. The managing underwriters of our IPO were J.P. Morgan Securities Inc. and UBS Securities LLC.

No payments for such expenses were made directly or indirectly to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

The net proceeds have been invested primarily into money market mutual funds. We have begun, and intend to continue to use, our net proceeds for sales and marketing activities to support the ongoing commercialization of the CyberKnife system, including, but not limited to, expansion of our sales force, additional participation in trade shows and symposia, and expanding our international sales and service presence, for research and development activities, including support of hardware and software product development and clinical study initiatives, and for increased working capital and general corporate purposes. We may also use a portion of the net proceeds for the acquisition of, or investment in, companies, technologies, products or assets that complement our business. We have no present understandings, commitments or agreements to enter into any material acquisitions or investments.

#### *Securities authorized for issuance under equity compensation plans*

Refer to Item 12. Equity Compensation Plan Information, for information on the Company's equity compensation plans.

**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, 2007, 2006 and 2005, and the consolidated balance sheet data at June 30, 2007 and 2006, 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, 2004 and 2003 and the consolidated balance sheet data at June 30, 2005, 2004 and 2003 are derived from our audited consolidated financial statements not included in this Form 10-K. The unaudited consolidated financial statements include, in the opinion of management, all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the financial data set forth in those statements. The historical results presented below are not necessarily indicative of future results.

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	Years Ended June 30,				
	2007	2006	2005	2004	2003
	(in thousands, except per share data)				
<b>Consolidated Statements of Operations Data:</b>					
Net revenue	\$ 140,452	\$ 52,897	\$ 22,377	\$ 19,569	\$ 2,710
Cost of revenue(1)	60,413	27,492	11,115	8,496	3,027
Gross profit	80,039	25,405	11,262	11,073	(317 )
Operating expenses:					
Selling and marketing(1)	37,889	25,186	16,361	10,647	6,710
Research and development(1)	26,775	17,788	11,655	7,311	5,844
General and administrative(1)	23,915	15,923	8,129	4,672	3,015
Total operating expenses	88,579	58,897	36,145	22,630	15,569
Loss from operations	(8,540 )	(33,492 )	(24,883 )	(11,557 )	(15,886 )
Interest and other income (expense), net	3,530	56	(238 )	(136 )	46
Loss before provision for income taxes and cumulative effect of change in accounting principle	(5,010 )	(33,436 )	(25,121 )	(11,693 )	(15,840 )
Provision for income taxes	1,444	258	68	3	
Loss before cumulative effect of change in accounting principle	(6,454 )	(33,694 )	(25,189 )	(11,696 )	(15,840 )
Cumulative effect of change in accounting principle, net of tax of \$0	838				
Net loss	(5,616 )	(33,694 )	(25,189 )	(11,696 )	(15,840 )
Deemed dividend(2)					(339 )
Net loss attributable to common stockholders	\$ (5,616 )	\$ (33,694 )	\$ (25,189 )	\$ (11,696 )	\$ (16,179 )
Net loss per common share, basic and diluted:					
Loss before cumulative effect of change in accounting principle	\$ (0.21 )	\$ (2.11 )	\$ (1.76 )	\$ (1.00 )	\$ (1.53 )
Cumulative effect of change in accounting principle	0.03				
Basic and diluted net loss per share	\$ (0.18 )	\$ (2.11 )	\$ (1.76 )	\$ (1.00 )	\$ (1.53 )
Weighted average common shares outstanding used in computing net loss per share:					
Basic and diluted	30,764	15,997	14,283	11,737	10,608

(1) Includes stock-based compensation expense as follows:

	Years Ended June 30,				
	2007	2006	2005	2004	2003
	(in thousands)				
Cost of revenue	\$ 1,205	\$ 863	\$ 454	\$ 190	\$ 71
Selling and marketing	\$ 3,958	\$ 2,569	\$ 1,903	\$ 826	\$ 453
Research and development	\$ 2,448	\$ 1,574	\$ 1,157	\$ 648	\$ 319
General and administrative	\$ 5,016	\$ 3,237	\$ 2,812	\$ 785	\$ 451



(2) In accordance with EITF Issue No. 98-5, Accounting for Convertible Securities With Beneficial Conversion Features or Contingently Adjustable Conversion Features and EITF Issue No. 00-27, Application of EITF Issue No. 98-5 to Certain Convertible Instruments, we recognized deemed dividends as related to the contingent beneficial conversion features of our preferred stock.

	Years Ended June 30,		
	2007	2006	2005
<b>Selected Operating Data:</b>			
Number of CyberKnife systems installed per year			
United States	22	22	14
International	11	6	10
Total	33	28	24

	As of June 30, 2007 (in thousands)	2006	2005	2004	2003
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 204,830	\$ 27,856	\$ 17,024	\$ 9,722	\$ 6,676
Deferred cost of revenue	\$ 61,231	\$ 56,588	\$ 36,476	\$ 22,443	\$ 10,987
Total assets	\$ 332,109	\$ 138,623	\$ 86,860	\$ 52,443	\$ 32,347
Short-term debt	\$	\$	\$ 2,893	\$ 817	\$ 277
Long-term debt, net of current portion	\$	\$	\$	\$	\$ 1,151
Deferred revenue	\$ 154,257	\$ 149,664	\$ 89,975	\$ 47,953	\$ 25,703
Working capital (deficit)	\$ 148,522	\$ (3,783 )	\$ 2,181	\$ (163 )	\$ 489
Redeemable convertible preferred stock	\$	\$ 27,504	\$ 27,504	\$ 27,504	\$ 27,504
Stockholders' equity (deficiency)	\$ 125,443	\$ (80,855 )	\$ (56,172 )	\$ (38,861 )	\$ (33,048 )

**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 prospectus, 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.

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. The CyberKnife system has also been approved for various indications in Japan, Korea, Taiwan, China and other countries. Our customers have reported that over 35,000 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 45 countries directly and through distributors. We have sales and service offices in Paris, France, Hong Kong, China and Tokyo, Japan. As of June 30, 2007, we had 51 sales personnel in our sales organization.

Our CyberKnife systems are either sold to our customers or placed with our customers pursuant to our shared ownership programs. As of June 30, 2007, we had 109 CyberKnife systems installed at customer sites, including 99 sold and 10 pursuant to shared ownership programs. Of the 109 systems sold and installed, 71 are in the Americas, 26 are in Asia and 12 are in Europe.

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 shared ownership programs to new customers and believe the number of

installed units pursuant to and revenue from our shared ownership programs to increase in future periods, but to decrease as a percentage of total revenue as we recognize revenue from CyberKnife systems sold to customers.

The shared ownership programs typically have a term of five years, during which the customer has the option to purchase the system at pre-determined prices. As of June 30, 2007, we had installed 10 systems under our shared ownership programs. During the year ended June 30, 2007, two former shared ownership program customers had each purchased their CyberKnife system. The total selling price in the aggregate for both systems was \$6.8 million, of which \$3.0 million has been recognized as product revenue and \$3.8 million remains recorded in deferred revenue at June 30, 2007.

We manufacture and assemble our CyberKnife systems at our manufacturing facility in Sunnyvale, California. We purchase major components, including the robotic manipulator, treatment table or robotic couch, magnetron, which creates the microwaves for use in the linear accelerator, imaging cameras and 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 list price for the CyberKnife system is approximately \$4.2 million, which includes installation, initial training 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. The Diamond plan has a list price of \$460,000 per year, and provides for annual renewal for four years including the one-year warranty period. The customer may cancel the service plan at any time. As of June 30, 2007, 77 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 2007, the CMS issued a final rule that resulted in a downward adjustment to the reimbursement rates for treatments using our technology in the hospital outpatient department. For 2007, under the finalized Medicare payment rules, the national payment rates for procedures billed using Medicare billing codes for treatments using the CyberKnife system are \$3,896 for the first treatment and \$2,645 for each treatment thereafter, up to a maximum of five treatments, which is an approximately 25 to 29 percent reduction as compared to 2006 payment rates. The implementation of this reimbursement reduction did not have a material impact on our consolidated financial position or results of operations for the year ended June 30, 2007. For 2008, CMS has proposed an increase in payment rates as compared to 2007. The proposed payment rates for 2008 are \$3,918 for the first treatment and \$3,017 for each treatment thereafter. However, we cannot assure you that these proposed payment rates will be implemented as proposed.

Our total net revenue was \$140.5 million, \$52.9 million and \$22.4 million during the years ended June 30, 2007, 2006 and 2005, respectively. Our net loss was \$5.6 million, \$33.7 million and \$25.2 million

during the years ended June 30, 2007, 2006 and 2005, respectively. Our net cash provided by operating activities was \$11.6 million, \$22.1 million and \$14.4 million during the years ended June 30, 2007, 2006 and 2005, respectively. As of June 30, 2007, our backlog was approximately \$618.8 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 technologies. Our business and sales and installation cycle does not immediately create recognizable revenue. As such, we must invest in sales and marketing activities 12 to 18 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.

#### **Material Weaknesses in Internal Controls**

In connection with the audit of our consolidated financial statements for the years ended June 30, 2007, 2006 and 2005, our independent registered public accounting firm identified material weaknesses and significant deficiencies in our internal controls over financial reporting. Material weaknesses and significant deficiencies relate to a lack of segregation of duties, inadequate review procedures and the misapplication of accounting policies, related to revenue recognition and stock-based compensation.

Our efforts to remediate these material weaknesses in our internal controls over financial reporting consist of the following corrective actions: (i) hiring and training additional, qualified finance and accounting personnel; and (ii) strengthening our processes and procedures related to complex revenue recognition and equity transactions. However, even after these corrective actions are implemented, the effectiveness of our controls and procedures may be limited by a variety of risks.

Although we have taken measures to remediate the material weaknesses as well as other significant deficiencies and control deficiencies, we cannot assure you that we have identified all, or that we will not in the future have additional material weaknesses, significant deficiencies and control deficiencies.

#### **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 12 to 18 months in duration and involves multiple steps. Initial steps may include pre-selling activity followed by execution of a letter of intent, or LOI, which is typically non-binding in nature but which sets forth the customer's intention to acquire a CyberKnife as well as, in the case of a purchase transaction, the proposed purchase price for the system. The next step is typically the execution of a terms agreement setting forth the business and economic terms for the purchase or acquisition of the CyberKnife system and multiyear service plan. After execution of a terms agreement, the customer typically has a 30 to 45 day window in which to complete final negotiation of legal terms for the purchase 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. 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, both of which must be granted by state and local government bodies. In addition, the purchasing institution must build a radiation shielded facility or upgrade an existing facility to house the CyberKnife system. On average it takes three months from the signing of an LOI to the execution of a terms agreement. We typically receive a deposit at the time the

terms agreement is entered into, and the remaining balance for the purchase of the CyberKnife system upon 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 purchase price minus 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 a \$460,000 payment at the beginning of each of the second, third and fourth years of the multiyear service plan and recognize the 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. These legacy service plans are 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 refunds of up to \$200,000. Since November 2005, we have not offered these legacy service plans to new customers. To date no refunds have been required or are due pursuant to these multiyear service plans.

The Platinum plan obligates us to deliver 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 plans until all upgrade obligations have been fulfilled. Therefore, the payments made by our customers who have our legacy Platinum plan are categorized as deferred revenue and are recognized as revenue when we fulfill all obligations to deliver upgrades. 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.

#### ***Warranty***

All customers purchasing a CyberKnife system receive a one-year warranty. In the event that a customer does not purchase a multiyear service plan, we recognize the CyberKnife system purchase price minus the fair value of one year of support upon installation. We recognize the value of one year of support pro rata over the twelve months following installation. If the customer does purchase a multiyear service plan, the revenue recognition is as described above.

#### ***Shared Ownership Programs Revenue***

As of June 30, 2007, our shared ownership programs involved U.S. sites only. We recognize revenue monthly from our shared ownership programs 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 shared ownership programs of \$10.1 million, \$8.1 million and \$8.1 million for the years ended June 30, 2007, 2006 and 2005, 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 ten years. Depreciation and warranty expense attributable to shared ownership systems are recorded within cost of shared ownership programs 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. Once the obligations under the upgrade programs for these 22 systems are complete, we do not plan to offer this customized service program and will instead be offering 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 vendor specific objective evidence, or VSOE, of fair value. In most cases, this occurs after the distributor has shipped the unit to the end user, assuming all other 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.

In November 2005, we introduced the Ruby multiyear service plan, or Ruby plan, for international customers. Under the Ruby plan, customers are eligible to receive software only upgrades when and if available. We expect to recognize revenue for Ruby plans in a manner similar to revenue recognition under our Diamond plans.

In situations with legacy plans where we have future obligations related to software 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 \$49.3 million, \$12.1 million and \$8.1 million for the years ended June 30, 2007, 2006 and 2005, respectively.

***Backlog***

We previously defined backlog as the sum of the following two components: deferred revenue and future payments that our customers are contractually committed to make, but which we have not yet received. Beginning with the quarter ended March 31, 2007, we revised our definition of backlog to consist of the sum of deferred revenue, future 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 purchase agreements, service plans and minimum payment requirements associated with our shared ownership programs. We adopted this new definition of backlog in part because of the changes in our customer contracting process under which customers initially enter into terms agreements setting forth the business and economic terms for purchase or acquisition of a CyberKnife system and then have a specified time frame in which to negotiate legal terms. Contingencies associated with contingent contracts that are included within backlog may include final negotiation and agreement upon our legal terms for the purchase or acquisition of the CyberKnife system, 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 legal entities by purchasers of systems. We review, on a quarterly basis with respect to each contingent contract included in backlog, whether customer engagement and progress toward satisfaction of contingencies warrants continued inclusion of the contract within backlog.

As of June 30, 2007, our backlog under this new definition was approximately \$618.8 million. Of the total backlog, \$321.3 million represented CyberKnife system sales, and \$297.5 million represented revenue from service plans and 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 all of this backlog into recognized revenue due to factors outside our control.

## **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 from the sale of CyberKnife systems and the sale of linacs for other uses), shared ownership programs revenue (revenue generated from shared ownership programs), services revenue (revenue generated from sales of plans and training) and other revenue (revenue from Japan upgrade services).

**Cost of revenue.** Cost of revenue consists primarily of material, labor and overhead costs. In future periods we expect cost of revenue to decrease as a percentage of total net revenue due to improved absorption of manufacturing overhead costs associated with increased production volumes, improved efficiencies for supplies and materials and improved labor and manufacturing efficiencies.

**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 promotional activities. In future periods, we expect selling and marketing expenses to grow in absolute terms as we increase headcount and further increase participation in trade shows and symposia and invest in other marketing and promotional activities, but to decrease as a percentage of total net revenue as we leverage our existing infrastructure and realize economies of scale.

**Research and development expenses.** Research and development expenses consist primarily of activities associated with our product development, regulatory, and clinical organizations. In future periods, we expect research and development expenses to grow in absolute terms as we increase headcount and development activities, but to decrease as a percentage of total net revenue as we leverage our existing infrastructure and realize economies of scale.

**General and administrative expenses.** General and administrative expenses consist primarily of compensation and related costs for finance and human resources, and expenses related to accounting, legal and other consulting fees. In future periods, we expect general and administrative expenses to grow in absolute terms as we become subject to the reporting requirements of a public company and incur additional costs related to the overall growth of our business, but to decrease as a percentage of total net revenue as we leverage our existing infrastructure and realize economies of scale.

**Interest and other income.** Interest and other income consists primarily of interest earned on our cash and cash equivalents.

**Interest and other expense.** Interest and other expense consists primarily of losses from the disposal of property and equipment and foreign exchange transaction losses.

### ***Deferred Revenue Legacy Multiyear Service Plans***

We are required to defer all of the revenue associated with our legacy multiyear service plans, including our Platinum and Gold service plans, 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 the cash received for the purchase of the CyberKnife system itself 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 plans, we recognize revenue ratably over the remaining life of the service plan. We have not offered these legacy multiyear service plans to new customers since we introduced our Diamond plan in October 2005, but have provided service for 46 legacy plans as of June 30, 2007. Therefore, our deferred revenue has been higher in certain periods where we have installed more units with legacy contracts, and it will be higher until we can satisfy the contractual obligations and recognize the revenue associated with those installed units. This has led to significant fluctuations in total net revenue in historical periods. Consequently, our operating expenses as a percentage of total net revenue are relatively higher, when compared to companies at a similar stage of commercialization, in the periods where we have had a higher mix of deferred revenue and thus lower total net revenue. In future periods, we expect our deferred revenue, and operating expenses as a percentage of total net revenue, to decline.

*Years Ended June 30, 2007, 2006 and 2005*

**Net revenue.**

	<b>Years Ended June 30,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(in thousands)</b>		
Net revenue	\$ 140,452	\$ 52,897	\$ 22,377
Products	\$ 110,320	\$ 36,089	\$ 9,636
Shared ownership programs	\$ 10,090	\$ 8,145	\$ 8,067
Services	\$ 16,860	\$ 4,848	\$ 3,050
Other	\$ 3,182	\$ 3,815	\$ 1,624

Total net revenue increased \$87.6 million from fiscal 2006 to fiscal 2007. Products revenue increased \$74.2 million from fiscal 2006 to fiscal 2007, primarily attributable to an increase in the number of CyberKnife system units shipped and installed and a change in the mix of service plans. In the year ended June 30, 2007, 33 CyberKnife system units were installed, including 31 units sold and two units attributable to our shared ownership programs, compared to 28 units installed, including 25 units sold and 3 units attributable to our shared ownership program in the year ended June 30, 2006. In accordance with our revenue recognition policy and reflecting the terms of our service plans, we recognized revenue from the sale of 33 and 11 CyberKnife systems during the years ended June 30, 2007 and 2006, respectively. In addition, we satisfied our upgrade delivery obligations for nine units and one unit attributable to our legacy multiyear service plans during the years ended June 30, 2007 and 2006, respectively, and began recognizing revenue ratably over the remaining lives of the service plans. Shared ownership revenue increased \$1.9 million from fiscal 2006 to fiscal 2007, primarily due to an increase in patient treatment volume at the existing sites as well as an increase in the number of shared ownership sites. Services revenue increased \$12.0 million from fiscal 2006 to fiscal 2007, primarily attributable to an increase in the number of customer sites under a service plan. Revenue from upgrade services in Japan, classified as Other revenue in our consolidated statements of operations, decreased \$633,000 from fiscal 2006 to fiscal 2007.

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Total net revenue increased \$30.5 million from fiscal 2005 to fiscal 2006. Products revenue increased \$26.5 million from fiscal 2005 to fiscal 2006, primarily attributable to an increase in the number of CyberKnife system units shipped and installed and a change in the mix of service plans. In the year ended June 30, 2006, 28 CyberKnife system units were installed, including 25 units sold and three units attributable to our shared ownership programs. In the year ended June 30, 2005, 24 were installed, including 21 that were sold, and three that were attributable to our shared ownership programs. Pursuant to our service plans, we recognized revenue from the sale of 11 and two CyberKnife systems in fiscal 2006 and fiscal 2005, respectively. Services revenue increased \$1.8 million from fiscal 2005 to fiscal 2006, primarily attributable to an increase in the number of customer sites under a service plan. Other revenue increased \$2.2 million from fiscal 2005 to fiscal 2006.

### Cost of revenue.

	Years Ended June 30,		
	2007	2006	2005
	(Dollars in thousands)		
Cost of revenue	\$ 60,413	\$ 27,492	\$ 11,115
<i>% of net revenue</i>	43.0	% 52.0	% 49.7

Total cost of revenue increased \$32.9 million from fiscal 2006 to fiscal 2007. The increase was primarily attributable to an increase in the number of CyberKnife systems installed and recognized as revenue during fiscal 2007 compared to fiscal 2006, as well as an increase of \$342,000 in stock-based compensation expense. The decrease in total cost of revenue as a percentage of total net revenue from fiscal 2006 to fiscal 2007 was a result of improved absorption of manufacturing overhead costs associated with increased production volumes of CyberKnife systems and the significant increase in product revenue, which typically has a lower cost of revenue as a percentage of revenue than other revenue streams.

Total cost of revenue increased \$16.4 million from fiscal 2005 to fiscal 2006. The increase was primarily attributable to an increase in CyberKnife systems installed and recognized as revenue during fiscal 2006 compared to fiscal 2005, as well as an increase of \$409,000 in stock-based compensation expense. The increase in total cost of revenue as a percentage of total net revenue was a result of costs associated with introducing our latest generation CyberKnife system.

### Selling and marketing expenses.

	Years Ended June 30,		
	2007	2006	2005
	(Dollars in thousands)		
Sales and marketing	\$ 37,889	\$ 25,186	\$ 16,361
<i>% of net revenue</i>	27.0	% 47.6	% 73.1

Selling and marketing expenses increased \$12.7 million from fiscal 2006 to fiscal 2007. The increase was primarily attributable to an increase of \$3.8 million in salary and related costs largely due to increased headcount, an increase of \$3.3 million in consulting expenses due to an increase in promotional activities, an increase of \$1.8 million in marketing and promotional activities, an increase of \$1.2 million in travel expense, an increase of \$914,000 in sales commissions expenses resulting from increased sales volume and an increase of \$1.4 million in stock-based compensation expense.

Selling and marketing expenses increased \$8.8 million from fiscal 2005 to fiscal 2006. The increase was primarily attributable to an increase of \$3.0 million in salary and related costs largely due to increased headcount, an increase of \$1.4 million in travel and related expenses attributable to selling and marketing activities, an increase of \$1.1 million in consulting expenses, an increase of \$1.0 million in marketing and

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promotional activities, an increase of \$820,000 in sales commission expenses resulting from increased sales volume and an increase of \$666,000 in stock-based compensation expense.

### Research and development expenses.

	<b>Years Ended June 30,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(Dollars in thousands)</b>		
Research and development	\$ 26,775	\$ 17,788	\$ 11,655
<i>% of net revenue</i>	<i>19.1</i>	<i>% 33.6</i>	<i>% 52.1</i>

Research and development expenses increased \$9.0 million from fiscal 2006 to fiscal 2007. The increase was primarily attributable to an increase of \$5.7 million in salary and related costs largely due to increased headcount, an increase of \$1.5 million in purchases of non-inventory materials, an increase of \$874,000 of stock-based compensation expense, an increase in consulting and outside services of \$227,000 and an increase of \$214,000 in travel expenses.

Research and development expenses increased \$6.1 million from fiscal 2005 to fiscal 2006. The increase was primarily attributable to an increase of \$3.4 million in salary and related costs largely due to increased headcount, an increase of \$1.5 million in consulting services, an increase of \$515,000 in purchases of non-inventory materials and an increase of \$417,000 in stock-based compensation expense.

### General and administrative expenses.

	<b>Years Ended June 30,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(Dollars in thousands)</b>		
General and administrative	\$ 23,915	\$ 15,923	\$ 8,129
<i>% of net revenue</i>	<i>17.0</i>		