

INTUITIVE SURGICAL INC
Form 10-K
January 29, 2010
[Table of Contents](#)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(MARK ONE)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2009

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)

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

DELAWARE
(State or Other Jurisdiction of

77-0416458
(I.R.S. Employer

Incorporation or Organization)

Identification Number)

1266 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:

Title of Each Class:
Common Stock, par value \$0.001 per share

Name of Each Exchange on which Registered
The NASDAQ Global Select Market

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

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

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

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

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

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

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

Large accelerated filer ☒

Accelerated filer ☐

Non-accelerated filer ☐
(Do not check if a smaller
reporting company)

Smaller reporting Company ☐

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

The aggregate market value of the voting stock held by non-affiliates of the registrant on June 30, 2009, based upon the closing price of Common Stock on such date as reported by NASDAQ Global Select Market, was approximately \$6,208,203,975. 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 January 21, 2010 was 38,504,605.

DOCUMENTS INCORPORATED BY REFERENCE

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

Part III incorporates information by reference to the definitive proxy statement for the Company's Annual Meeting of Stockholders to be held on or about April 21, 2010, to be filed within 120 days of the registrant's fiscal year ended December 31, 2009.

Table of Contents

Table of Contents

INTUITIVE SURGICAL, INC.

INDEX

PART I

Item 1.	<u>Business</u>	3
Item 1A.	<u>Risk Factors</u>	21
Item 1B.	<u>Unresolved Staff Comments</u>	33
Item 2.	<u>Properties</u>	33
Item 3.	<u>Legal Proceedings</u>	34
Item 4.	<u>Submission of Matters to a Vote of Security Holders</u>	34

PART II

Item 5.	<u>Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	35
Item 6.	<u>Selected Consolidated Financial Data</u>	37
Item 7.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	37
Item 7A.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	53
Item 8.	<u>Financial Statements and Supplementary Data</u>	55
Item 9.	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	86
Item 9A.	<u>Controls and Procedures</u>	86
Item 9B.	<u>Other Information</u>	86

PART III

Item 10.	<u>Directors, Executive Officers and Corporate Governance</u>	87
Item 11.	<u>Executive Compensation</u>	87
Item 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	87
Item 13.	<u>Certain Relationships and Related Transactions and Directors Independence</u>	87
Item 14.	<u>Principal Accountant Fees and Services</u>	87

PART IV

Item 15.	<u>Exhibits and Financial Statement Schedules</u>	88
----------	---	----

<u>SIGNATURES</u>	91
-------------------	----

Table of Contents

FORWARD LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as projects, believes, anticipates, plans, expects, intends, may, will, could, should, would, and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements related to our expected business, new product introductions, results of operations, future financial position, our ability to increase our revenues, the mix of our revenues between product and service revenues, our financing plans and capital requirements, our costs of revenue, our expenses, our potential tax assets or liabilities, the effect of recent accounting pronouncements, our investments, cash flows and our ability to finance operations from cash flows and similar matters and include statements based on current expectations, estimates, forecasts and projections about the economies and markets in which we operate and our beliefs and assumptions regarding these economies and markets. These forward-looking statements should be considered in light of various important factors, including the following: timing and success of product development and market acceptance of developed products; the impact of the global economic recession and tight credit market and related impact on health care spending; possible health care reform in the United States and its implications on hospital spending, reimbursement, and fees which may be levied on certain medical device companies; 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 market disruptions; delays in regulatory approvals of new manufacturing facilities or the inability to meet demand for products and other risk factors. Readers are cautioned that these forward-looking statements are based on current expectation and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those risk factors described throughout this filing and particularly in Part I, Item 1A: Risk Factors. Our actual results may differ materially and adversely from those expressed in any forward-looking statements. We undertake no obligation to revise or update any forward-looking statements for any reason.

PART I

ITEM 1. BUSINESS

COMPANY BACKGROUND

Intuitive Surgical, Inc. was founded in 1995. We are a Delaware corporation with our corporate headquarters located at 1266 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 wholly-owned subsidiaries. *Intuitive Surgical*, *da Vinci*, *da Vinci S*, *da Vinci S HD Surgical System*, *da Vinci Si*, *EndoWrist*, and *InSite* are trademarks of Intuitive Surgical, Inc.

We design, manufacture and market *da Vinci* Surgical Systems, *EndoWrist* instruments, and surgical accessories, which we believe are enabling a new generation of surgery. We believe that this new generation of surgery, which we call *da Vinci* surgery, is a significant advancement similar in scope to previous generations of surgery—open surgery and minimally invasive surgery, or conventional MIS. Our *da Vinci* Surgical Systems consist of a surgeon's console, or consoles, a patient-side cart and a high performance vision system. By placing computer-enhanced technology between the surgeon and patient, we believe that our products enable surgeons to perform advanced surgery in a manner never before experienced. The *da Vinci* Surgical System controls Intuitive Surgical endoscopic instruments, including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pickups, needle holders, endoscopic retractors, basic and advanced electrocautery instruments, ultrasonic cutters, and accessories during a wide range of surgical procedures. The *da Vinci* Surgical System translates the surgeon's natural hand movements performed on instrument controls at a surgeon's console into corresponding micro-movements of instruments positioned inside the patient through small incisions, or ports.

Table of Contents

Our *da Vinci* Surgical System provides the surgeon with the intuitive control, range of motion, fine tissue manipulation capability and high definition 3-D vision, while simultaneously allowing the surgeon to work through the small ports of MIS. The *da Vinci* Surgical System is used to perform surgery across multiple surgical specialties, including urology, gynecology, cardiothoracic surgery, transoral surgery, and general surgery.

In March 1997, surgeons using an early prototype of our technology performed the first *da Vinci* surgery on humans. In the second quarter of 1999, we began selling *da Vinci* products and services outside the United States. In July 2000, we obtained clearance from the U.S. Food and Drug Administration (FDA) to market our products in the United States for use in general laparoscopic procedures.

The following table summarizes our FDA clearances to date:

July 2000 General laparoscopic procedures

March 2001 Non-cardiac thoracoscopic procedures

May 2001 Prostatectomy procedures

November 2002 Cardiotomy procedures

July 2004 Cardiac revascularization procedures

March 2005 Urologic surgical procedures

April 2005 Gynecologic surgical procedures

June 2005 Pediatric surgical procedures

December 2009 Transoral Otolaryngologic surgical procedures

In January 2006 we began selling the *da Vinci S* Surgical System in the United States and Europe. In March 2008 we received clearance in the United States to market our system-held cardiac stabilizer and permission to remove the warning in our labeling regarding system use in non-arrested heart procedures. During first quarter of 2009, we received clearance to market our *da Vinci Si* Surgical System in the United States and Europe.

In November 2009, we received regulatory (Shonin) approval from the Japanese Ministry of Health, Labor, and Welfare (MHLW) for our *da Vinci S* System in Japan. With this approval, we are now focusing on meeting various trade and importation requirements necessary for commercialization and to obtain appropriate reimbursement rates for several *da Vinci* procedures in Japan. We have a separate independent distribution partner in Japan who will be responsible for selling, marketing, and servicing our products in Japan.

As of December 31, 2009, we had an installed base of 1,395 *da Vinci* Surgical Systems. During the year ended December 31, 2009 surgeons using our technology completed approximately 205,000 surgical procedures of various types in major hospitals throughout the world. Out of those *da Vinci* procedures performed in 2009, approximately 90,000 were *da Vinci* Prostatectomy (dVP) procedures and approximately 69,000 were *da Vinci* Hysterectomy (dVH) procedures.

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

We operate our business as one segment as defined by generally accepted accounting principles. Our financial results for the three years ended December 31, 2009 are discussed in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and Item 8. Financial Statements and Supplementary Data of this Annual Report.

da Vinci Surgery

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

Table of Contents

past two decades, MIS has reduced trauma to the patient by allowing selected surgeries to be performed through small ports rather than large incisions, often 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 conventional MIS and enables a new generation of surgery, *da Vinci* Surgery. Surgeons operate while seated comfortably at a console viewing a high resolution, 3-D HD 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 a surgeon's hand. In designing our products, we have focused on making our technology as simple as possible to use.

Our products are designed to convert a broad range of open surgical and conventional MIS procedures to *da Vinci* surgery. The *da Vinci* Surgical System is designed to enable surgeons to improve surgical outcomes while providing patients with the benefits of MIS. We believe that these advantages have begun to facilitate a fundamental change in surgery and that our technology overcomes many of the limitations of existing MIS tools and techniques in the following ways:

Immersive 3-D Visualization. Our vision system includes a 3-D endoscope with two independent vision channels linked to two separate color monitors. Our 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 conventional MIS. In addition, the *3-D High Definition* vision system with advanced image processing including edge enhancement and noise reduction provides a brighter and sharper image than any other 3-D endoscope vision system currently available. The *da Vinci* Surgical System provides visualization of the target anatomy with natural depth-of-field, enhanced contrast and magnification for more accurate tissue identification and tissue layer differentiation. Improved visualization also enables surgeons to perform delicate tissue handling and dissection with added precision even in confined spaces. This precision may help the surgeon avoid trauma to surrounding structures and tissues such as the neurovascular bundle located near the prostate.

Precise and Tremor-free Endoscope Control. 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. Endoscope control, provided through the hand controls and foot pedals, provides near-seamless transition between views. Surgeons can reposition the surgical camera in an instant with foot controls or zoom in, out, up, down, left and right by moving their hands in the desired direction while maintaining a stable image. Repositioning of the surgeon's head at the console does not affect image quality as with other 3-D display systems. The combination of these features offers what we believe is the most advanced surgical vision system available today.

Intuitive 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, with the *da Vinci* Surgical System, a hand movement to the right outside the body causes the instrument inside the patient to be moved to the right. 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. In conventional MIS, the instrument tip moves in the opposite direction from the surgeon's hand and surgeons must adjust 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 and enable more widespread use of advanced techniques as well as a reduced learning curve

Table of Contents

when compared to conventional MIS techniques. The surgeon controls the instrument movements from the surgeon's console using natural hand and wrist movements. 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. Added instrument range-of-motion enhances access and safety while operating in the confined space of the closed chest, abdomen or pelvis. *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, conventional MIS instruments in widespread use today do not have joints near their tips, and cannot replicate a surgeon's hand and wrist movements to perform manipulations, such as reaching behind tissue, suturing and fine dissection.

More Precise, Tremor-reduced Movement. 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 either open surgery or conventional MIS. In addition, our technology provides the filtering of tremor inherent in a surgeon's hands.

Superior Surgeon Ergonomics. The *da Vinci* Surgical System is designed to allow surgeons to operate while seated, which is not only more comfortable, but also may be clinically advantageous due to reduced surgeon fatigue. The *da Vinci* Surgical System's design provides natural hand to eye alignment at the surgeon's console, which provides improved ergonomics over traditional laparoscopic technology. Since the *da Vinci* Surgical System's robotic arms hold the camera and instruments steady, there is less surgeon assistance required and reduced surgeon fatigue and also potentially reduced abdominal wall torque.

Improved Ease-of-Use shortens learning curves. 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 using our products are as natural as hand movements in open surgery. In our experience, based on feedback from surgeons who have performed thousands of procedures, surgeons can learn to manipulate our instruments with less training than is typically required for the surgeon to become skilled in conventional 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 nearly 100 different types of surgical procedures.

We believe that these technological advantages provide the patient with benefits of reduced trauma while restoring to the surgeon the 3D visualization, range of motion and fine tissue control consistent with open surgery. We believe that our technology has the potential to change surgical procedures in two basic ways:

Convert a Large Percentage of Open Procedures to da Vinci Surgery. We believe that our technology has the potential to convert a large percentage of open procedures which are traditionally performed through large incisions to *da Vinci* surgery.

Facilitate Difficult MIS Operations. We believe that several surgical procedures are performed only rarely today using conventional MIS techniques can be performed routinely using *da Vinci* surgery. Some procedures have been adapted for MIS 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.

Table of Contents

Intuitive Surgical's Products and Services

Our principal products include three models of *da Vinci* Surgical System: *da Vinci Si* Surgical System, *da Vinci S* Surgical System and standard *da Vinci* Surgical System, along with a variety of *EndoWrist* instruments and accessories.

da Vinci Surgical System

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

Surgeon's Console or Consoles. The *da Vinci* Surgical System allows one or two surgeons 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 electronic hardware, software, algorithms, mechanics and optics, our technology translates the surgeon's hand movements into precise and corresponding real-time micro movements of the *EndoWrist* instruments positioned 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 representing 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 provides additional surgical capabilities by holding an additional *EndoWrist* instrument as well as potentially reducing 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 instrument arm extends surgical capabilities by enabling the surgeon to add a third *EndoWrist* instrument and perform additional tasks such as applying counter traction and following running sutures. The fourth instrument arm is a standard integrated feature on the *da Vinci Si* and *da Vinci S* surgical systems and is available as a field upgrade on three-arm standard *da Vinci* and three-arm *da Vinci S* Surgical Systems.

3-D Vision System. Our vision system includes our *InSite* 3-D endoscope with two separate vision channels linked to two separate color monitors through high 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 occurs in single monitor systems, and minimizes eye fatigue. Our HD vision system provides at least 20% more viewing area and enhances visualization of tissue planes and critical anatomy compared with our standard vision system. The digital zoom feature in the 3-D HD vision system allows surgeons to magnify the surgical field of view without adjusting endoscope position and reduces interference between the endoscope and instruments. The 3-D HD vision is a standard integrated feature on *da Vinci S* Surgical Systems sold today and as an upgrade option to our existing customers who own a *da Vinci S* Surgical System without HD vision.

Our newest *da Vinci* model, the *da Vinci Si*, was launched in April 2009. The *da Vinci Si* System retains and builds on the core technology at the heart of the existing *da Vinci* and *da Vinci S* Systems. The *da Vinci Si* brings to market three significant innovations.

First, our *InSite* imaging system has been substantially redesigned for increased visual acuity and improved ease-of-use. The HD imaging system's increased performance is similar to the move from 720p to 1080i in commercial television. We believe that the increased visual performance will continue to enhance surgeon precision and confidence, which may contribute to improved patient outcomes and shorter procedure times. Additionally, the *da Vinci Si* surgeon's user interface has been redesigned to allow simplified and integrated control of *da Vinci* products and other operating room devices, such as electro-surgical units. The new user interface also includes a set of ergonomic controls for surgeon comfort. We believe the simplified interface

Table of Contents

may allow for easier surgeon training. The third significant enhancement is the introduction of a second surgeon's console, which we envision to be used in two possible ways: to provide assistance to the primary surgeon during surgery, or, to be used as an active aid during surgeon-student training sessions. With the *da Vinci Si*, a surgeon sitting at a second console can view the same surgery as the primary surgeon and can be passed control of some or all of the *da Vinci* arms during a case. We believe this could both shorten the learning curve for new surgeons and will allow for collaborative surgery in complex cases.

EndoWrist Instruments, Accessories and Vision Components

We manufacture a variety of *EndoWrist* instruments, each of which incorporates wrist joints for natural dexterity, with tips customized for various surgical procedures. *EndoWrist* instruments are offered in both 5mm and 8mm diameter sizes. 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 conventional 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 sterilizable and most are reusable for a defined number of procedures. A programmed memory 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 communicates 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.

We also sell various vision and accessory products, which are used in conjunction with the *da Vinci* Surgical System as surgical procedures are performed. Accessory products include sterile drapes used to ensure a sterile field during surgery, vision products such as replacement 3-D stereo endoscopes, camera heads, light guides, and other miscellaneous items. Existing *da Vinci S* instruments and most *da Vinci S* accessories are compatible with the *da Vinci Si* system.

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. Once the ports have been placed by the surgeon, the arms of the *da Vinci* Surgical System are positioned and the *EndoWrist* instruments are introduced 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 high performance 3-D 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 conventional MIS. A scrub nurse standing near the patient removes the instrument from the electromechanical arm and replaces it with another 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 conventional MIS. At the conclusion of the operation, the small port incisions are closed with either suture or band-aids.

Table of Contents

Our Objective

Our objective is to bring the benefits of minimally invasive surgery to as many patients as possible. Our priorities to accomplish this are as follows:

1. *Patient Value.* We believe that the value of a surgical procedure to a patient can be defined as: Patient Value = Efficacy/Invasiveness. Most patients will place higher value on procedures that are not only more efficacious, but also less invasive than alternative treatments. Our goal is to provide patients with procedure options that are both highly effective and less invasive than other surgical options.
2. *Key Procedures.* We believe that the adoption of *da Vinci* surgery occurs based upon the patient value it brings to each surgical procedure. We therefore focus our development efforts on those procedures to which we believe our products bring the highest patient value. We currently focus on five surgical specialties: urologic surgery, gynecologic surgery, cardiothoracic surgery, general surgery and head and neck surgery. In 2009, the mix of procedures performed with the *da Vinci* Surgical System among these five surgical specialties was largest within urology, followed by gynecology, cardiothoracic, general surgery and head and neck surgery. The *da Vinci* Surgical System is used to perform, among other procedures, *da Vinci* Prostatectomy, *da Vinci* Partial Nephrectomy & Nephrectomy, *da Vinci* Cystectomy, *da Vinci* Pyeloplasty, *da Vinci* Hysterectomy, *da Vinci* Myomectomy, *da Vinci* Sacral Colpopexy, *da Vinci* Mitral Valve Repair, *da Vinci* Revascularization, *da Vinci* Thoracoscopy, *da Vinci* Gastric Bypass, *da Vinci* Low Anterior Colon Resection and *da Vinci* Thyroidectomy. The development of new specialties and key procedures in partnership with leading surgeons have been, and will continue to be, a catalyst for the growth of our company.
3. *Surgeon Value.* We train and assist surgeons in building their practices by delivering superior patient value through improved surgical efficacy and reduced surgical trauma.
4. *Hospital Value.* We assist both academic and community hospitals in building value by offering superior patient value in terms of improved surgical efficacy and reduced surgical trauma thereby increasing surgical revenue and reducing costs through lower complication rates and reduced length of patient stay. We expect these efforts to increase demand for our products among competitive hospitals, surgeons and referring physicians.

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 completed hundreds of thousands of surgical procedures of various types, including urologic, gynecologic, cardiothoracic, general and head and neck surgery procedures. 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 standard approach to removal of the prostate has been via an open surgical procedure. The laparoscopic approach, while not prevalent, is an option, but 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. Peer-reviewed clinical publications have reported that radical prostatectomy using the *da Vinci* Surgical System has improved oncologic results, reduced operative blood loss, reduced postoperative pain, improved cosmesis, quicker return to normal activity and may provide a better nerve-sparing operation. 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.

Nephrectomy (partial and total). Partial nephrectomy is the removal of a small portion of a kidney (typically, an area of the kidney containing a tumor), and total nephrectomy is the total removal of a kidney. Partial

Table of Contents

nephrectomies are most commonly performed in patients diagnosed with clinically localized renal cancer, when the tumor size is four centimeters or less in size. Total nephrectomies are also most commonly performed in patients diagnosed with clinically localized renal cancer that are not resectable with a partial nephrectomy and are also performed in patients suffering from various benign conditions. There are currently three surgical approaches to performing partial nephrectomies: open surgical technique, which requires a large incision; laparoscopy, which allows the surgeon to operate through several small incisions, and hand assisted, which incorporates both laparoscopy and a modified open surgical technique. Surgeons have reported that the combination of the *da Vinci* Surgical System's improved visualization capabilities and enhanced dexterity allows for greater precision and control during these complex surgical procedures, which could enable a large number of these procedures to be performed through this minimally invasive technique resulting in reduced operative blood loss, reduced postoperative pain, shorter length of hospital stay, quicker return to normal activity and improved cosmesis.

Cystectomy. Cystectomy is the removal of the bladder in patients diagnosed with bladder cancer. The current standard approach to the removal of the bladder is via an open surgical procedure. The laparoscopic approach, while not prevalent, is an option, but is difficult and poses challenges to even the most skilled urologist. The *da Vinci* Surgical System allows for improved visualization of the gross anatomy and tissue planes, which are critical for an anatomic dissection. The *da Vinci* Surgical System has enabled a number of these procedures to be converted from an open surgical technique to a minimally invasive technique, thus reducing blood loss and pain and allowing for the patient's quicker return to normal activity.

Pyeloplasty. Pyeloplasty is the surgical reconstruction or revision of the renal pelvis to drain and decompress the kidney. In nearly all cases, the goal of pyeloplasty surgery is to relieve a uretero-pelvic junction (UPJ) obstruction. There are currently two surgical approaches to performing pyeloplasties: open surgical technique, which requires a large incision, and laparoscopy, which allows the surgeon to operate through several small incisions. Surgeons have reported that the combination of the *da Vinci* Surgical System's improved visualization capabilities and enhanced dexterity allows for greater precision and control during these complex surgical procedures, which could enable a large number of these procedures to be performed through this minimally invasive technique resulting in reduced operative blood loss, reduced postoperative pain, shorter length of hospital stay, quicker return to normal activity and improved cosmesis.

Gynecologic Surgery

Hysterectomy. Removal of the uterus is one of the most commonly performed surgeries in gynecology and is performed for a variety of benign and malignant conditions. Hysterectomies can be performed using open surgery, a vaginal approach, or MIS techniques, which include both laparoscopic and robotic approaches. Performing a hysterectomy requires a significant degree of tissue manipulation in the dissection and ligation, or tying, of blood vessels, ligaments and other pelvic structures. An MIS approach to hysterectomy is associated with less pain, shorter hospital stay and quicker recovery compared to an open surgical technique. It is often difficult to ensure the identification and prevention of injury to the ureters and bladder with conventional laparoscopic instruments because of the limited angles at which these instruments can be positioned. Furthermore, in hysterectomy procedures for treating endometrial or cervical cancer, it is difficult to access and remove a large number of lymph nodes to better stage the cancer with conventional laparoscopic techniques. A robotic technique with use of the *da Vinci* Surgical System can bring the benefits of MIS to the patients while offsetting the limitations of conventional laparoscopy. Specifically, patients that would traditionally have a hysterectomy through an open surgical technique, for a complex-benign or a malignant clinical condition may see significant benefit from a robotic MIS approach including reduced operative blood loss, reduced postoperative pain, shorter length of hospital stay, quicker return to normal activity and improved cosmesis. We believe that our products will increase the surgeon's dexterity in this procedure and, as a result, may have a significant impact on safety, operating time, and rate of adoption of port-based techniques in hysterectomy.

Myomectomy. Myomectomy, or removal of a myoma/fibroid, is a surgical procedure performed when uterine preservation is sought. Women who desire to remain fertile are candidates for this procedure. Due to the substantial suturing required for this procedure, the standard surgical approach remains an open incision. There

Table of Contents

are some highly skilled gynecological laparoscopists who perform laparoscopic myomectomies, but to this point, it has remained a small minority. We believe that the *da Vinci* Surgical System's improved visualization capabilities and enhanced dexterity allows for greater precision and control during these complex surgical procedures, which could enable a large number of these procedures to be performed minimally invasively resulting in reduced operative blood loss, reduced postoperative pain, shorter length of hospital stay, quicker return to normal activity and improved cosmesis.

Sacral Colpopexy. The abdominal sacral colpopexy is one of the most successful operations for vaginal vault prolapse. Sacral colpopexy involves suturing a synthetic mesh that connects and supports the vagina to the sacrum (tailbone). A sacral colpopexy can be performed using conventional laparoscopic technique, it is however, generally described as difficult and cumbersome to perform. *da Vinci* sacral colpopexy combines the benefits of a minimally invasive procedure with the durability of a traditional abdominal approach resulting in reduced operative blood loss, reduced postoperative pain, shorter length of hospital stay, quicker return to normal activity and improved cosmesis.

Cardiothoracic Surgery

Mitral Valve Repair. When patients are diagnosed with mitral valve disease, there are two surgical treatment options from which they can choose: mitral valve replacement or mitral valve repair. Mitral valve repairs are generally preferred over mitral valve replacement for a number of reasons, which include longevity and durability of the repaired valve over a replacement valve and the elimination or reduction of the patient's post-surgical pharmaceutical regimen. Since mitral valve repairs are considered to be more technically challenging than mitral valve replacements, they are only performed approximately 50% of the time. When performing *da Vinci* mitral valve repairs, surgeons have reported that the enhanced 3-D visualization provides for essential identification of difficult to see anatomical structures and tissue planes. *EndoWrist* joints permit them to precisely manipulate delicate structures inside of the heart and accurately place sutures into the targeted tissues. In addition, surgeons using the *da Vinci* Surgical System to operate from a lateral right-sided approach have reported that this requires less tissue manipulation than operating through a sternotomy, while providing greater anatomical exposure. As a result of these factors, several of our surgeon customers have reported a significant improvement in their mitral valve repair rates (>95%) over mitral valve replacements within their practices. Our *da Vinci* Surgical System is enabling heart valve repairs to be performed through small ports in a manner that could not have been accomplished with open surgery resulting in reduced operative blood loss, reduced postoperative pain, shorter length of hospital stay, quicker return to normal activity and improved cosmesis.

Cardiac Revascularization or 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 *da Vinci* Surgical System, patients can undergo single or multi-vessel full surgical revascularization utilizing all arterial conduits (IMA/BIMA), while avoiding CPB and the median sternotomy incision, thus reducing the morbidities associated with these procedures. In Single-Vessel or Multi-Vessel Small Thoracotomy bypass, or SVST/MVST procedures, surgeons use the *da Vinci* Surgical 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 four- to six- centimeter incision, enabling the surgeon to complete the anastomoses directly through the incision resulting in reduced operative blood loss, reduced postoperative pain, shorter length of hospital stay, quicker return to normal activity and improved cosmesis. In addition to reducing known morbidities from standard open-chest coronary artery bypass surgery, revascularization with the *da Vinci* Surgical System places the patient on an accelerated path to recovery. When combined with percutaneous coronary intervention (PCI) in a hybrid approach, *da Vinci* Revascularization may also provide better outcomes than stenting alone, resulting in higher patency and lower re-intervention rates.

Table of Contents

Thoracic Surgery. A number of surgical procedures performed in the thorax, or chest cavity, can be accomplished by minimally invasive methods. These methods are generally referred to as video-assisted thoracoscopic (VATS) surgery. Procedures performed via these methods include wedge resection, lobectomy, thymectomy, mediastinal mass excision and esophagectomy. 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 counter-intuitive movement and limited range of motion. We believe that the capability of our technology to operate dexterously in the small and restrictive space of the chest cavity offers significant clinical value in the performance of advanced thoracic surgical procedures like lobectomy. Use of the *da Vinci* System allows formal, anatomical resection, along with complete mediastinal lymph node dissection the gold standard treatment for early stage non-small cell lung cancer. This approach provides effective treatment without the need for a formal thoracotomy (open technique), or facilitation-access mini-thoracotomy (video-assisted thoracic surgery or VATS technique).

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 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. We believe procedures performed with the *da Vinci* Surgical System incorporating a double-layered hand-sewn anastomosis results in fewer anastomotic leaks than in traditional laparoscopic procedures.

Low Anterior Resection. Low anterior resection (LAR) is a surgical procedure to treat rectal cancer. The surgeon dissects and removes the majority of the rectum, descending colon and a portion of healthy tissue and lymph nodes. Conventional laparoscopy is not widely employed to treat rectal cancer due to the high degree of difficulty. In fact, literature suggests that laparoscopic LAR may increase the rate of surgical complications and positive oncologic margins. Furthermore, pelvic nerve bundles that enable healthy bladder and sexual function may be compromised in *both* open and laparoscopic LAR procedures due to poor exposure, visualization and dexterity inherent in operating with conventional tools in a tight and deep surgical space. In contrast, the *da Vinci* Surgical System is a proven tool for performing precise cancer operations, with minimal complications, in the deep pelvis. As with *da Vinci* Prostatectomy, *da Vinci* Low Anterior Resection provides surgeons with greater dexterity, visualization and control when performing rectal cancer surgery as compared to open and laparoscopic approaches. We believe that *da Vinci* Low Anterior Resection not only enables a more precise operation with fewer complications and shorter recovery time, but may also improve oncologic outcomes.

Thyroidectomy. Thyroid cancer is most commonly treated by thyroidectomy, the removal of all or part of the thyroid gland. Complete resection of the cancer and surrounding gland is required for proper oncologic outcomes. The surgeon must also precisely dissect and preserve an important nerve that sits deep to the gland in order to maintain proper voice function and spare the parathyroid glands that regulate calcium levels in the blood. For these reasons, open surgery is the dominant surgical approach. Endoscopic approaches with good functional outcomes have proven too difficult for the majority of surgeons. Open surgery however leaves a prominent and unsightly neck scar often as large as four to six centimeters. In Asia, surgeons are now using the *da Vinci* Surgical System to perform thyroidectomies from a remote site in the axilla (armpit). The precision, exposure and visualization achieved with the *da Vinci* Surgical System enables an endoscopic technique that is accessible to a broader set of surgeons. With *da Vinci* Thyroidectomy, surgeons are now able to offer their patients a procedure with no neck scar while maintaining the outcomes of open surgery for cancer control, voice preservation and calcium blood levels.

Table of Contents

Head and Neck Surgery

Transoral Surgery. Head and neck cancer, which most often occurs in the throat due to prolonged tobacco and alcohol use, is treated by surgical resection or chemoradiation. Surgical resection is performed most often by an open approach, which at times requires a jaw-splitting mandibulotomy. This procedure, while effective in treating cancer, is traumatic and disfiguring to the patient and requires extensive recovery and rehabilitation. Minimally invasive approaches via the mouth (transoral surgery) have seen little adoption due to a high degree of difficulty and line-of-sight limitations of conventional endoscopic tools. While chemoradiation does allow patients to avoid traumatic surgical incisions, literature suggests that this modality diminishes patients' ability to speak and swallow normally. *da Vinci* Transoral Surgery, on the other hand, allows surgeons to treat cancers occurring in the oropharynx (e.g., tonsil and base of tongue) and larynx via the mouth. The *da Vinci* Surgical System extends the ability to resect tumors transorally, avoiding in many cases an open approach via mandibulotomy. We believe that *da Vinci* Transoral Surgery provides a more precise platform for complete resection of cancers of the oral cavity and maximizes the preservation of healthy tissue to maintain normal speech and swallowing function resulting in reduced length of hospital stay and time in which the patient requires a feeding tube.

Additional Clinical Applications

We believe there are numerous additional applications that can be addressed with the *da Vinci* Surgical System. Surgeons using the *da Vinci* Surgical System have performed nearly 100 different types of surgery throughout the world.

Sales and Customer Support

We market our products through a direct sales force in the United States and parts of Europe. We also market our products outside the United States through distributors. Our direct sales force is comprised of sales managers, clinical sales representatives, training specialists, and technical service representatives. Sales activities include educating surgeons and hospital staff across multiple surgical specialties on the advantages of *da Vinci* surgery and the clinical applications that our technology enables. We also train our sales force to educate hospital management on the potential benefits of adopting our technology, including clinical benefits of *da Vinci* Surgery, reductions in complications and length of stay and the resulting potential for increased patient satisfaction and volume. Once a hospital has installed a *da Vinci* Surgical System, our clinical sales representatives help drive the utilization of the system, and our technical service representatives provide service and maintenance for the system. No one customer accounted for more than 10% of revenue during the years ended December 31, 2009, 2008 and 2007.

As of December 31, 2009, we had approximately 490 employees in our field sales and service organizations, up from approximately 380 employees in these organizations as of December 31, 2008. We expect to continue growing these organizations as we expand our business.

Our *da Vinci* Surgical System typically has a lengthy sales cycle. It is viewed as a major capital equipment purchase by our customers and sales are often affected by the timing of their budgeting cycles. Our sales of *da Vinci* Surgical Systems tends to be heaviest during the third month of each quarter. A portion of our customers acquire *da Vinci* Surgical Systems through a capital lease or operating lease with a third-party leasing company. In these instances, we typically sell the *da Vinci* System to the hospital or leasing company, and the hospital enters into an independent arrangement with the leasing company. Therefore we treat these leasing transactions the same as sales transactions for purposes of recognizing revenue for the sale. During the twelve months ended December 31, 2009, approximately 15% of our *da Vinci* System sales involved a lease.

Our sales of *EndoWrist* instruments and accessories are driven by surgical procedures performed on installed systems. Our customers place orders to replenish their supplies of *EndoWrist* instruments and accessories on a regular basis. Orders received are typically shipped within one business day. Direct customers who purchase a new *da Vinci* System typically place an initial stocking order of *EndoWrist* instruments and accessories within one month of receiving their system.

Table of Contents

Our business is subject to seasonal fluctuations. During our fiscal third quarter, which are the three months ending September 30 each year, many physicians, hospital administrators, and patients take vacation, and we tend to see a reduction in surgical procedures performed, particularly in Europe. During our fiscal fourth quarter, which are the three months ending December 31 each year, we tend to see our strongest performance in sales of *da Vinci* Surgical Systems.

Customer Support and Training Programs

Our goal is to provide exceptional value to our customers: patients, surgeons and hospitals. We have a network of field service engineers across the United States, Europe and Asia and maintain relationships with various distributors around the globe. This infrastructure of service and support specialists offer a full complement of services, including 24/7 support, installation, repair and maintenance for our customers.

We generate service revenue by providing these services to our customers through comprehensive service contracts and time and material programs.

We provide basic system training to surgeons and operating room nurses that teaches the fundamental operating principles of the *da Vinci* Surgical System. We have established training centers where initial system training and ongoing surgical procedural training are provided, the latter by expert surgeons. In addition, we facilitate the proctoring of surgeons who are new to *da Vinci* Surgery by experienced *da Vinci* System users. Proctors provide training to other surgeons on how to perform certain surgical procedures with the *da Vinci* System.

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 improved and innovative surgical procedures with less difficulty. We maintain research and development and engineering staff responsible for product design and engineering. We invested \$95.1 million, \$79.4 million and \$48.9 million of research and development expenses for the years ended December 31, 2009, 2008 and 2007, respectively. This investment is applied generally to all product areas, with specific areas of focus being identified from time to time.

We establish strategic alliances with other medical device companies to complement our research and development effort. To date, these alliances have taken several forms, including cooperation in the areas of product development, training, and procedure development and marketing activities. We have formed alliances with several companies, including, but not limited to, Covidien Ltd., Johns Hopkins University, Johnson & Johnson, Luna Innovations, Inc., Medtronic, Inc., Novadaq Technologies, Inc., Olympus Corporation and USGI Medical, Inc.

Manufacturing

We manufacture our *da Vinci* Surgical Systems at our facility in Sunnyvale, California. We manufacture our *Endowrist* instruments at our Sunnyvale facility and at our Mexicali, Mexico facility. We began production in Mexicali in July 2008.

We purchase both custom and off-the-shelf components from a large number of suppliers and subject them to stringent quality specifications. Some of the components necessary for the assembly of our products are currently provided to us by sole-sourced suppliers (the only recognized supply source available to us) or single-sourced suppliers (the only approved supply source for us among other sources). We purchase components through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of finished goods.

Table of Contents

Competition

We consider our primary competition to be existing open surgery, conventional MIS, drug therapies, radiation treatment and emerging interventional surgical approaches. Our success depends on continued clinical and technical innovation, quality and reliability as well as educating hospitals, surgeons and patients on the demonstrated benefits associated with *da Vinci* surgery and its superiority to other techniques. We also face competition from several companies that are developing new approaches and products for the MIS market. While a few of these potential competitors are seeking to incorporate robotics into their product offerings, most are focused on adding capability to manual MIS systems. 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 number of companies are using or planning to use robots and computers in surgery, including Hitachi Ltd., Prosurge, Inc., EndoControls, Inc., Olympus, Alf-X, Titan Medical, and Toshiba, Inc. Any company with substantial experience in industrial robotics could potentially expand into the field of surgical robotics and become a competitor. Our revenues may be adversely impacted if our competitors develop and introduce products that compete in our markets.

Intellectual Property

We place considerable importance on obtaining and maintaining patent, copyright and trade secret protection for significant new technologies, products and processes.

We generally rely upon a combination of patents, copyrights, trademarks, trade secret and other laws (e.g., contractual restrictions on disclosure, copying and transferring title, including confidentiality agreements with vendors, strategic partners, co-developers, employees, consultants and other third parties) to protect our proprietary rights in the developments, improvements and inventions that we have originated and which are incorporated in our products or that fall within our fields of interest. We also have agreements with third parties that provide for several exclusive and non-exclusive licenses to their patents.

As of December 31, 2009, we held exclusive field-of-use as well as non-exclusive licenses for over 290 U.S. patents and over 300 foreign patents, and owned outright over 170 U.S. patents and over 80 foreign patents. We also own or have licensed numerous pending U.S. 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.

While our patents are an important element of our success, our business as a whole is not significantly dependent on any one patent. We have trademarks, both registered and unregistered, that are maintained and enforced to provide customer recognition for our products in the marketplace.

Government Regulation

United States

Our products and operations are subject to extensive and rigorous regulation by the FDA. The FDA regulates the development, 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 FFDC, 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.

Table of Contents

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 a statutory 90-day period 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.

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. Compliance with the QSR is necessary to receive FDA 510(k) clearance or approval to market new products and is necessary for a manufacturer to be able to continue to market cleared or approved product offerings. Among other things, these regulations require that manufacturers establish performance requirements before production. A company's facility, records, and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA, which may issue reports known as Form FDA 483 reports (listing instances where the manufacturer has failed to comply with applicable regulations and/or procedures), or Warning Letters which, if not adequately responded to, could lead to enforcement actions against the manufacturer, including fines and total shutdown of production facilities and criminal prosecution. Inspections usually occur every two years. Our last inspection occurred in April 2008 and the FDA issued a Form FDA 483 listing deficiencies under the QSR relating to complaint handling and supplier management. We later responded to each observation with proposed corrective actions. However, we cannot assure that, upon re-inspection, the FDA will find that our corrective actions are appropriate or that they have been adequately implemented. We also cannot assure that the FDA will not find other deficiencies in our compliance with the QSR and other postmarket regulations. We believe our quality systems are functioning properly and we continue to work with the FDA and agencies worldwide to satisfy their reporting requirements.

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

QSR, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process;

labeling regulations;

Table of Contents

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 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 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:

fining, 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.

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 last inspected in 2008 and were found to be in compliance. In accordance with the California State regulations, the license to manufacture is renewed annually with any updated manufacturing information.

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.

To be sold in Japan, most medical devices must undergo thorough safety examinations and demonstrate medical efficacy before they are granted approval, or Shonin. In November 2009, we received Shonin approval from the Japanese Ministry of Health, Labor, and Welfare, or MHLW, for our *da Vinci S* System in Japan. With this approval, we are now focusing on meeting various trade and importation requirements necessary for commercialization and to obtain appropriate reimbursement rates for several *da Vinci* procedures in Japan. We have a separate independent distribution partner in Japan who will be responsible for selling, marketing, and servicing Intuitive's products in Japan.

Commercialization of medical devices in Europe is regulated by the European Union (EU). The EU presently requires that all medical products bear the Conformance Europeene, or CE mark for compliance with the Medical Device Directive (93/42/EEC). The CE mark is an international symbol of adherence to certain essential principles of safety and effectiveness mandated in applicable European medical device directives, which

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

once affixed, enables a product to be sold in member countries of the EU. The CE mark is also recognized in many countries outside of the EU, such as Australia, and can assist in the clearance process. 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. We have received permission from DGM, our

Table of Contents

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 December 2010. The most recent audit of the facility was in November 2009, and the facility was found to be in compliance.

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. 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 EU.

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 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 medically necessary. 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 issued by the American Medical Association are copyrighted Current Procedural Terminology, or CPT, codes. In addition, CMS issues ICD-9-CM codes and reimburses hospitals by Diagnostic Related Groupings, or DRGs and Ambulatory Payment Classifications, or APCs. If a new procedure CPT code and/or reimbursement designation is required, an application would need to be submitted to the American Medical Association or CMS.

On October 1, 2008, CMS issued a new family of ICD-9-CM procedure codes for "Robotically Assisted Procedures". For laparoscopic procedures completed with the *da Vinci* System, U.S. hospitals are expected to report the primary surgical procedure code, along with ICD-9-CM 17.42, to describe a laparoscopic robotic assisted procedure. The purpose of the ICD-9-CM family of procedure codes, 17.4X, is to gather data on robotic assisted surgical procedures. It does not influence the MS-DRG assignment. A surgical procedure, completed with or without robotic assistance, continues to be assigned to the clinically relevant MS-DRG.

Governments and insurance companies carefully review and increasingly challenge the prices charged for medical products and surgical 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 both inpatient and outpatient surgical services, and reimburses physicians a prospectively determined fixed amount based on the professional service rendered. 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 products 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 for the primary surgical procedure that includes 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

Table of Contents

FDA, Medicare reimbursement is available for the primary surgical procedure that uses our 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 established surgical procedures that 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 need to seek a unique Current Procedural Terminology code for robotic-assisted surgery from the American Medical Association and/or a reimbursement adjustment from CMS. If an application for a unique code or modifier 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. In Japan, we intend to seek reimbursement approvals from the government for procedures performed with our products. The timing of these approvals can vary significantly, and could significantly impact our ability to commercialize our products in Japan. In some countries patients may be permitted to pay directly for surgical services. However, such co-pay practices are not common in countries such as Japan.

The U. S. government has in the past considered, is currently considering and may in the future, consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect both private and public reimbursement for healthcare services. State and local governments, as well as a number of foreign governments, are also considering or have adopted similar types of policies. While we believe that minimally invasive surgery using *da Vinci* Surgical Systems reduces healthcare costs, future significant changes in the healthcare systems in the United States or elsewhere, and current uncertainty about whether and how changes may be implemented, could have a negative impact on the demand for our products and services and our business. These include changes that may reduce reimbursement rates for procedures using our products and/or potential fees assessed on revenues generated by medical device companies that may be proposed or implemented by the current U.S. Presidential administration or Congress. It is unclear which, if any, of the various U.S. healthcare reforms currently being discussed and/or proposed might be enacted by the U.S. Congress and signed into law by the President.

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, 2009, we had 1,263 employees, 180 of whom were engaged directly in research and development, 403 in manufacturing and service and 680 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, including our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, our Code of Business Conduct and Ethics Policy and any

Table of Contents

amendments to those reports, free of charge, on our website as soon as practicable after such material is electronically filed or furnished with the Securities and Exchange Commission. Our website address is www.intuitivesurgical.com and the reports are filed under SEC Filings, on the Company Investor Relations portion of our website. We periodically webcast company announcements, product launch events and executive presentations which can be viewed via our Investor Relations web site. Additionally, we provide notifications of our material news including SEC filings, investor events, and press releases as part of our Investor Relations web site. The contents of these web sites are not intended to be incorporated by reference into this report or in any other report or document we file and any references to these web sites are intended to be inactive textual references only.

Table of Contents

ITEM 1A. RISK FACTORS

RISKS RELATING TO OUR BUSINESS

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 System and our other products represent a fundamentally new way of performing surgery. Achieving physician, patient and third-party payor acceptance of *da Vinci* 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 to use our products for any number of other reasons. For example, cardiologists may continue to recommend conventional 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, particularly in light of ongoing health care reform initiatives.

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.

ECONOMIC CONDITIONS COULD MATERIALLY ADVERSELY AFFECT OUR COMPANY.

During 2009 and 2008, the global economy experienced a severe downturn due to the sequential effects of the subprime lending crisis, the credit market crisis, collateral effects on the finance and banking industries, volatile currency exchange rates and energy costs, concerns about inflation, slower economic activity, decreased consumer confidence, reduced corporate profits and capital spending, adverse business conditions and liquidity concerns. Uncertainty about current global economic conditions pose a risk as customers may postpone spending in response to tighter credit and negative financial news, which could have a material negative effect on demand for our products. During 2009, the world-wide economic recession curtailed hospital demand for capital purchases of our *da Vinci* Surgical Systems. Although demand for our *da Vinci* Surgical Systems improved towards the end of 2009, there can be no assurance that it will continue to improve. In addition, there could be other follow-on effects from the credit crisis on our business, including the insolvency of key suppliers or their inability to obtain credit to finance development and/or manufacture products resulting in product delays and inability of customers, including distributors, to obtain credit to finance purchases of our products. If conditions become more severe or continue longer than we anticipate, our forecasted demand may not materialize to the levels we require to achieve our anticipated financial results, which could in turn have a material adverse effect on our revenue, profitability and the market price of our stock.

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

da Vinci surgery is a new technology that competes with established and emerging treatment options in both disease management and reconstructive medical procedures. These competitive treatment options include conventional MIS, 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,

Table of Contents

which could render our products obsolete or unmarketable. Studies could be published that show that other treatment options are more beneficial and/or cost-effective than *da Vinci* surgery. We cannot be certain that physicians will use our products to replace or supplement established treatments or that our products will continue to be competitive with current or future technologies.

In addition, we may face competition from companies that develop wristed, robotic or computer-assisted surgical systems and products 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.

NEW PRODUCT INTRODUCTIONS MAY ADVERSELY IMPACT OUR FINANCIAL RESULTS.

We introduce new products with enhanced features and extended capabilities from time to time. Our products are subject to various regulatory processes, and we must obtain and maintain regulatory approvals in order to sell our new products. If a potential purchaser believes that we plan to introduce a new product in the near future or if a potential purchaser is located in a country where a new product that we have introduced has not yet received regulatory approval, planned purchases may be deferred or delayed. As a result, new product introductions may adversely impact our financial results.

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. Our sales of *da Vinci* Surgical Systems tend to be heaviest during the third month of each fiscal quarter. These factors may contribute to substantial fluctuations in our quarterly operating results. 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. In addition, the introduction of new products could adversely impact our sales cycle, as customers take additional time to assess the benefits and costs of such products.

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 part on our activities in Europe and other foreign markets. Revenue from markets outside of the United States accounted for approximately 21%, 22%, and 22% of our revenue for the years ended December 31, 2009, 2008 and 2007, 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 rights;

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 fluctuations;

the expense of establishing facilities and operations in new foreign markets; and

building an organization capable of supporting geographically dispersed operations.

Table of Contents

A large portion 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 and/or less affordable 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.

WE UTILIZE DISTRIBUTORS FOR A PORTION OF OUR SALES, THE LOSS OF WHICH COULD HARM OUR REVENUES IN THE TERRITORY SERVICED BY THESE DISTRIBUTORS.

We have strategic relationships with a number of key distributors for sales and service of our products, in certain foreign countries. If these strategic relationships are terminated and not replaced, our revenues and/or ability to service our products in the territories serviced by these distributors could be adversely affected.

WE MAY INCUR LOSSES ASSOCIATED WITH CURRENCY FLUCTUATIONS AND MAY NOT BE ABLE TO EFFECTIVELY HEDGE OUR EXPOSURE.

Our operating results are subject to fluctuations in foreign currency exchange rates. We attempt to mitigate a portion of these risks through foreign currency hedging, based on our judgment of the appropriate trade-offs among risk, opportunity and expense. We have established a hedging program to partially hedge our exposure to foreign currency exchange rate fluctuations primarily for the Euro and the British Pound. We regularly review our hedging program and make adjustments as necessary based on our assessment of the relevant risks, opportunities and expenses. Our hedging activities may not offset more than a portion of the adverse financial impact resulting from unfavorable movement in foreign currency exchange rates, which could adversely affect our financial condition or results of operations.

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, optical 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 that our products will not experience component aging, 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;

regulatory actions;

increased service or warranty costs; or

product liability claims.

Table of Contents

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. Any weaknesses in training and services associated with our products may also be subject to product liability lawsuits. 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.

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

Manufacturing our products is a complex process. 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.

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-sourced suppliers or single-sourced suppliers. We purchase components through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of inventory. 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. 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 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

Table of Contents

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 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. Please see our risk factor below titled Healthcare Reforms, Changes in Healthcare Policies and Changes to Third-Party Reimbursements May Affect Demand for Our Products for additional risks related to the ability of institutions or surgeons to obtain reimbursements.

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.

NATURAL OR OTHER DISASTERS COULD DISRUPT OUR BUSINESS AND RESULT IN LOSS OF REVENUE OR IN HIGHER EXPENSES.

Natural disasters, terrorist activities and other business disruptions could seriously harm our revenue and financial condition and increase our costs and expenses. Our corporate headquarters and many of our operations are located in California, a seismically active region. A natural disaster in any of our major markets in North America or Europe could have a material adverse impact on our operations, operating results and financial condition. Further, any unanticipated business disruption caused by Internet security threats, damage to global communication networks or otherwise could have a material adverse impact on our operating results.

CHANGES TO FINANCIAL ACCOUNTING STANDARDS MAY AFFECT OUR REPORTED RESULTS OF OPERATIONS.

A change in accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing standards or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business.

OUR RESULTS OF OPERATIONS COULD VARY AS A RESULT OF THE METHODS, ESTIMATES, AND JUDGMENTS WE USE IN APPLYING OUR ACCOUNTING POLICIES.

The methods, estimates, and judgments we use in applying our accounting policies have a significant impact on our results of operations. Such methods, estimates, and judgments are, by their nature, subject to substantial risks, uncertainties, and assumptions, and factors may arise over time that lead us to change our methods, estimates, and judgments. Changes in any of our assumptions may adversely affect our reported financial results.

Table of Contents

CHANGES IN OUR EFFECTIVE TAX RATE MAY HARM OUR RESULTS OF OPERATIONS

A number of factors may harm our future effective tax rates including:

the jurisdictions in which profits are determined to be earned and taxed;

the resolution of issues arising from tax audits with various tax authorities;

changes in valuation of our deferred tax assets and liabilities;

increases in expenses not deductible for tax purposes, including write-offs of acquired intangibles and impairment of goodwill in connection with acquisitions;

changes in available tax credits;

changes in share-based compensation;

changes in tax laws or the interpretation of such tax laws and changes in generally accepted accounting principles; and

the repatriation of non-U.S. earnings for which we have not previously provided for U.S. taxes.

Any significant increase in our future effective tax rates could harm net income for future periods.

WE MAY REALIZE LOSSES ON OUR INVESTMENTS IN AUCTION RATE SECURITIES OR BE UNABLE TO LIQUIDATE THESE INVESTMENTS AT DESIRED TIMES AND IN DESIRED AMOUNTS.

At December 31, 2009, we held \$81.3 million in auction rate securities (ARS), whose underlying assets are student loans which are substantially backed by the federal government. Since the auctions for these securities have continued to fail since February 2008, these investments are not currently trading and therefore do not have a readily determinable market value. Accordingly, the estimated fair value of the ARS no longer approximates par value. A large portion of these ARS are held by UBS AG (UBS), one of our investment providers. In November 2008, we accepted an offer (the "Right") from UBS entitling us to sell at par value auction-rate securities originally purchased from UBS (approximately \$69.9 million, par value) at any time during a two-year period from June 30, 2010 through July 2, 2012. If the Right is not exercised before July 2, 2012, it will expire and UBS will have no further rights or obligation to buy our ARS. We intend to exercise the Right from UBS on June 30, 2010 and as a result have classified these ARS as short-term investments as of December 31, 2009. If UBS has insufficient funding to buy back the ARS and the auction process continues to fail, then we may incur further losses on the carrying value of the ARS.

The remaining ARS (approximately \$23.5 million, par value) are held by another investment advisor, who has not made an offer similar to UBS and we have continued to classify them as available-for-sale securities. Accordingly, changes in associated market value during the year ended December 31, 2009 have been recorded through other comprehensive income. If the market conditions deteriorate further, we may be required to record additional unrealized losses in other comprehensive income or impairment charges. We may not be able to liquidate these investments unless the issuer calls the security, a successful auction occurs, a buyer is found outside of the auction process, or the security matures.

DISRUPTION OF CRITICAL INFORMATION SYSTEMS COULD HARM OUR BUSINESS AND FINANCIAL CONDITION.

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

Information technology helps us operate efficiently, interface with customers, maintain financial accuracy and efficiency, and accurately produce our financial statements. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology infrastructure, we could be subject to transaction errors, processing inefficiencies, the loss of customers, business disruptions, or the loss of or damage to intellectual property through security breach. If our data management systems do not effectively collect, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, or human error, our ability to effectively plan, forecast and execute our

Table of Contents

business plan and comply with applicable laws and regulations will be impaired, perhaps materially. Any such impairment could materially and adversely affect our financial condition, results of operations, cash flows and the timeliness with which we report our internal and external operating results.

RISKS RELATING TO OUR REGULATORY ENVIRONMENT

HEALTHCARE REFORMS, CHANGES IN HEALTHCARE POLICIES AND CHANGES TO THIRD-PARTY REIMBURSEMENTS MAY AFFECT DEMAND FOR OUR PRODUCTS.

The U. S. government has in the past considered, is currently considering and may in the future, consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect both private and public reimbursement for healthcare services. State and local governments, as well as a number of foreign governments, are also considering or have adopted similar types of policies. While we believe that minimally invasive surgery using *da Vinci* Surgical Systems reduces healthcare costs, future significant changes in the healthcare systems in the United States or elsewhere, and current uncertainty about whether and how changes may be implemented, could have a negative impact on the demand for our products and services and our business. These include changes that may reduce reimbursement rates for procedures using our products and/or potential fees assessed on revenues generated by medical device companies that may be proposed or implemented by the current U.S. Presidential administration or Congress. It is unclear which, if any, of the various U.S. healthcare reforms currently being discussed and/or proposed might be enacted by the U.S. Congress and signed into law by the President. We are unable to predict what healthcare reform legislation or regulations, if any, will be enacted in the United States or elsewhere; whether other healthcare legislation or regulations affecting our business may be proposed or enacted in the future; what effect any legislation or regulation would have on our business; or the effect ongoing uncertainty about these matters will have on the purchasing decisions of our customers.

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

The Medicare and Medicaid anti-kickback laws, and several similar state laws, prohibit payments or other remuneration that is intended to induce hospitals, physicians or other potential purchasers of our products either to refer patients or to purchase, lease or order, or arrange for or recommend the purchase, lease or order of healthcare products or services for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid. These laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements we may have with hospitals, physicians or other potential purchasers of our products. They particularly impact how we structure our sales offerings, including discount practices, customer support, education and training programs, physician consulting and other service arrangements. These laws are broadly written, and it is often difficult to determine precisely how these laws will be applied to specific circumstances. Violating anti-kickback laws can result in civil and criminal penalties, which can be substantial and include potential exclusion from healthcare programs for noncompliance. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to defend, and thus could harm our business and results of operations. Additionally, several bills have been passed or are pending, at both the state and federal levels that expand anti-kickback laws, to require, among other things, extensive tracking and maintenance of databases regarding relationships and payments to physicians and healthcare providers. The implementation of the infrastructure to comply with these bills could be quite costly.

Table of Contents

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 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 FFDCA. 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 United States. 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 United States 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.

Table of Contents

COMPLYING WITH FDA REGULATIONS IS A COMPLEX PROCESS, AND OUR FAILURE TO COMPLY FULLY COULD SUBJECT US TO SIGNIFICANT ENFORCEMENT ACTIONS.

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 highlight specific procedures that we believe are within the scope of our existing 510(k) clearances. We cannot assure 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 that the FDA would agree with our determinations not to seek new 510(k) clearance for any of these changes. Computer Motion, which we acquired in 2003, also modified the hardware and software in its products subsequent to 510(k) clearance without seeking new clearance. 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.

Our last inspection occurred in April 2008 and the FDA issued a Form FDA 483 listing deficiencies under the QSR relating to complaint handling and supplier management. We later responded to each observation with proposed corrective actions. However, we cannot assure that, upon re-inspection, the FDA will find that our corrective actions are appropriate or that they have been adequately implemented. We also cannot assure that the FDA will not find other deficiencies in our compliance with the QSR and other postmarket regulations.

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 complex, 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 or maintain regulatory approval in any foreign country in which we plan to market our products, our ability to generate revenue will be harmed.

Table of Contents

The EU 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 EU. 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.

As we modify existing products or develop new products in the future, including new instruments, we 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 EU, which would have a material adverse effect on our results of operations.

In November 2009, we received Shonin approval from the Japanese MHLW for our *da Vinci S* System and certain of our instruments and accessories for use in certain *da Vinci* surgical procedures. We may seek additional approvals for other products and/or procedures, however, there can be no assurance that such approvals will be granted. In addition, given that only a subset of our instruments have been approved it is possible, depending on surgeon preference, that approved procedures will be adopted slowly or not at all. We are currently focusing efforts on meeting various trade and importation requirements necessary for commercialization and determining the appropriate reimbursement strategy for *da Vinci* procedures in Japan. Sales of our products depend, in part, on the extent to which the costs of our products are reimbursed by governmental health administration authorities. If we are not successful in obtaining the necessary reimbursement approvals or obtaining approvals for future products and procedures, then the demand for our products could be limited. These limitations could eliminate a significant market opportunity for our products in Japan.

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 WOULD 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 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. Our last inspection occurred in April 2008 and the FDA issued a Form FDA 483 listing deficiencies under the QSR relating to complaint handling and supplier management. We later responded to each observation with proposed corrective actions. However, we cannot assure that, upon re-inspection, the FDA will find that our corrective actions are appropriate or that they have been adequately implemented. 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.

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, which would have a material adverse effect on our results of operations.

Table of Contents

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

IF WE ARE UNABLE TO REPLACE OUR EXPIRING PATENTS, OUR ABILITY TO COMPETE IN THE MARKET WILL BE HARMED.

Some of our patents will begin to expire in 2012. While we will continue to work to add to our patent portfolio to protect the intellectual property contained in our products, we believe new competitors will emerge in medical robotics. We do not know whether we will have the patent protection we need, or whether the protection we do have 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.

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. Furthermore, the laws of certain foreign countries do not protect intellectual property rights to the same extent, as do the laws of the United States.

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 these measures do not protect our rights adequately, third parties could use our technology, and our ability to compete in the market would be reduced. 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, which would harm our ability to compete in the market.

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

Table of Contents

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 that a court or administrative body would agree with any arguments or defenses we may have concerning invalidity, unenforceability or non-infringement 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 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.

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 several industry partners. Any of these agreements may be terminated for breach. If any of these agreements are 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, which would have a material adverse effect on our results of operations.

RISKS RELATING TO OUR TRADING MARKETS

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. Our products typically have a lengthy sales cycle. 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;

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;

Table of Contents

product quality and supply 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.

OUR STOCK PRICE HAS BEEN, AND WILL LIKELY CONTINUE TO BE, VOLATILE.

The market price of our common stock has experienced fluctuations and is likely to fluctuate significantly in the future. For example, during fiscal 2009, the NASDAQ closing price of one share of our common stock reached a high of \$306.58 and a low of \$85.33. Our stock price can fluctuate for a number of reasons, including:

announcements about us or our competitors;

quarterly variations in operating results;

introduction or abandonment of new technologies or products;

regulatory approvals;

changes in product pricing policies;

changes in earnings estimates by analysts or changes in accounting policies;

economic changes and overall market volatility; and

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

political uncertainties.

In addition, stock markets have experienced significant price and volume volatility in the past, especially recently. This volatility has had a substantial effect on the market prices of securities of many public companies for reasons frequently unrelated or disproportionate to the operating performance of the specific companies. In addition, the securities of many medical device companies, including Intuitive Surgical, have historically been subject to extensive price and volume fluctuations that may affect the market price of their common stock. If these broad market fluctuations continue, they may adversely affect the market price of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of December 31, 2009, we owned approximately 394,000 square feet of space on 33 acres of land in Sunnyvale, California, where we house our headquarters, research and development, service, and support functions, and certain of our manufacturing operations. We lease 18,000 square feet of space in Sunnyvale, California for logistics and inventory, approximately 5,000 square feet of space for research and development in Milford, Connecticut, approximately 5,000 square feet of space for our international headquarters in Aubonne,

Table of Contents

Switzerland and a 34,000 square-foot building in Mexicali, Mexico where we manufacture most of our *Endowrist* instruments. In addition, a 158,000 square-foot multi-use building is currently under construction on the land we purchased in Sunnyvale, California in October 2007. We expect to complete construction by 2011.

ITEM 3. LEGAL PROCEEDINGS

We are involved in various legal proceedings and disputes that arise in the normal course of business. These matters include product liability actions, patent infringement actions, contract disputes, and other matters. 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. Based on currently available information, we believe that we have meritorious defenses to these actions and that the resolution of these cases is not likely to have a material adverse effect on our business, financial position or future results of operations. In accordance with generally accepted accounting principles in the United States (U.S. GAAP), 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, 2009.

Table of Contents**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 is being traded on The NASDAQ Global Select Market under the symbol ISRG. The following table sets forth the high and low closing prices of our common stock for each period indicated and are as reported by NASDAQ.

Fiscal	2009		2008	
	High	Low	High	Low
First Quarter	\$ 132.41	\$ 85.33	\$ 327.24	\$ 235.00
Second Quarter	\$ 166.52	\$ 94.33	\$ 353.88	\$ 265.92
Third Quarter	\$ 262.25	\$ 142.60	\$ 331.13	\$ 240.98
Fourth Quarter	\$ 306.58	\$ 246.35	\$ 236.55	\$ 111.74

As of January 21, 2010, there were 319 stockholders of record of our common stock, although we believe that there are 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 in the foreseeable future.

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The following table contains information as of December 31, 2009 for two categories of equity compensation plans. All of the equity compensation plans of the Company have been approved by security holders.

Plan Category	Number of securities to be issued upon exercise of outstanding options, and rights (a)	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	4,592,656	\$ 157.25	9,457,849
Equity compensation plans not approved by security holders		\$	
Total	4,592,656	\$ 157.25	9,457,849

RECENT SALE OF UNREGISTERED SECURITIES

None.

ISSUER PURCHASES OF EQUITY SECURITIES

On March 4, 2009, we announced that the Board of Directors had authorized the repurchase of up to \$300.0 million of our common stock. In March 2009, we repurchased 1.4 million shares of our common stock for \$150.0 million. During the fourth quarter ended December 31, 2009,

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

we did not repurchase any shares of common stock and had \$150.0 million remaining under this publicly announced program. See Note 8 of our Notes to Consolidated Financial Statements for information regarding our stock repurchase program.

Table of Contents

STOCK PERFORMANCE GRAPH

The graph set forth below compares the cumulative total stockholder return on our common stock between December 31, 2004 and December 31, 2009, with the cumulative total return of (i) the S&P Healthcare Index, (ii) the Nasdaq Composite Index and (iii) the S&P 500 Index, over the same period. This graph assumes the investment of \$100.00 on December 31, 2004 in our common stock, the S&P Healthcare Index, the Nasdaq Composite Index, and the S&P 500 Index and assumes the reinvestment of dividends, if any. We included the comparison with the S&P 500 Index because our Company became a component of the S&P 500 Index on June 2, 2008.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.

	12/31/04	12/31/05	12/31/06	12/31/07	12/31/08	12/31/2009
Intuitive Surgical, Inc.	100.00	293.03	239.63	807.10	317.32	758.20
NASDAQ Composite	100.00	101.37	111.03	121.92	72.49	104.31
S&P Healthcare Index	100.00	104.85	110.92	116.90	88.28	103.35
S&P 500 Index	100.00	103.00	117.03	121.16	74.53	92.01

Table of Contents**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,				
	2009	2008	2007	2006	2005
	(In thousands, except per share amounts and headcount)				
Revenue	\$ 1,052,168	\$ 874,919	\$ 600,828	\$ 372,682	\$ 227,338
Gross profit	\$ 751,052	\$ 620,777	\$ 414,286	\$ 247,836	\$ 153,569
Net income	\$ 232,606(1)	\$ 204,315(1)	\$ 144,537(1)	\$ 72,044(1)(2)	\$ 94,134(2)
Net income per common share:					
Basic	\$ 6.07	\$ 5.26	\$ 3.82	\$ 1.96	\$ 2.68
Diluted	\$ 5.93	\$ 5.12	\$ 3.70	\$ 1.89	\$ 2.51
Shares used in computing basic and diluted net income per common share:					
Basic	38,298	38,877	37,831	36,737	35,070
Diluted	39,205	39,943	39,021	38,093	37,488
Cash, cash equivalents and investments	\$ 1,171,980	\$ 901,873	\$ 635,381	\$ 330,296	\$ 202,739
Total assets	\$ 1,809,716	\$ 1,474,624	\$ 1,039,998	\$ 671,790	\$ 501,587
Long-term liabilities	\$ 69,665	\$ 43,342	\$ 19,554	\$ 1,418	\$ 1,009
Shareholders' equity	\$ 1,537,283	\$ 1,266,766	\$ 888,674	\$ 589,705	\$ 442,591
Total headcount	1,263	1,049	764	563	419

- (1) Net income for the years ended December 31, 2009, 2008, 2007, and 2006 included stock-based compensation expense under U.S. GAAP of \$70.5 million, \$53.4 million, \$23.6 million, and \$16.3 million, net of tax, related to employee stock options and employee stock purchases. Prior to fiscal 2006, there was no stock-based compensation expense related to employee stock options and employee stock purchases under then-current U.S. GAAP. Net income for the years ended December 31, 2009, 2008, 2007, 2006, and 2005 included amortization of purchased intellectual property of \$15.1 million, \$9.8 million, \$1.3 million, \$0.8 million and \$0.3 million, respectively.
- (2) Net income for the year ended December 31, 2005 included a deferred tax benefit of \$22.2 million related to the reversal of the valuation allowance. During 2006, we began reporting income taxes on a fully-taxed basis.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**Overview****2009 Business Events and Trends**

Products. We design, manufacture and market *da Vinci* Surgical Systems, which are advanced surgical systems that we believe represent a new generation of surgery. We believe that this new generation of surgery, which we call *da Vinci* surgery, is a significant advancement similar in scope to previous generations of surgery—open surgery and minimally invasive surgery, or conventional MIS. The *da Vinci* Surgical System consists of a surgeon's console, or consoles, a patient-side cart and a high performance vision system. The *da Vinci* Surgical System translates the surgeon's natural hand movements performed on instrument controls at a console into corresponding micro-movements of instruments positioned inside the patient through small incisions, or ports. We believe that the *da Vinci* Surgical System provides the surgeon with intuitive control,

Table of Contents

range of motion, fine tissue manipulation capability and high definition 3-D vision, while simultaneously allowing the surgeons to work through the small ports of MIS. By placing computer-enhanced technology between the surgeon and the patient, we believe that the *da Vinci* Surgical System enables surgeons to improve clinical outcomes while reducing the invasiveness of complex surgical procedures.

Business Model. In our business model, we generate revenue from both the initial capital sales of *da Vinci* Surgical Systems as well as recurring revenue, derived from sales of instruments, accessories, and service revenue. The *da Vinci* Surgical System generally sells for \$1.0 million to \$2.3 million, depending on configuration, and represents a significant capital equipment investment for our customers. We then generate recurring revenue as our customers purchase our *EndoWrist* instruments and accessory products for use in performing procedures with the *da Vinci* Surgical System. *EndoWrist* instruments and accessories will either expire or wear out as they are used in surgery and will need to be replaced as they are consumed. We generate additional recurring revenue from ongoing system service. We typically enter into service contracts at the time the system is sold. These service contracts have been generally renewable at the end of the service period, typically at an annual rate of approximately \$100,000 to \$180,000 per year, depending on the configuration of the underlying system.

Since the introduction of the *da Vinci* Surgical System in 1999, robotic surgery volume has increased and our established base of *da Vinci* Surgical Systems has grown. Recurring revenue has grown at an equal or faster rate than system revenue. Recurring revenue increased from \$276.4 million, or 46% of total revenue in 2007 to \$419.6 million, or 48% of total revenue in 2008 to \$561.7 million, or 53% of total revenue in 2009. The increase in recurring revenue relative to system revenue reflects continuing adoption of procedures on a growing base of installed *da Vinci* Surgical Systems. We expect recurring revenue to become a larger percentage of total revenue in the future. The installed base of *da Vinci* Surgical Systems has grown to 1,395 at December 31, 2009, compared with 1,111 at December 31, 2008 and 795 at December 31, 2007.

Regulatory Activities

We believe that we have obtained the clearances required to market our products to our targeted surgical specialties within the United States. As we make additions to target procedures, we will continue to seek the necessary clearances. The following table lists chronologically our FDA clearances to date:

July 2000	General laparoscopic procedures
March 2001	Non-cardiac thoracoscopic procedures
May 2001	Prostatectomy procedures
November 2002	Cardiotomy procedures
July 2004	Cardiac revascularization procedures
March 2005	Urologic surgical procedures
April 2005	Gynecologic surgical procedures
June 2005	Pediatric surgical procedures
December 2009	Transoral Otolaryngologic surgical procedures

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

In January 2006 we began selling the *da Vinci S* Surgical System in the United States and Europe. In March 2008 we received clearance in the United States to market our system-held cardiac stabilizer and permission to remove the warning in our labeling regarding system use in non-arrested heart procedures. During first quarter of 2009, we received clearance to market our *da Vinci Si* Surgical System in the United States and Europe.

In November 2009, we received regulatory (Shonin) approval from the Japanese Ministry of Health, Labor, and Welfare (MHLW) for our *da Vinci S* System in Japan. With this approval, we are now focusing on meeting

Table of Contents

various trade and importation requirements necessary for commercialization and to obtain appropriate reimbursement rates for *da Vinci* procedures in Japan. We have a separate independent distribution partner in Japan who will be responsible for marketing, selling, and servicing our products in Japan.

As of December 31, 2009, we had an installed base of 1,395 *da Vinci* Surgical Systems. During the year ended December 31, 2009 surgeons using our technology completed approximately 205,000 surgical procedures of various types in major hospitals throughout the world. Out of those *da Vinci* procedures performed in 2009, approximately 90,000 were *da Vinci* Prostatectomy (dVP) procedures and approximately 69,000 were *da Vinci* Hysterectomy (dVH) procedures.

2009 Business Events and Trends

Economic Environment. During 2009, the world-wide economic recession curtailed hospital demand for capital purchases of our *da Vinci* Surgical Systems. Demand for our *da Vinci* Surgical Systems improved towards the end of 2009 and the 338 total *da Vinci* Surgical Systems sold in 2009 slightly exceeded the 2008 total of 335.

da Vinci Si Surgical System Product Launch. During the second quarter of 2009 we launched our newest *da Vinci* model, the *da Vinci Si*. The *da Vinci Si* brings to market three significant innovations. First, our InSite imaging system has been substantially redesigned for increased visual acuity and improved ease-of-use. The HD imaging system's increased performance is similar to the move from 720p to 1080i in commercial television. We believe that the increased visual performance will continue to increase surgeon precision and confidence and will contribute to improved patient outcomes and shorter procedure times. Secondly, the *da Vinci Si* surgeon's user interface was redesigned to allow simplified and integrated control of *da Vinci* products and other operating room devices, such as electro-surgical units. The new user interface also includes a set of ergonomic controls for surgeon comfort. We believe the simplified interface will allow for easier surgeon training. The third significant improvement is the introduction of a dual surgeon's console for use during surgery, which will allow new methods of training *da Vinci* surgeons and enable collaborative *da Vinci* surgery. With the *da Vinci Si*, a surgeon sitting at a second console can view the same surgery as the primary surgeon and can be passed control of some or all of the *da Vinci* arms during a case. We believe this will both shorten the learning curve for new surgeons and will allow collaborative surgery in complex cases.

The *da Vinci Si* Surgical System was FDA approved and CE marked upon launch and is currently available in the United States and Europe. *da Vinci Si* Systems are available with an option to purchase a second console. Existing *da Vinci S* instruments and most *da Vinci S* accessories are compatible with the *da Vinci Si* system. An upgrade from a *da Vinci S* System to the *da Vinci Si* System is available for our current customers. We will continue to sell, service and support the *da Vinci S* Surgical System. While we will not be selling the standard *da Vinci* Surgical System, we will continue to service and support this product line as well.

We offered certain of our customers who purchased *da Vinci S* Surgical Systems in the first quarter of 2009 the opportunity to upgrade their recently purchased *da Vinci S* Surgical Systems to *da Vinci Si* Surgical Systems at a discount to the list price of our upgrade. The upgrade program also provided our customers the opportunity to return their recently purchased *da Vinci S* camera accessories and receive a credit towards the purchase of *da Vinci Si* camera or other accessories. These customers were given until June 30, 2009 to accept our offer. Total revenue in an amount equal to the discount, of approximately \$20.1 million, was deferred in the first quarter of 2009. During the second quarter of 2009, we recognized \$13.8 million of revenue from offers declined, upgrades completed or accessories delivered. In the third quarter of 2009, we completed all accepted *da Vinci Si* system upgrade offers and recognized the remaining \$6.3 million deferred revenue.

2009 Financial Highlights

Procedures grew 51% to approximately 205,000 procedures performed during the year ended December 31, 2009 compared to 136,000 procedures performed during the year ended December 31, 2008.

Table of Contents

Total revenue grew \$177 million, or 20%, to \$1,052 million during the year ended December 31, 2009 from \$875 million during the year ended December 31, 2008.

Recurring revenue grew 34% to \$562 million during the year ended December 31, 2009 from \$420 million during the year ended December 31, 2008.

Instruments and accessories revenue grew \$96 million, or 33%, to \$389 million during the year ended December 31, 2009 from \$293 million during the year ended December 31, 2008.

System revenue grew 8% to \$490 million during the year ended December 31, 2009 from \$455 million during the year ended December 31, 2008.

We sold 338 *da Vinci* Surgical Systems during the year ended December 31, 2009 compared with 335 for the year ended December 31, 2008.

As of December 31, 2009, we had a *da Vinci* Surgical System installed base of 1,395 systems, 1,028 in the United States, 248 in Europe, and 119 in the rest of the world.

Operating income increased by 21% to \$377 million, or 36% of revenue, during the year ended December 31, 2009 compared to \$311 million, or 36% of revenue, during the year ended December 31, 2008. Operating income included \$97 million and \$77 million during the years ended December 31, 2009 and 2008, respectively, of stock-based compensation expense related to employee stock programs.

Our business continues to demonstrate the ability to generate significant positive cash flow while supporting our rapid business growth. Cash, cash equivalents, and investments increased by \$270 million during 2009, including \$59 million generated from employee stock programs and \$38 million provided by additional working capital, offset by \$150 million used to repurchase 1.4 million shares and \$53 million used for capital expenditure and the purchase of intellectual property. We ended fiscal 2009 with \$1,172 million in cash, cash equivalents, and investments.

Procedure adoption

We believe the adoption of *da Vinci* surgery occurs surgical procedure by surgical procedure, and it is being adopted for those procedures which offer significant patient value. The value of a surgical procedure to a patient is higher if it offers superior clinical outcomes, less surgical trauma, or both.

Procedures grew 51% to approximately 205,000 procedures performed during the year ended December 31, 2009. The procedures that have driven the most growth in our business recently are the *da Vinci* Hysterectomy (dVH) and *da Vinci* Prostatectomy (dVP), which grew 101% and 23%, to approximately 69,000 and 90,000 procedures, respectively, in 2009. dVP is now the leading treatment choice for localized prostate cancer in the United States. While total dVH procedures were less than dVP procedures in 2009, dVH was a faster growing procedure from a percentage growth standpoint in 2009, and based on a larger market size, is expected to exceed dVP procedures in 2010. Other urologic procedures such as, *da Vinci* Nephrectomy, *da Vinci* Cystectomy, *da Vinci* Pyeloplasty, other gynecologic procedures such as *da Vinci* Myomectomy, *da Vinci* Sacral Colpopexy, cardiothoracic procedures such as *da Vinci* Mitral Valve Repair, *da Vinci* Revascularization, general surgery procedures such as the *da Vinci* Thyroidectomy, *da Vinci* Low Anterior Resection, and *da Vinci* Gastric Bypass have also contributed to our growth.

Table of Contents**Results of Operations**

The following table sets forth, for the years indicated, certain consolidated statements of income information (in thousands):

	Year Ended December 31,		Year Ended December 31,		Year Ended December 31,	
	2009	% of total revenue	2008	% of total revenue	2007	% of total revenue
Revenue:						
Products	\$ 879,901	84%	\$ 748,325	86%	\$ 516,089	86%
Services	172,267	16%	126,594	14%	84,739	14%
Total revenue	1,052,168	100%	874,919	100%	600,828	100%
Cost of revenue:						
Products	\$ 237,562	23%	\$ 200,074	23%	145,654	24%
Services	63,554	6%	54,068	6%	40,888	7%
Total cost of revenue	301,116	29%	254,142	29%	186,542	31%
Products gross profit	642,339	61%	548,251	63%	370,435	62%
Services gross profit	108,713	10%	72,526	8%	43,851	7%
Gross profit	751,052	71%	620,777	71%	414,286	69%
Operating expenses:						
Selling, general and administrative	\$ 278,511	26%	\$ 230,570	26%	158,685	27%
Research and development	95,102	9%	79,372	9%	48,859	8%
Total operating expenses	373,613	35%	309,942	35%	207,544	35%
Income from operations	377,439	36%	310,835	36%	206,742	34%
Interest and other income, net	18,672	2%	24,368	2%	30,492	5%
Income before income taxes	396,111	38%	335,203	38%	237,234	39%
Income tax expense	163,505	16%	130,888	15%	92,697	15%
Net income	\$ 232,606	22%	\$ 204,315	23%	\$ 144,537	24%

Total Revenue

Total revenue increased by 20%, 46% and 61% during the years ended December 31, 2009, 2008 and 2007, respectively. Revenue increased from \$600.8 million during the year ended December 31, 2007 to \$874.9 million during the year ended December 31, 2008 to \$1,052.2 million during the year ended December 31, 2009. Total revenue growth was driven by the continued adoption of *da Vinci* surgery. We believe that robotic surgery will be adopted surgical procedure by surgical procedure. Our revenue growth during the periods presented reflects adoption progress made in our target procedures. dVH and dVP have been our most successful procedures to date and have been significant sales catalysts. An increasing body of clinical evidence has indicated dVP to offer superior surgical outcomes compared to traditional open prostatectomy in the critical categories of cancer removal, continence, and sexual potency. From 2007 through 2009, dVH has been among one of our fastest growing procedures and we expect dVH procedures to exceed dVP procedures in 2010. Favorable clinical results have been reported in hysterectomies for cancerous pathology, which include increased lymph node retrieval counts and significant reduction in blood transfusion. For most patients, a minimally invasive approach using the *da Vinci* Surgical System offers reduced pain, less blood loss, shorter hospital stays and a quicker return to normal daily activities.

Revenue within the United States accounted for 79%, 78%, and 78% of total revenue during the years ended December 31, 2009, 2008, and 2007, respectively. We believe domestic revenue accounts for the large majority of total revenue due largely to the ability of patients to select their healthcare providers in the United States.

Table of Contents

The following table summarizes our revenue and *da Vinci* Surgical System unit sales for the past three years (in thousands, except unit sales and percentages):

Revenue	Year Ended December 31,		
	2009	2008	2007
Instruments and accessories	\$ 389,445	\$ 292,989	\$ 191,651
Systems	490,456	455,336	324,438
Total product revenue	879,901	748,325	516,089
Services	172,267	126,594	84,739
Total revenue	\$ 1,052,168	\$ 874,919	600,828
Recurring revenue	561,712	419,583	276,390
% of total revenue	53%	48%	46%
Revenue Domestic	827,005	679,682	468,938
Revenue International	225,163	195,237	131,890
Total revenue	1,052,168	874,919	600,828
Domestic Unit Sales	252	246	174
International Unit Sales	86	89	67
Total Unit Sales	338	335	241

Product Revenue

Product revenue increased to \$879.9 million during the year ended December 31, 2009 from \$748.3 million during the year ended December 31, 2008.

Instruments and accessories revenue increased to \$389.4 million for the year ended December 31, 2009, up 33%, compared with \$293.0 million for the year ended December 31, 2008. The increase in revenue is driven by an increase in procedures performed. Procedure growth occurred in all of our targeted procedures with dVH and dVP being the largest drivers of growth. Utilization per installed system for the year ended December 31, 2009 also increased as compared with the year ended December 31, 2008. Instrument and accessory pricing remained unchanged from 2008 to 2009.

Instrument and accessory revenue per procedure declined approximately 12% during 2009 primarily due to the impact of initial stocking orders. The amount of revenue related to stocking orders is less impactful as the base of installed systems grows. In addition, we believe our customers are becoming more efficient in their use of instruments and accessories as their procedure volumes increase. We expect these factors to continue to cause a decrease in our ratio of instrument and accessory revenue per procedure in 2010.

Systems revenue increased to \$490.5 million during the year ended December 31, 2009 from \$455.3 million during the year ended December 31, 2008 primarily due to more 2009 system upgrade revenue, higher 2009 average selling price (ASP), and 3 more systems sold. System upgrade revenue for the year ended December 31, 2009 increased to \$19.2 million compared to \$5.7 million for the year ended December 31, 2008, driven by the impact of 2009 *da Vinci Si* system upgrades. The 2009 ASP of \$1.39 million was higher than the 2008 ASP of \$1.34 million, primarily associated with the introduction of the *da Vinci Si* systems. We sold 338 *da Vinci* Surgical Systems during 2009, compared with 335 systems sold during 2008. 209 of 338 systems sold during 2009 were *da Vinci Si* Systems.

Product revenue increased to \$748.3 million during the year ended December 31, 2008 from \$516.1 million during the year ended December 31, 2007.

Instruments and accessories revenue increased to \$293.0 million for the year ended December 31, 2008, up 53%, compared with \$191.7 million for the year ended December 31, 2007. The increase in revenue is driven by

Table of Contents

an increase in procedures performed. Procedure growth occurred in all of our targeted procedures with dVH and dVP being the largest drivers of growth. Utilization per installed system for the year ended December 31, 2008 also increased as compared with the year ended December 31, 2007. Total instrument and accessory revenue per procedure was between \$2,000 and \$2,300. Instrument and accessory pricing remained unchanged from 2007 to 2008.

Systems revenue increased to \$455.3 million during the year ended December 31, 2008 from \$324.4 million during the year ended December 31, 2007 primarily due to the growth in the number of system unit sales reflecting adoption of robotic surgery. We sold 335 *da Vinci* Surgical Systems during 2008, compared with 241 systems sold during 2007. In addition, we recognized revenue from HD and fourth arm upgrades of \$5.7 million during year ended December 31, 2008, compared with \$4.8 million during the year ended December 31, 2007.

Service Revenue

Service revenue, comprised primarily of system service, increased to \$172.3 million for the year ended December 31, 2009 from \$126.6 million for the year ended December 31, 2008. We typically enter into service contracts at the time the system is sold. These service contracts have been generally renewed at the end of the service period. Higher service revenue for 2009 was driven by a larger base of *da Vinci* Surgical Systems and higher priced *da Vinci Si* service contract billings. The average service revenue per system was approximately \$143,000 during the year ended December 31, 2009 compared with \$139,000 during the year ended December 31, 2008, increasing primarily due to the slightly higher *da Vinci Si* contract rates.

Service revenue, comprised primarily of system service, increased to \$126.6 million for the year ended December 31, 2008 from \$84.7 million for the year ended December 31, 2007. Higher service revenue for 2008 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 average service revenue per system was approximately \$139,000 during the year ended December 31, 2008 compared with \$133,000 during the year ended December 31, 2007.

Gross Profit

Product gross profit during the year ended December 31, 2009 was \$642.3 million, or 73.0% of product revenue, compared to \$548.3 million, or 73.3% of product revenue, during the year ended December 31, 2008. The higher 2009 product gross profit was driven by the higher 2009 product revenue, as described above. The slightly lower 2009 product gross profit percentage was driven by lower margins associated with the launch of *da Vinci Si*. Product gross profit for the year ended December 31, 2009 and 2008 reflected stock-based compensation expense of \$7.7 million and \$6.3 million, respectively.

Product gross profit during the year ended December 31, 2008 was \$548.3 million, or 73.3% of product revenue, compared to \$370.4 million, or 71.8% of product revenue, during the year ended December 31, 2007. The higher 2008 product gross profit was driven by the higher 2008 product revenue, as described above. The higher 2008 product gross profit percentage was driven by instrument and system material cost reductions and leveraging manufacturing costs across higher production volumes. Product gross profit for the year ended December 31, 2008 and 2007 reflected stock-based compensation expense of \$6.3 million and \$3.5 million, respectively.

Service gross profit during the year ended December 31, 2009 was \$108.7 million, or 63.1% of service revenue, compared to \$72.5 million, or 57.3% of service revenue during the year ended December 31, 2008. The higher 2009 service gross profit was driven by a larger installed base. The higher 2009 gross service profit percentage was driven by leveraging service costs across a larger base of installed systems and lower service parts consumption and repair costs per system due to product quality and productivity gains. Service gross profit during the years ended December 31, 2009 and 2008 reflected stock-based compensation expense of \$6.6 million and \$5.1 million, respectively.

Table of Contents

Service gross profit during the year ended December 31, 2008 was \$72.5 million, or 57.3% of service revenue, compared to \$43.9 million, or 51.7% of service revenue during the year ended December 31, 2007. The higher 2008 service gross profit was driven by a larger installed base. The higher 2008 gross service profit percentage was driven by leveraging service costs across a larger base of installed systems and lower service parts consumption and repair costs per system due to product quality and productivity gains. Service gross profit during the years ended December 31, 2008 and 2007 reflected stock-based compensation expense of \$5.1 million and \$2.3 million, respectively.

Selling, General and Administrative Expenses

Selling, general and administrative expenses include costs for sales, marketing and administrative personnel, sales and marketing activities, tradeshow expenses, legal expenses, regulatory fees and general corporate expenses.

Selling, general and administrative expenses for the year ended December 31, 2009 increased 21% to \$278.5 million compared to \$230.6 million for the year ended December 31, 2008. The increase is due to organizational growth to support our expanding business, particularly in U.S. field sales, higher commissions and other variable compensation related to higher revenue levels, and increased stock-based compensation. Stock-based compensation expense charged to sales, general and administrative expenses during the years ended December 31, 2009 and 2008 were \$61.3 million and \$48.2 million, respectively.

Selling, general and administrative expenses for the year ended December 31, 2008 increased 45% to \$230.6 million compared to \$158.7 million for the year ended December 31, 2007. The increase is due to organizational growth to support our expanding business, higher commissions and other variable compensation related to higher revenue levels, and increased stock-based compensation. Stock-based compensation expense charged to sales, general and administrative expenses during the years ended December 31, 2008 and 2007 were \$48.2 million and \$22.6 million, respectively.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses include costs associated with the design, development, testing and significant enhancement of our products.

Research and development expenses during the year ended December 31, 2009 increased 20% to \$95.1 million compared to \$79.4 million during the year ended December 31, 2008. The increase is due to the growth in our research and development organization, higher prototype expenses, higher amortization expenses of purchased intellectual property, and higher stock-based compensation expense. Amortization expenses related to purchased intellectual property during the year ended December 31, 2009 was \$14.4 million, compared to \$9.1 million during the year ended December 31, 2008. Stock-based compensation expense charged to research and development expense during the years ended December 31, 2009 and 2008 were \$21.4 million and \$17.1 million, respectively. We expect to continue to make substantial investments in research and development and anticipate that research and development expenses, including the co-development arrangement with industry partners, will continue to increase in the future.

Research and development expenses during the year ended December 31, 2008 increased 62% to \$79.4 million compared to \$48.9 million during the year ended December 31, 2007. The increase is due to the growth in our research and development organization, higher costs related to co-development licensing arrangements, higher amortization expenses of purchased intellectual property, higher prototype expenses, and higher stock-based compensation expense. Amortization expenses related to purchased intellectual property during the year ended December 31, 2008 was \$9.1 million, compared to \$0.5 million during the year ended December 31, 2007. Stock-based compensation expense charged to research and development expense during the years ended December 31, 2008 and 2007 were \$17.1 million and \$8.0 million, respectively.

Table of Contents

Interest and Other Income, Net

Interest and other income, net, was \$18.7 million during the year ended December 31, 2009, compared to \$24.4 million for the year ended December 31, 2008. The decline of \$5.7 million during the year ended December 31, 2009 was primarily due to lower interest rates earned on cash and investment balances in 2009.

Interest and other income, net, was \$24.4 million during the year ended December 31, 2008, compared to \$30.5 million for the year ended December 31, 2007. The decline of \$6.1 million during the year ended December 31, 2008 was primarily due to the non-recurring gain on sale of equity securities of \$4.1 million recorded during the year ended December 31, 2007.

Income Tax Expense

Our income tax expense was \$163.5 million, \$130.9 million, and \$92.7 million during the years ended December 31, 2009, 2008, and 2007, respectively. The effective tax rate for 2009 was approximately 41.3%, which differed from the U.S. federal statutory rate of 35% due primarily to state income taxes net of federal benefit and non-deductible stock option compensation, partially offset by research and development tax credit and domestic production deductions generated in 2009. The effective tax rate for 2008 was approximately 39.0%, which differed from the U.S. federal statutory rate of 35% due primarily to state income taxes net of federal benefit and non-deductible stock option compensation, partially offset by research and development tax credit and domestic production deductions generated in 2008. The effective tax rate for 2007 was approximately 39.1%, which differed from the U.S. federal statutory rate of 35% due primarily to state income taxes net of federal benefit, partially offset by research and development tax credit generated in 2007. A significant portion of the income taxes recorded during years ended December 31, 2009, 2008 and 2007 did not result in cash outlays during the years due to the utilization of net operating loss carryforwards and tax credit carryforwards as well as tax deductions related to employee stock options.

A California tax law change enacted in February 2009 allows an elective single sales factor for state apportionment for taxable years beginning on or after January 1, 2011. We expect to benefit from the California single sales factor election for apportioning income for years 2011 and beyond. As a result of our anticipated election of the single sales factor, in accordance with ASC 740, Income Taxes, we have re-measured our deferred tax assets taking into account the reversal pattern and the expected California tax rate under the elective single sales factor. The impact of this change resulted in a decrease to California beginning deferred tax assets of \$1.6 million and this charge was recorded in the our income tax provision during the first quarter of 2009.

Liquidity And Capital Resources

Sources and Uses of Cash

Cash generation is one of the fundamental strengths of our business model and provides us with substantial financial flexibility in meeting our operating, investing and financing needs. Our principal source of liquidity is cash provided by operations and the exercise of stock options. Cash and cash equivalents plus short and long-term investments increased from \$635.4 million at December 31, 2007, to \$901.9 million at December 31, 2008, to \$1,172 million at December 31, 2009. The increase in cash and cash equivalents in fiscal year 2009 was primarily due to \$385.1 million of cash generated from operating activities, \$58.7 million of cash provided by stock option exercises and employee stock purchases, and \$25.1 million of realized excess tax benefits from share-based compensation offset by \$150.0 million used in the repurchase of 1.4 million shares of our common stock and capital expenditures of \$53.4 million.

See Item 7A. Quantitative and Qualitative Disclosures About Market Risk for discussion on impact of interest rate risk and market risk on our investment portfolio.

Table of Contents**Consolidated Cash Flow Data**

	2009	Year Ended December 31, 2008 (in thousands)	2007
Net cash provided by (used in)			
Operating activities	\$ 385,055	\$ 278,235	\$ 205,687
Investing activities	(292,377)	(304,528)	(236,400)
Financing activities	(66,169)	97,980	118,847
Effect of exchange rates on cash and cash equivalents	305	111	301
Net increase in cash and cash equivalents	\$ 26,814	\$ 71,798	\$ 88,435

Operating Activities

During the year ended December 31, 2009, cash flow from operations of \$385.1 million exceeded our net income of \$232.6 million for two primary reasons:

- 1) Our net income included substantial non-cash charges in the form of stock compensation, deferred taxes, and depreciation of long-lived assets and amortization of purchased intellectual property. These non-cash charges totaled \$114.4 million.

2) Cash provided by working capital and other assets during the year ended December 31, 2009 was approximately \$38.0 million. Working capital is comprised primarily of accounts receivable, deferred revenue and other liabilities. Accounts receivable increased \$35.3 million or 21% in 2009, primarily reflecting increased revenue. Deferred revenue, which includes deferred service contract revenue that is being amortized over the service contract period, increased \$21.3 million or 27% in 2009, which is primarily related to the increase in the number of installed systems for which service contracts exist. Other liabilities including accounts payable, accrued compensation and employee benefits, and accrued liabilities increased \$52.5 million or 41% in 2009, reflecting changes in the volume of our business and timing of vendor payments and increase in unrecognized tax benefits.

During the year ended December 31, 2008, cash flow from operations of \$278.2 million exceeded our net income of \$204.3 million for two primary reasons:

- 1) Our net income included substantial non-cash charges in the form of stock compensation, taxes, and depreciation of long-lived assets and amortization of purchased intellectual property. These non-cash charges totaled \$83.9 million.

2) We experienced rapid growth in our business with revenues increasing 46% during the year ended December 31, 2008. Our net investment in working capital and other operating assets totaled \$9.9 million. Working capital is comprised primarily of accounts receivable, inventory, deferred revenue and other current liabilities. Accounts receivable increased \$39.7 million or 30% in 2008, primarily reflecting increased revenue. Inventory increased \$31.1 million or 96% in 2008 primarily due to lower than expected system revenue in the fourth quarter of fiscal 2008. Deferred revenue, which includes deferred service contract revenue that is being amortized over the service contract period, increased \$24.6 million or 45% in 2008, which is primarily related to the increase in the number of installed systems for which service contracts exist. Other liabilities including accounts payable, accrued compensation and employee benefits, and accrued liabilities increased \$32.3 million or 34% in 2008, reflecting changes in the volume of our business, timing of vendor payments and increase in unrecognized tax benefits.

Table of Contents

During the year ended December 31, 2007, cash flow from operations of \$205.7 million exceeded our net income of \$144.5 million for two primary reasons:

- 1) Our net income included substantial non-cash charges in the form of stock compensation, taxes, and depreciation and amortization of long-lived assets. These non-cash charges totaled \$59.1 million. Also included in our net income is approximately \$4.1 million of gain on the sale of publicly-traded equity securities which has been classified as an investing activity.
- 2) We experienced rapid growth in our business with revenues increasing 61% in 2007. However, our net investment in working capital and other operating assets totaled only \$2.1 million.

Investing Activities

Net cash used in investing activities during the years ended December 31, 2009, 2008, and 2007 consisted primarily of purchases of investments (net of proceeds from sales and maturities of investments) of \$239.0 million, \$198.6 million and \$212.4 million, respectively, and purchases of property and equipment and licensing of intellectual property of \$53.4 millions, \$106.0 million and \$24.0 million, respectively. We invest predominantly in high quality, fixed income securities. Our investment portfolio may at any time contain investments in U.S Treasury and U.S. government agency securities, taxable and/or tax exempt municipal notes (some of which may have an auction reset feature), corporate notes and bonds, commercial paper, cash deposits and money market funds. We are not a capital-intensive business. Our purchases of property and equipment in 2009, 2008, and 2007 related mainly to facilities and information technology infrastructure to support capacity expansion in our business.

Financing Activities

Net cash used in financing activities in 2009 consisted primarily of \$150.0 million used for the repurchase of 1.4 million shares of our common stock through our accelerated repurchase program, offset by proceeds from stock options and employee stock purchases of \$58.7 million, and excess tax benefits from stock-based compensation of \$25.1 million. Net cash provided by financing activities in 2008 and 2007 consisted primarily of proceeds from stock options, employee stock purchases and warrants exercises of \$44.7 million and \$56.0 million, respectively, and excess tax benefits from stock-based compensation of \$53.3 million and \$62.9 million, respectively.

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. During 2009, despite the economic downturn, we experienced significant business expansion. We increased revenue by 20%, invested in new facilities, invested in several intellectual property rights, and increased our headcount by 20%. We generated \$232.6 million of net income, which represented the major driver of the net cash provided by operating activities in 2009. Based upon our business model, we anticipate that we will continue to be able to fund future growth through cash provided from operations. We believe that our current cash, cash equivalents and 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.

Table of Contents**Contractual Obligations and Commercial Commitments**

The following table summarizes our contractual obligations as of December 31, 2009 (in thousands):

	Total	Payments due by period		
		Less than 1 year	1 to 3 years	3 to 5 years
Operating leases	\$ 3,363	\$ 1,759	\$ 1,591	\$ 13
Purchase commitments and obligations	145,097	142,714	1,967	416
Total contractual obligations	\$ 148,460	\$ 144,473	\$ 3,558	\$ 429

Operating leases. We lease office spaces in the United States, Switzerland, Mexico and China. We also lease automobiles for certain sales employees. Operating lease amounts include future minimum lease payments under all our noncancelable operating leases with an initial term in excess of one year.

Purchase commitments and obligations. These amounts include an estimate of all open purchase orders and contractual obligations in the ordinary course of business, including commitments with contract manufacturers and suppliers, for which we have not received the goods or services and acquisition and licensing of intellectual property. A majority of these purchase obligations are due within a year. Although open purchase orders are considered enforceable and legally binding, the terms generally allow us the option to cancel, reschedule, and adjust our requirements based on our business needs prior to the delivery of goods or performance of services.

Other commitments. Effective January 1, 2007, the Company adopted the new accounting guidance for unrecognized tax benefits. We are unable to make a reasonably reliable estimate as to when payments may occur for our unrecognized tax benefits. Therefore, our liability for unrecognized tax benefits is not included in the table above. See Note 10 of Notes to the Consolidated Financial Statements for additional information.

Off-Balance-Sheet Arrangements

As of December 31, 2009, we did not have any significant off-balance-sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K promulgated under the Exchange Act.

Critical Accounting Estimates

Our Consolidated Financial Statements are prepared in conformity with generally accepted accounting principles in the United States, or U.S. GAAP, which requires us to make judgments, estimates and assumptions. Note 2, *Summary of Significant Accounting Policies*, in Notes to the Consolidated Financial Statements, which is included in Item 8. Financial Statements and Supplementary Data, describes our significant accounting policies and methods used in the preparation of our Consolidated Financial Statements. The methods, estimates and judgments that we use in applying our accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates regarding matters that are inherently uncertain. Our most critical accounting estimates include:

the valuation and recognition of investments, which impacts our investment portfolio balance when we assess fair value, and interest and other income, net, when we record impairments;

the valuation of revenue and allowance for sales returns and doubtful accounts, which impacts revenue;

the estimation of transactions to hedge, which impacts revenue and other expense;

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

the valuation of inventory, which impacts gross margins;

the assessment of recoverability of intangibles and the estimated useful lives, which primarily impacts gross margin or operating expenses when we record asset impairments or accelerate their amortization;

the valuation and recognition of share-based compensation, which impacts gross margin and operating expenses; and

Table of Contents

the recognition and measurement of current and deferred income taxes (including the measurement of uncertain tax positions), which impact our provision for taxes.

Investments in Debt Securities

Fair Value

Our investment portfolio may at any time contain investments in U.S. Treasury and U.S. government agency securities, taxable and/or tax exempt municipal notes (some of which may have an auction reset feature), corporate notes and bonds, commercial paper, cash deposits and money market funds. In the current market environment, the assessment of the fair value of the debt securities can be difficult and subjective. U.S. GAAP establishes three levels of inputs that may be used to measure fair value (see Note 4. Fair Value Measurements in the Notes to the Consolidated Financial Statements of this Form 10-K). Each level of input has different levels of subjectivity and difficulty involved in determining fair value. Valuation of Level 1 and 2 instruments generally do not require significant management judgment and the estimation is not difficult. Level 3 instruments include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The determination of fair value for Level 3 instruments requires the most management judgment and subjectivity.

All of the securities classified as Level 3 instruments are municipal bonds with an auction reset feature (auction rate securities or ARS) whose underlying assets are student loans which are substantially backed by the federal government. These ARS securities represent less than 10% of our total investment portfolio. Since the auctions for these securities have continued to fail since February 2008, these investments are not currently trading and therefore do not have a readily determinable market value. Accordingly, the estimated fair value of the ARS no longer approximates par value. A large portion of these ARS are held by UBS AG (UBS), one of the Company's investment providers. In November 2008, the Company accepted an offer (the Right) from UBS entitling the Company to sell at par value auction-rate securities originally purchased from UBS (approximately \$69.9 million, par value) at anytime during a two-year period from June 30, 2010 through July 2, 2012. The Company has valued the ARS and put option using a discounted cash flow model based on Level 3 assumptions. The assumptions used in valuing the ARS and the put option include estimates of, based on data available as of December 31, 2009, interest rates, timing and amount of cash flows, credit and liquidity premiums, expected holding periods of the ARS, loan rates per the UBS Rights offering and bearer risk associated with UBS's financial ability to repurchase the ARS beginning June 30, 2010. Given the current market environment, these assumptions are volatile and subject to change, thereby could result in significant changes to the fair value of ARS. The Company intends to exercise the Right from UBS on June 30, 2010 and as a result has classified these ARS as trading securities and recorded under short-term investments as of December 31, 2009. If UBS has insufficient funding to buy back the ARS and the auction process continues to fail, then we may incur further losses on the carrying value of the ARS.

The remaining ARS (approximately \$23.5 million, par value) is held by another investment advisor, who has not made an offer similar to UBS and we continue to classify them as available-for-sales securities. Accordingly, the change in associated market value has been recorded against other comprehensive income during the year ended December 31, 2009. If market conditions deteriorate further, we may be required to record additional unrealized losses in other comprehensive income or impairment charges. We may not be able to liquidate these investments unless the issuer calls the security, a successful auction occurs, a buyer is found outside of the auction process, or the security matures.

Other-than-temporary impairment

After determining the fair value of our available-for-sales debt instruments, gains or losses on these securities are recorded to other comprehensive income, until either the security is sold or we determine that the decline in value is other-than-temporary. The primary differentiating factors considered by us to classify its impairments between temporary and other-than-temporary impairments are our intent and ability to retain our

Table of Contents

investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value, the length of the time and the extent to which the market value of the investment has been less than cost, the financial condition and near-term prospects of the issuer. Given the current market conditions, these judgments could prove to be wrong, and companies with relatively high credit ratings and solid financial conditions may not be able to fulfill their obligations.

No impairment charges were recorded during the years ended December 31, 2009, 2008 and 2007. As of December 31, 2009 and 2008, our cumulative unrealized gains (losses) related to our investments classified as available-for-sale was approximately \$0.8 million and \$(3.2) million, respectively. These unrecognized losses could be recognized in the future if our other-than-temporary assessment changes.

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 uncollectibility 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. Credit evaluations are undertaken for all major sale transactions before shipment is authorized. On a quarterly basis, we evaluate aged items in the accounts receivable aging report and provide allowance in an amount we deem adequate 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 valuation. Inventory is stated at the lower of cost or market, with cost determined on a first-in, first-out basis. The carrying value of inventory is reduced for estimated obsolescence by the difference between its cost and the estimated market value based upon assumptions about future demand. We evaluate the inventory carrying value for potential excess and obsolete inventory exposures by analyzing historical and anticipated demand. 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, which could have a material adverse effect on our results of operations.

Intangible Assets. Our intangible assets include identifiable intangibles and goodwill. Identifiable intangibles include developed technology, patents, and licenses. All of our identifiable intangibles have finite lives.

ASC 350 provides that goodwill and intangible assets with indefinite lives are subject to an annual impairment review (or more frequent if impairment indicators arise) by applying a fair-value based test. There have been no impairments from the analysis required by ASC 350.

Identifiable intangible assets with finite lives are subject to impairment testing as prescribed by U.S. GAAP. Pursuant to the provisions U.S. GAAP, identifiable intangibles with finite lives are reviewed for impairment when events or circumstances indicate that such assets may not be recoverable at their carrying value. We evaluate the recoverability of the carrying value of these identifiable intangibles based on estimated undiscounted cash flows to be generated from such assets. If the cash flow estimates or the significant operating assumptions upon which they are based change in the future, we may be required to record additional impairment charges. When events or changes in circumstances indicate that the carrying amount of long-lived assets may not be recoverable, we recognize such impairment in the event the net book value of such assets exceeds the future undiscounted cash flows attributable to such assets.

Table of Contents

We have intangible assets and goodwill on our balance sheet related to the acquisition of Computer Motion, Inc. and the acquisition of other intellectual property. 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 and goodwill for impairment under established accounting guidelines is required on a recurring basis. Changes in business conditions could potentially require future adjustments to asset valuations. When we determine that the useful lives of assets are shorter than we had originally estimated, we accelerate the rate of depreciation over the assets' new, shorter useful lives. We conducted the required intangible assets impairment review during the fourth quarter of 2009. No impairment charge or material accelerated amortization was recorded for the years ended December 31, 2009, 2008 and 2007. A considerable amount of judgment is required in assessing impairment, which includes financial forecasts. Should conditions be different from management's current estimates, material write-downs of long-lived assets may be required, which would adversely affect our operating results.

Revenue recognition. We frequently enter into revenue arrangements that contain multiple elements or deliverables such as system and services. Judgments as to the allocation of the proceeds received from an arrangement to the multiple elements of the arrangement, the determination of whether any undelivered elements are essential to the functionality of the delivered elements and the appropriate timing of revenue recognition are critical in respect to these arrangements to ensure compliance with U.S. GAAP. Changes to the elements in an arrangement and the ability to establish objective and reliable evidence of fair value for those elements could affect the timing of revenue recognition. Revenue recognition also depends on the timing of shipment and is subject to customer acceptance. If shipments are not made on scheduled timelines or if the products are not accepted by the customer in a timely manner, our reported revenues may differ materially from expectations.

Hedge Accounting for Derivatives. We utilize foreign currency forward exchange contracts to hedge certain anticipated foreign currency sales transactions. When specific criteria required by ASC 815 have been met, changes in fair values of hedge contracts relating to anticipated transactions are recorded in other comprehensive income (OCI) rather than net income until the underlying hedged transaction affects net income. By their very nature, our estimates of anticipated transactions may fluctuate over time and may ultimately vary from actual transactions. When we determine that the transactions are no longer probable within a certain time frame, we are required to reclassify the cumulative changes in the fair values of the related hedge contracts from other comprehensive income to net income.

Accounting for stock options. We account for stock-based compensation in accordance with the fair value recognition provisions of ASC 718. We use the Black-Scholes-Merton option-pricing model which requires the input of highly subjective assumptions. These assumptions include estimating the length of time employees will retain their vested stock options before exercising them, the estimated volatility of our common stock price over the expected term and the number of options that will ultimately not complete their vesting requirements. The assumptions for expected volatility and expected term are the two assumptions that significantly affect the grant date fair value. Changes in expected risk-free rate of return do not significantly impact the calculation of fair value, and determining this input is not highly subjective.

We use implied volatility based on freely traded options in the open market, as we believe implied volatility is more reflective of market conditions and a better indicator of expected volatility than historical volatility. In determining the appropriateness of implied volatility, we considered the following:

the volume of market activity of freely traded options, and determined that there was sufficient market activity;

the ability to reasonably match the input variables of freely traded options to those options granted by the Company, such as the date of the grant and the exercise price, and determined that the input assumptions were comparable; and

the term of freely traded options used to derive implied volatility, which is generally at least one year, and determined that the length of term was sufficient.

Table of Contents

The expected term represents the weighted-average period that the Company's stock options are expected to be outstanding. The expected term is based on the observed and expected time to post-vesting exercise of options by employees. We use historical exercise patterns of previously granted options in relation to stock price movements to derive an employee behavioral pattern used to forecast expected exercise patterns.

ASC 718 requires us to develop an estimate of the number of share-based awards that will be forfeited due to employee turnover. Adjustments in the estimated forfeiture rates can have a significant effect on our reported share-based compensation, as we recognize the cumulative effect of the rate adjustments for all expense amortization in the period the estimated forfeiture rates were adjusted. We estimate and adjust forfeiture rates based on a periodic review of recent forfeiture activity and expected future employee turnover. If a revised forfeiture rate is higher than previously estimated forfeiture rate, we may make an adjustment that will result in a decrease to the expense recognized in the financial statements during the period when the rate was changed. Adjustments in the estimated forfeiture rates could also cause changes in the amount of expense that we recognize in future periods.

Changes in the subjective assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related amount recognized on the Consolidated Statements of Income.

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 in accordance with ASC 740. These estimates and judgments occur in the calculation of tax credits, benefits, and deductions, and in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes, as well as the interest and penalties related to uncertain tax positions. Significant changes to these estimates may result in an increase or decrease to our tax provision in the current or subsequent period.

We must assess the likelihood that we will be able to recover our deferred tax assets. If recovery is less than a 50% likelihood, we must increase our provision for taxes by recording a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be recoverable. We believe that we will ultimately recover substantially all of the deferred tax assets recorded on our Consolidated Balance Sheets as of December 31, 2009. However, should there be a change in our ability to recover our deferred tax assets, our tax provision would increase in the period in which such change takes place.

The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations. In accordance with the ASC 740 and related guidance, we recognize liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. If we determine that a tax position will more likely than not be sustained on audit, then the second step requires us to estimate and measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. It is inherently difficult and subjective to estimate such amounts, as we have to determine the probability of various possible outcomes. We reevaluate these uncertain tax positions on a quarterly basis. This evaluation is based on factors including, but not limited to, changes in facts or circumstances, changes in tax law, effective settlement of audit issues, and new audit activity. Such a change in recognition or measurement would result in the recognition of a tax benefit or an additional charge to the tax provision.

RECENT ACCOUNTING PRONOUNCEMENTS

See Note 2 under *Summary of Significant Accounting Policies* of the Notes to Consolidated Financial Statements in Item 8. Financial Statements and Supplementary Data for a full description of recent accounting pronouncements including the respective expected dates of adoption and effects on Consolidated Balance Sheets and Consolidated Statements of Income.

Table of Contents

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate and Market Risk

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. To achieve this objective, we maintain our portfolio of cash equivalents and short-term and long-term investments in a variety of high quality securities, including U.S. treasuries and government agencies, corporate debt, money market funds, commercial paper and taxable or tax exempt municipal bonds (some of which may have an auction reset feature). The securities, other than money market funds and the ARS, are classified as available for sale and consequently are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income (loss). The weighted-average maturity of our investments excluding auction rate securities as of December 31, 2009 was approximately 1.2 years. If interest rates rise, the market value of our investments may decline, which could result in a realized loss if we are forced to sell an investment before its scheduled maturity. A hypothetical increase in interest rate by 25 basis points would have resulted in a decrease in the fair value of our net investment position of approximately \$2.7 million as of December 31, 2009. We do not utilize derivative financial instruments to manage our interest rate risks.

The recent financial crisis affecting the banking system and financial markets has resulted in a tightening in the credit markets, a reduced level of liquidity in many financial markets, and extreme volatility in fixed income and credit markets. The credit ratings of the securities we have invested in could further deteriorate and may have an adverse impact on the carrying value of these investments.

At December 31, 2009, we held approximately \$81.3 million of municipal bonds with an auction reset feature (auction rate securities or ARS) whose underlying assets are student loans which are substantially backed by the federal government. These ARS securities represent less than 10% of our total investment portfolio. Since February 2008, these auctions have failed and therefore continue to be illiquid and we will not be able to access these funds until a future auction of these investments is successful or a buyer is found outside of the auction process. As a result, our ability to liquidate our investment and fully recover the carrying value of our investment in the near term may be limited or not exist. If the issuers are unable to successfully close future auctions and their credit ratings deteriorate, we may in the future be required to record an impairment charge on these investments. A large portion of the ARS are held by UBS. In November 2008, we accepted an offer (the Right) from UBS, entitling us to sell at par value auction-rate securities originally purchased from UBS at anytime during a two-year period from June 30, 2010 through July 2, 2012. If UBS has insufficient funding to buy back the ARS and the auction process continues to fail, then we may incur further losses on the carrying value of the ARS.

Foreign Exchange Risk

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 foreign exchange exposures to non-U.S.dollar revenues, operating expenses, accounts receivable, accounts payable and currency bank balances. Our primary exposure is with the Euro.

For the year ended December 31, 2009, sales denominated in foreign currencies were approximately 12% of total revenue. In January 2009, we began a hedging program to address the risk associated with non-functional currency financial statement exposures primarily to partially mitigate the impact of changes in currency exchange rates on our net cash flow from foreign currency denominated sales. We also hedge the net recognized non-functional currency balance sheet exposures with foreign exchange forward contracts to reduce the risk that our earnings and cash flows will be adversely affected by changes in exchange rates. For the year ended December 31, 2009, our revenue would have decreased by approximately \$5.0 million if the U.S. dollar exchange rate would have strengthened by 10%. In addition, we have assets and liabilities denominated in foreign currencies. A 10% strengthening of the U.S. dollar exchange rate against all currencies with which we

Table of Contents

have exposure, after taking into account hedges and offsetting positions at December 31, 2009 would have resulted in a \$0.5 million decrease in the carrying amounts of those net assets. Actual gains and losses in the future may differ materially from the hypothetical gains and losses discussed above based on changes in the timing and amount of foreign currency exchange rate movements and our actual exposure and hedging transactions. The bank counterparties to the foreign exchange forward contracts expose the Company to credit-related losses in the event of their nonperformance. However, to mitigate that risk, the Company only contracts with counterparties that meet certain minimum requirements under its counterparty risk assessment process. The Company monitors ratings and potential downgrades on at least a quarterly basis. Based on its on-going assessment of counterparty risk, the Company will adjust its exposure to various counterparties.

Our international operations are subject to risks typical of international operations, including, but not limited to, differing economic conditions, changes in political climate, differing tax structures, other regulations and restrictions, and foreign exchange rate volatility.

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial Statements

Index To Consolidated Financial Statements

<u>Reports of Independent Registered Public Accounting Firm</u>	56
<u>Consolidated Balance Sheets at December 31, 2009 and 2008</u>	58
<u>Consolidated Statements of Income for the years ended December 31, 2009, 2008 and 2007</u>	59
<u>Consolidated Statement of Stockholders' Equity for the years ended December 31, 2009, 2008 and 2007</u>	60
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2009, 2008 and 2007</u>	61
<u>Notes to the Consolidated Financial Statements</u>	62
<u>Schedule II Valuation and Qualifying Accounts</u>	85

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.

Table of Contents

REPORT OF 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, 2009 and 2008, and the related consolidated statements of income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009. 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, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, 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.

As discussed in Note 2 to the consolidated financial statements, Intuitive Surgical, Inc. changed its method of accounting for uncertain tax positions as of January 1, 2007.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Intuitive Surgical, Inc.'s internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated January 29, 2010 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California

January 29, 2010

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited Intuitive Surgical, Inc.'s internal control over financial reporting as of December 31, 2009 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 included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on 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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, 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, Intuitive Surgical, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Intuitive Surgical, Inc. as of December 31, 2009 and 2008, and the related consolidated statements of income, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2009, and the financial statement schedule listed in the index at Item 15(a) and our report dated January 29, 2010 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California

January 29, 2010

Table of Contents

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

	December 31, 2009	2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 221,437	\$ 194,623
Short-term investments	333,998	256,746
Accounts receivable, net of allowances of \$4,289 and \$4,100 at December 31, 2009 and 2008, respectively	205,384	170,107
Inventory	57,600	63,460
Prepays and other assets	20,870	9,496
Deferred tax assets	7,339	9,458
Total current assets	846,628	703,890
Property, plant and equipment, net	125,741	117,021
Long-term investments	616,545	450,504
Long-term deferred tax asset	53,341	35,899
Intangible assets, net	56,230	56,224
Goodwill	110,740	110,740
Other assets	491	346
Total assets	\$ 1,809,716	\$ 1,474,624
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 27,594	\$ 20,501
Accrued compensation and employee benefits	49,758	36,930
Deferred revenue	99,451	77,981
Other accrued liabilities	25,965	29,104
Total current liabilities	202,768	164,516
Deferred revenue	1,066	1,271
Other liabilities	68,599	42,071
Total liabilities	272,433	207,858
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, 2,500 shares authorized, \$0.001 par value, issuable in series; no shares issued and outstanding as of December 31, 2009 and 2008, respectively		
Common stock, 100,000 shares authorized, \$0.001 par value, 38,500 and 39,183 shares issued and outstanding as of December 31, 2009 and 2008, respectively	38	39
Additional paid-in capital	1,024,273	871,846
Retained earnings	511,716	397,824
Accumulated other comprehensive income (loss)	1,256	(2,943)
Total stockholders' equity	1,537,283	1,266,766
Total liabilities and stockholders' equity	\$ 1,809,716	\$ 1,474,624

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

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

	Year Ended December 31,		
	2009	2008	2007
Revenue:			
Products	\$ 879,901	\$ 748,325	\$ 516,089
Services	172,267	126,594	84,739
Total revenue	1,052,168	874,919	600,828
Cost of revenue:			
Products	237,562	200,074	145,654
Services	63,554	54,068	40,888
Total cost of revenue	301,116	254,142	186,542
Gross profit	751,052	620,777	414,286
Operating expenses:			
Selling, general and administrative	278,511	230,570	158,685
Research and development	95,102	79,372	48,859
Total operating expenses	373,613	309,942	207,544
Income from operations	377,439	310,835	206,742
Interest and other income, net	18,672	24,368	30,492
Income before income taxes	396,111	335,203	237,234
Income tax expense	163,505	130,888	92,697
Net income	\$ 232,606	\$ 204,315	\$ 144,537
Net income per common share:			
Basic	\$ 6.07	\$ 5.26	\$ 3.82
Diluted	\$ 5.93	\$ 5.12	\$ 3.70
Shares used in computing basic and diluted net income per common share:			
Basic	38,298	38,877	37,831
Diluted	39,205	39,943	39,021

See accompanying Notes to Consolidated Financial Statements.

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

	Common Stock	Stock Amount	Additional Paid-In Capital	Retained Earnings (Accumulated Deficit)	Accumulated Other Comprehensive Income (Loss)	Total
Balances at December 31, 2006	37,093,263	\$ 37	\$ 537,943	\$ 51,020	\$ 705	589,705
Issuance of common stock upon exercise of options and warrants, and under stock purchase plan	1,376,426	1	55,979			55,980
Income tax benefit from stock option exercises			65,391			65,391
Stock-based compensation expense related to employee stock plans			36,278			36,278
Adjustments to initially apply FIN 48			(994)	(2,048)		(3,042)
Components of comprehensive income, net of tax:						
Net income				144,537		144,537
Other comprehensive income (loss)					(175)	(175)
Total comprehensive income						144,362
Balances at December 31, 2007	38,469,689	38	694,597	193,509	530	888,674
Issuance of common stock upon exercise of options and under stock purchase plan	713,242	1	44,677			44,678
Income tax benefit from stock option exercises			55,926			55,926
Stock-based compensation expense related to employee stock plans			76,646			76,646
Components of comprehensive income, net of tax:						
Net income				204,315		204,315
Other comprehensive income (loss)					(3,473)	(3,473)
Total comprehensive income						200,842
Balances at December 31, 2008	39,182,931	39	871,846	397,824	(2,943)	1,266,766
Issuance of common stock upon exercise of options and under stock purchase plan	723,478		63,090			63,090
Income tax benefit from stock option exercises			23,641			23,641
Stock-based compensation expense related to employee stock plans			96,981			96,981
Repurchase and retirement of common stock	(1,406,049)	(1)	(31,285)	(118,714)		(150,000)
Components of comprehensive income, net of tax:						
Net income				232,606		232,606
Other comprehensive income (loss)					4,199	4,199
Total comprehensive income						\$ 236,805

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

Balances at December 31, 2009	38,500,360	\$ 38	\$ 1,024,273	\$ 511,716	\$ 1,256	\$ 1,537,283
-------------------------------	------------	-------	--------------	------------	----------	--------------

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

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

	Year Ended December 31,		
	2009	2008	2007
Operating activities:			
Net income	\$ 232,606	\$ 204,315	\$ 144,537
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	18,959	14,633	11,011
Amortization of intangible assets	15,618	10,451	2,016
Gain on sale of investments			(4,075)
Income tax benefits related to an acquisition			7,500
Deferred income taxes	(15,645)	(20,495)	3,913
Share-based compensation expense of stock options and employee stock purchases	96,981	76,646	36,292
Excess tax benefit from stock-based compensation	(25,140)	(53,303)	(62,868)
Income tax benefits related to stock option exercises	23,641	55,926	65,391
Changes in operating assets and liabilities:			
Accounts receivable	(35,275)	(39,740)	(35,687)
Inventory	5,860	(31,064)	(8,213)
Prepays and other assets	(6,316)	3,966	(6,771)
Accounts payable	7,040	(9,239)	18,646
Accrued compensation and employee benefits	12,803	6,890	8,802
Deferred revenue	21,315	24,559	17,306
Other accrued liabilities	32,608	34,690	7,887
Net cash provided by operating activities	385,055	278,235	205,687
Investing activities:			
Purchase of investments	(764,451)	(732,698)	(688,345)
Proceeds from sales and maturities of investments	525,490	534,143	475,952
Purchase of property and equipment and acquisition of intellectual property	(53,416)	(105,973)	(24,007)
Net cash used in investing activities	(292,377)	(304,528)	(236,400)
Financing activities:			
Proceeds from issuance of common stock, net	58,691	44,677	55,979
Excess tax benefit from stock-based compensation	25,140	53,303	62,868
Repurchase and retirement of common stock	(150,000)		
Net cash (used in) provided by financing activities	(66,169)	97,980	118,847
Effect of exchange rate changes on cash and cash equivalents	305	111	301
Net increase in cash and cash equivalents	26,814	71,798	88,435
Cash and cash equivalents, beginning of year	194,623	122,825	34,390
Cash and cash equivalents, end of year	\$ 221,437	\$ 194,623	\$ 122,825
Supplemental cash flow information:			
Income taxes paid	\$ 129,123	\$ 61,450	\$ 11,300

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

INTUITIVE SURGICAL, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. DESCRIPTION OF THE BUSINESS

Intuitive Surgical, Inc. (the Company or Intuitive) designs, manufactures, and markets the *da Vinci* Surgical System, which is an advanced surgical system that the Company believes represent a new generation of surgery. The *da Vinci* Surgical System consists of a surgeon's console or consoles, 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 the console into corresponding micro-movements of instruments positioned inside the patient through small incisions, or ports. The Company markets its products through sales representatives in the United States, and through a combination of sales representatives and distributors in its international markets.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and include the accounts of the Company and its wholly-owned subsidiaries. All significant inter-company balances and transactions have been eliminated in consolidation. During fiscal 2009, the Company established subsidiaries in Hong Kong and Singapore.

Subsequent Events Evaluation

Management has reviewed and evaluated material subsequent events from the balance sheet date of December 31, 2009 through the financial statements issue date of January 29, 2010. No subsequent events have been identified for disclosure.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the Consolidated Financial Statements and accompanying Notes to Consolidated Financial Statements. The accounting estimates that require management's most significant, difficult and subjective judgments include the valuation and recognition of investments, the valuation of the revenue and allowance for sales returns and doubtful accounts; the valuation of inventory, the assessment of recoverability of intangible assets and their estimated useful lives, the valuation and recognition of stock-based compensation and the recognition and measurement of current and deferred income tax assets and liabilities. Actual results could differ materially from these estimates.

Concentrations of Credit Risk and Other Risks and Uncertainties

The carrying amounts for financial instruments consisting of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate fair value due to their short maturities. Marketable securities are stated at their estimated fair values, based on quoted market prices for the same or similar instruments. The counterparties to the agreements relating to the Company's investment securities consist of various major corporations, financial institutions, municipalities and government agencies of high credit standing.

The Company's accounts receivable are derived from net revenue to customers and distributors located in the United States and other countries. The Company performs credit evaluations of its customers' financial condition and, generally, requires no collateral from its customers. The Company provides reserves for potential credit losses but has not experienced significant losses to date. As of December 31, 2009, 75% and 25% of

Table of Contents

accounts receivable were from customers located in the United States and other countries, respectively. As of December 31, 2008, 68% and 32% of accounts receivable were from customers located in the United States and other countries, respectively. No single customer represented more than 10% of net accounts receivable as of December 31, 2009 and 2008.

During the year ended December 31, 2009, domestic and international revenue accounted for 79% and 21%, respectively, of total revenue. During each of the years ended December 31, 2008 and 2007, domestic and international revenue accounted for 78% and 22%, respectively, of total revenue. No single customer represented more than 10% of total revenue for the years ended December 31, 2009, 2008 and 2007.

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.

Investments

Available-for-sale and trading investments. The Company's investments consist of U.S. treasury and U.S. government agency securities, taxable and tax exempt municipal notes, some of which may have an auction reset feature (auction rate securities or ARS), corporate notes and bonds, commercial paper, cash deposits and money market funds. We designated all investments, except for ARS held by UBS, as available-for-sale and therefore, such investments are reported at fair value, with unrealized gains and losses recorded in accumulated other comprehensive income. During the fourth quarter of fiscal 2008, the Company reclassified ARS held by UBS from available-for-sale to trading securities. Investments that the Company designates as trading assets are reported at fair value, with gains or losses resulting from changes in fair value recognized in earnings. See Note 4 for further detailed discussion. For securities sold prior to maturity, the cost of securities sold is based on the specific identification method. Realized gains and losses on the sale of investments are recorded in interest and other income, net. Investments with original maturities greater than approximately three months and remaining maturities less than one year are classified as short-term investments. Investments with remaining maturities greater than one year are classified as long-term investments.

Other-than-temporary impairment. All of the Company's available-for-sale investments are subject to a periodic impairment review. The Company recognizes an impairment charge when a decline in the fair value of its investments below the cost basis is judged to be other-than-temporary. Factors considered in determining whether a loss is temporary included the length of time and extent to which the investments fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, extent of the loss related to credit of the issuer, the expected cash flows from the security, the Company's intent to sell the security and whether or not the Company will be required to sell the security before the recovery of its amortized cost. During the years ended December 31, 2009, 2008 and 2007, the Company did not record any other-than-temporary impairment charges on its available-for-sale securities.

Allowance for Sales Returns and Doubtful Accounts

The allowance for sales returns is based on the Company's estimates of potential future product returns and other allowances related to current period product revenue. The Company analyzes historical returns, current economic trends and changes in customer demand and acceptance of our products.

The allowance for doubtful accounts is based on the Company's assessment of the collectability of customer accounts. The Company regularly reviews the allowance by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay.

Table of Contents

Inventory

Inventory is stated at the lower of cost or market value on a first-in, first-out basis. Inventory costs include direct materials, direct labor, direct subcontractor costs, and manufacturing overhead. The Company provides inventory write-downs based on excess and obsolete inventories determined primarily by future demand forecasts.

Property, Plant and Equipment

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

	Useful Lives
Building	15 years
Building improvements	Lesser of 5 years or useful life
Leasehold improvements	Lesser of useful life or term of lease
Equipment and furniture	5 years
Computer equipment	3 years
Purchased software	Lesser of 3 years or life of license

Depreciation expense for years ended December 31, 2009, 2008 and 2007 was \$19.0 million, \$14.6 million and \$11.0 million, respectively.

Capitalized Software Costs for Internal Use

Costs incurred for internally developed software during the application development stage are capitalized in accordance with ASC 350-40. Internally developed software primarily includes enterprise-level business software that the Company customizes to meet its specific operational needs. The Company capitalized costs for enhancement of the enterprise resource planning software system and other internal use software of approximately \$4.4 million and \$8.6 million during the years ended December 31, 2009 and 2008, respectively. Upon being placed in service, these costs are depreciated over an estimated useful life of 5 years.

Goodwill and Intangible Assets

Goodwill, which represents the excess of the purchase price over the fair value of net tangible and identifiable intangible assets acquired from Computer Motion, Inc., is not subject to amortization, but is subject to at least an annual assessment for impairment, applying a fair-value based test.

The Company's intangible assets are comprised of purchased intellectual property and acquired intangibles from the purchase of Computer Motion, Inc. These intangible assets are carried at cost, net of accumulated amortization. Amortization is recorded using the straight-line method, over their respective useful lives, which range from approximately 3 to 7 years.

Impairment of Long-lived assets

In accordance with ASC 350, goodwill and intangible assets with indefinite useful lives are not amortized, but are tested for impairment at least annually or as circumstances indicate their value may no longer be recoverable. The Company does not have intangible assets with indefinite useful lives other than goodwill. Goodwill impairment test is generally performed annually during the fourth fiscal quarter (or earlier if impairment indicators arise). The Company continues to operate in one segment, which is considered to be the sole reporting unit and therefore, goodwill was tested for impairment at the enterprise level. As of December 31, 2009, there has been no impairment of goodwill.

Table of Contents

The Company evaluates the recoverability of its long-lived assets, which include amortizable intangible and tangible assets, in accordance with ASC 360 and related guidance. Acquired intangible assets with definite useful lives are amortized over their useful lives. The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of long-lived assets may not be recoverable. The Company recognizes such impairment in the event the net book value of such assets exceeds the future undiscounted cash flows attributable to such assets. No impairment losses were incurred in the periods presented.

Revenue Recognition

The Company recognizes revenue in accordance with Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*, 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. The Company's revenues are derived from product revenue resulting from system revenue, and instruments and accessories revenue, and service revenue.

The Company's system revenue contains 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 ASC 730-10 is not applicable to the Company's revenues.

Provided all other criteria for revenue recognition have been met, the Company generally recognizes system revenue for system sales directly to end customers, when delivery and acceptance occurs which is deemed to have occurred upon the receipt by the Company of a form executed by the customer acknowledging delivery and acceptance. The Company recognizes revenue for system sales through distributors upon transfer of title and risk of loss, which is generally at the time of shipment, assuming all other criteria for revenue recognition have been met.

For an arrangement with multiple deliverables, the Company recognizes system revenue in accordance with multiple-element arrangements accounting codified under ASC 605-25, with revenues allocated among the different elements. 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 and service contracts. 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 do not contain a 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. In accordance with the guidance in ASC 605, the Company uses the residual method to allocate the arrangement consideration when it does not have fair value of the system sale.

In September 2009, the FASB issued Accounting Standard Update No. 2009-13, *Multiple-Deliverable Revenue Arrangements* a consensus of the FASB Emerging Issues Task Force (ASU 2009-13). It updates the existing multiple-element revenue arrangements guidance currently included under ASC 605-25. The revised guidance primarily provides two significant changes: 1) requires an entity to allocate revenue in an arrangement using estimated selling prices (ESP) of deliverables if a vendor does not have vendor-specific objective evidence of selling price (VSOE) or third-party evidence of selling price (TPE); and 2) eliminates the residual method and require an entity to allocate revenue using the relative selling price method. The Company adopted this new accounting guidance starting January 2010 on a prospective basis for applicable transactions originating or materially modified after December 31, 2009. This guidance does not generally change the units of accounting for the Company's revenue transactions. There would have been no significant change to revenue for the year ended December 31, 2009, if we had applied ASU 2009-13 for the entire year.

Revenue from sales of instruments and accessories is recognized when the product has been shipped, risk of loss and title has passed to the customer and collection of the resulting receivable is probable.

Table of Contents

Service contract revenue is recognized ratably over the term of the service period. Revenue related to services performed on a time-and-materials basis is recognized when it is earned and billable.

The Company's system contracts do not allow rights of return. The Company's distributors do not have price protection rights. The Company records an allowance on instruments and accessories sales returns based on historical returns experience.

Stock-Based Compensation

The Company accounts for stock-based employee compensation plans under the fair value recognition and measurement provisions codified under ASC 718. ASC 718 requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options. Pursuant to ASC 718, stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as expense over the requisite service period. ASC 718 requires the cash flows resulting from the tax benefits due to tax deductions in excess of the compensation cost recognized for those options (excess tax benefits) to be classified as financing cash flows.

See Note 9 for a detailed discussion of stock-compensation expense and related accounting.

Computation of Net Income per Share

Basic net income per share is computed using the weighted-average number of common shares outstanding during the period. Diluted net income per share is computed using the weighted-average number of common shares and dilutive potential common shares outstanding during the period. Dilutive potential common shares primarily consist of employee stock options.

ASC 260 requires that employee equity share options, non-vested shares and similar equity instruments granted by the Company be treated as potential common shares outstanding in computing diluted earnings per share. Diluted shares outstanding include the dilutive effect of in-the-money options, which is calculated based on the average share price for each fiscal period using the treasury stock method. Under the treasury stock method, the amount the employee must pay for exercising stock options, the amount of compensation cost for future service that the Company has not yet recognized, and the amount of tax benefits that would be recorded in APIC when the award becomes deductible are all assumed to be used to repurchase shares.

Shipping and Handling Costs

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

Research and Development Expenses

Research and development (or R&D) expenses include amortization of purchased intellectual property, costs associated with co-development R&D licensing arrangements, salaries, benefits and other headcount related costs, contract and other outside service fees, and facilities and overhead costs. The costs of acquisition of technology are capitalized if they have alternative future uses in other R&D projects and amortized over their estimated useful lives.

Foreign Currency and Other Hedging Instruments

For subsidiaries whose local currency is their functional currency, their assets and liabilities are translated into U.S. dollars at exchange rates at the balance sheet date and revenues and expenses are translated using average exchange rates in effect during the quarter. Gains and losses from foreign currency translation are included in accumulated other comprehensive income (loss) within stockholders' equity in the Consolidated Balance Sheets. For all non functional currency account balances, the re-measurement of such balances to the functional currency will result in either a foreign exchange gain or loss which is recorded to interest and other income, net in the same accounting period that the re-measurement occurred.

Table of Contents

In January 2009, the Company began a hedging program to address the risk associated with non-functional currency (primarily Euro) financial statement exposures. The Company accounts for these instruments in accordance with ASC 815, which requires that every derivative instrument be recorded on the balance sheet as either an asset or a liability measured at its fair value as of the reporting date. Derivative valuations are determined using Level 2 inputs (as defined on Note 4), including closing currency prices and observable inputs other than quoted prices, including interest rates, forward points and credit risk.

The Company sells products to certain European customers in foreign currencies. Fluctuations in exchange rates can change the Company's U.S. dollar equivalent revenue and hence the Company's U.S. dollar earnings. The Company hedges a portion of forecasted foreign currency denominated sales (Euro- and British Pound denominated) utilizing foreign exchange forward contracts. These transactions are designated as cash flow hedges and are accounted for under the hedge accounting provisions of ASC 815. The effective portion of the hedge gain or loss is reported as a component of accumulated other comprehensive income (loss) and subsequently reclassified into net revenues when the hedged exposure affects earnings. Any ineffective portions of related gains or losses are recorded in the statements of income immediately. In the event the underlying forecasted transaction does not occur, or it becomes probable that it will not occur, the Company will reclassify the gain or loss on the related cash flow hedge from accumulated other comprehensive income (loss) to interest and other income, net on its Consolidated Statement of Income.

The Company also hedges the net recognized non-functional currency balance sheet exposures with foreign exchange forward contracts to reduce the risk that its earnings and cash flows will be adversely affected by changes in exchange rates. These derivative instruments are carried at fair value with changes in the fair value recorded to interest and other income, net on the Company's Consolidated Statement of Income and are intended to offset gains and losses on the assets and liabilities being hedged.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts that are expected more likely than not to be realized in the future.

In 2006, the FASB issued an accounting update which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with income tax accounting, codified under ASC 740. This update prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on derecognition of tax benefits, classification on the balance sheet, interest and penalties, accounting in interim periods, disclosure, and transition. The Company adopted this update effective January 1, 2007.

As a result of the implementation of the above accounting update, the Company recognized a \$2.0 million increase in liability for unrecognized tax benefits, which was accounted for as a reduction to the January 1, 2007 balance of retained earnings. The Company has decided to classify interest and penalties as a component of tax expense in accordance with the provisions in this update. For further discussion, see Note 10 of the Notes to the Financial Statements.

Segments

The Company operates in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. As of December 31, 2009 and 2008, over 98% of all long-lived assets were maintained in the United States. For the years ended December 31, 2009, 2008 and 2007, 79%, 78% and 78%, respectively, of net revenue were generated in the United States.

Table of Contents

Recent Accounting Pronouncements

Adopted Accounting Pronouncements

Effective July 1, 2009, the Company adopted *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles* (ASC 105). This standard establishes only two levels of U.S. generally accepted accounting principles (GAAP), authoritative and nonauthoritative. The FASB Accounting Standards Codification (the Codification) became the source of authoritative, nongovernmental GAAP, except for rules and interpretive releases of the SEC, which are sources of authoritative GAAP for SEC registrants. All other non-grandfathered, non-SEC accounting literature not included in the Codification became nonauthoritative. The Company began using the new guidelines and numbering system prescribed by the Codification when referring to GAAP in the third quarter of fiscal 2009. As the Codification was not intended to change or alter existing GAAP, it did not have any impact on the Company's Consolidated Financial Statements.

Effective April 1, 2009, the Company adopted three accounting standard updates which were intended to provide additional application guidance and enhanced disclosures regarding fair value measurements and impairments of securities. They also provide additional guidelines for estimating fair value in accordance with fair value accounting. The first update, as codified in ASC 820-10-65, provides additional guidelines for estimating fair value in accordance with fair value accounting. The second accounting update, as codified in ASC 320-10-65, changes accounting requirements for other-than-temporary-impairment (OTTI) for debt securities by replacing the current requirement that a holder have the positive intent and ability to hold an impaired security to recovery in order to conclude an impairment was temporary with a requirement that an entity conclude it does not intend to sell an impaired security and it will not be required to sell the security before the recovery of its amortized cost basis. The third accounting update, as codified in ASC 825-10-65, requires fair value disclosures in the interim periods as well as in the annual financial statements. These updates were effective for fiscal years and interim periods ended after June 15, 2009. The adoption of these accounting updates did not have any impact on the Company's Consolidated Financial Statements.

Effective April 1, 2009, the Company adopted a new accounting standard for subsequent events, as codified in ASC 855-10. The update modifies the names of the two types of subsequent events either as recognized subsequent events (previously referred to in practice as Type I subsequent events) or non-recognized subsequent events (previously referred to in practice as Type II subsequent events). In addition, the standard modifies the definition of subsequent events to refer to events or transactions that occur after the balance sheet date, but before the financial statements are issued (for public entities) or available to be issued (for nonpublic entities). It also requires the disclosure of the date through which subsequent events have been evaluated. The update did not result in significant changes in the practice of subsequent event disclosures, and therefore the adoption did not have any impact on the Company's Consolidated Financial Statements.

Effective January 1, 2009, the Company adopted a new accounting standard update regarding business combinations. As codified under ASC 805, this update requires an entity to recognize the assets acquired, liabilities assumed, contractual contingencies, and contingent consideration at their fair value on the acquisition date. It further requires that acquisition-related costs be recognized separately from the acquisition and expensed as incurred; that restructuring costs generally be expensed in periods subsequent to the acquisition date; and that changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period be recognized as a component of the income tax provision. In addition, acquired in-process research and development is capitalized as an intangible asset and amortized over its estimated useful life. For Intuitive, this accounting update was effective on a prospective basis for all business combinations for which the acquisition date is on or after January 1, 2009, with the exception of the accounting for valuation allowances on deferred taxes and acquired contingencies under ASC 805-740. With the adoption of this accounting standard update, any tax related adjustments associated with acquisitions that closed prior to January 1, 2009 will be recorded through income tax expense, whereas the previous accounting treatment would have required any adjustment to be recognized through the purchase price. The adoption did not have any impact on the Company's Consolidated Financial Statements.

Table of Contents**NOTE 3. CASH, CASH EQUIVALENTS & INVESTMENTS**

The following table summarizes the Company's cash, cash equivalents and investments as of December 31, 2009 and 2008 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2009				
Cash and cash equivalents:				
Cash	\$ 28,592	\$	\$	\$ 28,592
Cash equivalents	192,846		(1)	192,845
Total cash and cash equivalents	\$ 221,438	\$	\$ (1)	\$ 221,437
Available for sale investments: short-term				
Commercial paper	\$ 13,107	\$ 15	\$	\$ 13,122
Municipal notes	21,267	214		21,481
U.S. corporate debt	150,483	1,267	(6)	151,744
U.S. treasuries	31,618	188	(2)	31,804
U.S. government agencies	45,478	519		45,997
Total available for sale investments: short-term	\$ 261,953	\$ 2,203	\$ (8)	\$ 264,148
Available for sale investments: long-term				
Municipal notes	\$ 160,994	\$ 1,450	\$ (4,505)	\$ 157,939
U.S. corporate debt	222,468	2,089	(118)	224,439
U.S. treasuries	29,477	18	(173)	29,322
U.S. government agencies	204,638	623	(416)	204,845
Total available for sale investments: long-term	\$ 617,577	\$ 4,180	\$ (5,212)	\$ 616,545
Total cash, cash equivalents and available for sale investments	\$ 1,100,968	\$ 6,383	\$ (5,221)	\$ 1,102,130
Other securities (included in short-term investments):				
Trading securities, action rate securities	\$ 62,253	\$	\$	\$ 62,253
Put option	7,597			7,597
Total cash, cash equivalents and investments	\$ 1,170,818	\$ 6,383	\$ (5,221)	\$ 1,171,980
December 31, 2008				
Cash and cash equivalents:				
Cash	\$ 24,696	\$	\$	\$ 24,696
Cash equivalents	169,925	2		169,927
Total cash and cash equivalents	\$ 194,621	\$ 2	\$	\$ 194,623
Available for sale investments: short-term				
Commercial paper	\$ 34,186	\$ 81	\$	\$ 34,267
U.S. corporate debt	109,048	590	(582)	109,056
U.S. treasuries	12,408	145		12,553
U.S. government agencies	100,032	858	(20)	100,870
Total available for sale investments: short-term	\$ 255,674	\$ 1,674	\$ (602)	\$ 256,746

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

Available for sale investments: long-term				
Municipal notes	\$ 48,438	\$ 170	\$ (3,992)	\$ 44,616
U.S. corporate debt	166,215	1,152	(3,970)	163,397
U.S. treasuries	21,987	648		22,635
U.S. government agencies	123,458	1,748		125,206
Total available for sale investments: long-term	\$ 360,098	\$ 3,718	\$ (7,962)	\$ 355,854
Total cash, cash equivalents and available for sale investments	\$ 810,393	\$ 5,394	\$ (8,564)	\$ 807,223
Other securities (included in short-term investments):				
Trading securities, action rate securities	\$ 83,045	\$	\$	\$ 83,045
Put option	11,605			11,605
Total cash, cash equivalents and investments	\$ 905,043	\$ 5,394	\$ (8,564)	\$ 901,873

Table of Contents

The following table summarizes the maturities of the Company's cash equivalents and available-for-sale investments at December 31, 2009 (in thousands):

	Amortized Cost	Fair Value
Less than 1 year	\$ 454,799	\$ 456,994
Due 1-5 years	594,077	597,535
Due >5 years	23,500	19,009
Total	\$ 1,072,376	\$ 1,073,538

During the years ended December 31, 2009 and 2008, realized gains or losses recognized on the sale of investments were not significant. During the year ended December 31, 2007, the Company realized gains of approximately \$4.1 million on the sale of publicly-traded equity securities. As of December 31, 2009 and 2008, unrealized gain (loss) on investments, net of tax, of \$0.8 million and \$(3.2) million, respectively, were included in accumulated other comprehensive income (loss) in the accompanying Consolidated Balance Sheets. During the years ended December 31, 2009 and 2008, the Company recognized (loss) or gain of (\$4.1) million and \$11.6 million, respectively, on put right from UBS largely offset by the gain or loss on the UBS ARS.

The following tables present the breakdown of the available for sale investments with unrealized losses at December 31, 2009 and 2008 (in thousands):

	Unrealized losses less than 12 months		Unrealized losses 12 months or greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
December 31, 2009						
Municipal notes	\$ 16,623	\$ (15)	\$	\$	\$ 16,623	\$ (15)
Auction rate securities			19,009	(4,490)	19,009	(4,490)
U.S. corporate debt	56,668	(124)			56,668	(124)
U.S. treasuries	29,794	(175)			29,794	(175)
U.S. government agencies	108,968	(416)			108,968	(416)
	\$ 212,053	\$ (730)	\$ 19,009	\$ (4,490)	\$ 231,062	\$ (5,220)
December 31, 2008						
Municipal notes	\$ 15,591	\$ (17)	\$	\$	\$ 15,591	\$ (17)
Auction rate securities	19,525	(3,975)			19,525	(3,975)
U.S. corporate debt	102,396	(4,281)	9,721	(271)	112,117	(4,552)
U.S. government agencies	9,984	(20)			9,984	(20)
	\$ 147,496	\$ (8,293)	\$ 9,721	\$ (271)	\$ 157,217	\$ (8,564)

The unrealized losses on the available for sale investments in ARS and U.S. government agencies were primarily the result of overall market risk aversion, lack of demand for securities that are non-government guaranteed, and the relative widening of credit spreads relative to the U.S. treasuries. The Company believes that it will be able to collect all principal and interest amounts due at maturity given the high credit quality of these investments. Since the decline in the market value is attributable to changes in market conditions and not credit quality, and since the Company has the ability and is not required to sell those investments until a recovery of par value, which may be maturity, the Company does not consider these investments to be other-than temporarily impaired as of December 31, 2009.

NOTE 4. FAIR VALUE MEASUREMENTS

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

ASC 820 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under

Table of Contents

ASC 820 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

In accordance with ASC 820, the following table represents the Company's fair value hierarchy for its financial assets (cash equivalents and investments) measured at fair value on a recurring basis as of December 31, 2009 and 2008 (in thousands):

Assets	Fair Value Measurements at December 31, 2009 Using			
	Level 1	Level 2	Level 3	Total
Money Market funds	\$ 175,729	\$	\$	\$ 175,729
U.S. treasuries	61,125			61,125
Commercial paper		27,421		27,421
Corporate debt		379,001		379,001
U.S. government agencies		250,842		250,842
Municipal notes		160,410	81,263	241,673
Put option			7,597	7,597
Total assets measured at fair value	\$ 236,854	\$ 817,674	\$ 88,860	\$ 1,143,388

Liabilities				
Foreign Currency Derivatives	\$	\$ 423	\$	\$ 423
Total liabilities measured at fair value	\$	\$ 423	\$	\$ 423

Assets	Fair Value Measurements at December 31, 2008 Using			
	Level 1	Level 2	Level 3	Total
Money Market funds	\$ 156,729	\$	\$	\$ 156,729
U.S. treasuries	45,188			45,188
Commercial paper		37,465		37,465
Corporate debt		272,453		272,453
U.S. government agencies		226,077		226,077
Municipal notes		48,590	79,070	127,660
Put option			11,605	11,605
Total assets measured at fair value	\$ 201,917	\$ 584,585	\$ 90,675	\$ 877,177

Table of Contents

The following table provides reconciliation for all assets measured at fair value using significant unobservable inputs (Level 3) for the year ended December 31, 2009 (in thousands):

	Fair Value Measurements at Reporting Date Using Significant Unobservable Inputs (Level 3)	
	Put Option	ARS
Balance at January 1, 2009	\$ 11,605	\$ 79,070
Sales/Maturities		(1,300)
Total gains or (losses):		
Included in other comprehensive income (loss)		(515)
Included in earnings	(4,008)	4,008
Balance at December 31, 2009	\$ 7,597	\$ 81,263

Level 3 assets consist of municipal bonds with an auction reset feature (ARS) whose underlying assets are student loans which are substantially backed by the federal government and put option from UBS. Since the auctions for these securities have continued to fail since February 2008, these investments are not currently trading and therefore do not have a readily determinable market value. Accordingly, the estimated fair value of the ARS no longer approximates par value. A large portion of these ARS are held by UBS AG (UBS), one of the Company's investment providers. In November 2008, the Company accepted an offer (the Right) from UBS entitling the Company to sell at par value auction-rate securities originally purchased from UBS (approximately \$69.9 million, par value) at anytime during a two-year period from June 30, 2010 through July 2, 2012. The Company elected to measure the put option at fair value on a recurring basis in order to match the changes in the fair value of the ARS. Although the Company expects to sell its ARS under the Right, if the Right is not exercised before July 2, 2012, it will expire and UBS will have no further rights or obligation to buy the Company's ARS. The Company has valued the ARS and put option using a discounted cash flow model based on Level 3 assumptions. The assumptions used in valuing the ARS and the put option include estimates of, based on data available as of December 31, 2009, interest rates, timing and amount of cash flows, credit and liquidity premiums, expected holding periods of the ARS, loan rates per the UBS Rights offering and bearer risk associated with UBS's financial ability to repurchase the ARS beginning June 30, 2010. The Company intends to exercise the Right from UBS on June 30, 2010 and as a result has classified these ARS as trading securities and as short-term investments as of December 31, 2009.

Foreign currency derivative

On a monthly basis, the Company enters into foreign currency forward contracts with one to seven month terms. Intuitive does not purchase derivatives for trading purposes. As of December 31, 2009, the Company had the notional amount of 22.0 million and £4.5 million outstanding currency forward contracts that were entered into to hedge non-functional currency denominated net monetary assets and 19.5 million and £3.9 million to hedge Euro and GBP denominated sales.

The fair value of derivative instruments in the Consolidated Balance Sheet as of December 31, 2009 was approximately \$0.4 million in liabilities. The effects of derivative instruments designated as cash flow hedges on the Company's Consolidated Statement of Income for the year ended December 31, 2009 were not significant. The effects of derivative instruments used to hedge against balance sheet foreign currency exposures during the year ended December 31, 2009 were also insignificant.

Table of Contents**NOTE 5. BALANCE SHEET DETAILS**

The following table provides details of selected balance sheet items (in thousands):

	December 31,	
	2009	2008
Inventory:		
Raw materials	\$ 16,250	\$ 19,901
Work-in-process	2,537	4,097
Finished goods	38,813	39,462
Total	\$ 57,600	\$ 63,460
 Property, plant and equipment, net:		
Building	\$ 28,000	\$ 22,944
Land	41,771	33,571
Computer equipment	6,555	5,598
Equipment and furniture	48,236	32,020
Building/leasehold improvements	20,511	15,378
Purchased software	31,173	25,953
Construction-in-process	15,086	28,751
	191,332	164,215
Less accumulated depreciation	(65,591)	(47,194)
Total Property, plant and equipment, net	\$ 125,741	\$ 117,021
 Other liabilities:		
Income taxes long term	\$ 67,598	\$ 36,460
Other long-term liabilities	1,001	5,611
Total Other liabilities	\$ 68,599	\$ 42,071

NOTE 6. GOODWILL AND INTANGIBLE ASSETS***Goodwill***

The Company's goodwill amounts relate to the acquisition of Computer Motion, Inc in June 2003. The changes in the carrying amount of goodwill during the year ended December 31, 2007 were the result of adjustments to deferred tax assets acquired and realized tax benefits from stock options issued in the Computer Motion acquisition.

Intangibles

The following tables present details of the Company's total intangible assets (in thousands):

December 31, 2009	Gross	Accumulated Amortization	Impairment	Net
Core technology	\$ 3,300	\$ 3,064	\$	\$ 236

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

Purchased intellectual property	89,012	33,031		55,981
Other intangible assets	500	196	291	13
Total intangible assets, net	\$ 92,812	\$ 36,291	\$ 291	\$ 56,230

73

Table of Contents

December 31, 2008	Gross	Accumulated Amortization	Impairment	Net
Core technology	\$ 3,300	\$ 2,592	\$	\$ 708
Purchased intellectual property	73,388	17,909		55,479
Other intangible assets	500	172	291	37
Total intangible assets, net	\$ 77,188	\$ 20,673	\$ 291	\$ 56,224

The Company acquired intellectual property for \$25.7 million and \$43.5 million during the years ended December 31, 2009 and 2008, respectively. The weighted average useful life was five years for each of the years ended December 31, 2009 and 2008. Amortization expense related to intangible assets was \$15.6 million, \$10.5 million and \$2.0 million for the years ended December 31, 2009, 2008 and 2007, respectively.

The estimated future amortization expense of intangible assets as of December 31, 2009 is as follows (in thousands):

Fiscal Year	Amount
2010	\$ 15,093
2011	13,075
2012	12,313
2013	8,204
2014	4,901
Thereafter	2,644
Total	\$ 56,230

NOTE 7. COMMITMENTS AND CONTINGENCIES**OPERATING LEASES**

The Company leases office space in Sunnyvale, California, Milford, Connecticut, Aubonne, Switzerland, Shanghai, China and Mexicali, Mexico. The Company leases automobiles for certain sales employees. These leases have varying terms, predominantly no longer than three years.

Future minimum lease commitments under the Company's operating leases as of December 31, 2009 are as follows (in thousands):

2010	\$ 1,759
2011	1,104
2012	487
2013	13
2014 and beyond	
	\$ 3,363

Other commitments include an estimated amount of approximately \$145.1 million of all open cancellable purchase orders and contractual obligations that occur in the ordinary course of business, including commitments with contract manufacturers and suppliers, for which we have not received the goods or services.

CONTINGENCIES

The Company is subject to various legal proceedings and disputes that arise in the normal course of business. These matters include product liability actions, patent infringements, contract disputes, and other matters. The Company does not know whether it will prevail in these matters.

nor can it assure that any remedy

Table of Contents

could be reached on commercially viable terms, if at all. Based on currently available information, the Company believes that it has meritorious defenses to these actions and should an unfavorable outcome arise, there can be no assurance such outcome would not have material adverse effect on its future results of operations, liquidity or financial position. In accordance with U.S. GAAP, 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.

NOTE 8. STOCKHOLDERS' EQUITY**STOCK REPURCHASE PROGRAM**

In March 2009, the Company's Board of Directors authorized the repurchase of up to \$300 million of the Company's common stock through open market and private block transactions pursuant to Rule 10b5-1 plans or privately negotiated purchases or other means, including accelerated stock repurchase transactions or similar arrangements. In connection with this stock repurchase authorization, the Company entered into a collared accelerated share repurchase program (the "ASR Program") with Goldman, Sachs & Co. ("Goldman") to repurchase \$150 million of the Company's common stock. The number of shares repurchased by Intuitive under the ASR Program was based generally on the average daily volume-weighted average price of Intuitive's common stock during a specific period less a predetermined discount per share. During the first quarter of 2009, the Company had received and retired approximately 1.4 million shares of the Company's common stock. All ASR Program purchases were completed during the second quarter of 2009 and the Company did not receive any additional shares. As of December 31, 2009, the Company had \$150 million remaining under the board authorized amount of stock repurchases.

In accordance with treasury stock accounting, the Company accounted for the accelerated share repurchase as two separate transactions: (a) as shares of common stock acquired in a treasury stock transaction recorded on the transaction date and (b) as a forward contract indexed to the Company's common stock. As such, the Company accounted for the approximately 1.4 million shares that it received as a repurchase of its common stock and retired those shares immediately for net income per share purposes. The Company has determined that the forward contract indexed to the Company's common stock met all of the applicable criteria for equity classification in accordance with U.S. GAAP and therefore, the contract was not accounted for as a derivative. The Company uses the par value method of accounting for its stock repurchases. As a result of the stock repurchases during March 2009, the Company reduced common stock and APIC by an aggregate of \$31.3 million and charged \$118.7 million to retained earnings.

COMPREHENSIVE INCOME

The components of accumulated other comprehensive income, net of tax, are as follows (in thousands):

	December 31,	
	2009	2008
Foreign currency translation adjustments	407	227
Accumulated net unrealized gains (losses) on derivatives, net of tax	3	
Accumulated net unrealized gains (losses) on available-for-sale securities, net of tax	\$ 846	\$ (3,170)
Total accumulated other comprehensive income (loss)	\$ 1,256	\$ (2,943)

Table of Contents

The components of comprehensive income and related tax effects are as follows (in thousands):

	Year Ended December 31,		
	2009	2008	2007
Net income	\$ 232,606	\$ 204,315	\$ 144,537
Foreign currency translation adjustments	180	109	12
Unrealized gains (losses) on derivative instruments, net of tax:			
Unrealized gains (losses) on derivative instruments	(1,147)		
Reclassification adjustment for (gains) losses on derivative instruments recognized during the period	1,150		
Unrealized gains (losses) on available-for-sale securities, net of tax:			
Unrealized gains (losses) arising during period	4,016	(15,187)	2,258
Reclassification adjustment for gains (losses) realized in net income		11,605	(2,445)
Total other comprehensive income	\$ 236,805	\$ 200,842	\$ 144,362

WARRANTS

In conjunction with the Computer Motion acquisition in June 2003, the Company assumed warrants to purchase 724,729 shares of common stock at a weighted average exercise price of \$20.52 per share. The warrants were fully vested and immediately exercisable. As of December 31, 2007, these warrants were no longer outstanding.

The following table summarizes the warrants activity during the year ended December 31, 2007:

	2007	
	Number of Shares Under Warrant	Weighted Average Exercise Price
Outstanding at January 1	87,149	\$ 13.24
Warrants exercised	(79,306)	\$ 12.84
Warrants expired	(7,843)	\$ 17.31
Outstanding at December 31		\$

NOTE 9. STOCK-BASED COMPENSATION**STOCK OPTION PLANS***2000 Equity Incentive Plan*

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. Under this plan, certain employees, consultants and non-employee directors may be granted Incentive Stock Options (ISOs) and Nonstatutory Stock Options (NSOs) to purchase shares of the Company's common stock. The 2000 Plan permitted ISOs to be granted at an exercise price not less than the fair value on the date of the grant and NSOs at an exercise price not less than 85% of the fair value on the date of grant. Options granted under the 2000 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 1/48th per month thereafter; however, options may have been granted with different vesting terms as determined by the Board of Directors. The plan expires in March 2010.

2000 Non-Employee Directors' Stock Option Plan

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

In March 2000, the Board of Directors adopted the 2000 Non-Employee Directors' Stock Option Plan (the "Directors' Plan"). In October 2009, the automatic evergreen increase provisions were eliminated so that no

Table of Contents

further automatic increases will be made to the number of shares reserved for issuance under the Directors' Plan. In addition, the common stock authorized for issuance under the Directors' Plan was reduced to 150,000. Options are granted at an exercise price not less than the fair market value of the stock on the date of grant and have a term not to exceed ten years. Initial grants are vested over a three-year period with one-third of the shares vesting after one year from the date of grant and 1/36th of the shares vesting monthly thereafter. Annual grants are vested one year from the date of the grant.

2000 Employee Stock Purchase Plan

In March 2000, the Board of Directors adopted the 2000 Employee Stock Purchase Plan (ESPP). The plan contains an evergreen provision whereby the authorized shares are automatically increased concurrent with the Company's annual meeting of shareholders. Employees are generally eligible to participate in the ESPP if they are customarily employed by the Company for more than 20 hours per week and more than 5 months in a calendar year and are not 5% stockholders of the Company. Under the ESPP, eligible employees may select a rate of payroll deduction up to 15% of their eligible compensation subject to certain maximum purchase limitations. The duration for each offering period is twenty-four months long and is divided into four shorter purchase periods approximately six months in length. Offerings are concurrent. The purchase price of the shares under the offering is the lesser of 85% of the fair market value of the shares on the offering date or 85% of the fair market value of the shares on the purchase date. A two-year look-back feature in the ESPP causes the offering period to reset if the fair value of the Company's common stock on the purchase date is less than that on the original offering date. ESPP purchases by employees are settled with newly-issued common stock from the ESPP's previously authorized and available pool of shares.

The Company issued 92,433, 85,850 and 103,943 shares under the ESPP, representing approximately \$8.0 million, \$8.9 million and \$6.2 million in employee contributions for the years ended December 31, 2009, 2008 and 2007, respectively. As of December 31, 2009, there were approximately 835,062 shares reserved for grant under this program.

2009 Employment Commencement Incentive Plan

In October 2009, the Board of Directors adopted the 2009 Employment Commencement Incentive Plan (New Hire Plan). The New Hire Plan provides for the reservation of 300,000 shares to be used exclusively for the grant of NSOs to new employees, who were not previously an employee or non-employee director of the Company. Options are granted at an exercise price not less than the fair market value of the stock on the date of grant and have a term not to exceed ten years. Currently, no options have been granted under this plan.

Table of Contents**STOCK OPTION PLAN INFORMATION**

Option activity during fiscal 2009 under the 2000 Equity Incentive Plan and Directors Plan were as follows (in thousands, except per share amounts):

	Shares Available for Grant	Number Outstanding	STOCK OPTIONS OUTSTANDING Weighted Average Exercise Price Per Share
Balance at December 31, 2008 (with 1,791 options exercisable at a weighted-average exercise price of \$100.71 per share and with 3,551 options vested and expected to vest at a weighted-average exercise price of \$160.68 per share)	8,449	3,749	\$ 163.25
Options authorized	1,648		
Options granted	(1,662)	1,662	122.31
Options exercised		(631)	87.32
Options canceled/expired	187	(187)	203.07

Balance at December 31, 2009 (with 2,261 options exercisable at a weighted-average exercise price of \$137.75 per share and with 4,353 options vested and expected to vest at a weighted-average exercise price of \$156.04 per share)	8,622	4,593	\$ 157.25
--	-------	-------	-----------

The aggregate intrinsic value of options exercised under our stock option plans determined as of the date of option exercise was \$94.9 million, \$140.9 million, and \$184.5 million during the years ended December 31, 2009, 2008, and 2007, respectively. Cash received from option exercises and employee stock purchase plans for the years ended December 31, 2009, 2008 and 2007 was \$63.1 million, \$44.7 million and \$55.0 million, respectively.

The following table summarizes significant ranges of outstanding and exercisable options as of December 31, 2009:

Range of Exercise Prices	Number of Shares	Options Outstanding Weighted Average Remaining Contractual Life	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (1)	Number of Shares	Options Exercisable Weighted Average Remaining Contractual Life	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (1)
\$0.00 47.86	639,835	3.96	\$ 28.98		639,835		\$ 28.98	
\$48.15 112.66	2,152,083	8.09	106.71		863,302		105.78	
\$113.06 303.00	858,170	8.35	215.43		320,720		210.50	
\$303.27 303.27	826,478	8.09	303.27		380,457		303.27	
\$309.46 353.00	116,090	7.89	331.45		56,553		330.23	
TOTAL	4,592,656	7.56	\$ 157.25	\$ 674,616,676	2,260,867	6.48	\$ 137.75	\$ 376,099,425

(1) The aggregate intrinsic value represents the total pre-tax intrinsic value, based on the Company's closing stock price of \$303.43 as of December 31, 2009, which would have been received by the option holders had all option holders exercised their options as of that date. As of December 31, 2009, the shares vested and expected to vest had a weighted average remaining contractual life of 7.51 years and aggregate intrinsic value of \$644.7 million.

Table of Contents**STOCK-BASED COMPENSATION**

The following table summarizes stock-based compensation charges:

	Year Ended December 31,		
	2009	2008	2007
Cost of sales - products	\$ 7,653	\$ 6,311	\$ 3,472
Cost of sales - services	6,634	5,077	2,276
Total cost of sales	14,287	11,388	5,748
Selling, general and administrative	61,271	48,149	22,560
Research and development	21,423	17,109	7,984
Stock-based compensation expense before income taxes	96,981	76,646	36,292
Income taxes	26,519	23,205	12,651
Stock-based compensation expense after income taxes	\$ 70,462	\$ 53,441	\$ 23,641

The Black-Scholes option pricing model is used to estimate the fair value of stock options granted under the Company's stock-based compensation plans and rights to acquire stock granted under the Company's employee stock purchase plan. The weighted average estimated fair values of the stock options and rights to acquire stock granted under the Company's employee purchase plan as well as the weighted average assumptions used in calculating these values during the years ended December 31, 2009, 2008 and 2007, were based on estimates at the date of grant as follows:

	Year Ended December 31,		
	2009	2008	2007
STOCK OPTION PLANS			
Average risk free interest rate	1.76%	2.79%	4.58%
Average expected term (years)	5.28	5.03	5.16
Average volatility	55%	52%	39%
Weighted average fair value at grant date	\$ 59.53	\$ 138.33	\$ 61.19
Total stock-based compensation expense (000 \$)	\$ 90,306	\$ 72,272	\$ 33,330
EMPLOYEE STOCK PURCHASE PLAN			
Average risk free interest rate	0.63%	2.18%	4.89%
Average expected term (years)	1.3	1.3	1.3
Average volatility	56%	54%	38%
Weighted average fair value at grant date	\$ 51.23	\$ 108.08	\$ 42.54
Total stock-based compensation expense (000 \$)	\$ 6,675	\$ 4,374	\$ 2,962

Expected Term: The Company's expected term represents the weighted-average period that the Company's stock options are expected to be outstanding. The expected term is based on the observed and expected time to post-vesting exercise of options by employees. The Company uses historical exercise patterns of previously granted options in relation to stock price movements to derive an employee behavioral pattern used to forecast expected exercise patterns.

Expected Volatility: The Company uses market-based implied volatility. Market-based implied volatility is derived based on at least one-year traded options on the Company's common stock. The selection of the proportion of market-based volatility depends, among other things, on the availability of traded options on the Company's stock and term of such options. Due to sufficient volume of the traded options, the Company used 100% market-based implied volatility. The selection of the implied volatility approach was based upon the availability of traded options on the Company's stock and the Company's assessment that implied volatility is more representative of future stock price trends than historical volatility.

Table of Contents

Risk-Free Interest Rate: The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for the expected term of the option.

As stock-based compensation expense recognized in the Consolidated Statements of Income during the years ended December 31, 2009, 2008 and 2007 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Stock compensation accounting requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimated.

As of December 31, 2009, there was \$208.9 million and \$8.4 million, respectively, of total unrecognized compensation expense related to non-vested stock options and employee stock purchases. The unrecognized compensation expenses are expected to be recognized over a weighted average period of 2.6 years for non-vested stock options and 1.2 years for employee stock purchases, respectively.

Excess tax benefits are realized tax benefits from tax deductions for exercised options in excess of the deferred tax asset attributable to stock compensation costs for such options. Excess tax benefits of \$25.1 million, \$53.3 million, and \$62.9 million for the years ended December 31, 2009, 2008 and 2007 have been classified as a financing cash inflow. The total income tax benefit recognized in the income statement for stock-based compensation costs was \$26.5 million, \$23.2 million and \$12.7 million for the years ended December 31, 2009, 2008 and 2007.

NOTE 10. INCOME TAXES

Income before provision for income taxes for the years ended December 31, 2009, 2008 and 2007 consisted of the following (in thousands):

	Year Ended December 31,		
	2009	2008	2007
U.S	\$ 334,524	\$ 284,473	\$ 209,539
Foreign	61,587	50,730	27,695
Total income before provision for income taxes	\$ 396,111	\$ 335,203	\$ 237,234

The provision for income taxes for the years ended December 31, 2009, 2008 and 2007 consisted of the following (in thousands):

	Year Ended December 31,		
	2009	2008	2007
Current			
Federal	\$ 159,044	\$ 134,722	\$ 85,858
State	19,096	16,137	5,521
Foreign	1,003	600	590
	\$ 179,143	\$ 151,459	\$ 91,969
Deferred			
Federal	\$ (16,058)	\$ (19,075)	\$ (1,777)
State	289	(1,759)	2,505
Foreign	131	263	
	\$ (15,638)	\$ (20,571)	\$ 728
Total income tax expense	\$ 163,505	\$ 130,888	\$ 92,697

Table of Contents

Income tax expense differs from amounts computed by applying the statutory rate of 35% for the years ended December 31, 2009, 2008 and 2007 as a result of the following (in thousands):

	Year Ended December 31,		
	2009	2008	2007
Federal tax at statutory rate	\$ 138,639	\$ 117,321	\$ 83,032
Increase (reduction) in tax resulting from:			
State taxes, net of federal benefits	19,385	14,378	8,026
Research and development credit	(2,666)	(2,854)	(2,336)
Stock compensation not benefitted	3,949	2,760	1,633
Other	4,198	(717)	2,342
	\$ 163,505	\$ 130,888	\$ 92,697

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

	December 31,	
	2009	2008
Deferred tax assets:		
Net operating loss carryforward	\$ 2	\$ 93
Stock-based compensation expense	46,047	30,101
Expenses deducted in later years for tax purposes	15,772	17,413
Other		1,071
Gross deferred tax assets	61,821	48,678
Valuation allowance		(1,071)
Deferred tax assets	\$ 61,821	\$ 47,607
Deferred tax liabilities:		
Identified intangible assets related to acquisitions	\$ (94)	\$ (1,965)
Other	(1,047)	(285)
Deferred tax liabilities	\$ (1,141)	\$ (2,250)
Net deferred tax assets	\$ 60,680	\$ 45,357

As of December 31, 2009, the Company had state net operating loss carry forwards of approximately \$700,000. If not utilized, the state loss carry forwards will begin to expire in 2015.

The valuation allowance for deferred tax assets of \$1.1 million for the year ended December 31, 2008 was primarily related to unrealized investment losses and was reversed for the year ended December 31, 2009, as the underlying investments generated cumulative net unrealized gains as of December 31, 2009.

A California tax law change enacted in February 2009 allows an elective single sales factor for state apportionment for taxable years beginning on or after January 1, 2011. The Company expects to benefit from the California single sales factor election for apportioning income for years 2011 and beyond. As a result of its anticipated election of the single sales factor, in accordance with ASC 740, Income Taxes, the Company has re-measured its deferred tax assets taking into account the reversal pattern and the expected California tax rate under the elective single sales factor. The impact of this change resulted in a decrease to California beginning deferred tax assets of \$1.6 million and this charge was recorded

in the Company's income tax provision during the first quarter of 2009.

Table of Contents

The Company recorded a net increase of its gross unrecognized tax benefits of approximately \$28.0 million during the year ended December 31, 2009. The Company had gross unrecognized tax benefits of approximately \$70.0 million and \$42.0 million as of December 31, 2009 and 2008, respectively, of which \$65.7 million and \$36.7 million, if recognized would result in a reduction of the Company's effective tax rate during the years ended December 31, 2009 and 2008, respectively. Upon adoption of ASC 740, the Company had elected to include interest expense and penalties accrued on unrecognized tax benefits as a component of our income tax expense. As of December 31, 2009 and 2008, gross interest related to unrecognized tax benefits accrued was approximately \$3.3 million and \$0.9 million, respectively, and an increase of \$2.4 million was included in our income tax expense of the year ended December 31, 2009. The Company classified its net unrecognized tax benefits and related interest in Other accrued liabilities on the Consolidated Balance Sheet.

A reconciliation of the beginning and ending amounts of gross unrecognized income tax benefits for 2009 and 2008 are as follows (in thousands):

	Year Ended December 31,	
	2009	2008
Beginning balance	\$ 42,011	\$ 21,955
Additions for tax positions related to current year	24,905	20,164
Increase (decrease) for tax positions related to prior year	3,083	(108)
Ending balance	\$ 69,999	\$ 42,011

The Company files federal, state and foreign income tax returns in many jurisdictions in the United States and abroad. For U.S. federal and California income tax purposes, the statute of limitation currently remains open for all years since inception due to utilization of net operating losses and research and development credits generated in prior years.

NOTE 11. NET INCOME PER SHARE

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

	Year Ended December 31,		
	2009	2008	2007
Net income	\$ 232,606	\$ 204,315	\$ 144,537
Basic:			
Weighted-average shares outstanding	38,298	38,877	37,831
Basic net income per share	\$ 6.07	\$ 5.26	\$ 3.82
Diluted:			
Weighted-average shares outstanding used in basic calculation	38,298	38,877	37,831
Add dilutive potential common shares	907	1,066	1,190
Weighted-average shares used in computing diluted net income per common share	39,205	39,943	39,021
Diluted net income per share	\$ 5.93	\$ 5.12	\$ 3.70

Employee stock options to purchase approximately 1,528,520, 1,212,700 and 74,000 shares for the years ended December 31, 2009, 2008 and 2007, respectively, were outstanding, but were not included in the computation of diluted earnings per share because their effect would have been antidilutive.

Table of Contents

NOTE 12. EMPLOYEE BENEFIT PLANS

The Company sponsors various retirement plans for its eligible U.S. and non-U.S. employees. For employees in the U.S., the Company maintains the Intuitive Surgical, Inc. 401(k) Plan (the "Plan"). As allowed under Section 401(k) of the Internal Revenue Code, the Plan provides tax-deferred salary contributions for eligible U.S. employees. The Plan allows employees to contribute up to 75% of their annual compensation to the Plan on a pretax and after-tax basis. Employee contributions are limited to a maximum annual amount as set periodically by the Internal Revenue Code. Employer matching contributions are made solely at the Company's discretion. No employer matching contributions were made to the Plan during the years ended December 31, 2009, 2008 and 2007.

The Plan allows employees who meet the age requirements and reach the Plan contribution limits to make a catch-up contribution not to exceed the limit set forth in the Internal Revenue Code. In addition, the Plan provides for discretionary profit-sharing contributions as determined by the Board of Directors. Such contributions to the Plan are allocated among eligible participants in the proportion of their salaries to the total salaries of all participants. There were no discretionary profit-sharing contributions made during the years ended December 31, 2009, 2008 and 2007.

Table of Contents

SELECTED QUARTERLY DATA

(UNAUDITED, IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

	2009			
	Q1	Q2	Q3	Q4
Revenue	\$ 188,372	\$ 260,624	\$ 280,134	\$ 323,038
Gross profit	128,704	190,185	199,004	233,159
Net income	28,142	62,388	64,524	77,552
Net income per common share				
Basic	\$ 0.72	\$ 1.65	\$ 1.69	\$ 2.02
Diluted	\$ 0.72	\$ 1.62	\$ 1.64	\$ 1.95

	2008			
	Q1	Q2	Q3	Q4
Revenue	\$ 188,194	\$ 219,189	\$ 235,992	\$ 231,545
Gross profit	129,807	156,056	169,575	165,340
Net income	44,781	51,182	57,594	50,758
Net income per common share				
Basic	\$ 1.16	\$ 1.32	\$ 1.48	\$ 1.30
Diluted	\$ 1.12	\$ 1.28	\$ 1.44	\$ 1.27

Table of Contents**SCHEDULE II****INTUITIVE SURGICAL, INC.****VALUATION AND QUALIFYING ACCOUNTS****(IN THOUSANDS)**

	Balance at Beginning of Year	Additions	Deductions (1)	Balance at End of Year
Allowance for doubtful accounts and sales returns				
Year ended December 31, 2009	\$ 4,100	10,177	(9,988)	\$ 4,289
Year ended December 31, 2008	\$ 3,793	11,976	(11,669)	\$ 4,100
Year ended December 31, 2007	\$ 1,978	7,446	(5,631)	\$ 3,793

(1) Primarily represents amounts returned.

Table of Contents

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 principal executive officer and principal 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 principal executive officer and principal 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 principal executive officer and principal 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, 2009.

The effectiveness of our internal control over financial reporting as of December 31, 2009 has been audited by an independent registered public accounting firm, as stated in their report, which is included herein.

Changes in Internal Control Over Financial Reporting

None.

ITEM 9B. OTHER INFORMATION

None.

Table of Contents

PART III

Certain information required by Part III is omitted from this Report on Form 10-K and is incorporated herein by reference to our definitive Proxy Statement for our next Annual Meeting of Stockholders (the "Proxy Statement"), which we intend to file pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, within 120 days after December 31, 2009.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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.

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 Related Stockholder Matters" and "Equity Compensation Plan Information" in our Proxy Statement.

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.

Table of Contents

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

Table of Contents

Table of Contents

EXHIBIT INDEX

Exhibit

Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation of the Company.
3.2(1)	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Company.
3.3(2)	Amended and Restated Bylaws of the Company.
4.1(3)	Specimen Stock Certificate.
10.1(3)	Form of Indemnity Agreement.
10.2(3)	2000 Equity Incentive Plan.
10.3(3)	2000 Non-Employee Directors' Stock Option Plan.
10.4(3)	2000 Employee Stock Purchase Plan.
10.5(3)	Amended and Restated Investor Rights Agreement dated March 31, 1999.
10.6(4)	Severance Plan.
10.7(5)	Master Confirmation and Supplemental Confirmation Agreement between Intuitive Surgical, Inc. and Goldman, Sachs & Co.
10.8(6)	Form of Intuitive Surgical, Inc. 2000 Equity Incentive Plan Stock Option Agreement (Incentive and Nonstatutory Stock Options).
10.9(7)	Amendment effective as of January 1, 2010, to Employment Agreement between the Company and Lonnie M. Smith, dated February 28, 1997.
10.10(8)	2009 Employment Commencement Incentive Plan adopted October 22, 2009.
21.1(8)	Intuitive Surgical, Inc. subsidiaries.
23.1(8)	Consent of Independent Registered Public Accounting Firm.
31.1(8)	Certification of Principal Executive Officer.
31.2(8)	Certification of Principal Financial Officer.
32.1(8)	Certification of Chief Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101(9)	The following materials from Intuitive Surgical, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2009, formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Income, (iii) Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements, tagged as blocks of text.

- (1) Incorporated by reference to exhibits filed with the Company's 2008 Annual Report on Form 10-K filed February 6, 2009 (File No. 000-30713).
- (2) Incorporated by reference to Exhibit 3.1 filed with the Company's Current Report on Form 8-K filed March 6, 2009 (File No. 000-30713).
- (3) Incorporated by reference to exhibits filed with the Company's Registration Statement on Form S-1 (File No. 333-33016).

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

- (4) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed December 2, 2008 (File No. 000-30713).
- (5) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed March 6, 2009 (File No. 000-30713).

Table of Contents

- (6) Incorporated by reference to Exhibit 10.2 filed with the Company's Quarterly Report on Form 10-Q filed July 23, 2009 (File No. 000-30713).
- (7) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed November 12, 2009 (File No. 000-30713).
- (8) Filed herewith.
- (9) Users of the XBRL data are advised pursuant to Rule 406T of Regulation S-T that this interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.

Table of Contents**SIGNATURES**

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

INTUITIVE SURGICAL, INC.

(Registrant)

By: /s/ GARY S. GUTHART
Gary S. Guthart

President and Chief Executive Officer

January 29, 2010

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ GARY S. GUTHART Gary S. Guthart	President, Chief Executive Officer and Director (Principal Executive Officer)	January 29, 2010
/s/ MARSHALL L. MOHR Marshall L. Mohr	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	January 29, 2010
/s/ LONNIE M. SMITH Lonnie M. Smith	Chairman of the Board of Directors	January 29, 2010
/s/ FLOYD D. LOOP, M.D. Floyd D. Loop, M.D.	Director	January 29, 2010
/s/ D. KEITH GROSSMAN D. Keith Grossman	Director	January 29, 2010
/s/ ERIC H. HALVORSON Eric H. Halvorson	Director	January 29, 2010
/s/ ALAN J. LEVY, PH.D. Alan J. Levy, Ph.D.	Director	January 29, 2010
/s/ ROBERT W. DUGGAN	Director	January 29, 2010

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

Robert W. Duggan

/s/ **GEORGE J. STALK**

Director

January 29, 2010

George J. Stalk

/s/ **MARK J. RUBASH**

Director

January 29, 2010

Mark J. Rubash