
**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 DECEMBER 31, 2004

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 000-30713

INTUITIVE SURGICAL, INC.

(Exact name of Registrant as Specified in its Charter)

DELAWARE
(State or Other Jurisdiction of
Incorporation or Organization)

77-0416458
(I.R.S. Employer
Identification Number)

**950 KIFER RD
SUNNYVALE, CA 94086**
(Address of Principal Executive Offices including Zip Code)

(408) 523-2100
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$.001 Par Value

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 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 an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes No

The aggregate market value of the voting stock held by non-affiliates of the registrant on June 30, 2004, based upon the closing price of Common Stock on such date as reported by Nasdaq, was approximately \$622,772,720. Shares of voting stock held by each officer and director have been excluded in that such persons may be deemed to be affiliates. This assumption regarding affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock on February 28, 2005 was 34,689,560.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Registrant's next Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

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INTUITIVE SURGICAL, INC.
2004 ANNUAL REPORT ON FORM 10-K

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PART I

ITEM 1: BUSINESS

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act. These forward-looking statements, including, without limitation, those relating to the future business prospects, revenues and income wherever they occur in this Annual Report or the documents incorporated herein or therein by reference, are necessarily estimates reflecting the best judgment of our management and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. These forward-looking statements should, therefore, be considered in light of various important factors, including those set forth in and incorporated by reference in this Annual Report. In addition to the risk factors identified elsewhere, important factors that could cause actual results to differ materially from estimates or projections contained in the forward-looking statements include but are not limited to the following:

- timing and success of product development and market acceptance of developed products;
- regulatory approvals, clearances and restrictions;
- guidelines and recommendations in the health care and patient communities;
- intellectual property positions and litigation;
- competition in the medical device industry and in the specific markets of surgery in which Intuitive Surgical operates;
- unanticipated manufacturing disruptions, delays in regulatory approvals of new manufacturing facilities or the inability to meet demand for products.

Words such as “estimate,” “project,” “plan,” “intend,” “expect,” “anticipate,” “believe” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are found at various places throughout this Annual Report and the documents incorporated by reference. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report, or in the case of documents incorporated by reference, as of the date of those documents. We undertake no obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this Annual Report or to reflect the occurrence of unanticipated events, except as required by law.

COMPANY BACKGROUND

Intuitive Surgical, Inc. was founded in 1995. We are a Delaware corporation with our corporate headquarters located at 950 Kifer Road, Sunnyvale, California 94086. Our telephone number is (408) 523-2100, and our website address is www.intuitivesurgical.com. In this report, “Intuitive Surgical,” “we,” “us,” and “our” refer to Intuitive Surgical, Inc. and its subsidiaries. Intuitive[®], *da Vinci*[®], EndoWrist[®], InSite[®], AESOP[®], HERMES[®], ZEUS[®], SOCRATES[™] and Navigator[™] are trademarks of Intuitive Surgical, Inc.

We design, manufacture and market the *da Vinci* Surgical System, an advanced surgical system that we believe represents a new generation of surgery—the third generation. We believe that this new generation of surgery, which we call *Intuitive* surgery, is a revolutionary advance similar in scope to the previous two generations of surgery—open surgery and minimally invasive surgery, or MIS. Our *da Vinci* Surgical System consists of a surgeon’s console, a patient-side cart, a high performance vision system and proprietary “wristed” instruments. By placing computer-enhanced technology between the surgeon and patient, we believe that our system enables surgeons to perform advanced MIS in a manner never before experienced. The *da Vinci* Surgical System controls Intuitive Surgical endoscopic instruments, including rigid endoscopes, blunt and sharp

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endoscopic dissectors, scissors, scalpels, forceps/pickups, needle holders, endoscopic retractors, electrocautery, ultrasonic cutters, and accessories during a wide range of surgical procedures. The *da Vinci* Surgical System seamlessly translates the surgeon's natural hand movements on instrument controls at the console into corresponding micro-movements of instruments positioned inside the patient through small puncture incisions, or ports. Our *da Vinci* Surgical System provides the surgeon with the intuitive control, range of motion, fine tissue manipulation capability and 3-D vision characteristic of open surgery, while simultaneously allowing the surgeon to work through the small ports of MIS.

In March 1997, surgeons using an early prototype of our technology successfully performed the first *Intuitive* surgery on humans. Beginning in May 1998, surgeons using our technology successfully performed what we believe were the world's first computer-enhanced closed chest heart surgeries, including mitral valve repair, dissection of an internal mammary artery and grafting of a coronary artery. In early 2000, surgeons using our technology successfully completed what we believe was the world's first beating heart bypass procedure through small ports. In July 2000, we received marketing clearance from the United States Food and Drug Administration, or FDA, for general surgery procedures. We received clearance for a non-cardiac thoroscopic surgery indication in March 2001. Additionally, in May 2001 we received clearance for use of our products in laparoscopic prostatectomy procedures, in November 2002 we received clearance for use of our products in thoroscopically-assisted cardiotomy procedures, and in July 2004 we received clearance for use of our products in coronary anastomosis with adjunctive mediastinotomy during cardiac revascularization procedures. As of December 31, 2004, we had sold 286 of our *da Vinci* Surgical Systems, and surgeons using our technology had successfully completed thousands of surgical procedures of various types in major hospitals throughout North America, Europe, the Middle East and Asia.

Open surgery remains the predominant form of surgery and is still used in almost every area of the body. However, the large incisions required for open surgery create trauma to the patient, resulting in longer hospitalization and recovery times, increased hospitalization costs, and additional pain and suffering. Over the past two decades, MIS has reduced trauma to the patient by allowing selected surgeries to be performed through small ports rather than large incisions, resulting in shorter recovery times, fewer complications and reduced hospitalization costs. MIS has been widely adopted for certain surgical procedures, but it has not been widely adopted within complex surgical procedures.

The *da Vinci* Surgical System enables surgeons to overcome many of the shortcomings of both open surgery and MIS. Surgeons operate while seated comfortably at a console viewing a bright and sharp 3-D image of the surgical field. This immersive visualization connects the surgeon to the surgical field and the instruments. While seated at the console, the surgeon manipulates instrument controls in a natural manner, just as he or she has been trained to do in open surgery. Our technology is designed to provide surgeons with a range of motion in the surgical field analogous to the motions of a human wrist, while filtering out the tremor inherent in every surgeon's hand. In designing our products, we have focused on making our technology as simple as possible to use. In our experience, based on thousands of procedures, surgeons can learn to manipulate our instruments with only a limited amount of training as compared to the training required for a surgeon to become skilled in MIS and can learn to perform *Intuitive* surgery with less training than is required for MIS.

Our products are designed to make a broad range of open surgical and MIS procedures suitable for *Intuitive* surgery. The *da Vinci* Surgical System is designed to allow surgeons to perform better surgery while providing patients with the benefits of MIS. We believe that these advantages will enable us to drive a fundamental change in surgery.

In June 2003, we acquired Computer Motion, Inc. in a stock transaction. In connection with the merger, each outstanding share of Computer Motion common stock was converted into the right to receive 0.25713472 of one share of our common stock after giving effect to our 1-for-2 reverse stock split effective July 1, 2003. In addition, we assumed all of Computer Motion's outstanding options and warrants. The total purchase price was approximately \$148.5 million. In connection with the acquisition, all pending patent litigation between the

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companies was dismissed and Robert Duggan, the Chief Executive Officer and Chairman of the Board of Directors of Computer Motion, and Eric Halvorson, a director of Computer Motion, were appointed to our board of directors.

We operate our business as one segment as defined by generally accepted accounting principles. Our financial results for the previous three fiscal years are discussed in “Item 7: Management’s Discussion and Analysis of Financial Condition and Results of Operation” and “Item 8: Financial Statements and Supplementary Data” of this Annual Report.

Next Generation Surgery—The Intuitive Surgical Solution

The *da Vinci* Surgical System is designed to provide the surgeon the range of motion, fine tissue control and 3-D vision characteristic of open surgery while simultaneously allowing the surgeon to work through small ports. All this is accomplished in an intuitive manner, in the same way that the movements of a surgeon’s hands in open surgery are entirely intuitive.

We believe that our technology overcomes many of the limitations of existing MIS tools and techniques in the following ways:

- *Natural Instrument Movements.* Our technology is designed to directly transform the surgeon’s natural hand movements outside the body into corresponding micro-movements inside the patient’s body. For example, a hand movement to the right outside the body causes the instrument inside the patient to be moved to the right, eliminating the backward nature of existing MIS. In contrast, conventional MIS instruments are essentially long rigid levers that rotate around a fulcrum, or pivot point, located at the port created in the body wall. As a result, the instrument tip moves in the opposite direction from the surgeon’s hand and surgeons must relearn their hand-eye coordination to translate their hand movements in this “backward” environment.
- *EndoWrist Instruments Provide Natural Dexterity and Range of Motion.* Our technology is designed to provide surgeons with a range of motion in the surgical field analogous to the motions of a human hand and wrist. Our proprietary instruments, which we call *EndoWrist* instruments, incorporate “wrist” joints that enable surgeons to reach behind tissues and suture with precision, just as they can in open surgery. The surgeon controls the joint’s movements from the surgeon’s console using natural hand and wrist movements. *EndoWrist* joints are located near the tips of all of our instruments. Conventional MIS instruments provide surgeons less flexibility, dexterity and range of motion than their own hands provide in open surgical procedures. For example, MIS instruments in widespread use today do not have joints near their tips to replicate a surgeon’s hand and wrist movements used in open surgery to perform manipulations, such as reaching behind tissue, suturing and fine dissection.
- *More Precise Movements and Reduced Tremor.* With our technology, the surgeon can also use “motion scaling,” a feature that translates, for example, a three millimeter hand movement outside the patient’s body into a one millimeter instrument movement in the surgical field inside the patient’s body. Motion scaling is designed to allow greater precision than is normally achievable in both open surgery and MIS. In addition, our technology is designed to filter out the tremor inherent in every surgeon’s hands.
- *Immersive 3-D Visualization.* Our vision system, which we call the InSite vision system, is designed to give surgeons the perception that their hands are immersed in the surgical field even though they are outside the patient’s body. As a result, we believe that surgeons no longer feel disconnected from the surgical field and the instruments, as they currently do with MIS. In addition, we believe that the InSite system provides a much brighter and sharper image than any other 3-D endoscope vision system. The InSite system also incorporates our proprietary Navigator camera control technology that allows the surgeon to easily change, move, zoom and rotate his or her field of vision. The combination of these features offers what we believe is the most advanced surgical vision system available today.
- *Easy to Learn, Easy to Master.* We have designed our products to make them as simple as possible to use, even though the underlying technology is inherently complex. We believe that tissue manipulations

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using our products are as natural as hand movements in open surgery. In our experience, based on feedback from surgeons who we believe have performed hundreds of procedures, surgeons can learn to manipulate our instruments with only a limited amount of training as compared to the training required for the surgeon to become skilled in MIS. The time required to learn to perform surgical procedures using the *da Vinci* Surgical System varies depending on the complexity of the procedure and the surgical team's experience with MIS techniques.

- *Multi-Specialty Surgical Platform.* The *da Vinci* Surgical System is designed to enable surgeons to perform a wide range of surgical procedures. To date, we believe surgeons have used the *da Vinci* Surgical System to perform over 100 different types of surgical procedures.

We believe that these advantages provide the patient with benefits of reduced trauma while restoring to the surgeon the range of motion and fine tissue control consistent with open surgery, along with further enhancements such as tremor reduction, motion scaling and superior visualization.

We believe that our technology has the potential to change surgical procedures in two basic ways:

- *Convert Open Procedures to Intuitive Surgery.* Convert procedures which are traditionally performed through large incisions to *Intuitive* surgery.
- *Facilitate Difficult MIS Operations.* We believe surgical procedures that today are performed only rarely using MIS techniques will be performed routinely and with confidence using *Intuitive* surgery. Some procedures have been adapted for port-based techniques but are extremely difficult and are currently performed by a limited number of highly skilled surgeons. We believe our *da Vinci* Surgical System will enable more surgeons at more institutions to perform these procedures.

Intuitive Surgical's Products

Our principal products include the *da Vinci* Surgical System and a variety of "smart disposable" *EndoWrist* instruments.

***da Vinci* Surgical System**

Our *da Vinci* Surgical System is comprised of the following components:

- *Surgeon's Console.* The *da Vinci* Surgical System allows the surgeon to operate while comfortably seated at an ergonomic console viewing a 3-D image of the surgical field. The surgeon's fingers grasp the instrument controls below the display with hands naturally positioned relative to his or her eyes. Using hardware, software, algorithms, mechanics and optics, our technology is designed to seamlessly translate the surgeon's hand movements into precise and corresponding real-time microsurgical movements of the *EndoWrist* instruments inside the patient.
- *Patient-Side Cart.* The patient-side cart, which can be easily moved next to the operating table, holds electromechanical arms that manipulate the instruments inside the patient. Up to four arms attached to the cart can be easily positioned as appropriate, and then locked into place. The first two arms, one representing the left hand and one the right hand of the surgeon, hold our *EndoWrist* instruments. The third arm positions the endoscope, allowing the surgeon to easily move, zoom and rotate his or her field of vision. The fourth arm option provides additional surgical capabilities by holding an additional *EndoWrist* instrument as well as potentially eliminating the need for an assistant surgeon. The surgeon has a choice of simultaneously controlling any two of the operating arms by tapping a foot pedal underneath the surgeon's console. The fourth arm is available as an option on new *da Vinci* Surgical Systems and can be added as an upgrade to existing *da Vinci* Surgical Systems.
- *3-D Vision System.* Our vision system includes our InSite high resolution three dimensional, or 3-D, endoscope with two separate vision channels linked to two high resolution, progressive scan color monitors. Our vision system also incorporates our InSite image processing equipment comprised of high

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performance video cameras and specialized edge enhancement and noise reduction equipment. The resulting 3-D image has high resolution and contrast and no flicker or cross fading, which sometimes occur in single monitor systems, and minimizes eye fatigue. Our vision system allows the surgeon to move his or her head in the viewer without affecting image quality.

EndoWrist Instruments

We manufacture a variety of *EndoWrist* instruments, each of which incorporates a wrist joint for natural dexterity, with tips customized for various surgical procedures. These *EndoWrist* instruments are currently approximately five or eight millimeters in diameter. The instruments mount onto the electromechanical arms that represent the surgeon's left and right hands and provide the mechanical capability necessary for performing complex tissue manipulations through ports. At their tips, the various *EndoWrist* instruments include forceps, scissors, electrocautery, scalpels and other surgical tools that are familiar to the surgeon from open surgery and MIS. Generally, a variety of *EndoWrist* instruments are selected and used interchangeably during a surgery. Where instrument tips need to incorporate a disposable component, such as scalpel blades, we sell disposable inserts. We plan to continue to add new types of *EndoWrist* instruments for additional types of surgical procedures.

The *EndoWrist* instruments are "smart disposables" because they are resterilizable and reusable for a defined number of procedures. A custom computer chip inside each instrument performs several functions that help determine how the system and instruments work together. When an *EndoWrist* instrument is attached to an arm of the patient-side cart, the chip performs an "electronic handshake" that ensures the instrument was manufactured by us and recognizes the type and function of the instrument and number of past uses. For example, the chip distinguishes between scissors and a scalpel and controls the unique functions of different instruments as appropriate. In addition, the chip will not allow the instrument to be used for more than the prescribed number of procedures so that its performance meets specifications during each procedure.

Other Products

Other products include the AESOP Endoscope Positioner, a surgical robot capable of positioning an endoscope in response to a surgeon's commands, the ZEUS Surgical System, a robotic platform designed to improve a surgeon's ability to perform complex surgical procedures, the HERMES Control Center, a voice activated operating room control system designed to enable a surgeon to directly control multiple operating room devices through simple verbal commands and the SOCRATES Telementoring System, an interactive telecollaborative system allowing a surgeon to mentor and collaborate with another surgeon during an operation. We are no longer promoting the ZEUS and SOCRATES products, however, we continue to support systems that are installed at customer sites. We have discontinued pursuing any further regulatory approvals for these products.

Using the *da Vinci* Surgical System

During a procedure, the patient-side cart is positioned next to the operating table with the electromechanical arms arranged to provide access to the initial ports selected by the surgeon. Metal tubes attached to the arms are inserted through the ports, and the *EndoWrist* instruments are introduced through the tubes into the patient's body. The surgeon then performs the procedure while sitting comfortably at the surgeon's console, manipulating the instrument controls and viewing the operation through our InSite vision system. When a surgeon needs to change an instrument, as is done many times during an operation, the instrument is withdrawn from the surgical field using the controls at the console, in similar fashion to the way a surgeon withdraws instruments from the patient in MIS. A scrub nurse standing near the patient removes the unwanted instrument from the electromechanical arm and replaces it with the new instrument, in a process designed to be rapid enough not to disturb the natural flow of the procedure. As a result, the scrub nurse plays a role similar to that played in open surgery and MIS. At the conclusion of the operation, the metal tubes are removed from the patient's body and the small incisions are sutured or stapled.

Our Strategy

Our goal is to establish *Intuitive* surgery as the standard approach for complex surgical procedures, displacing both open surgical technique and standard MIS within this segment. We intend to accomplish this objective both by pioneering new types of endoscopic surgery and by making existing MIS procedures easier, safer and more cost effective than the alternative methods. Over time, our strategy is to broaden the number of procedures performed using the *da Vinci* Surgical System and to educate surgeons, hospitals and patients as to the benefits of *Intuitive* surgery. Key elements of our strategy include the following:

- *Focus on Key Procedures.* Our procedure marketing efforts are primarily focused within three surgical specialties: urologic surgery, cardiothoracic surgery and general surgery. The mix of procedures being performed with the *da Vinci* Surgical System among these three surgical specialties is largest within urology, followed by cardiothoracic and general surgery. The *da Vinci* Surgical System is used to perform, among other procedures, *da Vinci* Prostatectomy, *da Vinci* Mitral Valve Repair, Multi-Vessel Small-Thoracotomy and *da Vinci* Gastric Bypass. The development of key procedures, which often are in parallel with our FDA clearances, has been a catalyst for the growth of our company.
- *Focus on Key Institutions.* Our marketing efforts are focused on both academic and community hospitals. Following the initial placement within a given hospital, we endeavor to expand the number of physicians who use the *da Vinci* Surgical System and work with the hospitals and their surgeons to promote patient education as to the benefits of *Intuitive* surgery. We believe that these efforts will result in increased usage per system, leading to higher volume sales of instruments and sales of additional systems at each hospital. In addition, we believe these efforts will benefit early-adopting hospitals by increasing their market share in the procedures and specialties that benefit from *Intuitive* surgery. We expect these efforts to increase demand for our products among competitive hospitals, surgeons and referring physicians.
- *Focus on Leading Surgeons to Drive Rapid and Broad Adoption.* We place significant emphasis on marketing the *da Vinci* Surgical System to leading surgeons who are considered to be “thought leaders” in their institutions and fields. These surgeons typically perform complex surgical procedures that are currently not adaptable to MIS techniques. For example, cardiac procedures are among the most difficult to perform using MIS techniques. This strategy puts surgeons at the forefront of procedure development and provides them an opportunity to maintain a competitive edge within their specialty. We believe that early adoption of our products by surgical thought leaders will give many other surgeons the confidence that the *da Vinci* Surgical System can be used for all types of surgical procedures. In addition to working with academic-based thought leaders, we will work with busy community-based surgeons who are focused on differentiating themselves within their community. We will help them expand their busy clinical practice by offering their patients an increased number of MIS procedures.
- *Develop Protocols for New Surgical Procedures.* We intend to leverage our relationships with key institutions and surgical thought leaders to develop protocols for new surgical procedures. These protocols will include guidance on patient screening, port placement, interaction of the surgical team and advice on the sequence and selection of tools and maneuvers. We believe that establishing protocols for a given procedure will facilitate the broader adoption of *Intuitive* surgery for that procedure.
- *Maintain Market Leadership.* We intend to maintain our leadership advantage by continuing to develop and enhance our technology and to communicate the benefits of our *da Vinci* Surgical System to surgeons, hospitals and patients. We will continue to improve our *da Vinci* Surgical System through software and hardware enhancements and by developing new surgical instruments. We will also continue to develop our surgical platform to facilitate and support future surgical innovations.
- *Develop Industry Alliances.* We intend to continue to establish strategic alliances with leading medical device companies. To date, these alliances have taken several forms, including cooperation in the areas of product development, training, procedure development and marketing activities. We have formed alliances with, among other companies, Ethicon Endo-Surgery, Inc., Olympus Corporation and Medtronic, Inc.

Clinical Applications

We believe our technology is capable of enhancing or enabling a wide variety of procedures in many surgical specialties. Surgeons using our *da Vinci* Surgical System have performed thousands of surgical procedures of various types, including urologic, cardiothoracic, and general surgery. These surgical applications, which are currently cleared by the FDA, are further described below.

Urologic Surgery

Prostatectomy. Radical prostatectomy is the removal of the prostate gland in patients diagnosed with clinically localized prostatic cancer. The current approach to removal of the prostate is via an open surgical procedure or a laparoscopic approach. The laparoscopic approach, while not prevalent, is difficult and poses challenges to even the most skilled urologist. The *da Vinci* Surgical system allows for improved visualization of the gross anatomy (dorsal veins, endopelvic fascia, bladder muscle, puboprostatic ligaments), microanatomy (bladder mucosa, nerve bundles) and tissue planes which are critical for an anatomic dissection. Radical prostatectomy using the *da Vinci* Surgical System allows for positive oncologic results, reduced operative blood loss, less postoperative pain, improved cosmesis and potentially a better nerve-sparing technique. The *da Vinci* Surgical System has enabled a large number of surgeons to convert from using an open surgical technique to a minimally invasive technique.

Cardiothoracic Surgery

Internal Mammary Artery Dissection. In a coronary artery bypass graft procedure used in cardiac surgery, a blocked coronary artery is bypassed with a graft. When available, an artery from the chest called the internal mammary artery is dissected from its natural position and grafted into place to perform the bypass. Because the internal mammary artery is located on the underside of the anterior surface of the chest, dissection of the vessel is challenging using existing surgical instruments through the three- to five-inch incision currently used in a coronary artery bypass graft procedure. The *da Vinci* Surgical System instruments have multiple joints that emulate the surgeon's arms and hands, allowing exact positioning of the instruments inside the patient's chest. In addition, the *EndoWrist* joints permit the surgeon to reach behind the tissues for easier dissection of the internal mammary artery. Thus, we believe that the internal mammary artery can be dissected with greater ease and precision using our technology.

Thoracoscopy. A number of procedures performed in the thorax, or chest cavity, can be accomplished by minimally invasive methods. These methods are generally referred to as thoracoscopic procedures. They include various types of lung resection, biopsy procedures, node dissections, nerve resections and esophageal surgery. Conventional thoracoscopic tools have all the limitations of conventional laparoscopic tools, such as "backward" movement and limited range of motion. We believe that the capability of our technology to operate dexterously in the often very small and restrictive space of the chest cavity offers significant clinical value in the performance of advanced thoracoscopic procedures.

Mitral Valve Repair. Valve repair surgeries are challenging even when using open surgical techniques. Significant exposure of the surgical field is essential to the identification and precise manipulation of valves and other structures inside the heart, and is key to successful surgical outcomes with minimal complications. Motion scaling allows a surgeon using our *da Vinci* Surgical System to maneuver instruments inside the patient even more precisely than is possible in open surgery. Our system has already enabled heart valve repairs to be performed through small ports in a manner that could not have been accomplished with open surgery.

Coronary Artery Bypass. The traditional approach to coronary artery bypass grafting, or CABG, involves splitting the breastbone via a median sternotomy incision, placing the patient on cardio pulmonary bypass, or CPB, and "bypassing" diseased segments of arteries in the heart with conduit arteries and veins. Over time, successful results from this operation have been widely reported. However, there are known morbidities from this approach that MIS techniques for coronary artery bypass surgery seek to overcome. With assistance from the

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da Vinci Surgical System, patients can undergo multi-vessel full surgical revascularization, while avoiding CPB and the median sternotomy incision, thus reducing the morbidities associated with these procedures. In Multi-Vessel Small Thoracotomy, or MVST, procedures, surgeons use the *da Vinci* System to precisely mobilize one or both internal mammary arteries for use in the bypass operation. This is accomplished through three small port incisions in the left chest and once completed, the middle port incision is extended into a 4-6 centimeter incision, enabling the surgeon to complete the anastomoses directly through the incision. Surgeons can also complete the anastomoses using the *da Vinci System* to avoid creating the 4-6 centimeter incision, thus completing the revascularization of the heart entirely with the *da Vinci* System. In addition to reducing known morbidities from standard open-chest coronary artery bypass surgery, revascularization with the *da Vinci* System sets a new standard in minimally invasive coronary artery bypass surgery by placing the patient on an accelerated path to recovery.

General Surgery

Gastric Bypass. A growing number of patients are undergoing surgical treatment for their morbid obesity. Laparoscopic Roux-en-Y gastric bypass, or LRYGB, is the most commonly performed surgical procedure for morbid obesity in the United States. Briefly, the LRYGB operation promotes weight loss by two mechanisms. First, the size of the stomach is greatly reduced by surgical “stapling” thus restricting the amount of food the patient can consume at a given time. Second, a long segment of intestine is bypassed causing less food to be absorbed. The LRYGB is arguably one of the most technically challenging laparoscopic procedures because of the suturing, stapling and tissue (bowel) manipulation that is required. A critical portion of the operation is anastomosing the stomach to the small intestine. Leaks in the anastomosis are the cause of major complications that can result in death. The *da Vinci*[®] Surgical System is used by surgeons in suturing this anastomosis. Surgeons using the *da Vinci* system have reported that a *da Vinci* hand-sewn anastomosis results in a patient anastomosis with fewer leaks.

Nissen Fundoplication. Nissen fundoplication is a general surgical procedure that is performed to correct esophageal reflux. Esophageal reflux disease is a digestive disorder that affects the muscle connecting the esophagus with the stomach. As an elective procedure, Nissen fundoplication is currently performed on only a small fraction of candidates who suffer from this condition because the open surgical procedure is quite invasive. An MIS alternative exists, but there are only a limited number of surgeons skilled in the procedure. We believe that our technology will significantly improve the ease of performing the Nissen procedure through ports. Specifically, our technology will address the two most difficult steps in this procedure, which are made more difficult by existing MIS techniques, esophageal dissection and suturing of the fundus of the stomach. If adoption of our technology becomes widespread for Nissen procedures, we believe that the number of surgeons able to perform a Nissen procedure using port-based techniques will increase. Further, we expect that the widespread availability of a port-based approach may significantly expand the number of surgeries performed.

Additional Clinical Applications

We believe there are numerous additional applications that can be addressed with the *da Vinci* Surgical System. The *da Vinci* Surgical System has full regulatory clearance in Europe and has been used in Europe for other applications which have not yet been cleared by the FDA. The following are examples of these additional clinical applications.

General Gynecologic Surgery. Laparoscopy has been used for several decades in a large number of diagnostic infertility procedures. Although there are a variety of therapeutic infertility procedures that can currently be performed by some gynecologists using existing MIS techniques, these procedures are relatively difficult to perform using existing MIS tools because of the lack of tissue control, inability to perform fine dissection, and limited suturing capability. We believe that our technology will provide gynecologists with the ability to do sophisticated procedures, such as tubal re-anastomosis and dissection of ovarian cysts, as well as common procedures, such as surgical removal of an ovary or fallopian tube.

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Hysterectomy. Removal of the uterus is one of the most commonly performed surgeries in gynecology and it can be done by using open surgery or MIS techniques. Like colon resection, it demands a significant degree of tissue manipulation in the dissection and ligation, or tying, of blood vessels, ligaments and other pelvic structures. Further, laparoscopic techniques used in this procedure increase the risk of injury to the ureters, which are vital structures that provide the conduit for urine between the kidney and bladder. It is often difficult to ensure the identification and prevention of injury to the ureters and bladder with conventional MIS instruments because of the limited angles at which these instruments can be positioned. We believe that our products will increase the surgeon's dexterity in this procedure and, as a result, will have a significant impact on safety, operating time, and rate of adoption of port-based techniques in hysterectomy.

Bladder Neck Suspension. Bladder incontinence is a widespread condition affecting middle aged women, which can be treated surgically with a procedure known as bladder neck suspension. This procedure involves elevation of the bladder neck by suspension with sutures, surgically recreating the normal angle of the urethra and re-establishing bladder sphincter control. The procedure works well in open surgery and is the "gold standard" for correction of bladder incontinence. However, because of its long recovery time, most candidates are discouraged from undergoing the procedure using open surgical technique. Instead, they use adult diapers for their incontinence, which is an embarrassment and inconvenience. Bladder neck suspension can currently be done laparoscopically but is difficult to perform because of the need to suture at awkward angles using existing MIS instruments. We believe our technology may provide a better solution for suturing the bladder neck and would represent an advance in the ease of performing incontinence surgery.

Marketing and Distribution

We market our products through a direct sales force in the United States and parts of Europe. We have also entered into agreements with distributors in Australia, Canada, India, Italy, Romania, Saudi Arabia, Singapore, Taiwan, Turkey, and the United Kingdom. Our marketing and sales strategy in the United States and Europe involves the use of a combination of clinical marketing managers, area sales managers, account managers and clinical training specialists. As of December 31, 2004, we had 140 employees in sales and marketing. We expect to increase our sales and marketing force as we expand our business. The role of our sales representatives is to educate physicians and surgeons on the advantages of *Intuitive* surgery and the clinical applications that our technology makes possible. We also train our sales representatives to educate hospital management on the potential benefits of early adoption of our technology and the potential for increased local market share that may result from *Intuitive* surgery. Once a hospital has installed a *da Vinci* Surgical System, our sales force helps introduce the technology to other surgical specialties within the hospital.

Clinical training specialists provide product training and support to physicians and other hospital staff. We employ service technicians to install our *da Vinci* Surgical Systems and to provide non-clinical technical expertise, service and maintenance. We believe that this combination of area sales managers, account managers, clinical training specialists and service technicians provides an appropriate balance of professional selling skills while maintaining an adequate level of technical expertise in the field.

Our *da Vinci* Surgical System has a lengthy sales and purchase order cycle because it is a major capital item and normally requires the approval of senior management at purchasing institutions. Particularly during periods in which our sales volume is low, this may contribute to fluctuations in our quarterly operating results.

Technology

Using key technologies, we have designed the *da Vinci* Surgical System to ensure intuitive control and fail-safe operation of the system. The system updates arm and instrument positions over 1,000 times per second, thereby ensuring real-time connectivity between the surgeon's hand movements and the movements of the instrument tips. A backup battery is included in the system that can power the system for more than 20 minutes in case of power loss or fluctuation. We believe this 20-minute period is sufficient either to reestablish the power supply or for the hospital back-up power system to become effective.

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Monitoring the operation of the system at all times is a network of approximately 20 micro-controllers that checks for proper system performance. System misuse or system fault can be detected and the system can be transitioned to a safe state in milli-seconds. The system also includes a sensor that detects the presence of the surgeon's head in the viewer. If the surgeon removes his or her head from the viewer, the system automatically disengages and locks the instruments in place to prevent inadvertent movement.

The instrument controls at the surgeon's console have eight degrees of freedom of motion that allow the surgeon to move each hand through a workspace approximately one cubic foot in volume. This range of motion allows the surgeon to orient his or her hands with minimal limitations. The instrument controls are constructed with very low friction cables and gear transmissions to ensure smooth operation. Furthermore, critical components are constructed of various alloys and other materials to provide high mechanical stiffness and low inertia, ensuring a light and responsive feel to the surgeon.

The electromechanical arms of the patient-side cart are gravitationally counterbalanced to allow for smooth, easy and safe positioning of the instruments in the patient. The arms have seven degrees of freedom, allowing for control of position, orientation, and grip of the instrument, inside the patient's body. Redundant sensors are designed to ensure fail-safe operation of the instrument.

Unlike other 3-D systems, our InSite vision system relies on two entirely separate vision channels. Two eyepieces are linked by a precisely designed optical assembly to two high contrast medical grade monitors, and accompanying electronics, which have been specially designed to have a refresh update rate that eliminates flicker and reduces eye fatigue. Our stereo endoscope uses two separate high-resolution optical channels to improve image clarity. The stereo images pass through video processing electronics that provide specialized edge enhancement and noise reduction. A foot switch at the surgeon's console operates a focus controller on the endoscope. The endoscope self-regulates the temperature of its tip to minimize fogging during procedures.

Our *EndoWrist* instruments use a wrist joint architecture driven by tiny but very high strength, flexible tungsten cables. Each tungsten cable is a "metal rope" constructed from over 200 fibers that are each less than one thousandth of an inch in diameter. These cables are similar in function to the tendons of a human wrist and are used to drive fluid motions of the wrist joint. The instruments each contain a memory chip that records and stores data each time the instrument is placed on the system. The chip contains encrypted security codes to protect against use of non-Intuitive Surgical instruments so that only our instruments will work with the *da Vinci* Surgical System. The chip identifies the type of tool being inserted so that different instrument types can be controlled uniquely by the system. The chip also records usage of the instrument and enables the system to expire the instrument after its prescribed life.

Intellectual Property

Since our inception in late 1995, we have encountered and solved a number of technical hurdles. We have patented and continue to pursue patent and other intellectual property protection for the technology that we have developed to overcome these hurdles. In addition to developing our own patent portfolio, we have spent significant resources in acquiring exclusive license rights to necessary and desirable patents and other intellectual property from SRI International and IBM, which were early leaders in applying robotics to surgery. One of the strengths of our portfolio is that the licensed SRI International and IBM patents have original filing dates as early as January 1992 and June 1991, respectively. We have also exclusively licensed a patent application from MIT concerning robotic surgery. In April 2000, we exclusively licensed an extensive minimally invasive heart surgery patent portfolio from Heartport, Inc. in the field of robotic surgery. These patents cover many different forms of minimally invasive robotic surgery, including single- and multi-vessel coronary artery bypass grafts, heart valve repair and replacement and beating heart stabilization. In June 2001, we entered into a non-exclusive patent license with Olympus Optical Co., Ltd. of Japan for several robotic surgery patents. As a result of our merger with Computer Motion, we now have the benefit of patent licenses previously held by Computer Motion. Computer Motion began filing patent applications by 1988, and over 38 US patents had issued from these filings as of February 2005. The first of these patents will expire in 2008. In January 2004, we licensed both exclusively and non-exclusively four patents from Brookhill-Wilk, LLC.

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As of February 2005, we held exclusive field-of-use as well as non-exclusive licenses for over 100 United States patents and over 35 foreign patents, and own outright 91 United States patents that expire no earlier than March 2008. We also own or have licensed numerous pending United States and foreign patent applications. Our patents and patent applications relate to a number of important aspects of our technology, including our surgeon's console, electromechanical arms, vision system, endoscope positioning system and EndoWrist instruments. We intend to continue to file additional patent applications both in the United States and in foreign jurisdictions to seek protection for our technology.

Our success will depend in part on our ability to obtain patent and copyright protection for our products and processes, to preserve our trade secrets, to operate without infringing or violating valid and enforceable proprietary rights of third parties, and to prevent others from infringing our proprietary rights. We intend to take action to protect our intellectual property rights when we believe doing so is necessary and appropriate. In addition, our strategy is to actively pursue patent protection in the United States and in foreign jurisdictions for technology that we believe is proprietary and that offers a potential competitive advantage, and to license appropriate technologies when necessary or desirable. We cannot be certain that we will be able to obtain adequate protection for our technology or licenses on acceptable terms. Furthermore, if any protection we obtain is reduced or eliminated, others could use our intellectual property without compensating us, resulting in harm to our business. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States. Others may assert that our products infringe their intellectual property rights, which may cause us to engage in costly disputes and, if we are not successful in defending ourselves, could also cause us to pay substantial damages and prohibit us from selling our products.

SRI International License Agreement

In the late 1980s and the early 1990s, SRI International conducted research to develop a "telesurgery" system to allow surgeons to perform surgery on the battlefield from a remote location. SRI International developed the precise electromechanics, force-feedback systems, vision systems and surgical instruments needed to build and demonstrate a prototype system that could accurately reproduce a surgeon's hand motions with remote surgical instruments. In 1995, John G. Freund, M.D., one of our founders, acquired an option to license SRI International's telesurgery technology, which resulted in SRI International granting us a license.

Under the terms of our license agreement with SRI International, we have an exclusive, worldwide, royalty-free license to use the SRI International technology developed before September 12, 1997, including all patents and patent applications resulting from that work, in the field of manipulating tissues and medical devices in animal and human medicine, including surgery, laparoscopic surgery and microsurgery. We also have the right of first negotiation with respect to any SRI International technology developed in these areas before September 12, 1999 but after September 12, 1997.

Our license with SRI International will terminate upon the last expiration of the patents licensed from SRI International or December 20, 2012, whichever is later. Currently, the last patent expiration date is in 2016, although this could change. SRI International may terminate the license in the event of a material, uncured breach of our obligations. In the event SRI International terminates the license, we do not know whether the necessary licenses could be reacquired from SRI International on satisfactory terms, if at all.

IBM License Agreement

IBM conducted research on the application of computers and robotics to surgery during the late 1980s and early 1990s. IBM performed some of this work in conjunction with the Johns Hopkins Medical Center. Our license agreement with IBM covers a number of technologies related to the application of computers and robotics to surgery. Under the terms of this agreement, we have an exclusive, worldwide, royalty-free license to a number of IBM patents and patent applications in the field of surgery performed on animals and humans. We also have a non-exclusive license from IBM to practice in the areas of neurology, ophthalmology, orthopedics and biopsies.

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Under the license, we made two payments tied to revenue milestones. We made the final payment in March 2002. The IBM license agreement will terminate upon the last expiration of the licensed patents. Currently, the last patent expiration date is in 2016, although this could change.

MIT License Agreement

After receiving funding from the United States Department of the Army, several researchers at MIT conducted research on various aspects of robotic surgical systems. As a result of that work, several patent applications were filed. Both MIT and the Army waived their rights to all but one of these applications, which the inventors ultimately assigned to us. MIT owns the other application. Under the terms of our license agreement with MIT, we have an exclusive, worldwide, royalty-free license to this patent application in the field of medical devices. The MIT license will terminate upon the last expiration of any patents issuing in the future from the licensed patent application, which is currently expected to occur in 2017. MIT also has the right to terminate the MIT license in the event of a material, uncured breach of our obligations under the license. In the event MIT terminates the license, we do not know whether we would be able to reacquire a license from MIT on satisfactory terms, if at all. MIT reserved the right to practice any patents for research, teaching, and educational purposes and the United States federal government is allowed to practice any government funded invention under any resulting United States patents as a result of its funding of the underlying project.

Heartport, Inc. License Agreement

Since its inception in the early 1990s, Heartport, Inc. has developed an extensive patent portfolio covering systems and methods for performing many different aspects of minimally invasive heart surgery, including single-and multi-vessel coronary artery bypass grafts, heart valve repair and replacement, and beating heart stabilization. In April 2000, we acquired an exclusive, worldwide license in the field of robotic surgery to much of Heartport's portfolio, including issued United States patents and pending United States and foreign applications. The license is royalty-free unless we sell instruments for robotic surgery procedures that are not operated by the robotic surgery system, in which case we pay a small royalty.

Our license will terminate upon the last expiration of the patents licensed from Heartport, which is currently expected to occur in 2015. This termination date may be extended beyond 2015 as a result of actions that could be taken by the United States Patent and Trademark Office, or USPTO, relating to pending patent applications. For example, the USPTO may extend the term of one or more of the patents licensed from Heartport in response to delays by the USPTO during prosecution of the patent application, or if requested, in response to delay by the Food and Drug Administration in approving a medical device. No such extension of the patents from Heartport may be available or requested, and if requested, an extension might not be granted by the USPTO. It is also possible that the USPTO could shorten the term of the last patent licensed from Heartport, so that the last patent may expire before 2015. For example, the USPTO may require that Heartport agree to an earlier expiration date as a condition for granting Heartport a particular patent. Additionally, Heartport might, with our input, ask the USPTO to shorten the term of one or more application or patent. The USPTO also has the power, on its own initiative or at the request of one of our competitors, to initiate proceedings during which Heartport could be required to agree to a shortened patent term. Although we are not aware of any such USPTO proceedings being considered or requested, we cannot guarantee outcome of any such proceedings. Heartport may terminate the license in the event of a material, uncured breach of our obligations. In the event Heartport terminates the license, we do not know whether the necessary or desirable licenses could be reacquired from Heartport on satisfactory terms, if at all.

In April 2001, Heartport became part of the Cardioventions Division of Ethicon Endo-Surgery, Inc., a Johnson & Johnson company. Our exclusive license survives Johnson & Johnson's acquisition of Heartport. Ethicon Endo-Surgery, Inc. therefore is our licensor under the Heartport license.

Wilk License Agreement

Dr. Peter J. Wilk graduated from Yale and the New York Medical College, and is a noted surgeon and inventor. Beginning in 1991, Dr. Wilk filed a series of patent applications for automated surgical apparatus and

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methods, with claims directed to robotic surgery. In January of 2004, Dr. Wilk and two entities with whom he is affiliated, Brookhill-Wilk 1, LLC and the Wilk Patent Development Corporation, granted a license to our company to those patent filings, thereby settling a patent infringement lawsuit. Pursuant to the agreement, our company was granted an exclusive license in the field of surgical robotic systems for two issued patents, a non-exclusive license to another issued patent, and an agreement that our company will not be sued under at least one additional issued patent. The license is fully paid and royalty-free, and covers patents which may issue from applications which are related to the licensed patents, but does not cover any new, separate patent applications Dr. Wilk may file or has filed after January 13, 2004.

Research and Development

We focus our research and development efforts on providing our customers with new products and product improvements that enable them to perform new and better surgical procedures with less difficulty. Our research and development team includes experienced personnel in robotic technology. Our design engineers span a number of disciplines, including software engineering, systems analysis and electrical and mechanical engineering. In addition, we have engineers who specialize in vision technology. Finally, we have a manufacturing engineering group that continues to improve the manufacturability and quality of our products. We incurred \$17.8 million, \$16.2 million and \$16.8 million of research and development expenses for the years ended December 31, 2004, 2003 and 2002, respectively.

Manufacturing

The manufacture of our products is a complex operation involving a number of separate processes and components. We purchase both custom and off-the-shelf components from a large number of certified suppliers and subject them to stringent quality specifications. We periodically conduct quality audits of suppliers and have established a supplier certification program. Some of the components necessary for the assembly of our products are currently provided to us by sole source suppliers or single source suppliers. We purchase components through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of finished goods. While alternative suppliers exist and could be identified for sole-sourced components, the disruption or termination of the supply of components could cause a significant increase in the costs of these components, which could affect our operating results. A disruption or termination in the supply of components could also result in our inability to meet demand for our products, which could harm our ability to generate revenues, lead to customer dissatisfaction and damage our reputation.

Competition

We consider our primary competition to be existing open surgery, MIS, drug therapies and emerging interventional surgical approaches. Our success depends in part on convincing hospitals, surgeons and patients that the demonstrated benefits associated with *Intuitive* surgery are superior to other techniques. We also face competition from several companies that are developing new approaches and products for the MIS market. Because many of these developments are aimed at MIS, we believe that our *da Vinci* Surgical System may actually prove complementary to these new technologies.

In addition, a limited number of companies are using or planning to use robots and computers in surgery, including Hitachi Ltd., Integrated Surgical Systems, Inc., Maquet AG, MicroDexterity Systems, Inc., Armstrong Healthcare Ltd., Sinters SA, and Ross-Hime Designs, Inc. Our revenues may be reduced or eliminated if our competitors develop and market products that are more effective or less expensive than our products.

We believe that the primary competitive factors in the market we address are capability, safety, efficacy, ease of use, price, quality, reliability, and effective sales, support, training and service. The length of time required for products to be developed and to receive regulatory and reimbursement approval is also an important competitive factor.

Government Regulation

United States

Our products and operations are subject to extensive and rigorous regulation by the FDA. The FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, promotion, distribution, and production of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical devices manufactured in the United States to international markets.

Under the Federal Food, Drug, and Cosmetic Act, or FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Our current products are Class II medical devices.

Class I devices are those for which safety and effectiveness can be assured by adherence to general controls, which include compliance with the applicable portions of the FDA’s Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are those which are subject to the general controls and most require premarket demonstration of adherence to certain performance standards or other special controls, as specified by the FDA, and clearance by the FDA. Premarket review and clearance by the FDA for these devices is accomplished through the 510(k) premarket notification process. For most Class II devices, the manufacturer must submit to the FDA a premarket notification submission, demonstrating that the device is “substantially equivalent” in intended use and technology to a “predicate device” that is either:

- (1) a device that has grandfather marketing status because it was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or
- (2) a Class I or II device that has been cleared through the 510(k) process.

If the FDA agrees that the device is substantially equivalent to a predicate device, it will grant clearance to commercially market the device. The FDA has 90 days to respond to a 510(k) submission. As a practical matter, clearance often takes longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not “substantially equivalent,” the FDA will place the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill much more rigorous pre-marketing requirements.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a pre-market approval application, or PMA, approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer’s decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

A Class III product is a product which has a new intended use or uses advanced technology that is not substantially equivalent to a predicate device. The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices almost always require formal clinical studies to demonstrate safety and effectiveness.

Approval of a PMA from the FDA is required before marketing of a Class III product can proceed. The PMA process is much more demanding than the 510(k) pre-market notification process and requires proof of the safety and effectiveness of Class III devices to the FDA’s satisfaction. A PMA application must be supported by

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extensive data, including data from pre-clinical studies and human clinical trials and existing research material, and must contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Once the FDA determines that an application is sufficiently complete to permit a substantive review, the FDA will accept the application for review. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application frequently occurs over a significantly longer period of time, sometimes up to several years. In approving a PMA application or clearing a 510(k) application, the FDA may also require some form of post-market surveillance, whereby the manufacturer follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. After approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process.

When FDA clearance or approval of a Class I, Class II or Class III device requires human clinical trials, and if the device presents a “significant risk” (as defined by the FDA) to human health, the device sponsor is required to file an investigational device exemption, or IDE, application with the FDA and obtain IDE approval prior to commencing the human clinical trial. If the device is considered a “non-significant” risk, IDE submission to the FDA is not required. Instead, only approval from the Institutional Review Board overseeing the clinical trial is required. The *da Vinci Surgical System* is considered a significant risk device that requires IDE approval for any clinical trial involving an investigational use.

Our manufacturing processes are required to comply with the FDA’s Good Manufacturing Practice, or GMP, requirements contained in its Quality System Regulation, or QSR. The QSR covers, among other things, the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging, and shipping of a company’s products. The QSR also requires maintenance of a device master record, device history record, design history file and complaint files. A company’s domestic facility, records, and manufacturing processes are subject to periodic unscheduled inspections by the FDA.

Other post-market regulatory requirements apply to our commercial distribution of the *da Vinci Surgical System*, including the following:

- labeling regulations;
- the FDA’s general prohibition against promoting products for unapproved or “off label” uses;
- the Reports of Corrections and Removals regulation, which requires that manufacturers report to FDA recalls and field corrective actions taken to reduce a risk to health or to remedy a violation of the FDCA that may pose a risk to health; and
- the Medical Device Reporting regulation, which requires 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 it were to recur.

Class II devices also must comply with applicable special controls, such as post-market surveillance or patient registries.

We are subject to inspection and marketing surveillance by the FDA to determine compliance with all regulatory requirements. If the FDA finds that we have failed to comply, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions including the following:

- fines, injunctions, 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 PMA approval of new products;
- withdrawing 510(k) clearance or PMA approvals already granted; and
- criminal prosecution.

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In July 1997, we received 510(k) clearance from the FDA for the surgeon's console and patient cart to be used with only rigid endoscopes, blunt dissectors, retractors and stabilizer instruments. In November 1997, we withdrew a subsequent 510(k) submission covering additional instruments necessary for performing most surgical procedures, including scissors, scalpels, forceps/pickups, needle holders, clip applicators and electrocautery, after the FDA indicated that substantial clinical data would be required to support clearance.

In January 1999, we filed a 510(k) submission with clinical data, seeking clearance for the *da Vinci* Surgical System and *EndoWrist* instruments for laparoscopic surgical procedures. In May 1999, the FDA determined that our products were not eligible for 510(k) clearance but would instead be required to undergo the PMA approval process. In June 1999, after review of the clinical data on the use of our products in laparoscopic surgical procedures, the FDA's General Surgery Advisory Panel recommended approval. In November 1999, we filed a PMA application to commercialize our products for laparoscopic surgery, which was accepted for review by the FDA in December 1999. In June 2000, the FDA determined that the PMA approval process was inappropriate for the *da Vinci* Surgical System and re-classified the device as Class II. The Premarket Approval Application submitted in November 1999 was closed and the original 510(k) application reactivated. In July 2000, we received a letter from the FDA informing us of their decision to clear the *da Vinci* Surgical System for use in laparoscopic surgery. The decision to reclassify the device to Class II also means that future submissions for the *da Vinci* Surgical System may be reviewed under the 510(k) process unless changes to the intended use significantly change the safety and effectiveness of the device, in which case a PMA may be required.

Subsequent to the July 2000 clearance of the *da Vinci* Surgical System, we have obtained additional 510(k) clearances from the FDA to include non-cardiac thoracoscopic surgical procedures (March 2001), laparoscopic radical prostatectomy (May 2001), thoracoscopically-assisted cardiectomy procedures (November 2002) and urologic surgical procedures (March 2005). FDA has also cleared the *da Vinci* Surgical System to be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization (July 2004).

In January 2001, we submitted an investigational device exemption application to the FDA requesting permission to conduct a multi-center evaluation of the *da Vinci* Surgical System for totally endoscopic coronary artery bypass grafting. In April 2001, we received a letter from the FDA approving trials for totally endoscopic coronary artery bypass grafting. We have commenced this clinical trial and submitted data in a 510(k) to the FDA requesting permission to expand the indications for use. As a result of this 510(k) submission, the FDA granted us permission to include coronary anastomosis during cardiac revascularization with adjunctive mediastinotomy as an indication for use.

Our 510(k) clearance for laparoscopic radical prostatectomy was obtained after a dispute with the FDA over the scope of the original clearance granted to the *da Vinci* Surgical System in July 2000 for laparoscopic surgical procedures. We believed that this general clearance allowed us to promote the *da Vinci* Surgical System specifically for use in laparoscopic radical prostatectomy without the need for a new 510(k) clearance. The FDA did not agree, and issued a Warning Letter on April 12, 2001, indicating that the *da Vinci* Surgical System could not lawfully be labeled or advertised for laparoscopic radical prostatectomy without additional 510(k) clearance. We therefore sought and received such clearance in May 2001.

At the same time, we reached an understanding with the FDA as to how to interpret the scope of our existing 510(k) clearance for general laparoscopic surgery in a meeting in May 2001. The FDA memorialized this understanding in a May 2002 letter to us, indicating that the labeling, advertising and user training for the *da Vinci* Surgical System may call out specific procedures that reasonably fall within general laparoscopic surgery, but may not call out gynecologic, urologic or vascular laparoscopic surgical procedures without new 510(k) clearance. The FDA also indicated that, prior to calling out any specific procedure, we should perform appropriate risk analysis and validation to ensure that the device design does not introduce new risks and that the instructions for use are appropriate. If clinical data are required for validation of a specific procedure within an existing clearance, we may conduct the study without an IDE (although Institutional Review Board, or IRB, approval is required). We must document our risk analysis and validation in the Design History File for the *da Vinci* Surgical System and have the results available for FDA inspection. In a meeting with the FDA in

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September 2002, we reached an understanding with the agency that this same approach will apply to our other general clearances, such as the clearance for non cardiac thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures.

We have modified the labeling, advertising, and user training for the *da Vinci* Surgical System to call out specific procedures that we believe are within the scope of our existing 510(k) clearances. We cannot assure you that the FDA would agree that all such specific procedures are within the scope of the existing general clearance or that we have compiled adequate information to support the safety and efficacy of using the *da Vinci* Surgical System for all such specific procedures. We also have modified the hardware and software in the *da Vinci* Surgical System in ways that we believe do not require new 510(k) clearance. We cannot assure you that the FDA would agree with our determinations not to seek new 510(k) clearance for any of these changes.

In December 2002, the FDA inspected our Sunnyvale manufacturing facility and issued a Form FDA 483 setting forth three observed compliance deficiencies under the QSR relating to management control, process control, and complaint handling. The Form FDA 483 also set forth two observed deficiencies relating to the failure to report field corrections or recalls to the FDA that the FDA believed should have been reported under the Reports of Corrections and Removals regulation and that, even if the activity was not reportable, required documentation to justify not reporting was not provided. In January 2003, we wrote to the FDA indicating our response to each observation with proposed corrective actions. That same month, FDA responded that the adequacy of our promised corrections and actions would be verified during the next inspection of our facility. To date, the FDA has not returned for another inspection and we continue to evaluate and upgrade our QSR compliance. We cannot assure you that, upon reinspection, the FDA will find that our promised corrective actions are appropriate or that they have been adequately implemented. We also cannot assure you that the FDA will not find other deficiencies in our compliance with the QSR and other postmarket regulations.

In June 2003, we acquired Computer Motion and have integrated its quality system into our own. As a result of the integration and review, we identified that Computer Motion has had deficiencies in complaint handling, Medical Device Reporting and Corrections and Removals reporting in the last several years that required submission of retroactive reports to the FDA. We decided to report 52 MDRs, and we believe that our reporting decisions regarding these 52 complaints are conservative in part because many of the complaints likely would not have been reportable if more information were available at this date. Also, to our knowledge, none of the reported events resulted in a death or serious injury, prolonged hospitalization, or medical intervention to prevent death or serious injury.

Computer Motion did respond to complaint trends, and it addressed the trends through corrective actions. Accordingly, the incidence of many of the types of events in the reports had been mitigated by June 2003. Our review also suggests that significant complaint trends identified by Computer Motion over the period of four years were addressed by corrective actions, which have proven to be effective over time. Computer Motion's product modifications were completed without 510(k) clearance and we believe that they do not require new 510(k) clearance. We cannot assure you that the FDA would agree with our determinations not to seek new 510(k) clearance for any of these changes.

California Regulation

The state of California requires that we obtain a license to manufacture medical devices and subjects us to periodic inspection. Our facilities and manufacturing processes were inspected in February 1998. We passed the inspection and received our device manufacturing license from the Food and Drug Branch, or FDB, of the California Department of Health Service in March 1998. In March 2002, our facilities and manufacturing processes in our Sunnyvale facility were re-inspected by the FDB and, after correction of two observed QSR deficiencies, we have received an updated device manufacturing license for our Sunnyvale facility.

Foreign Regulation

In order for us to market our products in other countries, we must obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. These regulations, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. Failure to obtain regulatory approval in any foreign country in which we plan to market our products may harm our ability to generate revenue and harm our business.

Commercialization of medical devices in Europe is regulated by the European Union. The European Union presently requires that all medical products bear the CE mark for compliance with the Medical Device Directive (93/42/EEC). In order to affix the CE mark on products, a recognized European Notified Body must certify a manufacturer's quality system for compliance with international and European requirements. In January 1999, following an audit of our quality system and Mountain View facility, we received permission from DGM, our Notified Body and agent of the Danish Government, to affix the CE mark to our *da Vinci* Surgical System and *EndoWrist* instruments. To maintain authorization to apply the CE mark, we are subject to annual surveillance audits and periodic re-certification audits. To date we have met these requirements and our certificate is valid until August 2006.

If we modify existing products or develop new products in the future, we may need to apply for permission to affix the CE mark to such products. In addition, we are subject to annual regulatory audits in order to maintain the CE mark permissions already obtained. We do not know whether we will be able to obtain permission to affix the CE mark for new or modified products or whether we will continue to meet the quality and safety standards required to maintain the permissions we have already received. If we are unable to maintain permission to affix the CE mark to our products, we will no longer be able to sell our products in member countries of the European Union.

The Ministry of Health, Labor, and Welfare, or MHLW, regulates commercialization and reimbursement of medical devices in Japan. In July 2002, the Japanese House of Representatives passed and enacted a revised Pharmaceutical Affairs Law, or PAL. The PAL is intended to ensure the safety, efficacy, and quality of medical products in Japan, and the MHLW is expected to fully implement the revised regulations by April 2005. We are evaluating the appropriate strategy for submitting documentation to the MHLW to obtain permission to commercialize our *da Vinci* Surgical System for laparoscopic surgical procedures in Japan. The details of the revised regulation are still being implemented, and we do not know whether the revised PAL will negatively impact our ability to obtain required approvals to market our products in Japan or elsewhere. Furthermore, we do not know whether we will succeed in procuring the required approvals to market our products in Japan or elsewhere, even if we develop a strategy and ultimately apply for these approvals.

The regulations in other countries, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. These regulations typically require regulatory approvals, and compliance with extensive safety and quality system regulations. Failure to obtain regulatory approval in any foreign country in which we plan to market our products, or failure to comply with any regulation in any foreign country in which we market our products, may impact our ability to generate revenue and harm our business.

Third Party Reimbursement

In the United States and international markets where we intend to sell our products, the government and health insurance companies together are responsible for hospital and surgeon reimbursement for virtually all surgical procedures. Governments and insurance companies generally reimburse hospitals and physicians for surgery when the procedures are considered non-experimental and non-cosmetic. In the United States, reimbursement for medical procedures under the Medicare and Medicaid programs is administered by Centers for Medicare & Medicaid Services. Generally, procedure codes are assigned by the American Medical

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Association using the copyrighted Current Procedural Terminology codes, which are in turn incorporated in the Medicare and Medicaid programs coding system. Applications for new procedure codes may be submitted to the American Medical Association.

Governments and insurance companies carefully review and increasingly challenge the prices charged for medical products and services. Reimbursement rates from private companies vary depending on the procedure performed, the third party involved, the insurance plan involved, and other factors. Medicare reimburses hospitals a prospectively determined fixed amount for the costs associated with an in-patient hospitalization based on the patient's discharge diagnosis, and reimburses physicians a prospectively determined fixed amount based on the procedure performed. This fixed amount is paid regardless of the actual costs incurred by the hospital or physician in furnishing the care and is unrelated to the specific devices used in that procedure. Thus, any reimbursements that hospitals obtain for performing surgery with our products will generally have to cover any additional costs that hospitals incur in purchasing our products.

Domestic institutions typically bill the services performed with our products to various third-party payors, such as Medicare, Medicaid and other government programs and private insurance plans. Because our *da Vinci* Surgical System has been cleared for commercial distribution in the United States by the FDA, Medicare reimbursement is available for use of the device in cleared procedures and procedures conducted under an approved investigational device exemption application. We believe that the additional procedures we intend to target are generally already reimbursable by government agencies and insurance companies. If hospitals do not obtain sufficient reimbursement from third-party payors for procedures performed with our products, or if governmental and private payors' policies do not permit reimbursement for surgical procedures performed using our products, we may not be able to generate the revenues necessary to support our business. In such circumstances, we may have to apply to the American Medical Association for a unique Current Procedural Terminology code covering computer-enhanced surgery. If an application for a unique code is required, reimbursement for any use of our products may be unavailable until an appropriate code is granted. The application process, from filing until adoption of a new code, can take two or more years.

In countries outside the United States, reimbursement is obtained from various sources, including governmental authorities, private health insurance plans, and labor unions. In most foreign countries, private insurance systems may also offer payments for some therapies. Additionally, health maintenance organizations are emerging in certain European countries. To effectively conduct our business, we may need to seek international reimbursement approvals, and we do not know if these required approvals will be obtained in a timely manner or at all. Any regulatory or legislative developments in domestic or foreign markets that eliminate or reduce reimbursement rates for procedures performed with our products could harm our ability to sell our products or cause downward pressure on the prices of our products, either of which would affect our ability to generate the revenues necessary to support our business.

Employees

As of December 31, 2004, we had 321 employees, 57 of whom were engaged directly in research and development, 102 in manufacturing and service and 162 in marketing, sales, and administrative activities. None of our employees are covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

Website Access to Reports

We make our periodic and current reports available, free of charge, on our website as soon as practicable after such material is electronically filed with the Securities and Exchange Commission. Our website address is www.intuitivesurgical.com and the reports are filed under "SEC Filings."

ITEM 2: PROPERTIES

Our headquarters and manufacturing facility are located in an approximately 105,000 square foot building in Sunnyvale, California which we purchased in April, 2004 for approximately \$20 million. In addition, we lease approximately 2,000 square feet for research and development in Milford, Connecticut and approximately 3,000 square feet for a sales office in St. Germain en Laye, France.

In connection with our acquisition of Computer Motion, we assumed leases for approximately 48,000 square feet in Goleta, California. These leases have varying terms, the longest of which extends to September 2007. As of December 31, 2004, we have subleased approximately 44,000 square feet of this space.

ITEM 3: LEGAL PROCEEDINGS

In February 2004, the University of Miami, a former customer of Computer Motion, filed a lawsuit against our company in the US District Court, Southern District of Florida. We received the complaint in April, 2004. The customer alleges that it relied to its detriment on representations made by Computer Motion in connection with Computer Motion's sale of products to the customer, which representations the customer believes were not fulfilled. The customer is seeking damages. We filed a motion to dismiss the fraud-based complaints and an answer defending the breach of contract claim. After discovery was completed, we filed a motion for summary judgment to dismiss the entire case. In January, 2005, the Court granted our motion for summary judgment and dismissed the case against us in its entirety. In February 2005, the customer filed a notice of appeal.

In November 2003, Tzamal Jacobson, Ltd., an Israeli company, filed suit against our company and Computer Motion in the District Court in Tel-Aviv – Jaffa, Israel, Civil File 2293/03 alleging breach of a distribution contract and seeking damages. We received the complaint in April, 2004. Following the acquisition of Computer Motion, we withdrew Computer Motion's distributorship offer to this Israeli company. We intend to vigorously defend the suit, and we have filed a motion to have the case dismissed on jurisdictional grounds. The court has not yet ruled on the motion.

In October 2003, SIC System, S.R.L., a former Italian distributor for Computer Motion, filed suit against our company and Computer Motion seeking damages in the Civil Court of Rome, Italy. In the complaint, SIC System alleges that we breached the distribution agreement between SIC System and Computer Motion when, following our acquisition of Computer Motion, we deleted two products previously covered under the distribution agreement. The distribution agreement provides, among other things, that (1) it shall be governed and construed under the laws of the State of California and (2) in the event of any dispute or controversy arising under the distribution agreement or the transactions contemplated thereunder, the parties mutually consent to the exclusive jurisdiction of a court of competent jurisdiction within Santa Barbara County, California. We are defending the lawsuit on both jurisdictional grounds and on the merits. To date, the Italian Court has ruled that SIC System's service of process in filing its complaint is defective and has ordered SIC System to re-serve its complaint on or about October 6, 2004, which service our Company did not receive. The parties have submitted briefs to the court on the service of process issue. The Italian court has not ruled on jurisdiction or other pending issues pertaining to the applicable law or appropriate forum.

In November, 2003, we filed a lawsuit against SIC System, S.R.L. in the United States District Court for the Central District of California for declaratory relief, breach of contract and preliminary and permanent injunction. In particular, we sought a judicial declaration of the rights and obligations of the parties under a distribution agreement, specifically that our company effectively deleted the products from the distribution agreement, and a preliminary and permanent injunction prohibiting SIC System from proceeding with the Italian Action. The complaint was served on SIC System in November, 2003, and the Court entered default against SIC System in March, 2004. In August, 2004, the Court entered a judgment in favor of our company in the amount of \$195,155 for breach of contract. The Court also awarded judgment in favor of our company as to its claim for declaratory relief. The Court awarded judgment in favor of SIC System as to our company's claim for preliminary and

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permanent injunction. The Court found our company as the prevailing party. We intend to enforce this judgment against SIC System in the Italian portion of the lawsuit.

The foregoing proceedings could be expensive to litigate, may be protracted and our confidential information may be compromised. Whether or not we are successful in these lawsuits, these proceedings could consume substantial amounts of our financial and managerial resources. At any time, the other parties may file additional claims against us, or we may file claims against them, which could increase the risk, expense and duration of the litigations.

We are subject to legal proceedings and claims, including those discussed above, that arise in the normal course of our business. We do not know whether we will prevail in these matters nor can we assure that any remedy could be reached on commercially viable terms, if at all. In accordance with Statement of Financial Accounting Standards, or SFAS, No. 5, "Accounting for Contingencies," we record a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. These provisions are reviewed at least quarterly and adjusted to reflect the impacts of negotiations, settlements, rulings, advice of legal counsel, and other information and events pertaining to a particular case.

ITEM 4: SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of security holders during the quarter ended December 31, 2004.

PART II

ITEM 5: MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

PRICE RANGE OF COMMON STOCK

Our common stock has been traded on The Nasdaq Stock Market under the symbol "ISRG" since June 13, 2000. The following table sets forth the high and low closing prices of our common stock for the periods indicated and are as reported by Nasdaq.

<u>Quarter</u>	<u>High</u>	<u>Low</u>
Year Ended December 31, 2004:		
First Quarter	\$ 18.90	\$ 16.47
Second Quarter	19.00	15.13
Third Quarter	27.42	17.90
Fourth Quarter	40.02	22.09
Year Ended December 31, 2003:		
First Quarter	\$ 13.50	\$ 7.52
Second Quarter	18.20	10.96
Third Quarter	18.08	12.08
Fourth Quarter	17.89	13.93

Our stockholders approved a one-for-two reverse stock split, or the Reverse Split, on June 30, 2003, and the Reverse Split was effected on July 1, 2003. The above stock prices reflect the Reverse Split for all periods presented above.

As of February 28, 2005, there were approximately 532 stockholders of record of our common stock, although we believe that there is a significantly larger number of beneficial owners of our common stock.

DIVIDEND POLICY

We have never declared or paid any cash dividends. We currently expect to retain earnings for use in the operation and expansion of our business, and therefore do not anticipate paying any cash dividends for the next several years.

The information required by this item regarding equity compensation is incorporated by reference to the information set forth in Item 12 of this Annual Report on Form 10-K.

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ITEM 6: SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and the accompanying notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this report. The selected data in this section is not intended to replace the consolidated financial statements.

	Year Ended December 31,				
	2004	2003(1)	2002	2001	2000
(In Thousands, Except Per Share Data)					
Consolidated Statements of Operations Data:					
Sales	\$ 138,803	\$ 91,675	\$ 72,022	\$ 51,673	\$ 26,624
Cost of sales	50,813	47,646	38,121	30,172	18,845
Gross profit	87,990	44,029	33,901	21,501	7,779
Operating costs and expenses:					
Selling, general, and administrative	48,994	39,719	37,327	28,033	18,322
Research and development	17,812	16,190	16,793	13,851	11,734
Total operating costs and expenses	66,806	55,909	54,120	41,884	30,056
Income (loss) from operations	21,184	(11,880)	(20,219)	(20,383)	(22,277)
Interest and other income, net	3,020	2,257	1,798	3,683	3,754
Income (loss) before income taxes	24,204	(9,623)	(18,421)	(16,700)	(18,523)
Income tax expense	(726)	—	—	—	—
Net income (loss)	\$ 23,478	\$ (9,623)	\$ (18,421)	\$ (16,700)	\$ (18,523)
Net income (loss) per share:					
Basic	\$ 0.70	\$ (0.41)	\$ (1.01)	\$ (0.93)	\$ (1.56)
Diluted	\$ 0.67	\$ (0.41)	\$ (1.01)	\$ (0.93)	\$ (1.56)
Shares used in computing basic and diluted net income (loss) per common share:					
Basic	33,693	23,626	18,229	17,908	11,898
Diluted	34,976	23,626	18,229	17,908	11,898
Consolidated Balance Sheet Data:					
Cash, cash equivalent and short-term investments	\$ 132,038	\$ 112,949	\$ 49,884	\$ 66,661	\$ 89,441
Working capital	138,299	118,307	51,731	67,922	83,836
Total assets	354,229	314,994	91,820	100,361	112,421
Notes payable, less current portion	—	695	1,838	771	1,861
Deferred revenue, less current portion	505	1,148	200	188	—
Other long-term accrued liabilities	407	553	—	—	—
Accumulated deficit	(114,936)	(138,414)	(128,791)	(110,370)	(93,670)
Total stockholders’ equity	\$ 314,932	\$ 278,957	\$ 63,680	\$ 78,293	\$ 90,730

(1) As more fully described in Note 3 of the consolidated financial statements in Item 8, the results of Computer Motion, Inc., subsequent to the acquisition on June 30, 2003, have been reflected in the 2003 consolidated statements of operations.

The consolidated statements of operations data for the years ended December 31, 2004, 2003, and 2002, and the consolidated balance sheet data at December 31, 2004 and 2003 are derived from our audited consolidated financial statements included elsewhere in this report. The consolidated statement of operations data for the years ended December 31, 2001 and 2000 and the consolidated balance sheet data at December 31, 2002, 2001, and 2000 are derived from our audited consolidated financial statements that are not included in this report. Historical results are not indicative of the results to be expected in the future.

ITEM 7: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We design, manufacture and market the *da Vinci* Surgical System, an advanced surgical system that we believe represents a new generation of surgery—the third generation. The *da Vinci* Surgical System consists of a surgeon's console, a patient-side cart, a high performance vision system and proprietary "wristed" instruments. The *da Vinci* Surgical System seamlessly translates the surgeon's natural hand movements on instrument controls at a console into corresponding micro-movements of instruments positioned inside the patient through small puncture incisions, or ports. We believe that the *da Vinci* Surgical System is the only commercially available technology that can provide the surgeon with the intuitive control, range of motion, fine tissue manipulation capability and 3-D visualization characteristic of open surgery, while simultaneously allowing the surgeons to work through the small ports of minimally invasive surgery, or MIS. By placing computer-enhanced technology between the surgeon and the patient, we believe that the *da Vinci* Surgical System enables surgeons to perform better surgery in a manner never before experienced. The *da Vinci* Surgical System is sold into multiple surgical specialties, principally urology, cardiac and general surgery.

To date, the majority of our revenues have come from the sales of the *da Vinci* Surgical System, which are high revenue dollar items. A smaller percentage of our revenues have come from sales of *EndoWrist* instruments and accessories, which are lower revenue dollar items. In addition, a portion of our revenue comes from ongoing service of installed *da Vinci* Surgical Systems. Due to the high dollar revenue per system sold, small variation in system unit sales may cause revenue to vary significantly from quarter to quarter. During the useful life of each installed *da Vinci* Surgical System, we expect to generate revenue through sales of the *EndoWrist* instrument and accessories and ongoing service. Over the past three years, revenue generated from the sale of instruments, accessories, service and training increased from \$15.7 million, or 22% of sales in 2002 to \$29.9 million, or 33% of sales in 2003 to \$60 million, or 43% of sales, in 2004.

2004 Summary

The year 2004 was our first profitable year of operations, during which we earned net income of \$23.5 million, or \$0.67 per diluted share. We were profitable in each of the four quarters. During 2004, sales grew 51% over 2003 and gross margin percentage improved to 63.4% from 48.0% in 2003. Operating expenses were leveraged during 2004 as they grew 19% to \$66.8 million while sales grew 51%. Our 2004 financial success was driven by the ongoing adoption of the *da Vinci* Surgical System for use in urologic, cardiac, and general surgery procedures.

Business highlights of 2004 were as follows:

- We shipped 76 *da Vinci* Surgical Systems, an increase of 25% over the 61 systems we shipped in 2003.
- We realized \$60 million of recurring revenue, comprised of instrument, accessory, service and training revenue, up over 100% compared to 2003.
- Use of the *da Vinci* Surgical System for radical prostatectomy procedures grew more than 200% from 2003 to 2004. This contributed significantly to our 2004 sales growth.
- In July, 2004, the FDA granted clearance for use of the *da Vinci* Surgical System for coronary anastomosis during cardiac revascularization procedures. With this clearance, the *da Vinci* System can be used to perform complete coronary bypass procedures in the United States.
- We launched a significant number of new instruments, including our 5 millimeter instrument line and our 8 millimeter Micro-Bipolar and Maryland Bipolar instruments. As we continue to expand our instrument offering, we provide customers more surgical options and clinical capability, leading to increased system usage.

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- We opened new overseas markets in 2004, including Turkey and Taiwan, and significantly grew our sales in Australia and Singapore.
- We completed the final integration of the Computer Motion acquisition.
- We met the requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

Computer Motion Acquisition

In June 2003, we acquired Computer Motion, Inc. in a stock transaction in which each outstanding share of Computer Motion common stock was converted into the right to receive 0.25713472 of one share of our common stock after giving effect to our 1-for-2 reverse stock split effective July 1, 2003. In addition, we assumed all of Computer Motion's outstanding options and warrants. The total purchase price was approximately \$148.5 million. We believe that the Computer Motion acquisition resulted in the following benefits to our company: our ownership of all of Computer Motion intellectual property; the addition of complementary products to our offerings; and the achievement of significant cost synergies and economies of scale.

Upon completion of our acquisition of Computer Motion, our management approved plans to restructure the operations of the combined entity. The plan provided for the elimination of redundant activities and facilities and the termination of the employment of approximately 150 employees, representing 75% of the Computer Motion positions, by December 31, 2003, generally with immediate severance payment upon termination. The plan called for vacating and subleasing 78% of the leased space in Goleta, California, consolidating European operations into a single site, and closing Computer Motion's Asia office.

We recorded a \$3.4 million accrual in accordance with Emerging Issues Task Force, or EITF, No. 95-3, "Recognition of Liabilities in Connection with a Purchase Business Combination." In accordance with EITF No. 95-3, the restructuring accrual was recorded as a component of the purchase price. Later in 2003, we increased the accrual by \$0.1 million primarily due to changes in estimates of employee severance costs. In 2004, we increased the accrual for the estimated losses to be incurred to sublet vacated facilities by \$0.2 million due to the change in estimates on assumptions used to calculate the losses on subleasing the vacated facilities. These amounts were recorded as adjustments to goodwill.

In the quarter ended December 31, 2003, based on our cost structure and future development plans, we elected to completely shut down the Goleta research and development facility effective March 31, 2004. As a result, we exited the last Goleta rented facility and terminated the employment of a majority of the Goleta-based employees.

We recorded restructuring charges related to costs of one-time employee termination in accordance with Statement of Financial Accounting Standards, or SFAS, No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." SFAS No. 146 requires that a liability for costs associated with an exit or disposal activity be recognized and measured initially at fair value only when the liability is incurred. We recorded restructuring charges of \$0.2 million in 2003 and incurred an additional \$0.7 million of employee termination costs and costs to exit the leased facility in 2004.

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The following table summarizes the restructuring activity for the years ended December 31, 2003 and 2004 (in thousands):

	EITF No. 95-3		SFAS No. 146		Total
	Employee Severance	Lease Commitments	Employee Severance	Lease Commitments	
Costs accrued	\$ 2,629	\$ 816	\$ 186	\$ —	\$ 3,631
Cash payments, net of subleasing proceeds	(2,486)	(277)	—	—	(2,763)
Currency impact	(23)	(23)	—	—	(46)
Adjustments	175	(26)	—	—	149
Balance at December 31, 2003	295	490	186	—	971
Costs accrued	—	—	224	525	749
Cash payments, net of subleasing proceeds	(295)	(316)	(410)	(207)	(1,228)
Adjustments	—	226	—	(177)	49
Balance at December 31, 2004	\$ —	\$ 400	\$ —	\$ 141	\$ 541

The remaining restructuring reserve balance at December 31, 2004 of \$0.5 million, which relates entirely to the remaining cost of the leased facility net of subleasing rental income, will be fully utilized in 2007.

Results Of Operations

Sales

The following table summarizes sales and the *da Vinci* Surgical System unit sales trend between 2002 and 2004. Overall sales increased from \$72.0 million in 2002 to \$91.7 million in 2003 to \$138.8 million in 2004. Sales growth during this period reflected growth in both product sales and service sales as discussed in more detail below.

Sales (\$ Millions)	Year Ended December 31,		
	2004	2003	2002
Systems	\$ 78.8	\$ 61.8	\$ 56.3
Instruments/accessories	37.5	18.8	10.1
Total product sales	116.3	80.6	66.4
Service/training	22.5	11.1	5.6
Total sales	\$ 138.8	\$ 91.7	\$ 72.0
Domestic	\$ 109.8	\$ 70.1	\$ 58.9
International	29.0	21.6	13.1
Total sales	\$ 138.8	\$ 91.7	\$ 72.0
<i>da Vinci</i> Surgical System unit sales	76	61	60

Product Sales

Product sales increased to \$116.3 million for the year ended December 31, 2004 from \$80.6 million for the year ended December 31, 2003. The \$35.7 million increase was due to higher sales of systems, instruments, and accessories. System sales increased to \$78.8 million in 2004 from \$61.8 million in 2003 reflecting growth in system unit sales of *da Vinci* Surgical Systems and *da Vinci* fourth arms. 76 systems were sold in 2004,

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compared to 61 in 2003. 65 fourth arms were sold in 2004 compared to 37 in 2003. The fourth arm product was launched during the second quarter 2003. Instrument and accessory sales increased to \$37.5 million in 2004 from \$18.8 million in 2003. The increase was driven by a larger number of installed systems in 2004 and higher utilization per system in 2004.

Product sales increased to \$80.6 million for the year ended December 31, 2003 from \$66.4 million for the year ended December 31, 2002. The increase was due to higher 2003 system and instrument and accessory revenue. Total system revenue increased to \$61.8 million in 2003 from \$56.3 million in 2002, resulting from higher *da Vinci* fourth arm revenue and the impact of Computer Motion products sold subsequent to the June 30, 2003 acquisition. We sold 61 *da Vinci* Surgical Systems during 2003, compared to 60 in 2002. We sold 37 fourth arm upgrades to the *da Vinci* platform in 2003 compared to none in 2002. Total 2003 Computer Motion system product sales were \$1.5 million, comprised in large part of 16 AESOP unit sales. Instrument and accessory revenue increased to \$18.8 million for the year ended December 31, 2003, compared to \$10.1 million for the year ended December 31, 2002. The larger base of installed *da Vinci* Surgical Systems and increased system utilization per site resulted in the increase in instrument and accessory revenue.

Service Sales

Service sales comprised of system service, installation and customer training, increased to \$22.5 million for the year ended December 31, 2004 from \$11.1 million for the year ended December 31, 2003. The increase in this area was driven by a larger base of *da Vinci* Surgical Systems producing contract service revenue and higher revenue earned per system under service contract. The larger base of *da Vinci* Surgical Systems under contract was driven by 2004 system sales adding to the installed base and the full year impact of EITF No. 00-21, "Revenue Arrangements with Multiple Deliverables," adopted prospectively during the third quarter of 2003. Beginning July 1, 2003, service sales related to the first year of service began to be recognized as a separate unit of accounting of each *da Vinci* Surgical System sale with service sales recognized over the first year. There were an average of 224 systems under service contract in 2004 generating an average of \$96,300 per system, compared to an average of 116 systems under service contract in 2003 generating an average of \$90,100 per system. The increase in service revenue per system was primarily driven by the introduction of the *da Vinci* fourth arm during the second quarter of 2003. Four arm systems typically carry a higher contractual service rate than three-arm systems.

Service sales increased to \$11.1 million for the year ended December 31, 2003 from \$5.6 million for the year ended December 31, 2002. The increase was primarily due to a larger installed base of *da Vinci* Surgical Systems generating service sales. The installed base of systems generating service revenue grew by 60 during 2003 reflecting the number of systems sold during 2002 for which service sales would be recognized throughout 2003. In addition, during the third quarter 2003, we prospectively adopted EITF No. 00-21. As a result, beginning July 1, 2003, service sales related to the first year of service began to be recognized as a separate unit of accounting of each *da Vinci* Surgical System sale with service sales recognized over the first year. In addition, Computer Motion's service sales added \$0.3 million to 2003 revenue as compared to 2002.

Gross Profit

Total gross profit for the year ended December 31, 2004 was \$88.0 million, or 63.4% of sales, compared to \$44.0 million, or 48.0% of sales in 2003, and \$33.9 million, or 47.1% of sales in 2002. The improvement in overall gross profit during the period resulted primarily from lower product material costs, improved product reliability, improved manufacturing throughput, and leveraging our service and training organizations across a larger base of installed systems.

Product sales gross profit for the year ended December 31, 2004 was \$75.9 million, or 65.2% of sales, compared to \$40.6 million, or 50.4% of sales, in 2003, and \$35.2 million, or 53.0% of sales, in 2002. The increase in gross profit percentage from 50.4% in 2003 to 65.2% in 2004 was driven by leveraging

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manufacturing overhead across higher revenue, material cost reductions, the impact of euro-denominated sales as the euro strengthened considerably against the US dollar, and the non-recurrence of the Computer Motion impairment charges and Brookhill-Wilk charges incurred in 2003. The decrease in product sales gross profit percentage from 53.0% in 2002 to 50.4% in 2003 was due to the Computer Motion impairment charges and Brookhill-Wilk charges incurred in 2003, partially offset by the lower product costs and improved system and instrument reliability.

Service sales gross profit for the year ended December 31, 2004 was \$12.1 million, or 54.0% of sales, compared to \$3.4 million, or 30.8% of sales, in 2003 and \$(1.3) million in 2002. The year over year improvements and transition to positive service revenue gross profit in 2003 resulted from leveraging relatively fixed service and training cost pools across a larger base of *da vinci* Surgical Systems generating service revenue. The larger base of *da Vinci* Surgical Systems under contract was driven by system sales adding to the installed base and the impact of EITF No. 00-21, adopted prospectively during the third quarter of 2003. Beginning July 1, 2003, service sales related to the first year of service began to be recognized as a separate unit of accounting of each *da Vinci* Surgical System sale with service sales recognized over the first year.

Selling, General and Administrative Expenses

Selling, general and administrative expenses include personnel costs for sales, marketing and administrative personnel, tradeshow expenses, legal expenses, regulatory fees and general corporate expenses. Selling, general and administrative expenses for 2004 were \$49.0 million, up 23% from \$39.7 million for 2003. The year-over-year increase was largely due to sales organization headcount growth to support higher 2004 sales, higher incentive compensation associated with achieving higher 2004 revenues and profitability, and additional accounting personnel, consulting, and auditing resources required to support Sarbanes-Oxley compliance.

Selling, general and administrative expenses for 2003 were \$39.7 million, up 6% from \$37.3 million for 2002. The year-over-year increase was due to higher compensation and employee travel costs, resulting primarily from higher sales volume and the Computer Motion acquisition, intangible asset amortization and impairment, accounting fees, and general legal and insurance expense, offset by lower litigation expenses.

Selling, general and administrative expenses are expected to increase in the future to support our expanding business.

Research and Development Expenses

Research and development expenses include costs associated with the design, development, testing and enhancement of our products. These enhancements represent significant improvements to our products. Research and development expenses also include expenditures for clinical trials and purchases of laboratory supplies.

Research and development expenses for 2004 were \$17.8 million, up 10% from \$16.2 million for 2003. The increase resulted primarily from higher 2004 compensation and project materials costs.

Research and development expenses for 2003 were \$16.2 million, down 4% from \$16.8 million for 2002. The year over year decrease resulted from lower 2003 project consulting and materials costs and lower 2003 clinical trials costs.

Research and development costs are expensed as incurred. We expect to continue to make substantial investments in research and development and anticipate that research and development expenses will continue to increase in the future.

Deferred Compensation

We record deferred compensation as the difference between the exercise price of options granted and the fair value of our common stock at the time of grant for financial reporting purposes. Deferred compensation is

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amortized to research and development expenses and selling, general and administrative expenses. For 2004, 2003 and 2002, we recorded amortization of deferred stock compensation and stock compensation totaling \$0.1 million, \$0.7 million and \$0.7 million, respectively. We did not record non-cash deferred compensation expense in research and development in 2004. For 2003 and 2002, non-cash deferred compensation expense included in research and development expenses was \$0.5 million and \$0.4 million, respectively. For 2004, 2003 and 2002, non-cash deferred compensation expense included in selling, general and administrative expenses was \$0.1 million, \$0.2 million and \$0.3 million, respectively. At December 31, 2004, all deferred compensation had been amortized.

Interest and Other Income, Net

Interest and other income, net was \$3.0 million, \$2.3 million and \$1.8 million for 2004, 2003 and 2002, respectively. The increase between 2004 and 2003 resulted primarily from higher interest income earned on higher 2004 cash and short-term investment balances. The increase between 2003 and 2002 resulted primarily from higher foreign exchange gains in 2003 resulting from transactions denominated in euro.

Income Tax Expense

Income tax expense was \$0.7 million for the year ended December 31, 2004. There was no income tax expense recorded for the years ended December 31, 2003 and December 31, 2002.

Liquidity And Capital Resources

Historically, our operations have been financed primarily through the sale of our equity securities. Sales of convertible preferred stock yielded proceeds of approximately \$127.3 million and public offerings of our common stock yielded proceeds of approximately \$124.5 million. We have also financed operations through employee stock purchase and option plans as well as equipment financing arrangements. At December 31, 2004, we had total stockholders equity of \$314.9 million and outstanding equipment financing debt of \$0.6 million.

As of December 31, 2004, we had cash, cash equivalents and short-term investments of \$132.0 million, compared to \$112.9 million at December 31, 2003 and \$49.9 million at December 31, 2002. Working capital at December 31, 2004 was \$138.3 million, compared to \$118.3 million at December 31, 2003 and \$51.7 million at December 31, 2002. The 2004 increase in cash, cash equivalents and short-term investments resulted primarily from our net income of \$23.5 million, non-cash expenses of \$7.4 million and proceeds from employee stock purchase and option plans of \$13.2 million, partially offset by net fixed asset additions of \$22.4 million. The 2003 increase in cash and cash equivalents and investments and working capital resulted primarily from the \$77.7 million of net proceeds received from our follow-on stock offering, offset mostly by the Computer Motion acquisition. The 2002 decreases in cash, cash equivalents and short-term investments and working capital were primarily attributable to cash used to fund operating losses and to acquire fixed assets.

Net cash provided by operating activities was \$30.3 million for the year ended December 31, 2004, compared to net cash used in operating activities of \$7.9 million in 2003 and \$14.1 million in 2002. Cash provided by operating activities in 2004 of \$30.3 million resulted from net income of \$23.5 million and non-cash expenses of \$7.4 million, partially offset by \$0.6 million of working capital requirements. Cash used in 2003 resulted from a net loss of \$9.6 million and working capital requirements of \$9.8 million, partially offset by non-cash expenses of \$11.5 million. Cash used in 2002 resulted from a net loss of \$18.4 million and working capital requirements of \$0.5 million, offset by non-cash expenses of \$4.8 million.

Net cash used in investing activities was \$48.2 million for the year ended December 31, 2004, compared to net cash used by investing activities of \$71.2 million in 2003 and net cash provided by investing activities of \$8.6 million in 2002. Net cash used in investing activities in 2004 resulted primarily from the net movement into short-term investments from cash received from profitable operations along with the purchase of the land and

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building at our headquarters. Net cash used in investing activities in 2003 resulted primarily from the net movement into short-term investments from cash received from the follow-on offering proceeds. The cash provided by investing activities in 2002 related primarily to the net conversion of short-term investments into cash to fund operations, partially offset by purchases of property and equipment.

Net cash provided by financing activities was \$12.1 million for the year ended December 31, 2004, compared to \$82.3 million for 2003 and \$3.0 million for 2002. The 2004 cash provided by financing activities resulted from \$13.2 million of employee stock purchases and option and warrant exercise proceeds, offset by debt repayment of \$1.1 million. The 2003 cash provided resulted primarily from our follow-on common stock offering yielding \$77.7 million of net proceeds, with the remainder coming mostly from employee stock purchases and option exercises. In 2002, cash provided by financing activities resulted from proceeds from the issuance of common stock resulting mainly from the employee stock purchase plan and the exercise of stock options of \$2.1 million and net long-term equipment financing proceeds of \$0.9 million.

Our capital requirements depend on numerous factors, including market acceptance of our products, the resources we devote to developing and supporting our products and other factors. We expect to devote substantial capital resources to continue our research and development efforts, to expand our customer support and product development activities and for other general corporate activities. We believe that our current cash, cash equivalents, and short-term investment balances, together with income to be derived from the sale of our products, will be sufficient to meet our liquidity requirements for the foreseeable future.

Contractual Obligations and Commercial Commitments

The following table summarizes all significant contractual payment obligations, net of sublease income of \$1.5 million, by payment due date:

Contractual Obligations	Payments by Period (\$ thousands)				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases	\$1,507	\$ 632	\$781	\$ 94	\$ —

Purchase obligations for inventory and other goods and services have not been included in the table above as these obligations have remaining terms less than one year.

Critical Accounting Estimates

The Consolidated Financial Statements are prepared in accordance with accounting principles generally accepted in the United States, which requires us to make estimates and assumptions. Note 2, "Summary of Significant Accounting Policies" in Notes to the Consolidated Financial Statements describes our significant accounting policies. We believe the following estimates are most critical to an understanding of our financial results and condition and require a higher degree of judgment and complexity:

Revenue Recognition. We recognize revenue when persuasive evidence of an arrangement exists, delivery has occurred or service has been rendered, the price is fixed or determinable and collectibility is reasonably assured.

In certain cases, revenue from direct system sales is earned pursuant to multiple-element arrangements that require judgment in the areas of the separability of units of accounting, the fair value of individual elements, customer acceptance, and collectibility. Effective July 1, 2003, we adopted the provisions of EITF No. 00-21, "Revenue Arrangements with Multiple Deliverables," on a prospective basis. The principles and guidance outlined in EITF No. 00-21 provide a framework to (a) determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and (b) determine how the arrangement consideration

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should be measured and allocated to the separate units of accounting in the arrangement. We determined that our multiple-element arrangements are generally comprised of the following elements that would qualify as separate units of accounting: system sales, service, installation, and training. Each of these elements represents individual units of accounting as the delivered item has value to a customer on a stand-alone basis, objective and reliable evidence of fair value exists for undelivered items, and arrangements generally do not contain a general right of return relative to the delivered item. We determine fair value based on the price of the undelivered element when it is sold separately or based on third-party evidence. In accordance with the guidance in EITF No. 00-21, we use the residual method to allocate the arrangement consideration when we do not have fair value of the system sale. Under the residual method, the amount of consideration allocated to the delivered item equals the total arrangement consideration less the aggregate fair value of the undelivered items. Assuming all other criteria for revenue recognition have been met, we recognize revenue for system sales when delivery and acceptance occurs, for installation and training when the services are rendered, and for service ratably over the service period, which is generally one year. Revenue from sales of replacement instruments and accessories is recognized upon delivery. Revenue related to future commitments under separately priced service contracts is deferred and recognized ratably over the service period. We assess probability of collection based on a number of factors, including our past transaction history with the customer and the credit-worthiness of the customer. New customers and certain existing customers are subject to a credit review process that evaluates each customer's financial position and ultimately its ability to pay according to the original terms of the arrangement.

Allowance for Sales Returns and Doubtful Accounts. We record estimated reductions in revenue for potential returns of products by customers and other allowances. As a result, management must make estimates of potential future product returns and other allowances related to current period product revenue. In making such estimates, management analyzes historical returns, current economic trends and changes in customer demand and acceptance of our products. If management were to make different judgments or utilize different estimates, material differences in the amount of reported revenue could result.

Similarly, management makes estimates of the uncollectability of accounts receivables, especially analyzing accounts receivable and historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in customer payment terms, when evaluating the adequacy of the allowance for doubtful accounts. If management were to make different judgments or utilize different estimates, material differences in the amount of our reported operating expenses could result.

Inventory Write-downs. We write our inventory down for estimated obsolete or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual future demand or market conditions are less favorable than those projected by management, additional inventory write-downs may be required in the future.

Intangible Assets. We have intangible assets on our balance sheet related to the acquisition of Computer Motion and the acquisition of other patents. The valuation and classification of these assets and the assignment of useful amortization lives involves judgments and the use of estimates. The evaluation of these intangibles for impairment under established accounting guidelines is required on an ongoing basis. Changes in business conditions could potentially require future adjustments to asset valuations. We conducted the required intangible assets impairment review during the fourth quarter of 2004. No impairment charge was recorded for the year ended December 31, 2004. For the year ended December 31, 2003, we impaired \$3.3 million of developed technology intangible assets related to a product for which futures sales were anticipated to be significantly lower than the original forecast, and \$0.3 million of trademark intangible assets and other intangible assets related to this product and to purchased software that has no future use. A considerable amount of judgment is required in calculating this impairment charge, principally in determining market premiums and financial forecasts.

Goodwill. We have goodwill on our balance sheet relating to the acquisition of Computer Motion. Goodwill is recorded as the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. Goodwill is not amortized, rather is tested for impairment at least annually in the fourth quarter of each

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fiscal year (more frequently if certain indicators are present). In the event we determine that goodwill has been impaired, we will record an accounting charge for the impairment during the fiscal quarter in which the determination is made. In the fourth quarter of 2004, we performed our assessment of whether there was an indication that goodwill was impaired at December 31, 2004. The quoted market price of our common stock was used to determine fair value for the impairment purpose. Our market capitalization continues to support the fair value of our reporting unit. We are required to identify our reporting units and determine the carrying value of each reporting unit by assigning the assets and liabilities, including the existing goodwill and intangible assets, to these reporting units. Since we currently operate in one reportable segment, all of the goodwill has been assigned to the enterprise as a whole. We completed the goodwill impairment tests and determined that the goodwill was not impaired at December 31, 2004. A considerable amount of judgment is required in calculating this impairment charge, principally in determining the reporting units.

Warranties. Effective July 1, 2003, for certain arrangements recorded under the provisions of EITF No. 00-21, actual warranty costs, which are not separable from other service costs, are expensed in the period incurred. For all other revenue arrangements, we provide for the estimated costs of product warranties at the time revenue is recognized. Our estimate of costs to service our warranty obligations is based upon historical experience and expectation of future conditions. If warranty claim activity and the costs associated with servicing those claims differ from our estimates, revisions to the estimated warranty liability may be required.

Contingencies. We are subject to proceedings, lawsuits and other claims related to our products, patents and other matters. We are required to assess the likelihood of any adverse judgments or outcomes to these matters as well as potential ranges of probable losses. A determination of the amount of reserves required, if any, for these contingencies is made after careful analysis of each individual issue. The required reserves may change in the future due to new developments in each matter or changes in approach such as a change in settlement strategy in dealing with these matters.

Accounting for income taxes. Significant management judgment is required in determining our provision for income taxes, deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets. We have recorded a valuation allowance due to uncertainties related to our ability to utilize our deferred tax assets, primarily consisting of certain net operating losses carried forward, before they expire. The valuation allowance is based on estimates of taxable income by jurisdiction in which we operate and the period over which these deferred tax asset could be realized in the foreseeable future. An adjustment to the deferred tax asset would increase income in the period such determination was made.

RECENT ACCOUNTING PRONOUNCEMENTS

See Note 2 under “Summary of Significant Accounting Policies” of the Notes to Consolidated Financial Statements for a full description of recent accounting pronouncements including the respective expected dates of adoption and effects on results of operations and financial condition.

FACTORS AFFECTING OPERATING RESULTS

OUR FUTURE OPERATING RESULTS MAY BE BELOW SECURITIES ANALYSTS’ OR INVESTORS’ EXPECTATIONS, WHICH COULD CAUSE OUR STOCK PRICE TO DECLINE.

Due to the nascent nature of our industry, we have limited insight into trends that may emerge in our market and affect our business. The revenue and income potential of our market are unproven, and we may be unable to continue to generate significant revenues. In addition, our costs may be higher than we anticipated. If we fail to generate sufficient revenues or our costs are higher than we expect, our results of operations will suffer. Further, future revenue from sales of our products is difficult to forecast because the market for new surgical technologies is still evolving. Our results of operations will depend upon numerous factors, including:

- the extent to which our products gain market acceptance;
- actions relating to regulatory matters;

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- our timing and ability to develop our manufacturing and sales and marketing capabilities;
- demand for our products;
- the size and timing of particular sales and any collection delays related to those sales;
- product quality problems;
- the progress of surgical training in the use of our products;
- our ability to develop, introduce and market new or enhanced versions of our products on a timely basis;
- third-party payor reimbursement policies;
- our ability to protect our proprietary rights and defend against third party challenges;
- our ability to license additional intellectual property rights; and
- the progress and results of clinical trials.

Our operating results in any particular period will not be a reliable indication of our future performance. It is likely that in some future quarters, our operating results will be below the expectations of securities analysts or investors. If this occurs, the price of our common stock, and the value of your investment, will likely decline.

WE EXPERIENCE LONG AND VARIABLE SALES CYCLES, WHICH COULD HAVE A NEGATIVE IMPACT ON OUR RESULTS OF OPERATIONS FOR ANY GIVEN QUARTER.

Our *da Vinci* Surgical System has a lengthy sales and purchase order cycle because it is a major capital item and generally requires the approval of senior management at purchasing institutions. These factors may contribute to substantial fluctuations in our quarterly operating results, particularly during the periods in which our sales volume is low. Because of these fluctuations, it is likely that in some future quarters our operating results will fall below the expectations of securities analysts or investors. If that happens, the market price of our stock would likely decrease. These fluctuations also mean that you will not be able to rely upon our operating results in any particular period as an indication of future performance.

BECAUSE A SMALL NUMBER OF CUSTOMERS HAVE AND ARE LIKELY TO CONTINUE TO ACCOUNT FOR A SUBSTANTIAL PORTION OF OUR REVENUE, OUR REVENUES COULD DECLINE DUE TO THE LOSS OR DELAY OF A SINGLE CUSTOMER.

A relatively small number of customers account for a significant portion of our total revenues. During 2004, 2003 and 2002, approximately 55%, 66% and 78%, respectively, of our revenues came from the sales of *da Vinci* Surgical Systems, which are high revenue dollar items. During 2004, 2003, and 2002, no customer accounted for more than 10% of total sales. However, due to the high average selling price of the *da Vinci* Surgical System, our failure to add new customers that make significant purchases of our products could reduce our future revenues. The loss or delay of individual orders could have a significant impact on revenues and operating results.

IF OUR PRODUCTS DO NOT ACHIEVE MARKET ACCEPTANCE, WE WILL NOT BE ABLE TO GENERATE THE REVENUE NECESSARY TO SUPPORT OUR BUSINESS.

The *da Vinci* surgical systems and our other products represent a fundamentally new way of performing surgery. Achieving physician, patient and third-party payor acceptance of *Intuitive* surgery as a preferred method of performing surgery will be crucial to our success. If our products fail to achieve market acceptance, hospitals will not purchase our products and we will not be able to generate the revenue necessary to support our business. We believe that physicians' and third-party payors' acceptance of the benefits of procedures performed using our products will be essential for acceptance of our products by patients. Physicians will not recommend the use of our products unless we can demonstrate that they produce results comparable or superior to existing surgical techniques. Even if we can prove the effectiveness of our products through clinical trials, surgeons may elect not

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to use our products for any number of other reasons. For example, cardiologists may continue to recommend conventional open-heart surgery simply because such surgery is already widely accepted. In addition, surgeons may be slow to adopt our products because of the perceived liability risks arising from the use of new products and the uncertainty of reimbursement from third-party payors.

We expect that there will be a learning process involved for surgical teams to become proficient in the use of our products. Broad use of our products will require training of surgical teams. Market acceptance could be delayed by the time required to complete this training. We may not be able to rapidly train surgical teams in numbers sufficient to generate adequate demand for our products.

BECAUSE OUR MARKETS ARE HIGHLY COMPETITIVE, CUSTOMERS MAY CHOOSE TO PURCHASE OUR COMPETITORS' PRODUCTS OR MAY NOT ACCEPT INTUITIVE SURGERY, WHICH WOULD RESULT IN REDUCED REVENUE AND LOSS OF MARKET SHARE.

Intuitive surgery is a new technology that will compete with established and emerging treatment options in both disease management and reconstructive medical procedures. These competitive treatment options may take the form of traditional minimally invasive surgery, open surgery, interventional approaches, or pharmacological regimens. Some of these procedures are widely accepted in the medical community and in many cases have a long history of use. Technological advances could make such treatments more effective or less expensive than using our products, which could render our products obsolete or unmarketable. We cannot be certain that physicians will use our products to replace or supplement established treatments or that our products will be competitive with current or future technologies.

In addition, we may face competition from companies that develop robotic and computer-assisted surgical systems in the future. Our revenues may be reduced or eliminated if our competitors develop and market products that are more effective or less expensive than our products. If we are unable to compete successfully, our revenues will suffer. We may not be able to maintain or improve our competitive position against current or potential competitors, especially those with greater resources.

INTERNATIONAL SALES OF OUR PRODUCTS ACCOUNT FOR A SIGNIFICANT PORTION OF OUR REVENUES, WHICH EXPOSES US TO RISKS INHERENT IN INTERNATIONAL OPERATIONS. OUR GROWTH MAY BE LIMITED IF WE ARE UNABLE TO SUCCESSFULLY MANAGE OUR INTERNATIONAL ACTIVITIES.

Our business currently depends in large part on our activities in Europe and other foreign markets. Sales to markets outside of the United States accounted for approximately 21%, 24%, and 18% of our sales for 2004, 2003 and 2002, respectively. We are subject to a number of challenges that specifically relate to our international business activities. These challenges include:

- 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, which could slow our growth in international markets;
- the risks associated with foreign currency exchange rate fluctuation;
- the expense of establishing facilities and operations in new foreign markets; and
- building an organization capable of supporting geographically dispersed operations.

Currently, more than half of our international sales are denominated in United States dollars. As a result, an increase in the value of the United States dollar relative to foreign currencies could make our products less competitive in international markets. If we are unable to meet and overcome these challenges, our international operations may not be successful, which would limit the growth of our business.

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IF DEFECTS ARE DISCOVERED IN OUR PRODUCTS, WE MAY INCUR ADDITIONAL UNFORESEEN COSTS, HOSPITALS MAY NOT PURCHASE OUR PRODUCTS AND OUR REPUTATION MAY SUFFER.

Our products incorporate mechanical parts, electrical components and computer software, any of which can contain errors or failures, especially when first introduced. In addition, new products or enhancements may contain undetected errors or performance problems that, despite testing, are discovered only after commercial shipment. Because our products are designed to be used to perform complex surgical procedures, we expect that our customers will have an increased sensitivity to such defects. In the past, we have voluntarily recalled certain products as a result of performance problems. We cannot assure you that our products will not experience errors or performance problems in the future. If we experience flaws or performance problems, any of the following could occur:

- delays in product shipments;
- loss of revenue;
- delay in market acceptance;
- diversion of our resources;
- damage to our reputation;
- product recalls;
- increased service or warranty costs; or
- product liability claims.

WE MAY ENCOUNTER MANUFACTURING PROBLEMS OR DELAYS THAT COULD RESULT IN LOST REVENUE.

We have manufactured a limited number of our products for sales to customers. We may be unable to maintain reliable, high-volume manufacturing capacity. Even if this capacity can be maintained, the cost of doing so may increase the cost of our products and reduce our ability to compete. We may encounter difficulties in scaling up production of our products, including:

- problems involving production yields;
- quality control and assurance;
- component supply shortages;
- shortages of qualified personnel; and
- compliance with state, federal and foreign regulations.

Manufacturing our products is a complex process. If demand for our products exceeds our manufacturing capacity, we could develop a substantial backlog of customer orders. If we are unable to maintain larger-scale manufacturing capabilities, our ability to generate revenues will be limited and our reputation in the marketplace could be damaged.

OUR RELIANCE ON SOLE AND SINGLE SOURCE SUPPLIERS COULD HARM OUR ABILITY TO MEET DEMAND FOR OUR PRODUCTS IN A TIMELY MANNER OR WITHIN BUDGET.

Some of the components necessary for the assembly of our products are currently provided to us by sole source suppliers or single source suppliers. We purchase components through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of inventory. The disruption or termination of the supply of components could cause a significant increase in the costs of these components, which could affect our profitability. A disruption or termination in the supply of components could also result in our inability to meet demand for our products, which could harm our ability to generate revenues, lead to customer

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dissatisfaction and damage our reputation. Furthermore, if we are required to change the manufacturer of a key component of our products, we may be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could delay our ability to manufacture our products in a timely manner or within budget.

IF WE ARE UNABLE TO PROTECT THE INTELLECTUAL PROPERTY CONTAINED IN OUR PRODUCTS FROM USE BY THIRD PARTIES, OUR ABILITY TO COMPETE IN THE MARKET WILL BE HARMED.

Our commercial success will depend in part on obtaining patent and other intellectual property protection for the technologies contained in our products, and on successfully defending our patents and other intellectual property against third party challenges. We will incur substantial costs in obtaining patents and, if necessary, defending our proprietary rights. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. We do not know whether we will obtain the patent protection we seek, or that the protection we do obtain will be found valid and enforceable if challenged. We also do not know whether we will be able to develop additional patentable proprietary technologies. If we fail to obtain adequate protection of our intellectual property, or if any protection we obtain is reduced or eliminated, others could use our intellectual property without compensating us, resulting in harm to our business. We may also determine that it is in our best interests to voluntarily challenge a third party's products or patents in litigation or administrative proceedings, including patent interferences or reexaminations. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States.

OTHERS MAY ASSERT THAT OUR PRODUCTS INFRINGE THEIR INTELLECTUAL PROPERTY RIGHTS, WHICH MAY CAUSE US TO ENGAGE IN COSTLY DISPUTES AND, IF WE ARE NOT SUCCESSFUL IN DEFENDING OURSELVES, COULD ALSO CAUSE US TO PAY SUBSTANTIAL DAMAGES AND PROHIBIT US FROM SELLING OUR PRODUCTS.

There may be United States and foreign patents issued to third parties that relate to computer-assisted surgery, remote surgery, and minimally invasive surgery. Some of these patents may be broad enough to cover one or more aspects of our present technology, and may cover aspects of our future technology. We do not know whether any of these patents, if challenged, would be held valid, enforceable and infringed. From time to time, we receive, and likely will continue to receive, letters from third parties inviting us to license their patents. We may be sued by, or become involved in an administrative proceeding with, one or more of these third parties. We cannot assure you that a court or administrative body would agree with any arguments or defenses we may have concerning invalidity, unenforceability or noninfringement of any third-party patent. In addition to the issued patents of which we are aware, other parties may have filed, and in the future are likely to file, patent applications covering surgical products that are similar or identical to ours. We cannot assure you that any patents issuing from applications filed by a third party will not cover our products or will not have priority over our patent applications.

The medical device industry has been characterized by extensive litigation and administrative proceedings regarding patents and other intellectual property rights, and companies have employed such actions to gain a competitive advantage. If third parties assert infringement or other intellectual property claims against us, our technical and management personnel will experience a significant diversion of time and effort and we will incur large expenses defending our company. If third parties in any patent action are successful, our patent portfolio may be damaged, we may have to pay substantial damages, including treble damages, and we may be required to stop selling our products or obtain a license which, if available at all, may require us to pay substantial royalties. We cannot be certain that we will have the financial resources or the substantive arguments to defend our patents from infringement or claims of invalidity or unenforceability, or to defend against allegations of infringement of third-party patents. In addition, any public announcements related to litigation or administrative proceedings initiated by us, or initiated or threatened against us, could cause our stock price to decline.

THE RIGHTS AND MEASURES WE RELY ON TO PROTECT THE INTELLECTUAL PROPERTY UNDERLYING OUR PRODUCTS MAY NOT BE ADEQUATE TO PREVENT THIRD PARTIES FROM USING OUR TECHNOLOGY, WHICH COULD HARM OUR ABILITY TO COMPETE IN THE MARKET.

In addition to patents, we typically rely on a combination of trade secret, copyright and trademark laws, nondisclosure agreements and other contractual provisions and technical security measures to protect our intellectual property rights. Nevertheless, 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. In addition, employees, consultants and others who participate in developing our products may breach their agreements with us regarding our intellectual property, and we may not have adequate remedies for the breach. We also may not be able to effectively protect our intellectual property rights in some foreign countries. For a variety of reasons, we may decide not to file for patent, copyright or trademark protection outside the United States. We also realize that our trade secrets may become known through other means not currently foreseen by us. Notwithstanding our efforts to protect our intellectual property, our competitors may independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing any of our intellectual property rights, or may design around our proprietary technologies.

OUR PRODUCTS RELY ON LICENSES FROM THIRD PARTIES, AND IF WE LOSE ACCESS TO THESE TECHNOLOGIES, OUR REVENUES COULD DECLINE.

We rely on technology that we license from others, including technology that is integral to our products. We have entered into license agreements with Heartport, Inc., now part of Johnson & Johnson, IBM Corporation, MIT, Olympus Optical Co., Ltd., SRI International, and Brookhill-Wilk, LLC. Any of these agreements may be terminated for breach. If any of these agreements is terminated, we may be unable to reacquire the necessary license on satisfactory terms, or at all. The loss or failure to maintain these licenses could prevent or delay further development or commercialization of our products.

THE USE OF OUR PRODUCTS COULD RESULT IN PRODUCT LIABILITY CLAIMS THAT COULD BE EXPENSIVE, DIVERT MANAGEMENT'S ATTENTION AND HARM OUR BUSINESS.

Our business exposes us to significant risks of product liability claims. The medical device industry has historically been litigious, and we face financial exposure to product liability claims if the use of our products were to cause injury or death. There is also the possibility that defects in the design or manufacture of our products might necessitate a product recall. Although we maintain product liability insurance, the coverage limits of these policies may not be adequate to cover future claims. Particularly as sales of our products increase, we may be unable to maintain product liability insurance in the future at satisfactory rates or in adequate amounts. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. Product liability claims have been made against our company in the past. A product liability claim or any product recalls could also harm our reputation or result in a decline in revenues.

TERMINATION OF RELATIONSHIPS WITH FORMER DISTRIBUTORS OF COMPUTER MOTION HAS RESULTED IN BREACH OF CONTRACT LITIGATION.

As part of our integration strategy related to our acquisition of Computer Motion, we terminated Computer Motion's relationships with a number of companies that served as Computer Motion's distributors prior to the acquisition. As a result, two former distributors (one in Italy and the other in Israel) have filed breach of contract suits against us. Due to the inherent uncertainties of litigation, we cannot accurately predict the ultimate outcome of any such litigation at this time and, therefore, cannot estimate the range of possible loss. These proceedings could be expensive to litigate, may be protracted and Computer Motion's and/or our confidential information may be compromised. Whether or not we are successful in these lawsuits, these proceedings could consume substantial amounts of our financial and managerial resources. See Item 3: Legal Proceedings.

PUBLIC ANNOUNCEMENTS OF LITIGATION EVENTS MAY CAUSE OUR STOCK PRICE TO DECLINE.

During the course of our administrative proceedings and/or lawsuits, there may be public announcements of the results of hearings, motions, and other interim proceedings or developments in the litigation. If securities analysts or investors perceive these results to be negative, it could have a substantial negative effect on the trading price of our stock.

OUR PRODUCTS ARE SUBJECT TO A LENGTHY AND UNCERTAIN DOMESTIC REGULATORY PROCESS. IF WE DO NOT OBTAIN AND MAINTAIN THE NECESSARY DOMESTIC REGULATORY APPROVALS, WE WILL NOT BE ABLE TO MARKET AND SELL OUR PRODUCTS IN THE UNITED STATES.

Our products and operations are subject to extensive regulation in the United States by the U.S. Food and Drug Administration, or FDA. The FDA regulates the research, testing, manufacturing, safety, labeling, storage, record keeping, promotion, distribution and production of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. In order for us to market certain products for use in the United States, we generally must first obtain clearance from the FDA pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or FDCA. Clearance under Section 510(k) requires demonstration that a new device is substantially equivalent to another device with 510(k) clearance or grandfather status. If we significantly modify our products after they receive FDA clearance, the FDA may require us to submit a separate 510(k) or premarket approval application, or PMA, for the modified product before we are permitted to market the products in the U.S. In addition, if we develop products in the future that are not considered to be substantially equivalent to a device with 510(k) clearance or grandfather status, we will be required to obtain FDA approval by submitting a PMA.

The FDA may not act favorably or quickly in its review of our 510(k) or PMA submissions, or we may encounter significant difficulties and costs in our efforts to obtain FDA clearance or approval, all of which could delay or preclude sale of new products in the United States. Furthermore, the FDA may request additional data or require us to conduct further testing, or compile more data, including clinical data and clinical studies, in support of a 510(k) submission. The FDA may also, instead of accepting a 510(k) submission, require us to submit a PMA, which is typically a much more complex and burdensome application than a 510(k). To support a PMA, the FDA would likely require that we conduct one or more clinical studies to demonstrate that the device is safe and effective. We may not be able to meet the requirements to obtain 510(k) clearance or PMA approval, or the FDA may not grant any necessary clearances or approvals. In addition, the FDA may place significant limitations upon the intended use of our products as a condition to a 510(k) clearance or PMA approval. Product applications can also be denied or withdrawn due to failure to comply with regulatory requirements or the occurrence of unforeseen problems following clearance or approval. Any delays or failure to obtain FDA clearance or approvals of new products we develop, any limitations imposed by the FDA on new product use, or the costs of obtaining FDA clearance or approvals could have a material adverse effect on our business, financial condition and results of operations.

In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a device, a company must, among other things, apply for and obtain Institutional Review Board, or IRB approval of the proposed investigation. In addition, if the clinical study involves a “significant risk” (as defined by the FDA) to human health, the sponsor of the investigation must also submit and obtain FDA approval of an investigational device exemption, or IDE, application. Most of our products to date have been considered significant risk devices requiring IDE approval prior to investigational use. We may not be able to obtain FDA and/or IRB approval to undertake clinical trials in the U.S. for any new devices we intend to market in the United States in the future. If we obtain such approvals, we may not be able to comply with the IDE and other regulations governing clinical investigations or the data from any such trials may not support clearance or approval of the investigational device. Failure to obtain such approvals or to comply with such regulations could have a material adverse effect on our business, financial condition and results of operations.

COMPLYING WITH FDA REGULATIONS IS AN EXPENSIVE AND TIME-CONSUMING PROCESS, AND OUR FAILURE TO COMPLY FULLY COULD SUBJECT US TO SIGNIFICANT ENFORCEMENT SANCTIONS.

Because our products, including the *da Vinci* Surgical System, are commercially distributed, numerous postmarket regulatory requirements apply, including the following:

- Quality System Regulation, or QSR, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- labeling regulations;
- the FDA’s general prohibition against false or misleading statements in the labeling or promotion of products for unapproved or “off-label” uses;
- the Reports of Corrections and Removals regulation, which requires that manufacturers report to the FDA recalls and field corrective actions taken to reduce a risk to health or to remedy a violation of the FDCA that may pose a risk to health; and
- the Medical Device Reporting regulation, which requires 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 it were to recur.

We are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. If the FDA finds that we have failed to comply, it can institute a wide variety of enforcement actions, ranging from a regulatory letter to a public warning letter to more severe civil and criminal sanctions. Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations.

We have modified the labeling, advertising and user training for the *da Vinci* Surgical System to call out specific procedures that we believe are within the scope of our existing 510(k) clearances. We cannot assure you that the FDA would agree that all such specific procedures are within the scope of the existing general clearance or that we have compiled adequate information to support the safety and efficacy of using the *da Vinci* Surgical System for all such specific procedures. We also have modified the hardware and software in the *da Vinci* Surgical System since clearance in ways that we believe do not require new 510(k) clearance. We cannot assure you that the FDA would agree with our determinations not to seek new 510(k) clearance for any of these changes. Computer Motion also modified the hardware and software in its products subsequent to 510(k) clearance without seeking new clearance. We cannot assure you that the FDA would agree with the determinations not to seek new 510(k) clearance for any of these changes. The FDA could impose enforcement sanctions and/or require us to obtain 510(k) clearance for any modification to our products or Computer Motion’s products. We may be prohibited from marketing the modified device until such 510(k) clearance is granted.

In December 2002, the FDA inspected our Sunnyvale manufacturing facility and issued a Form FDA 483 setting forth three observed compliance deficiencies relating to the QSR and two observed deficiencies relating to the Reports of Corrections and Removals regulation. In January 2003, we wrote to the FDA indicating our response to each observation with proposed corrective actions. That same month, the FDA informed us that the adequacy of our promised corrections and actions would be verified during the next inspection of our facility. To date, the FDA has not returned for another inspection and we continue to evaluate and upgrade our QSR compliance. We cannot assure you that, upon reinspection, the FDA will find that our promised corrective actions are appropriate or that they have been adequately implemented. We also cannot assure you that the FDA will not find other deficiencies in our compliance with the QSR and other postmarket regulations.

In June 2003, we acquired Computer Motion and have integrated its FDA compliance quality system into our own. As a result of the integration and review, we identified that Computer Motion has had deficiencies in complaint handling, MDR reporting and Corrections and Removals reporting in the last several years that required submission of retroactive reports to the FDA. We reported 52 MDRs and we believe that our reporting decisions regarding these 52 complaints is conservative in part because many of the complaints likely would not

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have been reportable if more information had been available. Also, to our knowledge, none of the reported events resulted in a death or serious injury, prolonged hospitalization, or medical intervention to prevent death or serious injury. Computer Motion did respond to complaint trends, and it addressed the trends through corrective actions. Accordingly, the incidence of many of the types of events in the reports had been mitigated by June 2003. Our review also suggests that significant complaint trends identified by Computer Motion over the period of four years were addressed by corrective actions, which have proven to be effective over time. Computer Motion's product modifications were completed without 510(k) clearance and we believe that they do not require new 510(k) clearance. We cannot assure you that the FDA would agree with our determinations not to seek new 510(k) clearance for any of these changes.

We cannot assure you that the FDA will not seek to impose enforcement sanctions on us for Computer Motion violations preceding our acquisition of Computer Motion, that the FDA will agree that since the acquisition we have corrected all regulatory problems, or that our review of Computer Motion's complaint handling will not lead us to initiate recalls or field actions to remedy problems with Computer Motion products already in the field.

OUR PRODUCTS ARE SUBJECT TO VARIOUS INTERNATIONAL REGULATORY PROCESSES AND APPROVAL REQUIREMENTS. IF WE DO NOT OBTAIN AND MAINTAIN THE NECESSARY INTERNATIONAL REGULATORY APPROVALS, WE WILL NOT BE ABLE TO MARKET AND SELL OUR PRODUCTS IN FOREIGN COUNTRIES.

To be able to market and sell our products in other countries, we must obtain regulatory approvals and comply with the regulations of those countries. These regulations, including the requirements for approvals and the time required for regulatory review, vary from country to country. Obtaining and maintaining foreign regulatory approvals are expensive, and we cannot be certain that we will receive regulatory approvals in any foreign country in which we plan to market our products. If we fail to obtain regulatory approval in any foreign country in which we plan to market our products, our ability to generate revenue will be harmed.

The European Union requires that manufacturers of medical products obtain the right to affix the CE mark to their products before selling them in member countries of the European Union. The CE mark is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain the right to affix the CE mark to products, a manufacturer must obtain certification that its processes meet certain European quality standards. In January 1999, we received permission to affix the CE mark to our *da Vinci* Surgical System and *EndoWrist* instruments.

If we modify existing products or develop new products in the future, including new instruments, we may need to apply for permission to affix the CE mark to such products. In addition, we will be subject to annual regulatory audits in order to maintain the CE mark permissions we have already obtained. We do not know whether we will be able to obtain permission to affix the CE mark for new or modified products or that we will continue to meet the quality and safety standards required to maintain the permissions we have already received. If we are unable to maintain permission to affix the CE mark to our products, we will no longer be able to sell our products in member countries of the European Union.

IF INSTITUTIONS OR SURGEONS ARE UNABLE TO OBTAIN REIMBURSEMENT FROM THIRD-PARTY PAYORS FOR PROCEDURES USING OUR PRODUCTS, OR IF REIMBURSEMENT IS INSUFFICIENT TO COVER THE COSTS OF PURCHASING OUR PRODUCTS, WE MAY BE UNABLE TO GENERATE SUFFICIENT SALES TO SUPPORT OUR BUSINESS.

Domestic institutions will typically bill the services performed with our products to various third-party payors, such as Medicare, Medicaid and other government programs and private insurance plans. If hospitals do not obtain sufficient reimbursement from third-party payors for procedures performed with our products, or if government and private payors' policies do not permit reimbursement for surgical procedures performed using our products, we may not be able to generate the revenues necessary to support our business. Our success in international markets also depends upon the eligibility of our products for reimbursement through government- sponsored health care payment systems and third-party payors. Reimbursement practices vary significantly by

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country. Many international markets have government-managed healthcare systems that control reimbursement for new products and procedures. Other foreign markets have both private insurance systems and government-managed systems that control reimbursement for new products and procedures. Market acceptance of our products may depend on the availability and level of reimbursement in any country within a particular time. In addition, health care cost containment efforts similar to those we face 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.

IF OUR MANUFACTURING FACILITIES DO NOT CONTINUE TO MEET FEDERAL, STATE OR EUROPEAN MANUFACTURING STANDARDS, WE MAY BE REQUIRED TO TEMPORARILY CEASE ALL OR PART OF OUR MANUFACTURING OPERATIONS, WHICH COULD RESULT IN PRODUCT DELIVERY DELAYS AND LOST REVENUE.

Our manufacturing facilities are subject to periodic inspection by regulatory authorities and our operations will continue to be regulated by the FDA for compliance with Good Manufacturing Practice requirements contained in the FDA's Quality System Regulations, or QSR. We are also required to comply with International Organization for Standardization, or ISO, quality system standards in order to produce products for sale in Europe. If we fail to continue to comply with Good Manufacturing Practice requirements or ISO standards, we may be required to cease all or part of our operations until we comply with these regulations. We are currently in compliance with ISO standards. The FDA inspected our Mountain View and Sunnyvale facilities in March 2000 and December 2002, respectively. The Good Manufacturing Practice issues raised by the FDA during the inspections either were satisfactorily resolved with the FDA, or we believe can be resolved by us to the FDA's satisfaction, although we cannot assure you that we will be able to do so. We continue to be subject to FDA inspections at any time. Maintaining such compliance is difficult and costly. We cannot be certain that our facilities will be found to comply with Good Manufacturing Practice requirements or ISO standards in future inspections and audits by regulatory authorities.

The FDA inspected the Goleta facilities of Computer Motion in 1998 and noted deficiencies in Computer Motion's systems for reviewing and reporting product-related complaints and defect information. We have determined that these deficiencies may not have been addressed. While the Goleta manufacturing facility has been closed and production of certain product has been transferred to our Sunnyvale facility, these issues raised by the FDA must nonetheless be resolved. The complaint records prior to acquisition of Computer Motion were reviewed and appropriate Medical Device Reports were filed with the FDA. Complaints received subsequent to our acquisition of Computer Motion are handled in accordance with Intuitive Surgical quality system requirements, which we believe is in accordance with FDA requirements, although we cannot assure you that FDA will agree, nor can we assess what regulatory impact, if any, this may have on our company.

As required, we are licensed by the State of California to manufacture medical devices. We are subject to periodic inspections by the California Department of Health Services and, if we are unable to maintain this license following any future inspections, we will be unable to manufacture or ship any products.

IF WE LOSE OUR KEY PERSONNEL OR ARE UNABLE TO ATTRACT AND RETAIN ADDITIONAL PERSONNEL, OUR ABILITY TO COMPETE WILL BE HARMED.

We are highly dependent on the principal members of our management and scientific staff. Our product development plans depend, in part, on our ability to attract and retain engineers with experience in mechanics, software and optics. Attracting and retaining qualified personnel will be critical to our success, and competition for qualified personnel is intense. We may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among technology and healthcare companies, and universities. The loss of any of these persons or our inability to attract and retain qualified personnel could harm our business and our ability to compete.

ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are not subject to any meaningful market risks related to currency, commodity prices or similar matters. We are sensitive to short-term interest rate fluctuations to the extent that such fluctuations impact the interest income we receive on the investment of our cash and cash equivalents and investments.

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The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the fair value amount of our investment will probably decline. To minimize this risk in the future, we intend to maintain our portfolio of cash equivalents and short-term investments in a variety of securities. We classify our cash equivalents and marketable securities as “fixed-rate” if the rate of return on such instruments remains fixed over their term. These “fixed-rate” investments include commercial paper and government and non-government debt securities. We classify our cash equivalents and marketable securities as “variable-rate” if the rate of return on such investments varies based on the change in a predetermined index or set of indices during their term. These “variable-rate” investments primarily include auction-rate securities with rates that re-set generally every 30 days. The weighted average maturity of all of our fixed-rate investments as of December 31, 2004 was approximately one-and-a-half years. At December 31, 2004 and 2003, approximately 25% and 9%, respectively, of our fixed-rate investment portfolio was composed of investments with maturities of one year or less. The following table presents the amounts of our short-term investments that may be subject to interest rate risk and the weighted average interest rates by year of maturity (\$ in thousands):

	As of December 31, 2004		As of December 31, 2003	
	Weighted Average Interest Rate	Fair Value	Weighted Average Interest Rate	Fair Value
Variable rate securities	2.46%	\$ 40,650	1.21%	\$ 31,500
Marketable securities				
Fixed rate (mature in 2004)	—	\$ —	4.30%	\$ 6,236
Fixed rate (mature in 2005)	2.85%	\$ 21,250	2.96%	\$ 23,541
Fixed rate (mature in 2006)	2.93%	\$ 48,282	2.99%	\$ 40,337
Fixed rate (mature in 2007)	3.01%	\$ 15,085	—	\$ —
Fixed rate (mature in 2008)	3.77%	\$ 1,000	—	\$ —

Fluctuations in interest rates would also impact interest expense on future fixed rate notes payable for equipment financing contracts, should we elect to finance future equipment purchases. The following table summarizes installment notes outstanding as of December 31, 2004 and 2003 and the associated interest rates by year of maturity (\$ in thousands):

Final Installment	As of December 31, 2004		As of December 31, 2003	
	Note Payable Outstanding	Weighted Average Rate	Note Payable Outstanding	Weighted Average Rate
2004	—	—	118	8.50%
2005	609	7.40%	1,607	7.55%
	\$ 609	7.40%	\$ 1,725	7.62%
Less current portion	(609)		(1,030)	
Long-term portion	\$ —		\$ 695	

The majority of our revenue, expense, and capital purchasing activities are transacted in U.S. dollars. However, since a portion of our operations consists of sales activities outside of the United States, we have entered into transactions in other currencies, primarily the euro.

For 2004, 2003 and 2002, sales denominated in foreign currencies were 8%, 12% and 7%, respectively, of total sales.

Foreign currency fluctuations resulted in \$0.2 million, \$0.4 million and \$22,000 of foreign exchange gain for 2004, 2003 and 2002 respectively.

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ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial Statements
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All other schedules have been omitted because they are not applicable or the required information is shown in the Consolidated Financial Statements or the Notes thereto.

REPORT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders' of Intuitive Surgical, Inc.

We have audited the accompanying consolidated balance sheets of Intuitive Surgical, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. Our audits also included the financial statement schedule listed in the index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Intuitive Surgical, Inc. at December 31, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Intuitive Surgical, Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 9, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 9, 2005

REPORT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders' of Intuitive Surgical, Inc.

We have audited management's assessment, included in the Management's Report on Internal Control over Financial Reporting, that Intuitive Surgical, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Intuitive Surgical, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Intuitive Surgical, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Intuitive Surgical, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria .

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2004 consolidated balance sheets of Intuitive Surgical, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2004 and the financial statement schedule listed in the index at Item 15(a) and our report dated March 9, 2005, expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 9, 2005

INTUITIVE SURGICAL, INC.
CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

	December 31,	
	2004	2003
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,771	\$ 11,335
Investments	126,267	101,614
Accounts receivable, net of allowances of \$1,334 and \$1,765 at December 31, 2004 and 2003, respectively	35,443	26,820
Inventory	5,966	8,788
Prepays	3,032	3,203
Restricted cash	205	188
	<u>176,684</u>	<u>151,948</u>
Total current assets	176,684	151,948
Property and equipment, net	27,065	10,288
Restricted cash	319	642
Intangible assets, net	6,221	8,089
Goodwill	143,332	143,106
Other assets	608	921
	<u>354,229</u>	<u>314,994</u>
Total assets	\$ 354,229	\$ 314,994
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,485	\$ 5,894
Accrued compensation and employee benefits	10,321	5,267
Deferred revenue	15,372	11,345
Restructuring accrual	541	971
Other accrued liabilities	7,057	9,134
Current portion of notes payable	609	1,030
	<u>38,385</u>	<u>33,641</u>
Total current liabilities	38,385	33,641
Long-term portion of notes payable	—	695
Deferred revenue	505	1,148
Other accrued liabilities	407	553
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock, 2,500,000 shares authorized, \$0.001 par value, issuable in series; no shares issued and outstanding as of December 31, 2004 and 2003, respectively	—	—
Common stock, 100,000,000 shares authorized, \$0.001 par value, 34,234,795 and 33,051,631 shares issued and outstanding as of December 31, 2004 and 2003, respectively	34	33
Additional paid-in capital	430,362	416,559
Deferred compensation	—	(99)
Accumulated deficit	(114,936)	(138,414)
Treasury Stock, at cost, 4,461 shares and no shares at December 31, 2004 and 2003, respectively	(136)	—
Accumulated other comprehensive income (loss)	(392)	878
	<u>314,932</u>	<u>278,957</u>
Total stockholders' equity	314,932	278,957
Total liabilities and stockholders' equity	\$ 354,229	\$ 314,994

See accompanying notes.

INTUITIVE SURGICAL, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

	Year Ended December 31,		
	2004	2003	2002
Sales:			
Products	\$ 116,338	\$ 80,586	\$ 66,407
Services	22,465	11,089	5,615
Total sales	138,803	91,675	72,022
Cost of sales:			
Products	40,472	39,977	31,183
Services	10,341	7,669	6,938
Total cost of sales	50,813	47,646	38,121
Gross profit	87,990	44,029	33,901
Operating costs and expenses:			
Selling, general and administrative	48,994	39,719	37,327
Research and development	17,812	16,190	16,793
Total operating costs and expenses	66,806	55,909	54,120
Income (loss) from operations	21,184	(11,880)	(20,219)
Interest income	2,869	2,066	2,040
Interest expense	(91)	(203)	(199)
Other income (expense)	242	394	(43)
Income (loss) before income taxes	24,204	(9,623)	(18,421)
Income tax expense	(726)	—	—
Net income (loss)	\$ 23,478	\$ (9,623)	\$ (18,421)
Net income (loss) per common share:			
Basic	\$ 0.70	\$ (0.41)	\$ (1.01)
Diluted	\$ 0.67	\$ (0.41)	\$ (1.01)
Shares used in computing basic and diluted net income (loss) per common share:			
Basic	33,693	23,626	18,229
Diluted	34,976	23,626	18,229

See accompanying notes.

INTUITIVE SURGICAL, INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(IN THOUSANDS, EXCEPT SHARE AMOUNTS)

	Common Stock	Stock Amount	Additional Paid-In Capital	Deferred Compensation	Accumulated Deficit	Treasury Stock	Stock Amount	Accumulated Other Comprehensive Income (Loss)	Total
Balances at December 31, 2001	18,111,820	\$ 18	\$ 188,980	\$ (886)	\$ (110,370)	—	\$ —	\$ 551	\$ 78,293
Issuance of common stock upon exercise of options	245,904	—	2,060	—	—	—	—	—	2,060
Repurchase of common stock	(211)	—	(2)	—	—	—	—	—	(2)
Amortization of deferred compensation	—	—	—	663	—	—	—	—	663
Comprehensive loss:									
Change in unrealized gain (loss) on available-for-sale securities	—	—	—	—	—	—	—	996	996
Change in foreign currency translation adjustments	—	—	—	—	—	—	—	91	91
Net loss	—	—	—	—	(18,421)	—	—	—	(18,421)
Comprehensive loss									(17,334)
Balances at December 31, 2002	18,357,513	\$ 18	\$ 191,038	\$ (223)	\$ (128,791)	—	\$ —	\$ 1,638	\$ 63,680
Issuance of common stock in connection with Computer Motion, Inc. acquisition	8,041,325	8	141,429	—	—	—	—	—	141,437
Issuance of common stock in connection with the public offering, net of issuance costs of \$5,645	5,750,000	6	77,724	—	—	—	—	—	77,730
Issuance of common stock upon exercise of options and under stock purchase plan	903,841	1	6,232	—	—	—	—	—	6,233
Repurchase of common stock	(1,048)	—	(6)	—	—	—	—	—	(6)
Deferred compensation	—	—	142	(434)	—	—	—	—	(292)
Amortization of deferred compensation	—	—	—	558	—	—	—	—	558
Comprehensive loss:									
Change in unrealized gain (loss) on available-for-sale securities	—	—	—	—	—	—	—	(683)	(683)
Change in foreign currency translation adjustments	—	—	—	—	—	—	—	(77)	(77)
Net loss	—	—	—	—	(9,623)	—	—	—	(9,623)
Comprehensive loss									(10,383)
Balances at December 31, 2003	33,051,631	\$ 33	\$ 416,559	\$ (99)	\$ (138,414)	—	\$ —	\$ 878	\$278,957
Issuance of common stock upon exercise of options and under stock purchase plan	1,183,164	1	13,368	—	—	—	—	—	13,369
Income tax benefit from stock option exercises	—	—	387	—	—	—	—	—	387
Repurchase of common stock	—	—	—	—	—	(4,461)	(136)	—	(136)
Stock Compensation	—	—	48	—	—	—	—	—	48
Amortization of deferred compensation	—	—	—	99	—	—	—	—	99
Comprehensive income:									
Change in unrealized gain (loss) on available-for-sale securities	—	—	—	—	—	—	—	(1,367)	(1,367)
Change in foreign currency translation adjustments	—	—	—	—	—	—	—	97	97
Net income	—	—	—	—	23,478	—	—	—	23,478
Comprehensive income									22,208
Balances at December 31, 2004	34,234,795	\$ 34	\$ 430,362	\$ —	\$ (114,936)	(4,461)	\$ (136)	\$ (392)	\$ 314,932

See accompanying notes.

INTUITIVE SURGICAL, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)

	Year Ended December 31,		
	2004	2003	2002
Operating Activities:			
Net income (loss)	\$ 23,478	\$ (9,623)	\$(18,421)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation	5,096	4,151	3,106
Provision (benefit) for doubtful accounts and write-offs	(374)	887	204
Loss on sales of Property and Equipment	270	5	66
Amortization of deferred compensation and stock compensation	147	700	663
Amortization/Impairment of intangible assets	1,868	5,778	780
Income tax benefit from stock option exercises	387	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(8,250)	(6,346)	(3,843)
Prepays	409	(778)	894
Inventory	2,822	4,622	(2,556)
Other assets	315	(580)	(166)
Accounts payable	(1,440)	(11,336)	982
Accrued compensation and employee benefits	5,014	(1,565)	2,129
Restructuring accrual	(612)	(2,565)	—
Other accrued liabilities	(2,199)	3,367	2,046
Accrued royalty expense	—	—	(1,000)
Deferred revenue	3,384	5,429	968
Net cash provided by (used in) operating activities	<u>30,315</u>	<u>(7,854)</u>	<u>(14,148)</u>
Investing activities:			
Acquisition of property and equipment	(22,439)	(2,525)	(5,788)
Disposition of property and equipment	—	150	62
Acquisition of patent	—	(2,600)	(40)
Acquisition of business, net of cash acquired	—	(5,861)	—
Release of restricted cash	306	223	—
Increase in restricted cash	—	(98)	(955)
Purchase of short-term investments	(121,890)	(91,592)	(35,874)
Proceeds from sales and maturities of short-term investments	95,870	31,127	51,212
Net cash provided by (used in) investing activities	<u>(48,153)</u>	<u>(71,176)</u>	<u>8,617</u>
Financing activities:			
Proceeds from issuance of common stock, net	13,233	83,963	2,060
Repurchase of common stock	—	(6)	(2)
Proceeds from notes payable	—	—	2,912
Repayment of notes payable	(1,116)	(1,624)	(1,965)
Net cash provided by financing activities	<u>12,117</u>	<u>82,333</u>	<u>3,005</u>
Effect of exchange rate changes on cash and cash equivalents	157	(20)	91
Net increase (decrease) in cash and cash equivalents	(5,564)	3,283	(2,435)
Cash and cash equivalents, beginning of period	11,335	8,052	10,487
Cash and cash equivalents, end of period	<u>\$ 5,771</u>	<u>\$ 11,335</u>	<u>\$ 8,052</u>
Supplemental Disclosure of Cash Flow Information:			
Non-cash investing activity:			
Common stock issued in connection with acquisition of business	\$ —	\$ 141,437	\$ —
Income taxes paid	\$ 60	\$ —	\$ —
Interest paid	\$ 91	\$ 203	\$ 199

See accompanying notes.



INTUITIVE SURGICAL, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. DESCRIPTION OF THE BUSINESS

Intuitive Surgical, Inc. (the “Company”) designs, manufactures, and markets the *da Vinci* Surgical System, an advanced surgical system that the Company believes represents a new generation of surgery. The *da Vinci* Surgical System consists of a surgeon’s console, a patient-side cart, a high performance vision system and proprietary instruments. The *da Vinci* Surgical System seamlessly translates the surgeon’s natural hand movements on instrument controls at a console into corresponding micro-movements of instruments positioned inside the patient through small puncture incisions, or ports. The Company began selling the *da Vinci* Surgical System in 1999 and has placed 286 total systems worldwide as of December 31, 2004.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States and include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

On June 30, 2003, Intuitive Surgical acquired Computer Motion, Inc. through the merger of Computer Motion with a wholly-owned subsidiary of Intuitive Surgical. In the merger, each outstanding share of Computer Motion common stock was converted into 0.25713472 shares of Intuitive Surgical common stock after giving effect to the 1-for-2 reverse stock split effective July 1, 2003, and Intuitive Surgical assumed all of Computer Motion’s outstanding options and warrants based on the same ratio. See “Note 3: Acquisition of Computer Motion, Inc.”

In accordance with Statement of Financial Accounting Standards (“SFAS”) No. 141, “Business Combinations,” Intuitive Surgical, Inc. has included in its results of operations the results of Computer Motion, Inc. from its date of acquisition, June 30, 2003.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from these estimates.

Reclassifications

Certain reclassifications have been made to prior years’ balances in order to conform to the current year presentation. These reclassifications have no impact on previously reported net loss or stockholders’ equity.

Concentrations of Risk

Financial instruments which subject the Company to potential risk consist of its cash equivalents, short-term investments, and accounts receivable. The counterparties to the agreements relating to the Company’s investment securities consist of various major corporations and financial institutions of high credit standing. The Company believes the financial risks associated with these financial instruments are minimal. For the years ended December 31, 2004, 2003 and 2002, no customer accounted for more than 10% of total sales. The Company does not require collateral. The Company provides reserves for potential credit losses but has not experienced significant losses to date.

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The Company's *da Vinci* Surgical System, HERMES Control Center, AESOP Endoscope Positioner and related instruments and accessories, accounted for substantially all of the Company's product sales for the years ended December 31, 2004, 2003 and 2002. Purchases of key parts and components used to manufacture the Company's products are from limited supply sources. The inability of any of these suppliers to fulfill the Company's supply requirements may negatively impact future operating results.

The Company operates in one segment, the development and marketing of products designed for use in surgery. The distribution of sales by geographic location is as follows (in thousands):

	For the years ended December 31,		
	2004	2003	2002
Domestic	\$ 109,782	\$ 70,070	\$ 58,914
International	29,021	21,605	13,108
Total Sales	\$ 138,803	\$ 91,675	\$ 72,022

For the year ended December 31, 2004, U.S. and international sales accounted for 79% and 21%, respectively, of total sales. For the year ended December 31, 2003, U.S. and international sales accounted for 76% and 24%, respectively, of total sales. For the year ended December 31, 2002, U.S. and international sales accounted for 82% and 18%, respectively, of total sales.

Foreign Currency Translation

The functional currency of each foreign subsidiary is its local currency. Foreign assets and liabilities are translated into U.S. dollars at year-end exchange rates when appropriate, while components of the income statement are translated using average exchange rates in effect throughout the year. Gains and losses arising from foreign currency transactions are included in the Consolidated Statement of Operations. Gains arising from foreign currency transactions totaled \$0.2 million, \$0.4 million and \$22,000 for the years ended December 31, 2004, 2003 and 2002, respectively. Translation adjustments of balance sheet items are included as a component of stockholders' equity.

Revenue Recognition

The Company recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred or service has been rendered, the price is fixed or determinable and collectibility is reasonably assured.

In certain cases, revenue from direct system sales is earned pursuant to multiple-element arrangements that require judgment in the areas of customer acceptance, collectibility, the separability of units of accounting, and the fair value of individual elements. Effective July 1, 2003, the Company adopted the provisions of Emerging Issues Task Force, or EITF, Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables," on a prospective basis. The principles and guidance outlined in EITF No. 00-21 provide a framework to (a) determine whether an arrangement involving multiple deliverables contains more than one unit of accounting, and (b) determine how the arrangement consideration should be measured and allocated to the separate units of accounting in the arrangement. The Company determined that its multiple-element arrangements are generally comprised of the following elements that would qualify as separate units of accounting: system sales, service, installation, and training. Each of these elements represents individual units of accounting as the delivered item has value to a customer on a stand-alone basis, objective and reliable evidence of fair value exists for undelivered items, and arrangements generally do not contain a general right of return relative to the delivered item. The Company determines fair value based on the price of the undelivered element when it is sold separately or based on third-party evidence. In accordance with the guidance in EITF No. 00-21, the Company uses the residual method to allocate the arrangement consideration when it does not have fair value of the system sale. Under the residual method, the amount of consideration allocated to the delivered item equals the total arrangement

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consideration less the aggregate fair value of the undelivered items. Assuming all other criteria for revenue recognition have been met, the Company recognizes revenue for system sales when delivery and acceptance occurs, for installation and training when the services are rendered, and for service ratably over the service period, which is generally one year.

The Company's distributors do not have price protection rights. The Company records an allowance on sales returns based on historical returns.

Revenue from sales of replacement instruments and accessories is recognized upon delivery. Revenue related to future commitments under separately priced service contracts is deferred and recognized ratably over the service period. All costs associated with the provision of service and maintenance, including salaries, benefits, travel, spare parts and equipment, are recognized in cost of sales as incurred. Amounts billed in excess of revenue recognized are included as deferred revenue in the consolidated balance sheets.

The Company's *da Vinci* Surgical System, HERMES Control Center and AESOP Endoscope Positioner contain a software component. The Company believes that this software element is an incidental part of each system. The software element within the Company's products is not sold or marketed separately to customers, and the software does not operate independently of each system. Furthermore, the software development effort does not require a significant cost to the Company relative to the overall development cost of the product. As such, the software the Company provides is incidental to each system as a whole and the software revenue guidance provided in Statement Of Position 97-2, "Software Revenue Recognition," is not applicable to the Company's revenues.

Cash and cash equivalents

The Company considers all highly liquid investments with an original maturity from date of purchase of 90 days or less to be cash equivalents for the purpose of balance sheet and statement of cash flows presentation. The carrying value of cash and cash equivalents approximates estimated market value at December 31, 2004 and December 31, 2003.

Short-Term Investments

All short-term investments are classified as available-for-sale and therefore carried at estimated fair value. The Company views its available-for-sale portfolio as available for use in its current operations. Accordingly, all investments are classified as short-term, even though the stated maturity date may be one year or more beyond the current balance sheet date. Available-for-sale securities are stated at estimated fair value based upon quoted market prices of the securities. Unrealized gains and losses on such securities are reported as a separate component of stockholders' equity. Realized gains and losses on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Inventory

Inventory is stated at the lower of cost or market value on a first-in, first-out basis.

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Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Property and equipment are depreciated on a straight-line basis over the estimated useful lives of the assets generally as follows:

	Useful Lives
Computer equipment	3 years
Purchased software	3-5 years
Laboratory and manufacturing equipment	5 years
Office furniture and equipment	5 years
Building improvements	5 years
Building	15 years
Leasehold improvements	Lesser of useful life or term of lease

Product Warranty Provisions

The Company's standard policy is to warrant all shipped systems against defects in design, materials and workmanship by replacing failed parts during the first year of ownership. The Company's estimate of costs to service the warranty obligations is based on historical experience and current product performance trends. Prior to July 1, 2003, these costs were included in cost of goods sold at the time revenue was recognized. The warranty accrual was reduced by material and labor costs used for replacement activities over the warranty period. Effective July 1, 2003, the Company adopted the provisions of EITF No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables," on a prospective basis. Under EITF No. 00-21, for certain arrangements, a portion of the overall system price attributable to the first year service is deferred and recognized as revenue over the service period. As such, the Company recognizes warranty and related service costs as incurred for these arrangements. A review of warranty obligations is performed regularly to determine the adequacy of the reserve. Based on the outcome of this review, revisions to the estimated warranty liability are recorded as appropriate.

The following table reconciles the changes to the product warranty liability, which is included in other accrued liabilities on the accompanying consolidated balance sheets, for the periods indicated (in thousands):

	Balance at Beginning of Period	Warranty Usage	Warranty Expensed	Balance at End of Period
Year ended December 31, 2004	\$ 702	\$ (723)	\$ 157	\$ 136

The remaining product warranty balance of \$0.1 million relates to sales that were not made in conjunction with service arrangements.

The Company from time to time enters into agreements to indemnify its customers against liability and damages arising from patent claims against the Company's products. The term of these agreements vary, but generally, a maximum obligation is not explicitly stated within the agreements. Historically, the Company has not been obligated to make any significant payments related to its customer indemnification clauses and the liabilities recorded for this obligation on its balance sheets as of December 31, 2004 and 2003 were not significant.

Stock-Based Compensation

The Company applies Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for its stock option plans. Accordingly, no compensation expense has been recorded for stock option grants issued with an exercise price equal to the market value of the

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underlying stock on the date granted. The Company has recorded stock-based compensation, primarily related to deferred compensation arising from the Company's initial public offering in 2000 and its acquisition of Computer Motion in June 2003. As required under Statement of Financial Accounting Standards, or SFAS, No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure," the Company has provided the following pro forma net income (loss) and pro forma net income (loss) per share disclosures for stock-based awards as if the fair value-based method defined in SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"), had been applied, amortizing expense ratably over the service period (amounts in thousands, except per share amounts):

	Year Ended December 31,		
	2004	2003	2002
Net income (loss), as reported	\$ 23,478	\$ (9,623)	\$ (18,421)
Add: Total stock-based employee compensation expense included in reported net income (loss), net of \$0 related tax effect	—	700	663
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of \$0 related tax effect	(9,769)	(8,176)	(7,197)
Pro forma net income (loss)	\$ 13,709	\$ (17,099)	\$ (24,955)
Net income (loss) per share:			
Basic—as reported	\$ 0.70	\$ (0.41)	\$ (1.01)
Basic—pro forma	\$ 0.41	\$ (0.72)	\$ (1.37)
Diluted—as reported	\$ 0.67	\$ (0.41)	\$ (1.01)
Diluted—pro forma	\$ 0.39	\$ (0.72)	\$ (1.37)

Research and Development

Research and development costs, which include clinical costs, are expensed to operations as incurred.

Advertising Costs

Advertising costs are expensed as incurred. Advertising costs for the years ended December 31, 2004, 2003 and 2002 were \$1.3 million, \$1.4 million, and \$1.3 million, respectively.

Shipping and Handling Costs

Costs incurred for shipping and handling are included in cost of sales at the time the related sale is recognized. Amounts billed to customers for shipping and handling are reported as sales.

Income Taxes

The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. A valuation allowance is established, as needed, to reduce net deferred tax assets to the amount for which recovery is more likely than not.

Net Income (Loss) Per Share

Basic net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common shares outstanding during the period less the weighted average common shares subject to repurchase. Diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common and potential common shares outstanding during the

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period less the weighted average common shares subject to repurchase if their effect is dilutive. Potential common shares were excluded in computing net income (loss) per share when the Company incurred a loss for the period as they were antidilutive.

The following table presents the computation of basic and diluted net income (loss) per share (in thousands, except per share amounts):

	Year Ended December 31,		
	2004	2003	2002
Net income (loss)	\$ 23,478	\$ (9,623)	\$(18,421)
Basic:			
Weighted-average shares outstanding	33,693	23,630	18,242
Less weighted-average shares subject to repurchase	—	(4)	(13)
Weighted-average shares used in computing basic net income (loss) per common share	33,693	23,626	18,229
Basic net income (loss) per common share	\$ 0.70	\$ (0.41)	\$ (1.01)
Diluted:			
Weighted average shares outstanding used in basic calculation	33,693	23,626	18,229
Stock options and warrants	1,283	—	—
Weighted average shares used in computing diluted net income (loss) per common share	34,976	23,626	18,229
Diluted net income (loss) per common share	\$ 0.67	\$ (0.41)	\$ (1.01)
Potentially dilutive securities excluded from diluted net income (loss) per common share computation because they are antidilutive	1,302	3,981	2,463

Comprehensive Income (loss)

Comprehensive income (loss) includes net loss and other comprehensive income (loss), which primarily consists of unrealized gains and losses on available-for-sale securities and cumulative translation adjustments. Total comprehensive income (loss) is presented in the accompanying Consolidated Statement of Stockholders' Equity. Total accumulated other comprehensive income is displayed as a separate component of stockholders' equity in the accompanying Consolidated Balance Sheets.

At December 31, the components of accumulated other comprehensive income (loss), net of related taxes, are comprised of the following (in thousands):

	2004	2003
Accumulated net unrealized gain (loss) on available-for-sale securities	\$ (427)	\$ 940
Foreign currency translation adjustments	35	(62)
Total accumulated other comprehensive income (loss)	\$ (392)	\$ 878

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123R "Share Based Payment" ("SFAS 123R"). This statement is a revision to SFAS 123 and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees," and amends SFAS No. 95, "Statement of Cash Flows." This statement requires a public entity to expense the cost of employee services received in exchange for an award of

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equity instruments. This statement also provides guidance on valuing and expensing these awards, as well as disclosure requirements of these equity arrangements. This statement is effective for the first interim reporting period that begins after June 15, 2005.

SFAS 123R permits public companies to choose between the following two adoption methods:

1. A “modified prospective” method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123R for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date, or
2. A “modified retrospective” method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

As permitted by SFAS 123, the Company currently accounts for share-based payments to employees using APB Opinion 25’s intrinsic value method and, as such, the Company generally recognizes no compensation cost for employee stock options. The impact of the adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, valuation of employee stock options under SFAS 123R is similar to SFAS 123, with minor exceptions. The impact on the results of operations and earnings per share had the Company adopted SFAS 123 is described in the stock based compensation section above. Accordingly, the adoption of SFAS 123R’s fair value method will have a significant impact on the Company’s results of operations, although it will have no impact on the Company’s overall financial position. SFAS 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. Due to the timing of the release of SFAS 123R, the Company has not yet completed the analysis of the ultimate impact that this new pronouncement will have on the results of operations, nor the method of adoption for this new standard.

In November 2004, the FASB issued SFAS No. 151, “Inventory Costs,” an amendment of ARB No. 43, Chapter 4, “Inventory Pricing.” This standard clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and waste material (spoilage). Such abnormal expenses must be recognized in the period in which they are incurred. In addition, SFAS No. 151 requires the allocation of fixed production overhead to inventory based on the normal capacity of the production facilities. Unallocated overheads must be recognized as an expense in the period in which they are incurred. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company does not expect the adoption of this new accounting pronouncement to have a material impact on its financial position or results of operations.

In March 2004, the FASB issued EITF Issue No. 03-1, “The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments” which provides new guidance for assessing impairment losses on debt and equity investments. Additionally, EITF Issue No. 03-1 includes new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB delayed the accounting provisions of EITF Issue No. 03-1; however, the disclosure requirements remain effective and have been adopted for the Company’s year ended December 31, 2004. The Company will evaluate the effect, if any, of EITF Issue No. 03-1 when final guidance is released.

NOTE 3. ACQUISITION OF COMPUTER MOTION, INC.

On June 30, 2003, the Company acquired all of the outstanding shares of Computer Motion, Inc. through a merger of Computer Motion with a wholly-owned subsidiary of Intuitive Surgical. In the merger, each outstanding share of Computer Motion common stock converted into 0.25713472 shares of Intuitive Surgical

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common stock after giving effect to the 1-for-2 reverse stock split effective July 1, 2003, and Intuitive Surgical assumed all of Computer Motion's outstanding options and warrants to purchase Computer Motion common stock based on the same ratio. The acquisition of Computer Motion was intended to enhance the Company's combined competitive position in key industries, while strengthening its work force. It also eliminated ongoing intellectual property litigation between the two companies. The acquisition was intended to enable the Company to focus on strategic products and customers, achieve significant cost synergies and economies of scale and improve results of its combined application of robotics to minimally invasive surgery bringing benefits to patients, surgeons and medical centers throughout the world. The exchange ratio in the acquisition was derived from estimates of future revenue and earnings of the combined company, in addition to measuring the relative ownership of the combined company implied by their contributions. The purchase price of this acquisition was \$148.5 million resulting from the issuance to former Computer Motion stockholders the right to receive approximately 8.0 million shares of Intuitive Surgical common stock on June 30, 2003, after giving effect to the 1-for-2 stock reverse split effected on July 1, 2003, or the Reverse Split, with a fair value of approximately \$125.7 million, the assumption of options and warrants to purchase approximately 1.4 million and 0.7 million shares, respectively, of Intuitive Surgical common stock at weighted average exercise prices of \$13.68 and \$20.52, after giving effect to the Reverse Split, with an aggregate estimated fair value of approximately \$15.7 million, the funding of Computer Motion's second quarter operations through a working capital loan in the amount of \$5.3 million, and estimated direct transaction costs of \$1.8 million. The fair value of the Company's common stock was derived using an average market price per share of the Company's common stock of \$15.64, after giving effect to the 1-for-2 stock reverse split effected on July 1, 2003, which was based on the closing prices for a range of trading days prior to and including the date of the acquisition, June 30, 2003 (June 24, June 25, June 26, June 27 and June 30). The measurement date for this transaction was the June 30, 2003 closing date, as the number of shares to be issued to Computer Motion stockholders was not fixed until that date.

In accordance with SFAS No. 141 "Business Combinations" ("SFAS 141"), the Company allocated the purchase price of the acquisition to the tangible assets, liabilities and intangible assets acquired, including in-process research and development, or IPR&D, based on their estimated fair values. The excess purchase price over those fair values is recorded as goodwill. The fair value assigned to intangible assets acquired is based on valuations prepared by an independent third party appraisal firm using estimates and assumptions provided by management. The goodwill recorded as a result of the acquisition is not expected to be deductible for tax purposes. In accordance with SFAS No. 142 "Goodwill and Other Intangible Assets" ("SFAS 142"), goodwill and purchased intangible assets with indefinite useful lives acquired after June 30, 2001 are not amortized but will be reviewed at least annually for impairment. Purchased intangible assets with finite lives are amortized on a straight-line basis over their respective useful lives.

The total purchase price was comprised of the following (in thousands):

Value of Intuitive Surgical common stock issued	\$ 125,734
Assumption of Computer Motion warrants and options	15,703
Total value of Intuitive Surgical securities	141,437
Direct transaction costs	1,774
Bridge loan facility	5,302
Total estimated purchase price	\$ 148,513

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Future business results may differ from inherent estimates contained in the allocation, including employee severance costs, obligations related to exiting lease commitments, and other underlying assumptions. The total purchase price has been allocated as follows (in thousands):

Cash and cash equivalents	\$ 1,214
Accounts receivable, net	4,476
Inventories, net	4,672
Prepaid and other assets	269
Property, plant, and equipment	1,644
Other assets	70
Amortizable intangible assets:	
Customer relationships	1,300
Developed and core technology	6,800
Trademark	200
Internal use software	300
In process research and development	100
Goodwill	143,106
Accounts and notes payable	(7,892)
Restructuring accrual	(3,594)
Other accrued liabilities	(2,361)
Deferred revenue	(2,225)
Deferred compensation	434
Total purchase price	<u>\$ 148,513</u>

Goodwill

Of the total purchase price, \$143.1 million was allocated to goodwill. Goodwill represents the excess of the purchase price over the estimated fair value of the underlying net tangible and intangible assets. Goodwill is not deductible for tax purposes. In accordance with SFAS No. 142, goodwill will not be amortized, but instead will be tested for impairment at least annually (more frequently if certain indicators are present). In the event management determines that goodwill has been impaired, the Company will incur an accounting charge for the impairment during the fiscal quarter in which the determination is made.

Amortizable Intangible Assets

Of the total purchase price, \$8.6 million was allocated to amortizable intangible assets, comprised of developed technology of \$3.5 million, core technology of \$3.3 million, customer relationships of \$1.3 million, and other intangible assets totaling \$0.5 million.

Developed technology, comprised of products that have reached technological feasibility, includes most of Computer Motion's products, including AESOP, ZEUS, SOCRATES and HERMES. Developed technology will be amortized on a straight-line basis over a period of seven years, representing the weighted average of the remaining product lives of the developed technology.

Core technology represents the value of patents, processes, and trade secrets, including certain designs and product features that Intuitive may integrate into future products. Core technology will be amortized on a straight-line basis over a period of seven years.

Customer relationships represent the value of Computer Motion's relationships with its then existing customers and was valued based upon the fair value of future business with those customers. Customer relationships and other intangible assets will be amortized on a straight line basis over a period of three to seven years.

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In-process research and development

Of the total purchase price, \$0.1 million was allocated to IPR&D. Projects which qualify as IPR&D represent those that have not yet reached technological feasibility and for which no future alternative uses exist. IPR&D was immediately, fully amortized into selling, general and administrative expenses in Intuitive Surgical's operating results for the year ended December 31, 2003.

Deferred Revenue

Of the total purchase price, \$2.2 million was allocated to deferred revenue. Deferred revenue represents primarily the fair value of fulfilling obligations under contracts assumed in the Computer Motion acquisition.

Deferred Compensation

Of the total purchase price, \$0.4 million was allocated to deferred compensation for unvested options assumed, which represents the intrinsic value of unvested stock options for employees and fair value for non-employees.

Pro forma results of operations

The following unaudited pro forma financial information (in thousands, except per share amounts) for the year ended December 31, 2003 gives effect to the acquisition by Intuitive Surgical of Computer Motion as if it had occurred on January 1, 2003. The pro forma financial information excludes charges for acquired in-process research and development. The unaudited pro forma financial information is not intended to represent or be indicative of the consolidated results of operations that Intuitive Surgical would have reported had the acquisition been completed as of the dates presented, and should not be taken as representative of the future consolidated results or financial position of Intuitive Surgical.

	<u>Year Ended December 31, 2003</u>
Sales	\$ 102,085
Net loss	\$ (29,133)
Net loss per share	\$ (0.92)

NOTE 4. RESTRUCTURING CHARGES

Upon the consummation of the acquisition of Computer Motion, Intuitive's management approved plans to restructure the operations of the combined entity. The restructuring plan eliminated redundant activities and infrastructure and resulted in eliminating approximately 150 employees, or 75%, of the Computer Motion positions by December 31, 2003 generally with immediate severance payment upon termination. The plan included vacating and subleasing 78% of the leased space in Goleta, California, consolidating European operations into a single site, and closing Computer Motion's Asia office and transitioning to the Intuitive distribution sales model for that area. The Company now has a single sales and marketing organization and has consolidated all manufacturing and administrative functions in Sunnyvale, California. Based upon this plan, the Company recorded a \$3.4 million accrual in accordance with EITF No. 95-3, "Recognition of Liabilities in Connection with a Purchase Business Combination." In accordance with EITF No. 95-3, the restructuring accrual has been recorded as a component of the purchase price. The accrual was comprised of \$2.6 million for employee severance costs, which were substantially paid out by the end of 2003, and \$0.8 million to exit existing lease commitments, based upon total future lease commitments for facilities to be vacated of \$2.6 million, offset by subleasing proceeds of \$1.8 million. The Company has estimated vacancy periods of between one month and three years between exiting various sites and realizing subleasing proceeds. During the year ended December 31, 2003, the Company increased the accrual by \$0.1 million primarily due to changes in estimates of employee

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severance costs. During the year ended December 31, 2004, the Company increased the accrual for the estimated losses to be incurred to sublet vacated facilities by \$0.2 million due to the change in estimates on assumptions used to calculate the losses on subleasing the vacated facilities. These amounts were recorded as adjustments to goodwill.

During the three months ended December 31, 2003, based on the Company's cost structure and future development plans, the Company planned to completely shut down the Goleta research and development facility. This plan called for exiting the last Goleta rented facility and terminating the majority of the Goleta-based employees. In accordance with SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities," the Company recorded restructuring charges of \$0.2 million, which were related to the costs of one-time employee terminations. SFAS No. 146 requires that a liability for costs associated with an exit or disposal activity be recognized and measured initially at fair value only when the liability is incurred. As employees were generally required to render service beyond the minimum retention period or 60 days, the severance payments were recognized ratably over the service periods. During the year ended December 31, 2004, the Company completed the shutdown of the Goleta research and development facilities and accrued \$0.2 million of employee severance costs and \$0.5 million of lease commitment costs to exit the leased facility. The Company later decreased its restructuring liability by \$0.2 million due to changes in estimates of subleasing proceeds. The charges incurred in the year ended December 31, 2004 were recorded in research and development expenses on the Consolidated Statement of Operations. The Company expects to fully utilize the accrual by the third quarter of 2007, when existing lease commitments expire.

The following table summarizes the restructuring activity for the years ended December 31, 2003 and 2004 (in thousands):

	EITF No. 95-3		SFAS No. 146		Total
	Employee Severance	Lease Commitments	Employee Severance	Lease Commitments	
Costs accrued	\$ 2,629	\$ 816	\$ 186	\$ —	\$ 3,631
Cash payments, net of subleasing proceeds	(2,486)	(277)	—	—	(2,763)
Currency impact	(23)	(23)	—	—	(46)
Adjustments	175	(26)	—	—	149
Balance at December 31, 2003	295	490	186	—	971
Costs accrued	—	—	224	525	749
Cash payments, net of subleasing proceeds	(295)	(316)	(410)	(207)	(1,228)
Adjustments	—	226	—	(177)	49
Balance at December 31, 2004	\$ —	\$ 400	\$ —	\$ 141	\$ 541

NOTE 5. GOODWILL AND OTHER INTANGIBLE ASSETS

Goodwill and Intangible Assets

Goodwill represents the excess of the purchase price over the fair value of the underlying net tangible and intangible assets. In accordance with SFAS No. 142, goodwill and intangible assets with indefinite useful lives can no longer be amortized; however, they will be tested for impairment at least annually in the fourth quarter of each fiscal year (more frequently if certain indicators are present). Intangible assets with finite useful lives will continue to be amortized over their respective useful lives. In the event management determines that goodwill has been impaired, the Company will incur an accounting charge for the impairment during the fiscal quarter in which the determination is made. Of the total purchase price related to the acquisition of Computer Motion, \$143.1 million was allocated to goodwill and \$8.6 million was allocated to amortizable intangible assets, comprised of developed technology of \$3.5 million, core technology of \$3.3 million, customer relationships of \$1.3 million, and other intangible assets totaling \$0.5 million. (See Note 3.) In 2004, the Company increased

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goodwill by \$0.2 million due to changes in estimates related to the restructuring accrual recorded in accordance with EITF No. 95-3. (See Note 4.)

Other purchased intangible assets represent patents which are carried at cost less accumulated amortization. Amortization is computed using the straight-line method over the expected useful life of generally six to seven years.

At December 31, 2004, net intangible assets is comprised of the following (in thousands):

	<u>Gross</u>	<u>Accumulated Amortization</u>	<u>Impairment</u>	<u>Net</u>
Developed Technology	\$ 3,500	\$ 250	\$ 3,250	\$ —
Core Technology	3,300	707	—	2,593
Customer Relationships	1,300	501	—	799
Patents	7,310	4,616	—	2,694
Other Intangible assets	500	74	291	135
Total intangible assets, net	\$15,910	\$ 6,148	\$ 3,541	\$6,221

At December 31, 2003, net intangible assets was comprised of the following (in thousands):

	<u>Gross</u>	<u>Accumulated Amortization</u>	<u>Impairment</u>	<u>Net</u>
Developed Technology	\$ 3,500	\$ 250	\$ 3,250	\$ —
Core Technology	3,300	236	—	3,064
Customer Relationships	1,300	233	—	1,067
Patents	7,310	3,511	—	3,799
Other Intangible assets	500	50	291	159
Total intangible assets, net	\$15,910	\$ 4,280	\$ 3,541	\$8,089

Amortization expense related to intangible assets was \$1.9 million, \$2.2 million and \$0.8 million for the years ended December 31, 2004, 2003 and 2002, respectively.

Estimated future amortization expense related to intangible assets at December 31, 2004 is as follows (in thousands):

Fiscal Year	
2005	1,870
2006	1,260
2007	1,074
2008	807
2009	810
Thereafter	400
Total	\$6,221

Impairment of Goodwill

In accordance with SFAS No. 142, the Company performed its assessment of whether there was an indication that goodwill was impaired at December 31, 2004. To accomplish this, the Company was required to identify its reporting units and determine the carrying value of each reporting unit by assigning the assets and liabilities, including the existing goodwill and intangible assets, to these reporting units. The Company currently

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operates in one reportable segment, which is also the only reporting unit for purposes of SFAS No. 142. Since the Company currently only has one reporting unit, all of the goodwill has been assigned to the enterprise as a whole. The Company completed the goodwill impairment tests required by SFAS No. 142 and determined that the goodwill was not impaired at December 31, 2004. The quoted market price of the Company's common stock was used to determine fair value for SFAS No. 142 impairment purposes.

Impairment of Long-Lived Assets

SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," requires recognition of impairment of long-lived assets when circumstances indicate impairment has occurred and in the event the net book value of such assets exceeds the future undiscounted cash flows attributable to such assets. Accordingly, the Company evaluates asset recoverability when an event occurs that may impair recoverability of the asset. The Company determines the recoverability of the carrying amount of each asset by reviewing the following factors: the undiscounted value of expected operating cash flows, the estimated useful or contractual life of the asset and the contract or product supporting the asset. In the third and fourth quarter of 2003, the Company impaired \$0.1 million and \$3.2 million, respectively, of developed technology intangible assets related to products for which future sales were anticipated to be significantly lower than the original forecast. These amounts are included in product cost of sales in the accompanying Consolidated Statement of Operations. In addition, in the third and fourth quarter of 2003, the Company impaired \$0.1 million and \$0.2 million, respectively, of trademark intangible assets and other intangible assets related to this product and to purchased software that has no future use. These amounts are included in selling, general, and administrative expenses in the accompanying Consolidated Statement of Operations. No impairment losses were incurred for the year ended December 31, 2004 or 2002.

NOTE 6. AVAILABLE-FOR-SALE SECURITIES

The following table summarizes available-for-sale securities included in short-term investments as of the respective dates (in thousands):

	December 31, 2004				December 31, 2003			
	Amortized Cost	Unrealized		Fair Value	Amortized Cost	Unrealized		Fair Value
		Gains	Losses			Gains	Losses	
U.S. corporate debt	\$ 54,577	\$ 203	\$ (350)	\$ 54,430	\$ 44,106	\$ 805	\$ (7)	\$ 44,904
U.S. government debt	33,468	14	(294)	33,188	28,069	165	(24)	28,210
Municipal debt	38,649	—	—	38,649	28,500	—	—	28,500
	<u>\$126,694</u>	<u>\$217</u>	<u>\$ (644)</u>	<u>\$126,267</u>	<u>\$100,675</u>	<u>\$ 970</u>	<u>\$ (31)</u>	<u>\$101,614</u>

The fair value of investments with loss positions at December 31, 2004, consists of the following (in thousands):

	Unrealized Loss	Fair Value
U.S. corporate debt	\$ (350)	\$ 43,489
U.S. government debt	(294)	29,186
	<u>\$ (644)</u>	<u>\$72,675</u>

The Company evaluated the nature of these investments, the duration of the impairments (all less than twelve months), and the amount of impairments relative to the underlying portfolio and concluded that such amounts were not "other-than-temporary" as defined by SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities."

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The following is a summary of the amortized cost and estimated fair value of available-for-sale securities at December 31, 2004, by maturity date (in thousands):

	Amortized Cost	Fair Value
Mature in less than one year	\$ 59,952	\$ 59,900
Mature in one to five years	66,742	66,367
Total	\$ 126,694	\$ 126,267

Realized gains on available-for-sale securities were \$0.1 million, \$0.6 million and \$39,000 for the years ended December 31, 2004, 2003, and 2002, respectively. There were no realized losses on available-for-sale securities for the years ended December 31, 2004, 2003, and 2002. These gains have been recognized with other income and expense in the period to which they relate. For the purposes of determining gross realized gains and losses, the cost of securities is based upon specific identification.

NOTE 7. INVENTORY

Inventory consists of the following (in thousands):

	December 31,	
	2004	2003
Raw materials	\$ 2,404	\$ 1,247
Work-in-process	1,183	1,797
Finished goods	2,379	5,744
Total	\$5,966	\$ 8,788

NOTE 8. PROPERTY AND EQUIPMENT

Property and equipment consists of the following (in thousands):

	December 31,	
	2004	2003
Building	\$ 14,633	\$ —
Land	5,400	—
Computer equipment	2,463	4,262
Laboratory and manufacturing equipment	8,473	9,270
Office furniture and equipment	1,171	1,264
Building/leasehold improvements	2,805	2,714
Purchase software	6,015	5,187
	40,960	22,697
Less accumulated depreciation	(13,895)	(12,409)
Property and equipment, net	\$ 27,065	\$ 10,288

NOTE 9. EMPLOYEE BENEFIT PLAN

Effective May 1, 1996, the Company established a defined contribution retirement plan (the "Plan"). All U.S. employees who are at least 21 years of age are eligible to participate. Contributions of up to 15% of compensation may be made by employees to the Plan through salary withholdings. Employer contributions are made solely at the Company's discretion. No employer contributions were made to the Plan during the years ended December 31, 2004, 2003 and 2002.

NOTE 10. COMMITMENTS AND CONTINGENCIES

OPERATING LEASES

The Company entered into a lease arrangement of office and manufacturing space in Sunnyvale, California effective January 2002 (the "Sunnyvale Lease"). Under the Sunnyvale Lease, the Company was required to lease additional space in the same building starting in January 2004. The Sunnyvale Lease was scheduled to expire on April 30, 2007. On April 30, 2004, the Company purchased the property for approximately \$20.0 million and canceled the Sunnyvale Lease. In addition, the Company leases office space for research and development in Milford, Connecticut and sales office space in St. Germain en Laye, France. In connection with the acquisition of Computer Motion, the Company assumed leases in Goleta, California. These leases have varying terms, the longest of which extends to September 2007. As of December 31, 2004, the Company sublet approximately 92% of its office space in Goleta.

Future minimum lease commitments, net of sublease income of \$1.5 million, under the Company's operating leases as of December 31, 2004 are as follows (in thousands):

2005	\$ 632
2006	506
2007	275
2008	55
2009	39
	<hr/>
	\$1,507
	<hr/>

Rent expense was approximately \$0.4 million, \$3.2 million, and \$2.5 million for the years ended December 31, 2004, 2003, and 2002, respectively.

CONTINGENCIES

In September 2002, the Company discovered that one of its employees had purchased approximately \$900,000 in administrative supplies without the authorization or knowledge of its management. This matter was investigated by law enforcement authorities and the Company's advisors. The Company has since terminated this employee's employment and have taken actions intended to ensure that no similar incidents can occur in the future, including implementing additional controls relating to its cash disbursement process. In addition, the Company is seeking to recover its loss. The Company has filed a claim with its insurance carrier, from which the Company received proceeds of \$500,000, and filed suit against the sellers of the administrative supplies in December 2002. The Company's complaint alleged that each of the defendants has (i) violated various sections of the Racketeer Influenced and Corrupt Organization, or RICO, Act through their extortion, coercion, intimidation, fraud, bribery and racketeering activity in connection with the unauthorized purchase of office supplies and (ii) committed unlawful business acts and practices in violation of Cal. Bus. & Prof. Code Section 17200 et seq. The Company's suit seeks to recover actual and treble damages, costs and attorney fees for the damage caused by each of defendants through their illegal conduct. In January 2003, the Company amended its complaint to allege that each defendant further unlawfully offered prizes and gifts in violation of Cal. Bus. & Prof. Code Section 17537 and unlawfully failed to advertise limitations on the quantity of its sales in violation of Cal. Bus. & Prof. Code Section 17500.5. The amended complaint reiterates the Company's claim to recover actual and treble damages, costs and attorney fees. A settlement was reached in July 2004 in which the other parties in the lawsuit agreed to pay the Company \$250,000 over a maximum of three years.

In February 2004, the University of Miami, a former customer of Computer Motion filed a lawsuit against the Company in the US District Court, Southern District of Florida. The Company received the complaint in April, 2004. The customer alleges that it relied to its detriment on representations made by Computer Motion in connection with Computer Motion's sale of products to the customer, which representations the customer

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believes were not fulfilled. The customer is seeking damages. The Company filed a motion to dismiss the fraud-based complaints and an answer defending the breach of contract claim. After discovery was completed, the Company filed a motion for summary judgment to dismiss the entire case. In January, 2005, the Court granted the Company's motion for summary judgment and dismissed the case against the Company in its entirety. In February 2005, the customer filed a notice of appeal.

In November 2003, Tzamal Jacobson Ltd., an Israeli company, filed suit against the Company and Computer Motion in the District Court in Tel-Aviv—Jaffa, Israel, Civil File 2293/03 alleging breach of a distribution contract and seeking damages. The Company received the complaint in April, 2004. Following the acquisition of Computer Motion, the Company withdrew Computer Motion's distributorship offer to this Israeli company. The Company intends to vigorously defend the suit, and it has filed a motion to have the case dismissed on jurisdictional grounds. The court has not yet ruled on the motion.

In October 2003, SIC System, S.R.L., a former Italian distributor for Computer Motion, filed suit against the Company and Computer Motion seeking damages in the Civil Court of Rome, Italy. In the complaint, SIC System alleges that the Company breached the distribution agreement between SIC System and Computer Motion when, following its acquisition of Computer Motion, the Company deleted two products previously covered under the distribution agreement. The distribution agreement provides, among other things, that (1) it shall be governed and construed under the laws of the State of California and (2) in the event of any dispute or controversy arising under the distribution agreement or the transactions contemplated thereunder, the parties mutually consent to the exclusive jurisdiction of a court of competent jurisdiction within Santa Barbara County, California. The Company is defending this lawsuit on both jurisdictional grounds and on the merits. To date, the Italian Court has ruled that SIC System's service of process in filing its complaint is defective and has ordered SIC System to re-serve its complaint on or about October 6, 2004, which service the Company did not receive. The parties have submitted briefs to the court on the service of process issue. The Italian court has not ruled on jurisdiction or other pending issues pertaining to the applicable law or appropriate forum.

In November, 2003, the Company filed a lawsuit against SIC System, S.R.L. in the United States District Court for the Central District of California for declaratory relief, breach of contract and preliminary and permanent injunction. In particular, the Company sought a judicial declaration of the rights and obligations of the parties under a distribution agreement, specifically that the Company effectively deleted the products from the distribution agreement, and a preliminary and permanent injunction prohibiting SIC System from proceeding with the Italian Action. The complaint was served on SIC System in November, 2003, and the Court entered default against SIC Systems in March, 2004. In August, 2004, the Court entered a judgment in favor of the Company in the amount of \$195,155 for breach of contract. The Court also awarded judgment in favor of the Company as to its claim for declaratory relief. The Court awarded judgment in favor of SIC Systems as to the Company's claim for preliminary and permanent injunction. The Court found the Company as the prevailing party. The Company intends to enforce this judgment against SIC System in the Italian portion of the lawsuit.

The foregoing proceedings could be expensive to litigate, may be protracted and the Company's confidential information may be compromised. Whether or not the Company is successful in these lawsuits, these proceedings could consume substantial amounts of its financial and managerial resources. At any time, the other parties may file additional claims against the Company, or the Company may file claims against them, which could increase the risk, expense and duration of the litigations.

The Company is subject to legal proceedings and claims, including those discussed above, that arise in the normal course of its business. The Company does not know whether it will prevail in these matters nor can it assure that any remedy could be reached on commercially viable terms, if at all. In accordance with SFAS No. 5, "Accounting for Contingencies," the Company records a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. These provisions are reviewed at least quarterly and adjusted to reflect the impacts of negotiations, settlements, rulings, advice of legal counsel, and other information and events pertaining to a particular case.

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NOTE 11. NOTES PAYABLE

Notes payable consists of the following (in thousands):

	December 31,	
	2004	2003
Notes payable, due in monthly installments through August 1, 2004; Interest rate of 8.5% at August 1, 2004	\$ —	\$ 118
Notes payable, due in monthly installments through April 1, 2005; Interest rate of 8.6% at December 31, 2004	89	425
Notes payable, due in monthly installments through September 1, 2005; Interest rate of 7.3% at December 31, 2004	333	803
Notes payable, due in monthly installments through November 30, 2005; Interest rate of 6.9% at December 31, 2004	187	379
	<u>609</u>	<u>1,725</u>
Less current portion	(609)	(1,030)
	<u>\$ —</u>	<u>\$ 695</u>

Notes payable are collateralized by fixed assets specified under each agreement. Assets collateralized under these agreements totaled \$2.9 million and \$3.5 million at December 31, 2004 and 2003, respectively. Certain of the notes payable contain covenants pertaining to results of operations and certain other financial ratios. As of December 31, 2004, the Company is in compliance with all covenants. The notes payable at December 31, 2004 are scheduled to mature in 2005. The weighted average borrowing rate was 7.4% as of December 31, 2004 and 7.6% as of December 31, 2003.

The fair value of notes payable is estimated based on current interest rates available to the Company for debt instruments with similar terms, degrees of risk and remaining maturities. The carrying values of these obligations approximate their respective fair values as of December 31, 2004 and 2003.

NOTE 12. STOCKHOLDERS' EQUITY

REVERSE STOCK SPLIT

The Company's stockholders approved a one-for-two reverse stock split, or the Reverse Split, on June 30, 2003 and the Reverse Split was effected on July 1, 2003. The par value of the Company's common stock after the Reverse Split remained at \$0.001 per share. The rights of the holders of these securities were not otherwise modified. All shares outstanding and earnings per share information for all periods presented in these financial statements give effect to the Reverse Split. All shares, per share and market price data related to the Company's common shares outstanding and under employee stock plans reflect the retroactive effects of the Reverse Split.

FOLLOW-ON OFFERING

In the fourth quarter of 2003, the Company sold 5,750,000 shares of newly issued common stock in an underwritten public offering at a price of \$14.50 per share. The Company received net proceeds of approximately \$77.7 million, after deducting the underwriting discount and offering expenses.

TREASURY STOCK

The Company records treasury stock under the cost method. Stock repurchased by the Company for the year ended December 31, 2004, was \$0.1 million.

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COMMON STOCK

The Company has reserved the following shares of common stock for the exercise of warrants and the issuance of options and rights granted under the Company's stock option plans as follows:

	December 31,	
	2004	2003
Warrants	637,151	662,256
Stock option plans	8,234,117	7,583,723
	<u>8,871,268</u>	<u>8,245,979</u>

The Company has previously issued shares of common stock, which are subject to the Company's right to repurchase at the original issuance price upon the occurrence of certain events as defined in the agreements relating to the sale of such stock. As of December 31, 2004 no shares were subject to repurchase. As of December 31, 2003 and 2002, shares subject to repurchase were 366 and 7,937 respectively.

WARRANTS

In June 2000, the Company issued a warrant to purchase 2,540 shares of common stock at an exercise price of \$18.00 per share to one company. The warrant, which was fully vested and immediately exercisable, expires in June 2010. The value of the warrant was estimated using the Black-Scholes option pricing model and was determined to be immaterial. The warrant was outstanding as of December 31, 2004.

In conjunction with the Computer Motion acquisition, the Company assumed warrants to purchase 724,729 shares of common stock at a weighted average exercise price of \$20.52 per share. During the year ended December 31, 2004, warrants to purchase 23,667 shares were exercised with a weighted-average exercise price of \$15.30. In December 2003, warrants to purchase 65,013 shares with a weighted-average exercise price of \$15.42 expired. As of December 31, 2004, warrants to purchase 634,611 shares of common stock were outstanding at a weighted-average exercise price of \$19.70. As of December 31, 2003, warrants to purchase 659,716 shares of common stock were outstanding at a weighted-average exercise price of \$19.59. The warrants, which were fully vested and immediately exercisable, expire from February 2006 through February 2007.

STOCK OPTION PLANS

In January 1996, the Board of Directors adopted, and the stockholders approved, the 1996 Equity Incentive Plan (the "1996 Plan") under which certain employees, consultants and directors may be granted Incentive Stock Options ("ISOs") and Nonstatutory Stock Options ("NSOs") to purchase shares of the Company's common stock. The 1996 Plan permitted ISOs to be granted at an exercise price not less than the fair value on the date of grant and NSOs at an exercise price not less than 85% of the fair value on the date of grant. Options granted under the 1996 Plan generally expire 10 years from the date of grant and become exercisable upon grant subject to repurchase rights in favor of the Company until vested. Options generally vest 12.5% upon completion of 6 months service and 1/48 per month thereafter; however, options may have been granted with different vesting terms as determined by the Board of Directors. A total of 2,420,000 shares of common stock have been authorized for issuance pursuant to the 1996 Plan as of December 31, 2004.

In March 2000, the Board of Directors adopted the 2000 Equity Incentive Plan, which took effect upon the closing of the Company's initial public offering. The Company has reserved an additional 2,580,000 shares under this plan. This plan is an amendment and restatement of the 1996 Plan. Also in March 2000, the Board of Directors adopted the 2000 Non-Employee Directors' Stock Option Plan and the 2000 Employee Stock Purchase Plan. The Company has reserved 150,000 and 500,000 shares for the issuances under these plans, respectively. These plans were also effective upon the closing of the Company's initial public offering. Each of these plans

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contains an evergreen provision whereby the authorized shares are automatically increased concurrent with the Company's annual meeting of shareholders. In May 2004, the Company reserved an additional 1,677,018 shares for the 2000 Equity Incentive Plan, 100,000 shares for the 2000 Non-Employee Directors' Stock Option Plan and 176,705 shares for the 2000 Employee Stock Purchase Plan. In June 2003, the Company reserved an additional 980,763 shares for the 2000 Equity Incentive Plan, 55,821 shares for the 2000 Non-Employee Directors' Stock Option Plan and 166,176 shares for the 2000 Employee Stock Purchase Plan. In May 2002, the Company reserved an additional 982,375 shares for the 2000 Equity Incentive Plan, 54,562 shares for the 2000 Non-Employee Directors' Stock Option Plan and 102,182 shares for the 2000 Employee Stock Purchase Plan. In May 2001, the Company reserved an additional 993,300 shares for the 2000 Equity Incentive Plan, 53,743 shares for the 2000 Non-Employee Directors' Stock Option Plan and 89,572 shares for the 2000 Employee Stock Purchase Plan.

In conjunction with the Computer Motion acquisition, the Company assumed stock options under Computer Motion's 1997 Stock Incentive Plan (The "1997 Plan") and Tandem Stock Option Plan (the "Tandem Plan"), resulting in an additional 1.4 million options to purchase the Company's common stock. The Tandem Plan has expired, and the Company does not anticipate issuing any new options under the 1997 Plan.

Option activity under the 1996, 1997, 2000 and Tandem Plans was as follows:

	2004		2003		2002	
	Number of Shares Under Option	Weighted Average Exercise Price	Number of Shares Under Option	Weighted Average Exercise Price	Number of Shares Under Option	Weighted Average Exercise Price
Outstanding at January 1	3,725,429	\$ 14.50	2,452,080	\$ 14.48	1,696,292	\$ 11.70
Options granted	1,350,805	19.14	2,552,791	13.17	1,000,500	18.06
Options exercised	(967,945)	11.36	(696,145)	6.04	(117,080)	5.28
Options canceled	(446,493)	21.34	(583,297)	16.84	(127,632)	17.10
Outstanding at December 31	3,661,796	16.20	3,725,429	14.50	2,452,080	14.48
Exercisable at December 31	1,874,256	\$ 15.24	2,185,236	\$ 14.57	1,133,703	\$ 11.62

Additional information concerning options outstanding at December 31, 2004 is as follows:

Exercise Prices	Options Outstanding			Options Exercisable	
	Number of Shares	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
\$ 0.00– \$ 0.00	3,085	7.8	\$ —	3,085	\$ —
1.00– 1.00	5,250	2.4	1.00	5,250	1.00
2.29– 3.43	78,886	6.1	2.91	78,886	2.91
3.69– 4.17	32,213	7.8	3.98	26,427	4.04
5.72– 7.74	148,957	5.0	6.02	148,593	6.02
8.94– 13.40	702,022	8.0	11.77	300,834	11.76
13.44– 20.12	2,399,592	7.9	17.30	1,178,874	16.77
20.17– 30.14	182,426	8.5	24.49	61,042	24.46
30.85– 43.76	107,309	6.6	34.78	69,209	34.87
\$49.10– \$50.08	2,056	3.4	49.58	2,056	49.58
	3,661,796	7.7	\$ 16.20	1,874,256	\$ 15.24

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Under the 1996 and 2000 Plans, the Company may also grant rights to purchase restricted stock. Terms and conditions of these rights are determined by the Board of Directors. However, no right shall be granted at an exercise price which is less than 85% of the fair value of the Company's common stock on the date of grant. Exercise of these share purchase rights are made pursuant to restricted stock purchase agreements containing provisions established by the Board of Directors. These provisions give the Company the right to repurchase the shares at the original purchase price of the stock. The right expires at a rate determined by the Board of Directors, generally at a rate of 12.5% after 6 months and 1/48 per month thereafter. For the years ended December 31, 2003 and 2002, the Company repurchased 1,048 and 211 shares, respectively, under the 1996 and 2000 Plans. The Company did not repurchase any shares under the 1996 and 2000 Plans for the year ended December 31, 2004.

As of December 31, 2004, 2003 and 2002, 4,572,321, 3,858,294 and 3,554,946 shares, respectively, were available for future grant under the 1996 and 2000 Plans.

No deferred stock compensation was recorded for the years ended December 31, 2004 and 2002. The Company recorded deferred stock compensation of \$0.4 million for the year ended December 31, 2003. Deferred stock compensation represents the difference between the exercise price and the fair value for accounting purposes of the Company's common stock on the date such options were granted. For the years ended December 31, 2004, 2003 and 2002, the Company recorded amortization of deferred stock compensation of \$0.1 million, \$0.7 million and \$0.7 million, respectively. As of December 31, 2004, the deferred stock compensation balance was fully amortized. As of December 31, 2003, the Company had \$0.1 million of remaining unamortized deferred compensation.

STOCK-BASED COMPENSATION

Pro forma information regarding net income (loss) is required by SFAS No. 123 as if the Company had accounted for its employee stock options under the fair value method of SFAS No. 123. (See Note 2, Summary of Significant Accounting Policies.) Option valuation models require the input of highly subjective assumptions.

The weighted-average estimated fair value of options granted during fiscal 2004, 2003 and 2002 was \$10.43, \$7.44 and \$11.00 per share, respectively. The fair value of these options was estimated at the date of grant using the Black-Scholes option pricing model using the following weighted-average assumptions:

	Year Ended December 31,		
	2004	2003	2002
Stock Option Plans:			
Average risk free interest rate	3.14%	2.52%	3.9%
Average expected life (years)	4	4	4
Volatility	67%	78%	80%
Stock Purchase Plans:			
Average risk free interest rate	1.39%	1.36%	1.71%
Average expected life (years)	1.29	0.5	0.5
Volatility	60%	48%	48%

The Company has elected to follow APB No. 25 in accounting for employee stock options. Under APB No. 25, the Company recognizes no compensation expense in its financial statements except in connection with the grant of restricted stock for nominal consideration and unless the exercise price of employee stock options is less than the market price of the underlying stock on the grant date.

NOTE 13. INCOME TAXES

There is no provision for income taxes for the years ended December 31, 2003 and 2002 as the Company incurred losses during those years. The provision for income taxes, all of which is current, for the year ended December 31, 2004 consisted of the following (in thousands):

	Year Ended December 31, 2004
Federal	\$ 400
State	245
Foreign	81
	<u>\$ 726</u>

The tax benefit associated with dispositions from employee stock plans reduced taxes currently payable for 2004 by \$387,000.

Income tax expense (benefit) differs from amounts computed by applying the statutory rate of 35% for the years ended December 31, 2004, 2003 and 2002 as a result of the following (in thousands):

	Year Ended December 31,		
	2004	2003	2002
Federal tax at statutory rate	\$ 8,471	\$ (3,368)	\$ (6,447)
Increase (reduction) in tax resulting from:			
States taxes, net of federal benefits	1,486	(481)	(91)
Valuation allowance	(9,520)	3,399	6,538
Other	289	450	—
	<u>\$ 726</u>	<u>\$ —</u>	<u>\$ —</u>

Deferred income taxes reflect tax carryforwards and the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amount used for income tax purposes. Significant components of the Company's deferred tax assets are as follows (in thousands):

	As of December 31,	
	2004	2003
Deferred tax assets:		
Net operating loss carryforward	\$ 66,597	\$ 70,217
Research and other credits	11,210	10,609
Expenses deducted in later years for tax purposes	17,019	19,203
Gross deferred tax assets	94,826	100,029
Deferred tax liabilities:		
Identified intangible assets related to acquisitions	(2,431)	(3,160)
Net deferred tax assets	92,395	96,869
Less valuation allowance	(92,395)	(96,869)
	<u>\$ —</u>	<u>\$ —</u>

Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance decreased by \$4.5 million and increased by \$43.5 million during the years ended December 31, 2004 and 2003, respectively. As of December 31, 2004, the Company had net operating loss carry forwards for federal

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tax purposes of approximately \$183.5 million which expire in the years 2018 through 2023 and for state tax purposes of approximately \$58.4 million, which expire beginning in 2005. As of December 31, 2004, the Company had federal research and development tax credits of approximately \$6.6 million which expire in the years 2011 through 2024 and state research and development tax credits of approximately \$6.5 million which carry forward indefinitely until utilized. The Company also has state manufacturing credit carryforwards of approximately \$0.5 million, which expire in various years from 2006 through 2010, and federal minimum tax credit carryforwards of approximately \$0.2 million which carry forward until utilized. Utilization of the Company's net operating loss may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. The annual limitation may result in the expiration of the net operating loss before utilization.

NOTE 14. SELECTED QUARTERLY DATA (UNAUDITED, IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

	2004			
	Q1	Q2	Q3	Q4
Net sales	\$ 27,059	\$ 31,057	\$ 35,493	\$ 45,194
Gross profit	15,836	19,628	22,722	29,804
Operating expenses	15,553	15,161	17,235	18,857
Income from operations	283	4,467	5,487	10,947
Interest and other income, net	606	626	692	1,096
Income before taxes	889	5,093	6,179	12,043
Net income	853	4,830	6,113	11,682
Net income per share				
Basic	\$ 0.03	\$ 0.14	\$ 0.18	\$ 0.34
Diluted	\$ 0.02	\$ 0.14	\$ 0.17	\$ 0.32
Shares used in calculation of net income per share:				
Basic	33,282	33,559	33,823	34,098
Diluted	34,137	34,210	35,305	36,244
	2003			
	Q1	Q2 (1)	Q3 (1)	Q4 (1)
Net sales	\$ 19,235	\$ 21,453	\$ 23,394	\$ 27,593
Gross profit	9,741	12,688	12,064	9,536
Operating expenses	12,877	12,157	15,727	15,150
Income (loss) from operations	(3,136)	531	(3,663)	(5,614)
Interest and other income, net	842	347	311	758
Net income (loss)	(2,294)	878	(3,352)	(4,856)
Net income (loss) per share				
Basic	\$ (0.12)	\$ 0.05	\$ (0.12)	\$ (0.16)
Diluted	\$ (0.12)	\$ 0.05	\$ (0.12)	\$ (0.16)
Shares used in calculation of net income (loss) per share:				
Basic	18,431	18,580	26,878	30,616
Diluted	18,431	18,973	26,878	30,616

(1) As more fully described in Note 3, the Company's results of operations reflect the acquisition of Computer Motion, Inc. subsequent to June 30, 2003.

INTUITIVE SURGICAL, INC.
VALUATION AND QUALIFYING ACCOUNTS
(IN THOUSANDS)

	<u>Balance at Beginning of Year</u>	<u>Additions Charged to Cost and Expenses or Sales</u>	<u>Additions due to acquisition of Computer Motion, Inc.</u>	<u>Deductions (1)</u>	<u>Balance at End of Year</u>
Allowance for doubtful accounts and sales returns					
Year ended December 31, 2004	\$ 1,765	2,026	—	(2,457)	\$ 1,334
Year ended December 31, 2003	\$ 806	2,710	1,621	(3,372)	\$ 1,765
Year ended December 31, 2002	\$ 446	360	—	—	\$ 806

(1) Represents amounts written off or returned.

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ITEM 9: CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

None.

ITEM 9A: CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2004.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by an independent registered public accounting firm, as stated in the report which is included herein.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal controls over financial reporting during our most recent quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

ITEM 9B: OTHER INFORMATION

None.

PART III

Certain information required by Part III is omitted from this Report on Form 10-K since we intend to file our definitive Proxy Statement for our next Annual Meeting of Stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended (the "Proxy Statement"), no later than April 30, 2005, and certain information to be included in the Proxy Statement is incorporated herein by reference.

ITEM 10: DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this item concerning our directors is incorporated by reference to the information set forth in the section titled "Election of Directors" in our Proxy Statement. Information required by this item concerning our executive officers is incorporated by reference to the information set forth in the section entitled "Executive Officers of the Company" in our Proxy Statement. Information regarding Section 16 reporting compliance is incorporated by reference to the information set forth in the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" in our Proxy Statement.

Our Board of Directors adopted a Code of Business Conduct and Ethics for all of our directors, officers and employees on June 19, 2003. Those interested may request a free copy of our Code of Business Conduct and Ethics from:

Intuitive Surgical, Inc.
Attention: Investor Relations
950 Kifer Road
Sunnyvale, CA 94086
408-523-2100

To the extent required by law or the rules of the Nasdaq National Market, any amendments to, or waivers from, any provision of the Code of Business Conduct and Ethics will be promptly disclosed publicly. To the extent permitted by such requirements, we intend to make such public disclosure by posting the relevant material on our website (www.intuitivesurgical.com) in accordance with SEC rules.

ITEM 11: EXECUTIVE COMPENSATION

The information required by this item regarding executive compensation is incorporated by reference to the information set forth in the sections titled "Executive Compensation" in our Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth in the section titled "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plans" in our Proxy Statement to be filed within 120 days.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item regarding certain relationships and related transactions is incorporated by reference to the information set forth in the section titled "Certain Relationships and Related Transactions" in our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item regarding principal accountant fees and services is incorporated by reference to the information set forth in the section titled "Principal Accountant Fees and Services" in our Proxy Statement.

PART IV

ITEM 15: EXHIBITS AND FINANCIAL STATEMENT SCHEDULE

- (a) The following documents are filed as part of this Annual Report on Form 10-K
 - (1) Financial Statements—See Index to Consolidated Financial Statements at Item 8 of this Report on Form 10-K.
 - (2) The following financial statement schedule of Intuitive Surgical, Inc. is filed as part of this Report and should be read in conjunction with the financial statements of Intuitive Surgical:
 - Schedule II: Valuation and Qualifying Accounts.All other schedules have been omitted because they are not applicable, not required under the instructions, or the information requested is set forth in the consolidated financial statements or related notes thereto.
 - (3) Exhibits
 - The exhibits filed as part of this report are listed under “Exhibits” at subsection (b) of this Item 15.
- (b) Exhibits

EXHIBIT INDEX

Exhibit Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation of the Company.
3.2(2)	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Company.
3.3(1)	Bylaws of the Company.
4.1(1)	Specimen Stock Certificate.
4.2(1)	Warrant to Purchase Shares of Common Stock, dated April 26, 2000.
4.3(3)	Form of Warrant to purchase Common Stock of Computer Motion, Inc. dated February 13, 2002.
4.4(4)	Form of Warrant to purchase Common Stock of Computer Motion, Inc. dated February 16, 2001.
4.5(5)	Form of Redeemable Warrant to purchase Common Stock of Computer Motion, Inc. dated September 22, 2000.
4.6(6)	Form of Redeemable Warrant to purchase Common Stock of Computer Motion, Inc.
10.1(1)	Form of Indemnity Agreement.
10.2(1)	2000 Equity Incentive Plan.
10.3(1)	2000 Non-Employee Directors' Stock Option Plan.
10.4(1)	2000 Employee Stock Purchase Plan.
10.5(1)	Amended and Restated Investor Rights Agreement dated March 31, 1999.
10.6(1)	Equipment Financing Agreement (No. 10809), dated April 2, 1997, between the Registrant and Lease Management Services, Inc., and related addendums.
10.7(1)	Security Agreement, dated May 20, 1999, between the Registrant and Heller Financial Leasing, Inc., and related amendments.
10.8(1)	License Agreement, dated December 20, 1995, between the Registrant and SRI International.
10.9(1)	License Agreement, dated December 29, 1997, between the Registrant and International Business Machines Corporation.
10.10(1)	License Agreement, dated April 1, 1999, between the Registrant and Massachusetts Institute of Technology.
10.11(1)	Employment Agreement, dated February 28, 1997, between the Registrant and Lonnie M. Smith.
10.12(7)	Lease between Computer Motion, Inc. and University Business Center Associates dated March 1, 1994 and amendment thereto dated October 19, 1996.
10.13(8)	Leases between Computer Motion, Inc. and University Business Center Associates dated September 19, 1997.
10.14(9)	Wilk License Agreement Dated January 13, 2005, between the Registrant and Brookhill-Wilk, LLC.
23.1(9)	Consent of Independent Registered Public Accounting Firm.
31.1(9)	Certification of Principal Executive Officer.
31.2(9)	Certification of Principal Financial Officer.
32.1(9)	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference to exhibits filed with the Company's Registration Statement on Form S-1 (333-33016).

(2) Incorporated by reference to Exhibit 3.2 of the Company's Registration statement on Form S-3 filed September 11, 2003 (File No. 333-108713).

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- (3) Incorporated by reference to Exhibit 4.2 of Computer Motion, Inc.'s Registration Statement on Form S-3 (File No. 333-83552).
- (4) Incorporated by reference to Exhibit 4.3 of Computer Motion, Inc.'s Current Report on Form 8-K filed March 26, 2001.
- (5) Incorporated by reference to Exhibit 10.2 of Computer Motion, Inc.'s Quarterly Report on Form 10-Q filed November 14, 2000.
- (6) Incorporated by reference to Exhibit 10.15 of Computer Motion, Inc.'s Registration Statement on Form S-1 (File No. 333-29505).
- (7) Incorporated by reference to Exhibit 10.17 of Computer Motion, Inc.'s Registration Statement on Form S-1 (File No. 333-29505).
- (8) Incorporated by reference to Exhibit 10.19 of Computer Motion, Inc.'s Annual Report on Form 10-K for the year ended December 31, 1997.
- (9) Filed herewith.

SETTLEMENT AND LICENSE AGREEMENT

This Settlement and License Agreement (“Agreement”) is entered into by and between on the one hand Brookhill-Wilk 1, LLC, a New York corporation having a principal place of business at 501 Madison Avenue, New York, NY 10022 (“Brookhill-Wilk”), Wilk Patent Development Corporation, a New York corporation having a principal place of business at 475 East 72nd Street, Suite L1, New York, NY 10021 (referred to as “WPDC”), and Peter J. Wilk, an individual (“Wilk” and collectively with Brookhill-Wilk and WPDC, “Licensors”), and on the other hand Intuitive Surgical, Inc., a Delaware corporation, having a principal place of business at 950 Kifer Road, Sunnyvale, CA 94086. Brookhill-Wilk, WPDC, Licensors, and Intuitive Surgical, Inc. may be referred to singly and jointly as “Party,” or “Parties,” respectively.

WHEREAS, Brookhill-Wilk claims to have exclusive licenses to and the exclusive right to protect and enforce and to bring any legal and equitable actions based on United States Patent Nos. 5,217,003 (the “003 Patent”), and 5,368,015 (the “015 Patent”) both entitled “Automated Surgical System and Apparatus,” (collectively, the “Brookhill-Wilk Patents”);

WHEREAS, Wilk is a joint owner as co-inventor of U.S. Patent No. 5,776,126, entitled “Laparoscopic Surgical Apparatus and Associated Method” (“the “126 Patent”);

WHEREAS, Wilk claims to own the entire right, title and interest in U.S. Patent No. 5,217,453, entitled “Automated Surgical System and Apparatus” and additional issued United States patents and patent applications and issued foreign patents and patent applications on which Wilk is named as a sole or co-inventor and/or which are assigned to entities owned in whole or part by Wilk, and which relate to surgical robotic systems, procedures, products, accessories, and methods for their use that may be alleged to have been, currently be, or may in the future be practiced by Intuitive (as the term “Intuitive” is specifically defined below) (collectively, the “Wilk Patents”);

WHEREAS, Brookhill-Wilk brought in the United States District Court for the Southern District of New York, a civil action asserting infringement by Intuitive Surgical, Inc. of the ‘003 and ‘015 Patents entitled *Brookhill Wilk 1, LLC v. Intuitive Surgical, Inc.*, Civil Action No. 00-CV-6599;

WHEREAS, Brookhill-Wilk brought in the United States District Court for the Southern District of New York, a civil action asserting infringement by Computer Motion, Inc. (“CMI”) of the ‘003 and ‘015 Patents entitled *Brookhill Wilk 1, LLC v. Computer Motion, Inc.*, Civil Action No. 01-CV-1300, which action was dismissed without prejudice;

WHEREAS, Brookhill-Wilk brought in the United States District Court for the Southern District of New York, a civil action asserting infringement by Intuitive Surgical, Inc.’s customers of the ‘003 Patent entitled *Brookhill Wilk 1, LLC v. The Mount Sinai Hospital, New York Presbyterian Healthcare System, Inc., and Lenox Hill Hospital*, Civil Action No. 03-CV-4977;

WHEREAS, on or about June 30, 2003, Intuitive Surgical, Inc. and CMI entered into a merger agreement under which CMI became a wholly owned subsidiary of Intuitive Surgical, Inc.;

WHEREAS, Brookhill-Wilk, on remand of its suit against Intuitive Surgical, Inc. by the United States Court of Appeals for the Federal Circuit amended its complaint against Intuitive Surgical, Inc. to assert in addition to its claims against Intuitive Surgical, Inc., the claims it had previously brought against CMI in Civil Action No. 01-CV-1300 in a lawsuit entitled *Brookhill Wilk 1, LLC v. Intuitive Surgical, Inc. and Computer Motion, Inc.*, Civil Action No. 00-CV-6599;

WHEREAS, on the terms and conditions set forth below, Brookhill-Wilk and Intuitive Surgical, Inc. want to resolve all pending litigation between the Parties, and between Brookhill-Wilk and Intuitive Surgical, Inc.’s

customers, and seek an amicable and final business resolution and settlement of other possible claims relating to the past, present, and future use, manufacture, offer for sale, sale and importation of surgical robotic systems, procedures, methods, products, and accessories by or on behalf of Intuitive Surgical, Inc., CMI, and their subsidiaries and customers which claims were, could have been, or can in the future be asserted by Licensors;

WHEREAS, Licensors represent that this Agreement is dispositive of all infringement claims that were or that could have been brought by Licensors against Intuitive Surgical, Inc., CMI, their subsidiaries and its (and their) respective direct and indirect customers, other transferees, manufacturers, distributors and resellers related to their alleged infringement of the '003 and '015 Patents;

WHEREAS, Licensors represent that this Agreement is dispositive of all infringement claims that can be brought by Licensors against Intuitive Surgical, Inc., CMI, their subsidiaries and its (and their) respective direct and indirect customers, other transferees, manufacturers, distributors and resellers relating to any claim of infringement by them of the Wilk Patents;

NOW, THEREFORE, in accordance with the above recitals and in consideration of the mutual covenants contained in this Agreement, Licensors and Intuitive Surgical, Inc. agree as follows:

SECTION 1 DEFINITIONS

As used in this Agreement, the following terms shall be deemed to have the following meanings:

1.1 "Effective Date" shall mean January 13, 2004.

1.2 "Intuitive" shall mean Intuitive Surgical, Inc., any of its subsidiaries, and its (and their) respective direct and indirect customers and users of its products, other transferees, manufacturers, distributors and resellers of the Licensed Products, and each of their officers, directors, employees, stockholders, cooperative members, affiliates, subsidiaries, predecessors, successors and successors in interest, and assigns.

1.3 "Licensed Patents" shall mean the Brookhill-Wilk Patents, the '126 Patent, and the Wilk Patents and each issued patent and all patent applications pending as of the Effective Date related thereto, including:

1.3.1 reissued and reexamined patents and their applications,

1.3.2 divisional, continuation and continuation-in-part applications,

1.3.3 each patent issuing from each of said applications, and

1.3.4 the foreign counterparts of each of said patents and applications.

1.3.5 Licensed Patents does not include any patent or patent applications that are filed after the Effective Date except as to those identified in Paragraphs 1.3.1, 1.3.2, 1.3.3, and 1.3.4 of this Agreement.

1.4 "Licensed Product," singular or plural, shall mean any surgical robotic system, procedure, product, or accessory made by or for Intuitive and/or the method by which any or all are used, where the use, offer for sale, sale, manufacture, importation or other disposition of such procedure, product, or accessory would, whether directly or indirectly (e.g., through contribution or inducement), constitute an infringement of any claim of the Licensed Patents, but for the rights and licenses granted in this Agreement.

SECTION 2 SETTLEMENT UNDERSTANDING

The Parties understand and agree that this Agreement, any consideration given or accepted in connection with it, and the covenants made in it are all made, given and accepted in settlement and compromise of disputed claims.

SECTION 3
GRANT OF LICENSES, COVENANTS AND RELEASE

3.1 Subject only to the timely payment by Intuitive of the one-time license fee referenced in Section 4 (“LICENSE FEE, TERMINATION”) of this Agreement, Brookhill-Wilk hereby grants to Intuitive, under the Brookhill-Wilk Patents, a perpetual, exclusive, fully paid-up, royalty-free transferable, license to use, supply, make (and have made), sell, offer to sell, import, and export any surgical robotic system, product, or accessory and to practice any methods and procedures with those systems, products, and accessories, and to otherwise practice any of the Brookhill-Wilk Patent rights as Intuitive sees fit in its sole discretion without limitation as to field.

3.2 Subject only to the timely payment by Intuitive of the one-time license fee referenced in Section 4 (“LICENSE FEE, TERMINATION”) of this Agreement, Wilk and WPDC on behalf of themselves and their successors, hereby grant to Intuitive a perpetual, fully paid-up, royalty-free covenant not to sue Intuitive on the Wilk Patents. This covenant not to sue applies to past, current and future Licensed Products.

3.3 Subject only to the timely payment by Intuitive of the one-time license fee referenced in Section 4 (“LICENSE FEE, TERMINATION”) of this Agreement, Wilk and WPDC hereby grant to Intuitive, a perpetual, fully paid-up, royalty-free non-exclusive license on the ‘126 Patent to use, supply, make (and have made), sell, offer to sell, import, and export any surgical robotic system, product, or accessory and to practice any methods and procedures with those systems, products, and accessories, and to otherwise practice the ‘126 Patent rights as Intuitive sees fit in its sole discretion without limitation as to field.

3.4 Subject only to the timely payment by Intuitive of the one-time license fee referenced in Section 4 (“LICENSE FEE, TERMINATION”) of this Agreement, Intuitive, Brookhill-Wilk, Wilk and WPDC agree that they shall within five (5) business days after the Effective Date:

3.4.1 dismiss with prejudice all claims, demands, and causes of action that Licensors have asserted or could have asserted against Intuitive and/or Computer Motion, Inc. in Civil Action No. 00-CV-6599. Concurrently with said dismissal by Brookhill-Wilk, Intuitive shall also dismiss with prejudice all counterclaims, demands and causes of actions it asserted or could have asserted against Brookhill-Wilk, Wilk and WPDC in Civil Action Nos. 00-CV-6599;

3.4.2 dismiss with prejudice all claims, demands, and causes of action that Licensors have asserted or could have asserted against The Mount Sinai Hospital, New York Presbyterian Healthcare System, Inc., and Lenox Hill Hospital in Civil Action No. 03-CV-4977.

3.4.3 Intuitive and Licensors, for themselves and for each of their subsidiaries, related companies, predecessors, successors, heirs, assigns, and agents irrevocably release and forever discharge each other from and for any and all claims, causes of action, suits, damages, demands, duties, rights, obligations, liabilities, adjustments, responsibilities, judgments, trespasses and liabilities of any nature whatsoever, at law or in equity, whether asserted or unasserted, whether known or unknown, whether suspected or unsuspected to exist, and Licensors further covenant not to sue Intuitive directly or indirectly based on activities, that relate in any way to any of the Licensed Patents or any claims which were, could have been, or could be brought or made in any lawsuit relating to infringement of any of the Licensed Patents which it has the rights to;

3.5 LICENSORS RECOGNIZE THAT A GENERAL RELEASE MAY NOT EXTEND TO CLAIMS WHICH THE LICENSORS DO NOT KNOW OR SUSPECT TO EXIST IN HIS OR THEIR FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY ANY OR ALL OF THE LICENSORS WOULD HAVE MATERIALLY AFFECTED HIS OR THEIR ENTRY INTO THIS AGREEMENT WITH INTUITIVE. IN GRANTING THE LICENSES AND COVENANTS CONTAINED IN THIS AGREEMENT, LICENSORS EXPRESSLY INTEND THAT THIS AGREEMENT SHALL INCLUDE ALL CLAIMS

KNOWN, UNKNOWN, AND UNSUSPECTED, AND LICENSORS EXPRESSLY WAIVE THEIR RIGHTS UNDER ANY APPLICABLE STATUTE REGARDING THE UNENFORCEABILITY OF GENERAL RELEASES.

**SECTION 4
LICENSE FEE, TERMINATION**

4.1 In full consideration of the value received under this Agreement from Licensors, Intuitive agrees to pay a one-time license fee in the amount of Two Million Six Hundred Thousand U.S. Dollars (\$2,600,000.00). This license fee is non-refundable. Payment of this license fee shall be made within five (5) business days of the Effective Date.

4.2 The \$2,600,000.00 license fee shall be paid as follows, via wire-transfer from Intuitive to the following accounts:

4.2.1 Recipient's name: Wilk Patent Development Corp.
Recipient's address: 475 East 72nd Street, New York, NY 10021
Bank name: Citibank N.A.
Address: 162 Amsterdam Avenue, New York, NY 10021
Recipient's account number: 47589078
Routing number: 021000089
Amount: \$1,075,000.00

4.2.2 Recipient's name: Brookhill Management Corp.
Bank name: United States Trust Co. of NY
Bank address: 11 West 54th Street, New York, NY 10019
Recipient's account number: 20-2602-3
ABA#: 021001318
Amount: \$1,525,000.00

4.3 Upon payment of the one-time license fee of Section 4.1 in accordance with the payment instructions of Section 4.2, this Agreement, the payment, and the license grants and releases contained in it become non-terminable and non-revocable.

**SECTION 5
TERM**

5.1 The rights, licenses and covenants not to sue or assert and the releases granted under this Agreement shall commence on the Effective Date.

5.2 This Agreement shall remain in full force and effect during the pendency and life of, and until the expiration of the last to expire of, the Licensed Patents.

5.3 All rights and licenses granted under or pursuant to this Agreement by Licensors to Intuitive are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, U.S. Code (the "Bankruptcy Code"), licenses and rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The Parties agree that Intuitive, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code.

**SECTION 6
NOTICE**

6.1 Any notice required or permitted to be given under this Agreement shall be given to each other Party in writing and delivered by overnight courier, signature of receipt required, and shall be deemed delivered upon

written confirmation of delivery by the courier, if sent to the following respective addresses or such new addresses as may from time to time be supplied by the Parties.

To Brookhill-Wilk, LLC: Brookhill-Wilk, LLC
501 Madison Avenue,
New York, NY 10022
Attention: Ronald B. Bruder

With a copy to: Levisohn, Berger & Langsam, LLP
805 Third Avenue, 19th Floor
New York, New York 10022
Attention: Peter L. Berger
Telephone: (212) 486-7272
Facsimile: (212) 486-0323

To Peter J. Wilk: 475 East 72nd Street, Suite L1
New York, NY 10021
Telephone: (212) 744-5122
Facsimile: (212) 982-3202

With a copy to: Donald G. Leka, Esq.
140 Sewall Avenue
Brookline, MA 02446
Telephone: (617) 359-3664
Facsimile: (617) 734-0745

To Wilk Patent Development Corp. 475 East 72nd Street, Suite L1
New York, NY 10021
Attention: Peter J. Wilk
Telephone: (212) 744-5122
Facsimile: (212) 982-3202

With a copy to: Sol V. Slotnik, Esq.
11 East 44th Street, 17th Floor
New York, New York 10017
Telephone: (212) 687-1222
Facsimile: (212) 986-2399

With a copy to: Donald G. Leka, Esq.
140 Sewall Avenue
Brookline, MA 02446
Telephone: (617) 359-3664
Facsimile: (617) 734-0745

To Intuitive: Intuitive Surgical, Inc.
950 Kifer Road
Sunnyvale, CA 94086
Attention: Lonnie Smith
Telephone: (408) 523-2100
Facsimile: (408) 5231390

With a copy to: Fish & Richardson, P.C.
500 Arguello Street, Suite 500
Redwood City, CA 94063
Attention: David M. Barkan
Telephone: (650) 839-5070
Facsimile: (650) 839-5071

SECTION 7
WARRANTIES AND INDEMNIFICATION

7.1 Brookhill-Wilk represents and warrants that:

7.1.1 it is a company in good standing under the laws of the State of New York;

7.1.2 it has the authority to enter into this Agreement;

7.1.3 this Agreement is valid, binding and enforceable in accordance with its terms;

7.1.4 it has all necessary right, title, and interest in the Brookhill-Wilk Patents to grant the rights, licenses, covenants not to sue or assert, and releases contained in paragraphs 3.1 and 3.4 of this Agreement;

7.1.5 Mr. Bruder has full right and authority to execute this Agreement on behalf of Brookhill-Wilk;

7.1.6 there are no licenses, liens, conveyances, mortgages, assignments and/or other agreements that would prevent or impair the full and complete exercise by Intuitive of any or all of the rights and licenses, or the full and complete enjoyment by Intuitive of any or all of the covenants not to sue, or the release, granted in paragraphs 3.1 and 3.4 of this Agreement; and

7.1.7 no person or entity other than Brookhill-Wilk, Wilk and WPDC has a right to enforce any of the Licensed Patents or to collect damages for past, present or future infringement of any of them except as noted for US Patent 5,776,126.

7.2 Wilk represents and warrants that:

7.2.1 he has the authority to enter into this Agreement;

7.2.2 this Agreement is valid, binding and enforceable in accordance with its terms;

7.2.3 he has all necessary right, title, and interest in the Wilk Patents, and the '126 Patent to grant the rights, licenses, covenants not to sue or assert, and releases contained in paragraphs 3.2, 3.3, and 3.4 of this Agreement;

7.2.4 he has sought the advice of independent counsel and enters into this Agreement freely, willingly, and without reservation;

7.2.5 there are no licenses, liens, conveyances, mortgages, assignments and/or other agreements that would prevent or impair the full and complete exercise by Intuitive of any or all of the rights and licenses, or the full and complete enjoyment by Intuitive of any or all of the covenants not to sue, or the release, granted in this Agreement; and

7.2.6 no person or entity other than Brookhill-Wilk, Wilk and WPDC has a right to enforce any of the Licensed Patents and the '126 Patent or to collect damages for past, present or future infringement of any of them except as noted for US Patent 5,776,126.

7.3 WPDC represents and warrants that:

7.3.1 it is a company in good standing under the laws of the State of New York;

7.3.2 it has the authority to enter into this Agreement;

7.3.3 this Agreement is valid, binding and enforceable in accordance with its terms;

7.3.4 it has all necessary right, title, and interest in the Wilk Patents, and the '126 Patent to grant the rights, licenses, covenants not to sue or assert, and releases contained in paragraphs 3.2, 3.3, and 3.4, of this Agreement;

7.3.5 it has sought the advice of independent counsel and enters into this Agreement freely, willingly, and without reservation;

7.3.6 Dr. Wilk has full right and authority to execute this Agreement on behalf of WPDC;

7.3.7 there are no licenses, liens, conveyances, mortgages, assignments and/or other agreements that would prevent or impair the full and complete exercise by Intuitive of any or all of the rights and licenses, or the full and complete enjoyment by Intuitive of any or all of the covenants not to sue, or the release, granted in this Agreement; and

7.3.8 no person or entity other than Brookhill-Wilk, Wilk and WPDC has a right to enforce any of the Licensed Patents or to collect damages for past, present or future infringement of any of them except as noted for US Patent 5,776,126.

7.4 Licensors agree to indemnify Intuitive and pay all associated costs of defense, including attorney fees attributable to any specific claim, in the event that any such specific claim is brought by any third party against Intuitive, where the third party claims rights that Brookhill-Wilk, WPDC, and Wilk have conveyed to Intuitive by this Agreement.

**SECTION 8
RELATIONSHIP OF THE PARTIES**

Nothing in this Agreement shall be construed to make Licensors and Intuitive partners, joint venturers, or create a fiduciary status or relationship between them or make either Licensors or Intuitive an agent of the other; nor will any similar relationship be deemed to exist between them. Neither Licensors nor Intuitive shall make representations contrary to the terms of this Paragraph, nor shall either become liable by reason of any representation, act, or omission of the other contrary to the provisions of this Paragraph. This agreement is not for the benefit of any third party (except to the extent of the dismissal of the suit brought by Brookhill-Wilk against Intuitive Surgical, Inc.'s customers) and shall not be deemed to give any right or remedy to such party.

**SECTION 9
ASSIGNABILITY**

A Party may assign its rights and obligations under this Agreement only to an entity or entities that acquire(s) all or substantially all of the Party's business or assets related to this Agreement, whether through purchase, merger, reorganization or otherwise. In the case of such assignment, the assignee shall have the rights and obligations of the assignor under this Agreement to the same extent as if the assignee had been named as a Party to the agreement.

**SECTION 10
MISCELLANEOUS**

10.1 Counterparts: This Agreement may be executed in counterparts, which taken together shall constitute one document.

10.2 Entire Agreement: This Agreement constitutes the entire agreement among the Parties concerning its subject matter and supersedes all written or oral prior or contemporaneous agreements and understandings with respect to the subject matter of this Agreement. No Party shall be bound by any condition, definition, warrantee, understanding, or representation with respect to the subject matter of this Agreement except as expressly provided in this Agreement. No variation or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the authorized representatives of Licensors and Intuitive.

10.3 Severability. If any provision of this Agreement is declared by a court of competent jurisdiction or by operation of law to be invalid, illegal, unenforceable, or void, then Licensors and Intuitive shall be relieved of all obligations arising under such provision, but only to the extent that such provision is invalid, illegal,

unenforceable, or void. If the remainder of this Agreement is capable of substantial performance, then each provision not so affected shall be enforced to the extent permitted by law, and the invalid term or provision shall be replaced by such valid term or provision as comes closest to the intentions of the Licensors and Intuitive underlying the invalid term or provision.

10.4 Mutual Drafting. This Agreement is the joint product of the Parties and their respective counsel, and each provision of this Agreement has been subject to the mutual consultation, negotiation and agreement of the Parties and counsel, and shall not be construed for or against any Party on the basis of authorship.

10.5 No Other Agreement. Licensors and Intuitive each represent that in entering into this Agreement, they rely on no promise, inducement, or other agreement not expressly contained in this Agreement; that they have read this Agreement and discussed it thoroughly with their respective legal counsel; that they understand all of the provisions of this Agreement and intend to be bound by them; and that they enter into this Agreement voluntarily.

10.6 Governing Law/Venue. This Agreement is made and entered into in the State of New York and shall be construed, governed, interpreted, and enforced in accordance with the laws of the State of New York, except that questions affecting the construction and effect of the Licensed Patents shall be determined by the law of the United States. Except as provided otherwise in this Agreement, any dispute, claim or controversy arising out of or relating to this Agreement, or the breach, or validity of this Agreement shall be adjudicated only by a court of competent jurisdiction in the County of New York, State of New York, and all parties hereby consent to jurisdiction and venue in such County.

10.7 Attorneys Fees. The prevailing Party shall be entitled to recover from the losing Party or Parties its reasonable attorneys' fees and costs incurred in any lawsuit or other action with respect to any claim arising from the facts or obligations set forth in this Agreement.

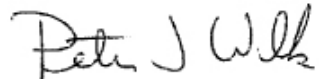
IN WITNESS WHEREOF, the duly authorized representatives of Licensors and Intuitive have executed this Agreement.

BROOKHILL-WILK 1, LLC



RONALD B. BRUDER
CHAIRMAN

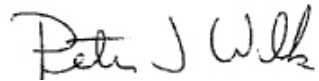
DATE: 1/8/04



PETER J. WILK
PRESIDENT

DATE: 1/8/04

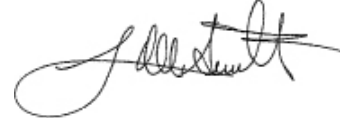
WILK PATENT DEVELOPMENT CORP.



PETER J. WILK
CHAIRMAN

DATE: 1/8/04

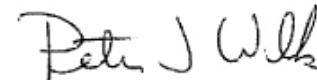
INTUITIVE SURGICAL, INC.



LONNIE SMITH
CHAIRMAN

DATE: 1/13/04

PETER J. WILK



PETER J. WILK

DATE: 1/8/04

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-116499, 333-43558, 333-65342 and 333-99893) pertaining to the Intuitive Surgical 2000 Equity Incentive Plan, 2000 Non-Employee Directors' Stock Option Plan and 2000 Employee Stock Purchase Plan, and Form S-3 (Nos. 333-108713, 333-110229 and 333-110972) of our reports dated March 9, 2005, with respect to the consolidated financial statements and schedule of Intuitive Surgical, Inc., Intuitive Surgical, Inc. management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Intuitive Surgical, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2004.

/s/ Ernst & Young LLP

Palo Alto, California
March 14, 2005

**Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Lonnie M. Smith, certify that:

1. I have reviewed this annual report on Form 10-K of Intuitive Surgical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2005

By:

/s/ LONNIE M. SMITH

Lonnie M. Smith
President and Chief Executive Officer

Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Susan K. Barnes, certify that:

1. I have reviewed this annual report on Form 10-K of Intuitive Surgical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2005

/s/ SUSAN K. BARNES

Susan K. Barnes
Chief Financial Officer

**Certification of Chief Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Intuitive Surgical, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

- (i) the accompanying Annual Report on Form 10-K of the Company for the period ended December 31, 2004 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ LONNIE M. SMITH

Lonnie M. Smith
President and Chief Executive Officer

March 16, 2005

**Certification of Chief Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Intuitive Surgical, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

- (i) the accompanying Annual Report on Form 10-K of the Company for the period ended December 31, 2004 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ SUSAN K. BARNES

Susan K. Barnes
Chief Financial Officer

March 16, 2005