

INTUITIVE SURGICAL INC
Form 10-K
February 01, 2011
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, 2010

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) (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:	Name of Each Exchange on which Registered
Common Stock, par value \$0.001 per share	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.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting Company
 (Do not check if a smaller reporting company)

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates on June 30, 2010, based upon the closing price of Common Stock on such date as reported by NASDAQ Global Select Market, was approximately \$11,157,929,000. 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 20, 2011 was 38,866,512.

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, 2011, to be filed within 120 days of the registrant's fiscal year ended December 31, 2010.

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>	35
Item 2.	<u>Properties</u>	35
Item 3.	<u>Legal Proceedings</u>	36

PART II

Item 5.	<u>Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	37
Item 6.	<u>Selected Consolidated Financial Data</u>	40
Item 7.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	40
Item 7A.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	57
Item 8.	<u>Financial Statements and Supplementary Data</u>	59
Item 9.	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	89
Item 9A.	<u>Controls and Procedures</u>	89
Item 9B.	<u>Other Information</u>	89

PART III

Item 10.	<u>Directors, Executive Officers and Corporate Governance</u>	90
Item 11.	<u>Executive Compensation</u>	90
Item 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	90
Item 13.	<u>Certain Relationships and Related Transactions</u>	90
Item 14.	<u>Principal Accountant Fees and Services</u>	90

PART IV

Item 15.	<u>Exhibits, Financial Statement Schedules</u>	91
----------	--	----

	<u>SIGNATURES</u>	94
--	-------------------	----

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, procedures and procedure adoption, 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: the impact of the global and regional economic conditions and related credit markets and related impact on health care spending; health care reform legislation in the United States and its implications on hospital spending, reimbursement and fees which will be levied on certain medical device revenues; timing and success of product development and market acceptance of developed products; procedure counts; regulatory approvals, clearances and restrictions; guidelines and recommendations in the health care and patient communities; intellectual property positions and litigation; competition in the medical device industry and in the specific markets of surgery in which Intuitive Surgical operates; unanticipated manufacturing disruptions; delays in regulatory approvals of new manufacturing facilities or the inability to meet demand for products; the results of legal proceedings to which we are or may become a party; the results of the year-end audit 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, Intuitive, the Company, 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, da Vinci® Si-e HD Surgical System, EndoWrist®, Single-Site, DVSTAT, and InSite® are trademarks of Intuitive Surgical, Inc.

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, which are 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, 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.

Table of Contents

By placing computer-enhanced technology between the surgeon and the patient, we believe that the *da Vinci* Surgical System enables surgeons to deliver higher value minimally invasive surgical procedures to their patients. We model patient value as equal to: *procedure efficacy / invasiveness*. Here *procedure efficacy* is a measure of the success of the surgery in resolving the underlying disease and *invasiveness* is how disruptive and painful the treatment is itself. When the patient value of robotic surgery is significantly higher than competing treatment options, we have seen that patients will seek out surgeons and hospitals that offer *da Vinci* procedures, potentially resulting in a local shift of treatment approach and market share. The combination of these local adoptions can drive a disruptive change in the marketplace and can lead to the broad adoption of robotic surgery. These adoptions occur procedure by procedure, and are driven by the relative patient value of *da Vinci* procedures against alternatives for the same disease state.

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 is a chronological summary of 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 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. During the year ended December 31, 2010, we sold 13 *da Vinci S* Systems in Japan. These sales were primarily made to early adopters. We are currently focusing our efforts with Johnson & Johnson K.K. Medical Company (Japan) on obtaining specific reimbursement approvals for *da Vinci* procedures in Japan. If we are not successful in obtaining system wide single procedure reimbursements

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

or obtaining approvals for future products and procedures, then the demand for our products could be limited. We have partnered with the experienced regulatory team from Johnson & Johnson K.K. Medical Company (Japan) in our Japanese regulatory process and are continuing to work with them to meet government requirements. We have partnered with Adachi Co., LTD as our separate independent distribution partner in Japan who is responsible for marketing, selling, and servicing our products in Japan.

As of December 31, 2010, we had an installed base of 1,752 *da Vinci* Surgical Systems. During the year ended December 31, 2010, we estimate that surgeons using our technology completed approximately 278,000

Table of Contents

surgical procedures of various types in major hospitals throughout the world. Out of those *da Vinci* procedures performed in 2010, we estimate that approximately 110,000 were *da Vinci* Hysterectomy (dVH) procedures and approximately 98,000 were *da Vinci* Prostatectomy (dVP) procedures.

We operate our business as one segment as defined by generally accepted accounting principles. Our financial results for the three years ended December 31, 2010 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 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.

Table of Contents

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 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.

Table of Contents

Facilitate Difficult MIS Operations. We believe that several surgical procedures that 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.

Intuitive Surgical's Products

Using the da Vinci Surgical System

During a procedure, the patient-side cart is positioned next to the operating table with the electromechanical arms arranged to provide access to the initial ports selected by the surgeon. 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.

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

Table of Contents

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 the *da Vinci* Surgical System including the ability to set and recall individual surgeon preferred ergonomic and visualization settings. We believe the simplified interface 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* instruments during a case. In addition, the surgeons can control 3D virtual pointers to augment the dual surgeon experience. We believe the dual console configuration could both shorten the learning curve for new surgeons and will allow for collaborative surgery in complex cases.

In the third quarter of 2010, we introduced the new *Si-e* model of the *da Vinci* Surgical System. The 3-arm *Si-e* System is designed to deliver core *da Vinci* functionality, providing a flexible, capable and economical solution for many robotic-assisted procedures. The *da Vinci Si-e* system is fully upgradeable to the *da Vinci Si* model by adding a fourth arm (third instrument arm), and other enhancements. During the year ended December 31, 2010, we sold 9 *da Vinci Si-e* systems.

In the fourth quarter of 2010, we introduced the *da Vinci* Skills Simulator. The simulator is a practice tool which will begin shipping in early 2011 for the *da Vinci Si* Surgical System that gives a user the opportunity to practice his or her facility with the surgeon console controls. The simulator incorporates three-dimensional, physics-based computer simulation technology to immerse the user within a virtual environment. The user navigates through the environment and completes exercises by controlling virtual instruments from the surgeon console. The suite of exercises includes novice, intermediate, and advanced levels. Upon completion of a skills exercise, the simulator provides a quantitative assessment of user performance based on a variety of task-specific metrics. The Skills Simulator is intended to augment, not replace, existing training programs for the *da Vinci Si* Surgical System.

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

Table of Contents

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.

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 2010, the mix of procedures performed with the *da Vinci* Surgical System among these five surgical specialties was largest within gynecology, followed by urology, 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* Lobectomy, *da Vinci* Gastric Bypass, *da Vinci* Low Anterior Colon Resection, *da Vinci* Thyroidectomy and *da Vinci* Trans Oral Robotic Surgery (for cancers of the throat). 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.

Table of Contents

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 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.

Table of Contents

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 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

Table of Contents

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.

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

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.

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

Table of Contents

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.

Head and Neck Surgery

Transoral Surgery. Head and neck cancer, which most often occurs in the throat due to prolonged tobacco and alcohol use, and has been linked to human papilloma virus, 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.

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. 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.

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*

Table of Contents

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, 2010, 2009 and 2008.

As of December 31, 2010, we had approximately 700 employees in our field sales and service organizations, up from approximately 490 employees in these organizations as of December 31, 2009, primarily reflecting growth in our clinical sales force supporting procedures performed at customer sites. 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, 2010, approximately 19% 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.

Our business is subject to seasonal fluctuations. Historically, our sales of *da Vinci* Surgical Systems have tended to be heaviest during the third month of each fiscal quarter, and lighter in the third and first fiscal quarters and heavier in the fourth fiscal quarter. In addition, historically, we have experienced lower procedure counts in the third fiscal quarter, higher procedure counts in the fourth fiscal quarter and lower procedure counts in the first fiscal quarter. Timing of procedures and changes in procedure growth directly affect the timing of instrument and accessory purchases and capital purchases.

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 that teaches the fundamental operating principles of the *da Vinci* Surgical System to surgeons and operating room nurses. 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

Table of Contents

maintain research and development and engineering staff responsible for product design and engineering. We invested \$116.0 million, \$95.1 million and \$79.4 million of research and development expenses for the years ended December 31, 2010, 2009 and 2008, 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, USGI Medical, Inc and Cardica, 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.

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 but not limited to Alf-X , EndoControls, Inc., Meere Company, Inc., Olympus, and Titan Medical. 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.

Table of Contents

As of December 31, 2010, we held ownership or exclusive field-of-use license for more than 850 U.S. and foreign patents and more than 950 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 FFDCFA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Our current products are Class II medical devices.

Class 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,

Table of Contents

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 July 2010 and the FDA issued a Form FDA 483 listing deficiencies under the QSR relating to complaint handling and manufacturing/inspection handling. 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;

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:

fines, injunctions, and civil penalties;

recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

refusing our requests for 510(k) clearance or PMA approval of new products;

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

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 February 2009 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.

Table of Contents

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. We are currently focusing our efforts with Johnson & Johnson K.K. Medical Company (Japan) on obtaining specific reimbursement for *da Vinci* procedures in Japan. If we are not successful in obtaining system wide single procedure reimbursements or obtaining approvals for future products and procedures, then the demand for our products could be limited. We have partnered with the experienced regulatory team from Johnson & Johnson K.K. Medical Company (Japan) in our Japanese regulatory process and are continuing to work with them to meet government requirements. We have partnered with Adachi Co., LTD as our separate independent distribution partner in Japan who is responsible for marketing, selling, and servicing our 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 (MDD) (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 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 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 CE certificate is valid until March 2012 and the MDD certificate is valid until March 2014. The most recent audit of the facility was in October 2010, 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 Coverage and 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 covered surgical procedures. Governments and insurance companies generally reimburse hospitals and physicians for surgery when the procedures are considered medically necessary. In the United States, the Centers for

Table of Contents

Medicare & Medicaid Services, or CMS, administers the Medicare and Medicaid programs. Generally, reimbursement for professional services performed at the hospital by physicians is reported under separate billing codes issued by the American Medical Association, or AMA, known as Current Procedural Terminology, or CPT, codes. Physician reimbursement is based on a prospective payment system based on the professional service rendered. In addition, CMS and the National Center for Health Statistics, or NCHS, are jointly responsible for overseeing changes and modifications to billing codes known as ICD-9-CM codes used by hospitals to report inpatient procedures. CMS generally reimburses hospitals for services provided during an inpatient stay based on a prospective payment system that is determined by a classification system known as Medicare-Severity Diagnostic Related Groupings, or DRGs and Ambulatory Payment Classifications, or APCs for hospital outpatient services. MS-DRGs are assigned using a number of factors including the principal diagnosis, major procedures, discharged status, patient age and complicating secondary diagnoses among other things.

On October 1, 2008, CMS and NCHS 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 amount paid to hospitals. A surgical procedure, completed with or without robotic assistance, continues to be assigned to the same 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 payor and other factors. Because both hospitals and physicians receive the same reimbursement amount for their respective services 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, hospitals and physicians may decide not to use our products if reimbursement amounts are insufficient 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 FDA, Medicare coverage and reimbursement are generally available for the primary surgical procedure using our device. 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 cover 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 CPT code for robotic-assisted surgery from the AMA and/or work with CMS to obtain coverage and/or establish a higher reimbursement amount. If an application for a unique code or modifier is required, reimbursement for any use of our products may be unavailable until appropriate new 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.

Table of Contents

In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the PPACA), which makes changes that are expected to significantly impact the pharmaceutical and medical device industries. One of the principal aims of the PPACA as currently enacted is to expand health insurance coverage to approximately 32 million Americans who are currently uninsured. The consequences of these significant coverage expansions on the sales of the Company's products are unknown and speculative at this point.

The PPACA contains a number of provisions designed to generate the revenues necessary to fund the coverage expansions among other things. This includes new fees or taxes on certain health-related industries, including medical device manufacturers. Beginning in 2013, medical device manufacturers will have to pay an excise tax (or sales tax) of 2.3 percent of certain U.S. medical device revenues. Though there are some exceptions to the excise tax, this excise tax applies to most of the Company's products and product candidates sold within the U.S..

The PPACA provisions on comparative clinical effectiveness research extend the initiatives of the American Recovery and Reinvestment Act of 2009, also known as the stimulus package, which included \$1.1 billion in funding to study the comparative effectiveness of health care treatments and strategies. This stimulus funding was designated for, among other things, conducting, supporting or synthesizing research that compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products. The PPACA appropriates additional funding to comparative clinical effectiveness research. Although Congress has indicated that this funding is intended to improve the quality of health care, it remains unclear how the research will impact current Medicare coverage and reimbursement or how new information will influence other third-party payor policies. The PPACA, as well as other federal or state health care reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and our ability to successfully commercialize our products or could limit or eliminate our spending on certain development projects. The taxes imposed by the new federal legislation and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursement by payors for our products, and/or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

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, 2010, we had 1,660 employees, 218 of whom were engaged directly in research and development, 511 in manufacturing and service and 931 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, 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 amendments to those reports, available 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 continue to pose a risk as customers may postpone spending in response to restraints on credit. There could be additional effects from the credit crisis on our business, including the insolvency of key suppliers or their inability to obtain credit to finance the development and/or manufacture of our products resulting in product delays, and the inability of our customers and distributors, to obtain credit to finance purchases of our products. If conditions worsen or if the improved economic conditions are slower than anticipated, 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, 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.

Table of Contents

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 CAPITAL SALES CYCLES AND SEASONALITY IN OUR BUSINESS, WHICH MAY CAUSE FLUCTUATIONS IN OUR FINANCIAL RESULTS.

Our *da Vinci* Surgical System has a lengthy sales and purchase order cycle because it is a major capital item and its purchase generally requires the approval of senior management of hospitals, their parent organizations, purchasing groups, and government bodies, as applicable. This approval process can be lengthy. In addition, hospitals may delay or accelerate system purchases in conjunction with timing of their capital budget timelines. As a result, it is difficult for us to predict the length of capital sales cycles and, therefore, the exact timing of capital sales. Historically, our sales of *da Vinci* Surgical Systems have tended to be heaviest during the third month of each fiscal quarter, and lighter in the third and first fiscal quarters and heavier in the fourth fiscal quarter.

Recently, we have experienced procedure growth for a number of benign conditions, including hysterectomies for benign conditions, sacrocolpoplexies, myomectomies, and certain other surgeries. Surgeries for benign conditions represented more than 40% of our total procedures in 2010. Many of these types of surgeries may be postponed in the short term by patients to avoid vacation periods and for other personal scheduling reasons. Patients may also accelerate procedures to take advantage of insurance funding cut-off dates. Historically, we have experienced lower procedure counts in the third fiscal quarter, higher procedure counts in the fourth fiscal quarter and lower procedure counts in the first fiscal quarter. Timing of procedures and changes in procedure growth directly affect the timing of instrument and accessory purchases and capital purchases.

The above 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, among other factors, 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 20%, 21%, and 22% of our revenue for the

Table of Contents

years ended December 31, 2010, 2009 and 2008, 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.

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;

Table of Contents

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.

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

Table of Contents

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 COVERAGE AND 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.

In the United States, hospitals generally bill the services performed with our products to various third-party payors, such as Medicare, Medicaid and other government programs and private insurance plans. If hospitals do not obtain sufficient reimbursement from third-party payors for procedures performed with our products, or if government and private payors' policies do not cover 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 coverage and 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 coverage and 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 Policy Changes, Including Recently Enacted Legislation Reforming the U.S. Healthcare System, May Have a Material Adverse Effect on Our Financial Condition and Results of Operations" and "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.

Table of Contents

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.

UNFAVORABLE RESULTS OF LEGAL PROCEEDINGS COULD MATERIALLY ADVERSELY AFFECT US.

We are and may become subject to various legal proceedings and claims that arise in or outside the ordinary course of business.

On August 6, 2010, a purported class action lawsuit was filed against us and several of our officers and directors in the United States District Court for the Northern District of California seeking unspecified damages on behalf of a putative class of persons who purchased or otherwise acquired our common stock between February 1, 2008 and January 7, 2009. The complaint alleges that we violated federal securities laws by making allegedly false and misleading statements and omitting certain material facts in our filings with the Securities and Exchange Commission. Two purported derivative actions making substantially similar allegations were filed in the Superior Court of California for the County of Santa Clara shortly thereafter. Those actions are described more fully under Part I, Item 3, Legal Proceedings.

The results of these lawsuits and other legal proceedings cannot be predicted with certainty. Accordingly, we cannot determine whether our insurance coverage would be sufficient to cover the costs or potential losses, if any. Regardless of merit, litigation may be both time-consuming and disruptive to our operations and cause significant expense and diversion of management attention. If we do not prevail in the purported class action lawsuit or other legal proceedings, we may be faced with significant monetary damages or injunctive relief against us that may adversely affect our business, financial condition and results of operations, possibly materially.

WE ARE SUBJECT TO SIGNIFICANT, UNINSURED LIABILITIES.

For certain risks, we do not maintain insurance coverage because of cost and/or availability. For example, we indemnify our directors and officers for third-party claims and do not insure for the underlying losses, and we do not carry earthquake insurance, among others. In addition, in the future, we may not continue to maintain certain existing insurance coverage or adequate levels of coverage. Premiums for many types of insurance have increased significantly over the years, and depending on market conditions and our circumstances, in the future, certain types of insurance such as directors and officers insurance or products liability insurance may not be available on acceptable terms or at all. Because we retain some portion of our insurable risks, and in some cases self-insure completely, unforeseen or catastrophic losses in excess of insurance coverage could require us to pay substantial amounts, which would materially adversely affect our financial condition and operating results.

WE USE ESTIMATES, MAKE JUDGMENTS AND APPLY CERTAIN METHODS IN MEASURING THE PROGRESS OF OUR BUSINESS. IN DETERMINING OUR FINANCIAL RESULTS AND IN APPLYING OUR ACCOUNTING POLICIES. AS THESE ESTIMATES, JUDGMENTS, AND METHODS CHANGE, OUR ASSESSMENT OF THE PROGRESS OF OUR BUSINESS AND OUR RESULTS OF OPERATIONS COULD VARY.

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

In addition, we utilize methods for determining surgical market sizes and *da Vinci* procedures completed that involve estimates and judgments, which are, by their nature, subject to substantial risks, uncertainties, and assumptions. Our estimates of surgical market sizes or *da Vinci* procedures performed do not have an impact on our results of operations but are used to estimate the progress of our business. Estimates and judgments for determining surgical market sizes and *da Vinci* procedures may vary over time with changes in treatment modalities, hospital reporting behavior, increases in procedures per field employee and other factors. In addition, over time, we may change the method for determining market sizes and *da Vinci* procedures, causing variation in our reporting.

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, 2010, we held \$18.6 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. Accordingly, changes in associated market value during the year ended December 31, 2010 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.

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

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

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 POLICY CHANGES, INCLUDING RECENTLY ENACTED LEGISLATION REFORMING THE U.S. HEALTHCARE SYSTEM, MAY HAVE A MATERIAL ADVERSE EFFECT ON OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the PPACA), which makes changes that are expected to significantly impact the pharmaceutical and medical device industries. One of the principal aims of the PPACA as currently enacted is to expand health insurance coverage to approximately 32 million Americans who are currently uninsured. The consequences of these significant coverage expansions on the sales of our products are unknown and speculative at this point.

The PPACA contains a number of provisions designed to generate the revenues necessary to fund the coverage expansions among other things. This includes new fees or taxes on certain health-related industries, including medical device manufacturers. Beginning in 2013, medical device manufacturer will have to pay an excise tax (or sales tax) of 2.3 percent of certain U.S. medical device revenues. Though there are some exceptions to the excise tax, this excise tax does apply to all of our products and product candidates sold within the U.S..

The PPACA provisions on comparative clinical effectiveness research extend the initiatives of the American Recovery and Reinvestment Act of 2009, also known as the stimulus package, which included \$1.1 billion in funding to study the comparative effectiveness of health care treatments and strategies. This stimulus funding was designated for, among other things, conducting, supporting or synthesizing research that compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products. The PPACA appropriates additional funding to comparative clinical effectiveness research. Although Congress has indicated that this funding is intended to improve the quality of health care, it remains unclear how the research will impact current Medicare coverage and reimbursement or how new information will influence other third-party payor policies. We expect that the PPACA, as well as other federal or state health care reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and our ability to successfully commercialize our products or could limit or eliminate our spending on certain development projects. The taxes imposed by the new federal legislation and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursement by payors for our products, and/or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

HEALTHCARE REFORMS, CHANGES IN HEALTHCARE POLICIES AND CHANGES TO THIRD-PARTY COVERAGE AND 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. We are unable to predict 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.

Table of Contents

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. Further, the recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Moreover, some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs to ensure compliance with these laws. 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.

The PPACA also imposes new reporting and disclosure requirements on device manufacturers for any transfer of value made or distributed to prescribers and other healthcare providers, effective March 30, 2013. Such information must be made publicly available in a searchable format beginning September 30, 2013. In addition, device manufacturers will also be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (and up to an aggregate of \$1 million per year for knowing failures), for all payments, transfers of value or ownership or investment interests not reported in an annual submission.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians, including the tracking and reporting of gifts, compensation, and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Compliance with complex foreign and U.S. laws and regulations that apply to our international operations increases our cost of doing business in international jurisdictions and could expose us or our employees to fines and penalties in the U.S. and/or abroad. These numerous and sometimes conflicting laws and regulations include US laws such as the Foreign Corrupt Practices Act, and local laws prohibiting corrupt payments to government officials. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, prohibitions on the conduct of our business, and damage to our reputation. Although we have implemented policies and procedures designed to ensure compliance with these laws, there can be no assurance that our employees, contractors, or agents will not violate our policies.

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 FFDC. 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. Regulatory policy affecting our products can change at any time. The changes and their impact on our business cannot be accurately predicted. Changes in the FDA 510(k) process could make approval more difficult to obtain, increase delay, add uncertainty and have other significant adverse effects on our ability to obtain and maintain approval for our products. 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 July 2010 and the FDA issued a Form FDA 483 listing deficiencies under the QSR relating to complaint handling and manufacturing/inspection handling. 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

Table of Contents

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.

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 currently plan to apply for permission to affix the CE mark to such products. In addition, we will be subject to annual regulatory audits in order to maintain the CE mark permissions we have already obtained. We do not know whether we will be able to obtain permission to affix the CE mark for new or modified products or that we will continue to meet the quality and safety standards required to maintain the permissions we have already received. If we are unable to maintain permission to affix the CE mark to our products, we will no longer be able to sell our products in member countries of the 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 obtaining the appropriate reimbursement approvals 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. Our last inspection occurred in July 2010 and the FDA issued a Form FDA 483 listing deficiencies under the QSR relating to complaint handling and manufacturing/inspection handling. 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;

Table of Contents

the size and timing of particular sales and any collection delays related to those sales;

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 and during fiscal 2010, it reached a high of \$388.01 and a low of \$247.50. 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;

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

economic changes and overall market volatility; and

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, 2010, we owned approximately 540,000 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. In addition, we entered into an agreement in August 2010

Table of Contents

to purchase 17.7 acres of land and buildings for \$33.0 million in Sunnyvale, California by June 2011. 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, Switzerland and a 34,000 square-foot building in Mexicali, Mexico where we manufacture most of our *Endowrist* instruments. We also lease facilities for sales and operations in Tokyo, Japan and Shanghai, China.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in a variety of claims, lawsuits, investigations and proceedings relating to securities laws, product liability, patent infringement, contract disputes and other matters relating to various claims that arise in the normal course of our business. Certain of these lawsuits are described in further detail below. We do not know whether we will prevail in these matters nor can we assure that any remedy could be reached on commercially reasonable 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 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.

Purported Shareholder Class Action Lawsuit filed August 6, 2010

On August 6, 2010, a purported class action lawsuit entitled *Perlmutter v. Intuitive Surgical et al.*, No. CV10-3451, was filed against us and seven of our current and former officers and directors in the United States District Court for the Northern District of California. The lawsuit seeks unspecified damages on behalf of a putative class of persons who purchased or otherwise acquired our common stock between February 1, 2008 and January 7, 2009. The complaint alleges that the defendants violated federal securities laws by making allegedly false and misleading statements and omitting certain material facts in our filings with the Securities and Exchange Commission.

Purported Derivative Actions

On August 19, 2010, an alleged shareholder caused a purported shareholder's derivative lawsuit entitled *Himmel v. Smith et al.*, No. 1-10-CV-180416, to be filed in the Superior Court of California for the County of Santa Clara naming us as a nominal defendant, and naming 14 of our current and former officers and directors as defendants. The lawsuit seeks to recover, for the company's benefit, unspecified damages purportedly sustained by us in connection with allegedly misleading statements and/or omissions made in connection with our financial reporting for the period between February 1, 2008 and January 7, 2009. It also seeks a series of changes to our corporate governance policies and an award of attorney's fees. On September 15, 2010, another purported shareholder filed an essentially identical lawsuit entitled *Applbaum v. Guthart et al.*, No. 1-10-CV-182645, in the same court against 15 of our current and former officers and directors. On October 5, 2010, the court ordered that the two cases be consolidated for all purposes.

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	2010		2009	
	High	Low	High	Low
First Quarter	\$ 362.80	\$ 304.39	\$ 132.41	\$ 85.33
Second Quarter	\$ 388.01	\$ 311.90	\$ 166.52	\$ 94.33
Third Quarter	\$ 340.51	\$ 265.03	\$ 262.25	\$ 142.60
Fourth Quarter	\$ 292.89	\$ 247.50	\$ 306.58	\$ 246.35

As of January 20, 2011, there were 480 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, 2010 for two categories of equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants 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	4,588,376	\$ 204.42	2,050,528
Equity compensation plans not approved by security holders	224,694	\$ 303.20	75,306
Total	4,813,070	\$ 209.03	2,125,834

RECENT SALE OF UNREGISTERED SECURITIES

None.

ISSUER PURCHASES OF EQUITY SECURITIES

On March 4, 2009, we announced that our Board of Directors (the Board) had authorized the repurchase of up to \$300.0 million of our common stock. In the first quarter ended March 31, 2009, we repurchased \$150.0 million of our common stock, leaving \$150.0 million remaining to be

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

repurchased under the program. On July 23, 2010, we announced that the Board authorized an additional \$150.0 million for share repurchase, with no specific expiration date, increasing the remaining amount to be repurchased under the program to \$300.0 million.

Table of Contents

The table below summarizes our share repurchase activity for the three months ended December 31, 2010:

Fiscal Period	Total Number of Shares Repurchased	Average Price Paid Per Share	Total Number of Shares Purchased As Part of a Publicly Announced Program	Approximate Dollar Amount of Shares That May Yet be Purchased Under the Program
October 1, 2010 to October 31, 2010	40,000	\$ 265.28	40,000	\$ 230.5 million
November 1, 2010 to November 30, 2010	290,000	\$ 265.28	290,000	\$ 153.6 million
December 1, 2010 to December 31, 2010	200,000	\$ 261.29	200,000	\$ 101.3 million
Total during quarter ended December 31, 2010	530,000	\$ 263.77	530,000	\$ 101.3 million

Table of Contents**STOCK PERFORMANCE GRAPH**

The graph set forth below compares the cumulative total stockholder return on our common stock between December 31, 2005 and December 31, 2010, 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, 2005 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.

	12/31/05	12/31/06	12/31/07	12/31/08	12/31/09	12/31/10
Intuitive Surgical, Inc.	100.00	81.78	275.43	108.29	258.74	219.79
NASDAQ Composite	100.00	109.52	120.27	71.51	102.89	120.29
S&P Healthcare Index	100.00	105.78	111.49	84.20	98.57	99.26
S&P 500 Index	100.00	113.62	117.63	72.36	89.33	100.75

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,				
	2010	2009	2008	2007	2006
	(In millions, except per share amounts and headcount)				
Revenue	\$ 1,413.0	\$ 1,052.2	\$ 874.9	\$ 600.8	\$ 372.7
Gross profit	\$ 1,030.0	\$ 751.1	\$ 620.8	\$ 414.3	\$ 247.8
Net income (1)	\$ 381.8	\$ 232.6	\$ 204.3	\$ 144.5	\$ 72.0
Net income per common share:					
Basic	\$ 9.74	\$ 6.07	\$ 5.26	\$ 3.82	\$ 1.96
Diluted	\$ 9.47	\$ 5.93	\$ 5.12	\$ 3.70	\$ 1.89
Shares used in computing basic and diluted net income per share:					
Basic	39.2	38.3	38.9	37.8	36.7
Diluted	40.3	39.2	39.9	39.0	38.1
Cash, cash equivalents and investments	\$ 1,608.9	\$ 1,172.0	\$ 901.9	\$ 635.4	\$ 330.3
Total assets	\$ 2,390.4	\$ 1,809.7	\$ 1,474.6	\$ 1,040.0	\$ 671.8
Long-term liabilities	\$ 79.2	\$ 69.6	\$ 43.3	\$ 19.6	\$ 1.4
Shareholders' equity	\$ 2,037.4	\$ 1,537.3	\$ 1,266.8	\$ 888.7	\$ 589.7
Total headcount	1,660	1,263	1,049	764	563

- (1) Net income for the years ended December 31, 2010, 2009, 2008, 2007 and 2006 included stock-based compensation expense under U.S. GAAP of \$78.4 million, \$70.5 million, \$53.4 million, \$23.6 million, and \$16.3 million, respectively, net of tax, related to employee stock options and employee stock purchases. Net income for the years ended December 31, 2010, 2009, 2008, 2007, and 2006 included amortization of purchased intellectual property of \$16.3 million, \$15.1 million, \$9.8 million, \$1.3 million and \$0.8 million, respectively.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**Overview****2010 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, which are 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, 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 deliver higher value minimally invasive surgical procedures to their patients. We model patient value as equal to: *procedure efficacy / invasiveness*. Here *procedure efficacy* is a

Table of Contents

measure of the success of the surgery in resolving the underlying disease and *invasiveness* is how disruptive and painful the treatment is itself. When the patient value of robotic surgery is significantly higher than competing treatment options, we have seen that patients will seek out surgeons and hospitals that offer *da Vinci* procedures, potentially driving a disruptive change in the marketplace and can lead to the broad adoption of robotic surgery. These adoptions occur procedure by procedure, and are driven by the relative patient value of *da Vinci* procedures against alternatives for the same disease state.

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. The *da Vinci* Surgical System generally sells for between \$1.0 million and \$2.3 million, depending on configuration and geography, and represents a significant capital equipment investment for our customers. We then generate recurring revenue as our customers consume our *EndoWrist* instruments and accessory products for use in performing procedures with the *da Vinci* Surgical System. *EndoWrist* instruments and accessories have a limited life and will either expire or wear out as they are used in surgery, at which point they are replaced. We also generate 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 \$170,000 per year, depending on the configuration of the underlying system.

Recurring revenue has generally grown at a faster rate than system revenue. Recurring revenue increased from \$419.6 million, or 48% of total revenue in 2008, to \$561.7 million, or 53% of total revenue in 2009 to \$752.7 million, or 53% of total revenue in 2010. 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 1,752 at December 31, 2010, compared with 1,395 at December 31, 2009 and 1,111 at December 31, 2008.

Regulatory Activities

We believe that we have obtained the necessary clearances 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

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

December 2009 Transoral Otolaryngologic surgical procedures

During first quarter of 2009, we received clearances 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. During the year ended December 31, 2010, we sold 13 *da Vinci S* Systems in Japan. These sales were primarily made to early adopters. We are currently focusing our

Table of Contents

efforts with Johnson & Johnson K.K. Medical Company (Japan) on obtaining specific reimbursement approvals for *da Vinci* procedures in Japan. If we are not successful in obtaining system wide single procedure reimbursements or obtaining approvals for future products and procedures, then the demand of our products could be limited. We have partnered with the experienced regulatory team from Johnson & Johnson K.K. Medical Company (Japan) in our Japanese regulatory process and are continuing to work with them to meet government requirements. We have partnered with Adachi Co., LTD as our separate independent distribution partner in Japan who is responsible for marketing, selling, and servicing our products in Japan.

2010 Business Events and Trends

Economic Environment. During the first half of 2009, the world-wide economic recession curtailed capital purchases of our *da Vinci* Surgical Systems. The 441 total *da Vinci* Surgical Systems sold in the year ended December 31, 2010 exceeded those sold during the same period of 2009 by 103 systems.

***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 enhance surgeon precision and confidence and may contribute to improved patient outcomes and shorter procedure times. Secondly, the *da Vinci Si* surgeon console'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 most countries other than Japan. *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, excluding endoscopes and drapes, are compatible with the *da Vinci Si* system. We will continue to sell, service and support the *da Vinci S* Surgical System. Our sales of the standard *da Vinci* Surgical System have substantially ended; however, we continue to service and support this product line.

Most customers who purchased *da Vinci S* Surgical Systems in the first quarter of 2009 were offered 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 of deferred revenue. The deferral and subsequent recognition did not impact the comparability of the results for the year ended 2010 to any other year.

Market acceptance of the *da Vinci Si* Surgical System has been positive since its market introduction in the second quarter of 2009. In the year ended December 31, 2010, 372 out of 441 systems sold were *da Vinci Si* Surgical Systems, representing approximately 84% of system sales.

Table of Contents

In the third quarter of 2010, we introduced the new *Si-e* model of the *da Vinci* Surgical System. The 3-arm *Si-e* System is designed to deliver core *da Vinci* functionality, providing a flexible, capable and economical solution for many robotic-assisted procedures. The *da Vinci Si-e* system is fully upgradeable to the *da Vinci Si* model by adding a fourth arm (third instrument arm), and other enhancements. During the year ended December 31, 2010, we sold 9 *da Vinci Si-e* systems.

In the fourth quarter of 2010, we introduced the *da Vinci* Skills Simulator. The simulator is a practice tool which will begin shipping in early 2011 for the *da Vinci Si* Surgical System that gives a user the opportunity to practice his or her facility with the surgeon console controls. The simulator incorporates three-dimensional, physics-based computer simulation technology to immerse the user within a virtual environment. The user navigates through the environment and completes exercises by controlling virtual instruments from the surgeon console. The suite of exercises includes novice, intermediate, and advanced levels. Upon completion of a skills exercise, the simulator provides a quantitative assessment of user performance based on a variety of task-specific metrics. The Skills Simulator is intended to augment, not replace, existing training programs for the *da Vinci Si* Surgical System.

2010 Financial Highlights

Total revenue increased to \$1,413.0 million, or 34%, during the year ended December 31, 2010 from \$1,052.2 million during the year ended December 31, 2009.

Approximately 278,000 *da Vinci* procedures were performed during the year ended December 31, 2010, up approximately 35% from last year.

Instruments and accessories revenue increased to \$528.8 million or 36% during the year ended December 31, 2010 from \$389.4 million during the year ended December 31, 2009.

Recurring revenue increased to \$752.7 million, or 34% during the year ended December 31, 2010, representing 53% of total revenue from \$561.7 million during the year ended December 31, 2009, representing 53% of total revenue.

We sold 441 *da Vinci* Surgical Systems during the year ended December 31, 2010, compared with 338 for the year ended December 31, 2009.

System revenue increased to \$660.3 million, or 35% during the year ended December 31, 2010 from \$490.5 million during the year ended December 31, 2009.

As of December 31, 2010, we had a *da Vinci* Surgical System installed base of 1,752 systems, 1,285 in the United States, 316 in Europe, and 151 in the rest of the world.

Operating income increased to \$555.2 million, or 47% during the year ended December 31, 2010 compared to \$377.4 million during the year ended December 31, 2009. Operating income included \$117.6 million and \$97.0 million during the years ended December 31, 2010 and 2009, respectively, of stock-based compensation expense related to employee stock programs.

We ended fiscal 2010 with \$1,608.9 million in cash, cash equivalents and investments. Cash, cash equivalents, and investments increased by \$436.9 million during 2010 driven by cash flow from operations and \$141.1 million generated from employee stock programs, partially offset by \$198.6 million used to repurchase and retire 0.7 million shares of common stock, and \$96.0 million used for capital expenditure and the purchase of intellectual property.

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 greater patient value than non *da Vinci* alternatives . We believe the value of a surgical procedure to a patient is higher if it offers superior clinical outcomes, less surgical trauma, or both.

Table of Contents

An increasing body of peer review literature has indicated that dVP offers improved functional outcomes compared to traditional open prostatectomy with less surgical and post-surgical morbidity. Favorable clinical outcomes have also 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, reduced post-operative complications and a quicker return to normal daily activities when compared to open surgery.

In 2010, approximately 278,000 surgical procedures were performed with the *da Vinci* Surgical System, up approximately 35% compared to 2009. The growth in our overall procedure volume was driven primarily by: *da Vinci* Hysterectomy (dVH) in the U.S., *da Vinci* Prostatectomy (dVP) outside the U.S. and pull-through procedures in the Urology and Gynecology categories (Nephrectomy (partial and full), Sacralcolpopexy, Myomectomy, Cystectomy, Pyeloplasty) in the U.S.

During 2010, dVH became our highest volume procedure, surpassing dVP. dVH procedure volume grew from approximately 69,000 cases in 2009 to approximately 110,000 cases in 2010, of which approximately 32,000 were for the treatment of cancer and the remaining 78,000 related to benign conditions. The very large majority of our 2010 dVH volume came from the US market, where we estimate the total annual addressable robotic market to be approximately 300,000 to 350,000 cases, of which about 50,000 are for cancer.

dVP procedure volume grew from approximately 90,000 cases in 2009 to approximately 98,000 cases worldwide, in 2010. The large majority of the approximately 85,000 prostatectomies performed each year in the US are done robotically with the *da Vinci*. 2010 US dVP volume was essentially flat, with the majority of our 2010 worldwide dVP growth coming from European markets.

Other procedures (non-dVH/dVP) grew over 50% in 2010 to approximately 70,000 cases. Growth in these other *da Vinci* procedures is comprised of pull-through procedures such as *da Vinci* Partial Nephrectomy in Urology and *da Vinci* Sacralcolpopexy in Gynecology as well as other procedures, which we term emerging procedures. Emerging procedures are earlier in their development, such as *da Vinci* Transoral Robotic Surgery (TORS) in head and neck surgery. While early results in emerging procedures are encouraging and may point to significant patient value, their growth is off of a small absolute base and their future growth rates are uncertain.

Technology Acquisitions

We continue to make several strategic acquisitions of intellectual property and related technologies. Total investments in intellectual property and related technologies during the year ended December 31, 2010 were \$38.2 million, compared to \$25.7 during the year ended December 31, 2009. Amortization expense related to purchased intellectual property for the year ended December 31, 2010 and 2009 were \$16.3 million and \$15.1 million, respectively.

Building Acquisition

During the third quarter of 2010, we entered into an agreement to purchase 17.7 acres of land and buildings for \$33.0 million in Sunnyvale, California by June 2011. This property is in close proximity to our existing headquarters. Although we entered into the agreement to support the potential growth of our business there is no guarantee that the planned growth and expansion will take place in the timeframe we expected, or at all.

Table of Contents**Results of Operations**

The following table sets forth, for the years indicated, certain Consolidated Statements of Income information (in millions):

	2010	% of total revenue	Year Ended December 31, 2009	% of total revenue	2008	% of total revenue
Revenue:						
Product	\$ 1,189.1	84%	\$ 879.9	84%	\$ 748.3	86%
Service	223.9	16%	172.3	16%	126.6	14%
Total revenue	1,413.0	100%	1,052.2	100%	874.9	100%
Cost of revenue:						
Product	297.3	21%	237.6	23%	200.1	23%
Service	85.7	6%	63.5	6%	54.0	6%
Total cost of revenue	383.0	27%	301.1	29%	254.1	29%
Product gross profit	891.8	63%	642.3	61%	548.2	63%
Service gross profit	138.2	10%	108.8	10%	72.6	8%
Gross profit	1,030.0	73%	751.1	71%	620.8	71%
Operating expenses:						
Selling, general and administrative	358.8	25%	278.6	26%	230.6	26%
Research and development	116.0	8%	95.1	9%	79.4	9%
Total operating expenses	474.8	33%	373.7	35%	310.0	35%
Income from operations	555.2	40%	377.4	36%	310.8	36%
Interest and other income, net	17.1	1%	18.7	2%	24.4	2%
Income before income taxes	572.3	41%	396.1	38%	335.2	38%
Income tax expense	190.5	14%	163.5	16%	130.9	15%
Net income	\$ 381.8	27%	\$ 232.6	22%	\$ 204.3	23%

Total Revenue

Total revenue increased by 34% and 20% during the years ended December 31, 2010 and 2009, respectively. Total revenue increased to \$1,413.0 million during the year ended December 31, 2010 from \$1,052.2 million during the year ended December 31, 2009 from \$874.9 million during the year ended December 31, 2008. 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, driving higher system and recurring revenue. Our revenue growth during the periods presented reflects penetration in our target procedures. dVH and dVP are our two largest procedures, representing more than 70% of our total procedures over the past several years.

Revenue within the United States accounted for 80%, 79%, and 78% of total revenue during the years ended December 31, 2010, 2009, and 2008, respectively. We believe domestic revenue has accounted for the large majority of total revenue primarily due to the ability of patients to choose their provider and method of treatment in the U.S.

Table of Contents

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

Revenue	Year Ended December 31,		
	2010	2009	2008
Instruments and accessories	\$ 528.8	\$ 389.4	\$ 293.0
Systems	660.3	490.5	455.3
Total product revenue	1,189.1	879.9	748.3
Services	223.9	172.3	126.6
Total revenue	\$ 1,413.0	\$ 1,052.2	\$ 874.9
Recurring revenue	\$ 752.7	\$ 561.7	\$ 419.6
% of total revenue	53%	53%	48%
Revenue Domestic	\$ 1,126.0	\$ 827.0	\$ 679.7
Revenue International	287.0	225.2	195.2
Total revenue	\$ 1,413.0	\$ 1,052.2	\$ 874.9
Domestic Unit Sales	335	252	246
International Unit Sales	106	86	89
Total Unit Sales	441	338	335

Product Revenue

Product revenue increased to \$1,189.1 million during the year ended December 31, 2010 from \$879.9 million during the year ended December 31, 2009.

Instruments and accessories revenue increased to \$528.8 million for the year ended December 31, 2010, up 36% compared with \$389.4 million for the year ended December 31, 2009. The increase in revenue was driven by an increase in procedures performed and, to a lesser extent, higher initial instrument and accessory stocking orders associated with higher 2010 system unit sales.

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, 2010 also increased as compared with the year ended December 31, 2009. Instrument and accessory list pricing remained unchanged from 2009 to 2010.

Systems revenue increased to \$660.3 million during the year ended December 31, 2010, up 35% from \$490.5 million during the year ended December 31, 2009 primarily due to 103 more systems sold in 2010. We sold 441 *da Vinci* Surgical Systems during the year ended December 31, 2010, compared with 338 in the year ended December 31, 2009. 372 of the 441 systems sold during the year ended December 31, 2010 were the *da Vinci Si* Surgical Systems, of which 68 systems were dual console configurations. We had 75 *da Vinci* standard and 9 *da Vinci S* Surgical Systems traded in during the year ended December 31, 2010, compared with 54 standard systems traded in during the year ended December 31, 2009. All 9 of the 2010 *da Vinci S* trade ins occurred during the fourth quarter. Prior to the fourth quarter 2010, transactions involving customers transitioning from *da Vinci S* to a *da Vinci Si* system were included in upgrade revenue and excluded from the system count. The fourth quarter 2010 treatment reflects the current nature of the higher-priced transactions where customers are now shipped completely new *da Vinci Si* systems in exchange for their used *da Vinci Ss*, rather than receiving component level field upgrades of their *da Vinci S* units. The 2010 average selling price (ASP) of \$1.44 million was higher than the 2009 ASP of \$1.39 million, resulting from a higher percentage of the higher-priced single and dual console *da Vinci Si* Surgical Systems in the systems product mix. System upgrade revenue was \$25.1 million for the year ended December 31, 2010 compared to \$19.1 million for the year ended 2009.

Table of Contents

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 was 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 list 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 the future.

Systems revenue increased to \$490.5 million during the year ended December 31, 2009, up 8% from \$455.3 million during the year ended December 31, 2008 primarily due to more 2009 system upgrade revenue, higher 2009 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.

Service Revenue

Service revenue, comprised primarily of system service and customer training, increased 30% to \$223.9 million for the year ended December 31, 2010 from \$172.3 million for the year ended December 31, 2009. We typically enter into service contracts at the time systems are sold. These service contracts have been generally renewed at the end of the service period. Higher service revenue for 2010 was driven by a larger base of *da Vinci* Surgical Systems producing contract service revenue.

Service revenue increased to \$172.3 million for the year ended December 31, 2009, up 36% from \$126.6 million for the year ended December 31, 2008. 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.

Gross Profit

Product gross profit during the year ended December 31, 2010 increased 39% to \$891.8 million, or 75.0% of product revenue, compared to \$642.3 million, or 73.0% of product revenue, during the year ended December 31, 2009. The higher product gross profit was driven by higher 2010 product revenue, as described above. The higher product gross profit percentage was driven by higher 2010 system ASPs, system and instrument material cost reductions, lower 2010 charges for excess and obsolete inventory, and leveraging manufacturing overhead across higher revenue. Product gross profit for the year ended December 31, 2010 and 2009 reflected stock-based compensation expense of \$9.6 million and \$7.7 million, respectively.

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.

Table of Contents

Service gross profit during the year ended December 31, 2010 increased to \$138.2 million, or 61.8% of service revenue, compared to \$108.8 million, or 63.1% of service revenue during the year ended December 31, 2009. The higher 2010 service gross profit was driven by a larger installed base. The lower 2010 gross service profit percentage was primarily driven by higher 2010 field upgrade costs. Service gross profit during the years ended December 31, 2010 and 2009 reflected stock-based compensation expense of \$8.4 million and \$6.6 million, respectively.

Service gross profit during the year ended December 31, 2009 was \$108.8 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.

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, 2010 increased 29% to \$358.8 million compared to \$278.6 million for the year ended December 31, 2009. The increases were due to organizational growth to support our expanding business, particularly in the expansion of our clinical sales force, where headcount increased from 309 at December 31, 2009 to 467 at December 31, 2010, higher commissions 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, 2010 and 2009 were \$77.0 million and \$61.3 million, respectively.

Selling, general and administrative expenses for the year ended December 31, 2009 increased 21% to \$278.6 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 \$48.1 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. These enhancements represent significant improvements to our products.

Research and development expenses during the year ended December 31, 2010 increased 22% to \$116.0 million compared to \$95.1 million during the year ended December 31, 2009. The increase is due to the growth in our research and development organization, and higher product prototype expenses. Amortization expense related to purchased intellectual property during the years ended December 31, 2010 and 2009 was \$14.4 million. Stock-based compensation expense charged to research and development expense during the years ended December 31, 2010 and 2009 were \$22.6 million and \$21.4 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.

Table of Contents

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 product 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.

Interest and Other Income, Net

Interest and other income, net, was \$17.1 million during the year ended December 31, 2010, compared to \$18.7 million for the year ended December 31, 2009. Lower interest and other income, net for the year ended December 31, 2010 was driven by lower interest rates earned on cash and investment balances in 2010, partially offset by fluctuations in foreign exchange gains and losses.

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.

Income Tax Expense

Our income tax expense was \$190.5 million, \$163.5 million, and \$130.9 million during the years ended December 31, 2010, 2009, and 2008, respectively. The effective tax rate for 2010 was approximately 33.3%, 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, offset by 2010 research and development (R&D) credit, and by the effect of income earned by certain of our foreign subsidiaries being taxed at rates lower than the federal statutory rate. We intend these foreign earnings to be indefinitely reinvested outside the United States. 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 R&D 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 R&D credit and domestic production deductions generated in 2008. The lower effective tax rate in 2010 as compared to 2009 and 2008 is due primarily to an increase in foreign earnings on which U.S. income taxes have not been provided as such earnings are intended to be indefinitely reinvested outside the U.S.

In December 2010, a retroactive two-year extension of federal R&D credit through the end of year 2011 was signed into law. The federal R&D credit has previously expired at the end of year 2009. As a result of this change in federal tax law, we recorded a federal R&D credit benefit of \$4.6 million for the full year 2010 discretely in the fourth quarter of 2010.

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 in the first quarter of 2009, taking into account the reversal pattern and the expected California tax rate under the elective single sales factor.

Table of Contents**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 \$901.9 million at December 31, 2008, to \$1,172.0 million at December 31, 2009, to \$1,608.9 million at December 31, 2010.

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.

Consolidated Cash Flow Data

	Year Ended December 31,		
	2010	2009 (in millions)	2008
Net cash provided by (used in)			
Operating activities	\$ 528.0	\$ 385.1	\$ 278.2
Investing activities	(476.5)	(292.4)	(304.5)
Financing activities	7.7	(66.2)	98.0
Effect of exchange rates on cash and cash equivalents	(0.8)	0.3	0.1
Net increase in cash and cash equivalents	\$ 58.4	\$ 26.8	\$ 71.8

Operating Activities

During the year ended December 31, 2010, cash flow from operations of \$528.0 million exceeded our net income of \$381.8 million for two primary reasons:

- 1) Our net income included substantial non-cash charges in the form of stock-based compensation, amortization of intangible assets, taxes and depreciation. These non-cash charges totaled \$129.2 million during the year ended December 31, 2010.

- 2) Cash provided by working capital during the year ended December 31, 2010 was approximately \$17.0 million. Working capital is comprised primarily of accounts receivable, inventory, deferred revenue and other liabilities. Inventory increased by \$29.2 million or 51% in 2010. The growth in inventory reflects increased revenue, increases to ensure adequate supply of key components as December 31st quantities were below optimal levels and inventory associated with new product introductions. Deferred revenue, which includes deferred service contract revenue that is being amortized over the service contract period, increased \$26.5 million or 26% in 2010 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 \$60.1 million or 35% in 2010, primarily due to timing of vendor and tax payments and employee compensation during 2010.

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-based compensation, amortization of intangible assets, taxes and depreciation. These non-cash charges totaled \$114.5 million during the year ended December 31, 2009.

- 2) Cash provided by working capital and other assets during the year ended December 31, 2009 was approximately \$38.0 million.

Table of Contents

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 \$52.4 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-based compensation, amortization of intangible assets, taxes and depreciation. These non-cash charges totaled \$83.9 million during the year ended December 31, 2008.
- 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 \$32.4 million or 34% in 2008, reflecting changes in the volume of our business, timing of vendor payments and increase in unrecognized tax benefits.

Investing Activities

Net cash used in investing activities during the years ended December 31, 2010, 2009, and 2008 consisted primarily of purchases of investments (net of proceeds from sales and maturities of investments) of \$380.5 million, \$239.0 million and \$198.5 million, respectively, and purchases of property and equipment and licensing of intellectual property of \$96.0 million, \$53.4 million and \$106.0 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.

Financing Activities

Net cash provided by financing activities in 2010 consisted primarily of proceeds from stock option exercises and employee stock purchases of \$141.1 million and excess tax benefits from stock-based compensation of \$65.2 million, offset by \$198.6 million for the repurchase of approximately 0.7 million shares of our common stock through open market transactions. 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 an accelerated repurchase program, offset by proceeds from stock option exercises 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 consisted primarily of proceeds from stock option exercises and employee stock purchases of \$44.7 million and excess tax benefits from stock-based compensation of \$53.3 million.

Our cash 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 continue to

Table of Contents

devote substantial resources to expand procedure adoption and acceptance of our products investments. In 2010, we made substantial investments in our sales force, product development activities, facilities and intellectual property. 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.

Contractual Obligations and Commercial Commitments

The following table summarizes our contractual obligations as of December 31, 2010 (in millions):

	Total	Payments due by period			More than 5 years
		Less than 1 year	1 to 3 years	3 to 5 years	
Operating leases	\$ 4.8	\$ 2.1	\$ 1.9	\$ 0.5	\$ 0.3
Purchase commitments and obligations	212.2	210.8	1.4		
Total contractual obligations	\$ 217.0	\$ 212.9	\$ 3.3	\$ 0.5	\$ 0.3

Operating leases. We lease office spaces in the United States, Switzerland, Mexico, Japan and China. We also lease automobiles for certain sales and field service employees. Operating lease amounts include future minimum lease payments under all our non-cancelable 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, acquisition and licensing of intellectual property and commitment to purchase land and buildings in Sunnyvale, California. 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. In addition to the above, we have committed to make potential future milestone payments to third parties as part of licensing, collaboration and development arrangements. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory and/or commercial milestones. Because the achievement of these milestones is neither probable nor reasonably estimable, such contingencies have not been recorded on our Consolidated Balance Sheets and have not been included in the table above.

Other commitments. 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.

Off-Balance-Sheet Arrangements

As of December 31, 2010, 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:

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

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;

Table of Contents

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;

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

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 approximately 1% of our total investment portfolio as of December 31, 2010. 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. On June 30, 2010, pursuant to the terms of the UBS rights offering, we exercised our right to sell all ARS subject to the rights offering to UBS at the par value of \$34.4 million. As a result on July 1, 2010, we received the full par value in cash from UBS. The remainder of the ARS investment portfolio (approximately \$22.6 million, par value) is classified 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, 2010. 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 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.

Table of Contents

No impairment charges were recorded during the years ended December 31, 2010, 2009 and 2008. As of December 31, 2010 and 2009, our cumulative unrealized gains related to our investments classified as available-for-sale was approximately \$1.3 million and \$0.9 million, respectively.

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.

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 U.S. GAAP.

Identifiable intangible assets with finite lives are subject to impairment testing and 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.

We have intangible assets and goodwill on our balance sheet. 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

Table of Contents

amortization over the assets' new, shorter useful lives. We conducted the required intangible assets impairment review during the fourth quarter of 2010. No impairment charge or material accelerated amortization was recorded for the years ended December 31, 2010, 2009 and 2008. 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.

In September 2009, the FASB amended the accounting standards related to revenue recognition for arrangements with multiple deliverables and arrangements that include software elements (new accounting principles). The new accounting principles permit prospective or retrospective adoption, and we elected prospective adoption at the beginning of the first quarter of 2010.

These new accounting principles do not generally change the units of accounting for our revenue transactions and we continue to have system and service as the different elements in our multiple element arrangements. For multiple element arrangements entered into on or after January 1, 2010, we allocate revenue to all deliverables based on their relative selling prices. Because we have neither vendor-specific objective evidence (VSOE) nor third-party evidence of selling price (TPE) for our systems, the allocation of revenue has been based on estimated selling prices (ESPs). The objective of ESP is to determine the price at which we would transact a sale if the product was sold on a stand-alone basis. We determine ESP for our systems by considering multiple factors including, but not limited to, features and functionality of the system, geographies, type of customer and market conditions. We expect to review ESP regularly and maintain internal controls over the establishment and updates of these estimates. We do not expect material changes to ESPs established as of January 1, 2010 in future periods. However, since we apply significant judgment in arriving at the ESPs, any material changes would significantly affect the allocation of the total consideration to the different elements of a multiple element arrangement.

Hedge Accounting for Derivatives. We utilize foreign currency forward exchange contracts to hedge certain anticipated foreign currency sales transactions. When specific criteria required by relevant accounting standards 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 U.S. GAAP. 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.

Table of Contents

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, 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.

The expected term represents the weighted-average period that our 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.

U.S. GAAP 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 U.S. GAAP. 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, 2010. 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. 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

Table of Contents

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.

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 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, 2010 was approximately 1.1 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 \$3.8 million as of December 31, 2010. 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, 2010, we held approximately \$18.6 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 approximately 1% 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.

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.

Table of Contents

For the year ended December 31, 2010, sales denominated in foreign currencies were approximately 11% of total revenue. The objective of our hedging program to mitigate the impact of changes in currency exchange rates on our net cash flow from foreign currency denominated sales. For the year ended December 31, 2010, our revenue would have decreased by approximately \$2.5 million if the U.S. dollar exchange rate would have strengthened by 10%. 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. A 10% strengthening of the U.S. dollar exchange rate against all currencies with which we have exposure, after taking into account hedges and offsetting positions at December 31, 2010 would have resulted in a \$0.6 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. Bank counterparties to foreign exchange forward contracts expose us to credit-related losses in the event of their nonperformance. To mitigate that risk, we only contract with counterparties that meet certain minimum requirements under our counterparty risk assessment process. We monitor ratings and potential downgrades on at least a quarterly basis. Based on our on-going assessment of counterparty risk, we 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>	60
<u>Consolidated Balance Sheets at December 31, 2010 and 2009</u>	62
<u>Consolidated Statements of Income for the years ended December 31, 2010, 2009 and 2008</u>	63
<u>Consolidated Statement of Stockholders' Equity for the years ended December 31, 2010, 2009 and 2008</u>	64
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2010, 2009 and 2008</u>	65
<u>Notes to the Consolidated Financial Statements</u>	66
<u>Schedule II - Valuation and Qualifying Accounts</u>	88

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, 2010 and 2009, and the related consolidated statements of income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010. 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, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Intuitive Surgical, Inc.'s internal control over financial reporting as of December 31, 2010, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 1, 2011 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California

February 1, 2011

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, 2010 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, 2010, 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, 2010 and 2009, and the related consolidated statements of income, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2010, and the financial statement schedule listed in the index at Item 15(a) and our report dated February 1, 2011 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California

February 1, 2011

Table of Contents**INTUITIVE SURGICAL, INC.****CONSOLIDATED BALANCE SHEETS****(IN MILLIONS, EXCEPT PAR VALUE AMOUNTS)**

	December 31,	
	2010	2009
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 279.8	\$ 221.4
Short-term investments	630.6	334.0
Accounts receivable, net of allowances of \$4.8 and \$4.3 at December 31, 2010 and 2009, respectively	246.8	205.4
Inventory	86.8	57.6
Prepays and other assets	23.3	21.4
Deferred tax assets	8.5	7.3
Total current assets	1,275.8	847.1
Property, plant and equipment, net	159.8	125.7
Long-term investments	698.5	616.6
Long-term deferred tax asset	73.3	53.4
Intangible assets, net	66.1	56.2
Goodwill	116.9	110.7
Total assets	\$ 2,390.4	\$ 1,809.7
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 35.6	\$ 27.6
Accrued compensation and employee benefits	63.4	49.8
Deferred revenue	126.1	99.4
Other accrued liabilities	48.7	26.0
Total current liabilities	273.8	202.8
Other long-term liabilities	79.2	69.6
Total liabilities	353.0	272.4
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, 2.5 shares authorized, \$0.001 par value, issuable in series; no shares issued and outstanding as of December 31, 2010 and 2009, respectively		
Common stock, 100.0 shares authorized, \$0.001 par value, 38.9 and 38.5 shares issued and outstanding as of December 31, 2010 and 2009, respectively		
Additional paid-in capital	1,316.9	1,024.3
Retained earnings	718.9	511.7
Accumulated other comprehensive income	1.6	1.3
Total stockholders' equity	2,037.4	1,537.3
Total liabilities and stockholders' equity	\$ 2,390.4	\$ 1,809.7

See accompanying Notes to Consolidated Financial Statements.

Table of Contents**INTUITIVE SURGICAL, INC.****CONSOLIDATED STATEMENTS OF INCOME****(IN MILLIONS, EXCEPT PER SHARE AMOUNTS)**

	Year Ended December 31,		
	2010	2009	2008
Revenue:			
Product	\$ 1,189.1	\$ 879.9	\$ 748.3
Service	223.9	172.3	126.6
Total revenue	1,413.0	1,052.2	874.9
Cost of revenue:			
Product	297.3	237.6	200.1
Service	85.7	63.5	54.0
Total cost of revenue	383.0	301.1	254.1
Gross profit	1,030.0	751.1	620.8
Operating expenses:			
Selling, general and administrative	358.8	278.6	230.6
Research and development	116.0	95.1	79.4
Total operating expenses	474.8	373.7	310.0
Income from operations	555.2	377.4	310.8
Interest and other income, net	17.1	18.7	24.4
Income before income taxes	572.3	396.1	335.2
Income tax expense	190.5	163.5	130.9
Net income	\$ 381.8	\$ 232.6	\$ 204.3
Net income per common share:			
Basic	\$ 9.74	\$ 6.07	\$ 5.26
Diluted	\$ 9.47	\$ 5.93	\$ 5.12
Shares used in computing basic and diluted net income per common share:			
Basic	39.2	38.3	38.9
Diluted	40.3	39.2	39.9

See accompanying Notes to Consolidated Financial Statements.

Table of Contents**INTUITIVE SURGICAL, INC.****CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY****(IN MILLIONS)**

	Common Stock	Stock Amount	Additional Paid-In Capital	Retained Earnings (Accumulated Deficit)	Accumulated Other Comprehensive Income (Loss)	Total
Balances at December 31, 2007	38.5	\$	\$ 694.6	\$ 193.5	\$ 0.6	\$ 888.7
Issuance of common stock upon exercise of options and under stock purchase plan	0.7		44.7			44.7
Income tax benefit from stock option exercises			55.9			55.9
Stock-based compensation expense related to employee stock plans			76.6			76.6
Components of comprehensive income, net of tax:						
Net income				204.3		204.3
Other comprehensive income (loss)					(3.5)	(3.5)
Total comprehensive income						200.8
Balances at December 31, 2008	39.2		871.8	397.8	(2.9)	1,266.7
Issuance of common stock upon exercise of options and under stock purchase plan	0.7		63.2			63.2
Income tax benefit from stock option exercises			23.6			23.6
Stock-based compensation expense related to employee stock plans			97.0			97.0
Repurchase and retirement of common stock	(1.4)		(31.3)	(118.7)		(150.0)
Components of comprehensive income, net of tax:						
Net income				232.6		232.6
Other comprehensive income (loss)					4.2	4.2
Total comprehensive income						236.8
Balances at December 31, 2009	38.5		1,024.3	511.7	1.3	1,537.3
Issuance of common stock upon exercise of options and under stock purchase plan	1.1		141.1			141.1
Income tax benefit from stock option exercises			57.9			57.9
Stock-based compensation expense related to employee stock plans			117.6			117.6
Repurchase and retirement of common stock	(0.7)		(24.0)	(174.6)		(198.6)
Components of comprehensive income, net of tax:						
Net income				381.8		381.8
Other comprehensive income (loss)					0.3	0.3
Total comprehensive income						382.1
Balances at December 31, 2010	38.9	\$	\$ 1,316.9	\$ 718.9	\$ 1.6	\$ 2,037.4

See accompanying Notes to Consolidated Financial Statements.

Table of Contents**INTUITIVE SURGICAL, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****(IN MILLIONS)**

	Year Ended December 31,		
	2010	2009	2008
Operating activities:			
Net income	\$ 381.8	\$ 232.6	\$ 204.3
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	23.7	19.0	14.6
Amortization of intangible assets	16.7	15.6	10.5
Deferred income taxes	(21.5)	(15.6)	(20.6)
Share-based compensation expense of stock options and employee stock purchases	117.6	97.0	76.6
Excess tax benefit from stock-based compensation	(65.2)	(25.1)	(53.3)
Income tax benefits related to stock option exercises	57.9	23.6	55.9
Changes in operating assets and liabilities:			
Accounts receivable	(41.5)	(35.3)	(39.7)
Inventory	(29.2)	5.9	(31.1)
Prepays and other assets	1.1	(6.3)	4.0
Accounts payable	8.1	7.0	(9.2)
Accrued compensation and employee benefits	13.8	12.8	6.9
Deferred revenue	26.5	21.3	24.6
Other accrued liabilities	38.2	32.6	34.7
Net cash provided by operating activities	528.0	385.1	278.2
Investing activities:			
Purchase of investments	(1,385.4)	(764.5)	(732.7)
Proceeds from sales and maturities of investments	1,004.9	525.5	534.2
Purchase of property and equipment and acquisition of intellectual property	(96.0)	(53.4)	(106.0)
Net cash used in investing activities	(476.5)	(292.4)	(304.5)
Financing activities:			
Proceeds from issuance of common stock, net	141.1	58.7	44.7
Excess tax benefit from stock-based compensation	65.2	25.1	53.3
Repurchase and retirement of common stock	(198.6)	(150.0)	
Net cash (used in) provided by financing activities	7.7	(66.2)	98.0
Effect of exchange rate changes on cash and cash equivalents	(0.8)	0.3	0.1
Net increase in cash and cash equivalents	58.4	26.8	71.8
Cash and cash equivalents, beginning of year	221.4	194.6	122.8
Cash and cash equivalents, end of year	\$ 279.8	\$ 221.4	\$ 194.6
Supplemental cash flow information:			
Income taxes paid	\$ 124.4	\$ 129.1	\$ 61.5

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. designs, manufactures, and markets the *da Vinci* Surgical System, which is an advanced surgical system that the Company believes represents a new generation of surgery. The *da Vinci* Surgical System consists of a surgeon's console 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 puncture incisions, or ports. By placing computer-enhanced technology between the surgeon and the patient, the *da Vinci* Surgical System enables higher value surgical procedures to patients through increased effectiveness and reduced invasiveness.

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.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP 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 estimation of hedging transactions; 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 and derivative instruments 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 and derivative instruments 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, 2010 and 2009, 76% and 75%, respectively, of accounts receivable were from domestic customers. No single customer represented more than 10% of net accounts receivable as of December 31, 2010 and 2009.

During the years ended December 31, 2010, 2009 and 2008, domestic revenue accounted for 80%, 79% and 78%, respectively, of total revenue, while international revenue accounted for 20%, 21% and 22%, respectively, of total revenue, for each of the years. No single customer represented more than 10% of total revenue for the years ended December 31, 2010, 2009 and 2008.

Table of Contents

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 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. The Company has designated all investments as available-for-sale and therefore, such investments are reported at fair value, with unrealized gains and losses recorded in accumulated other comprehensive income. 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 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, 2010, 2009 and 2008, the Company did not record any other-than-temporary impairment charges on its available-for-sale securities, because the Company does not intend to sell the security and it is not more likely than not that the Company will be required to sell these securities before the recovery of their amortized cost basis.

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 collectibility 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.

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.

Table of Contents***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	up to 30 years
Building improvements	up to 15 years
Leasehold improvements	Lesser of useful life or term of lease
Equipment and furniture	5 years
Computer equipment	3 years
Enterprise-wide software	5 years
Purchased software	Lesser of 3 years or life of license

Depreciation expense for years ended December 31, 2010, 2009 and 2008 was \$23.7 million, \$19.0 million and \$14.6 million, respectively.

Capitalized Software Costs for Internal Use

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 \$4.1 million and \$4.4 million during the years ended December 31, 2010 and 2009, 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, 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. 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 9 years.

Impairment of Long-lived assets

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, 2010, there has been no impairment of goodwill.

The Company evaluates the recoverability of its long-lived assets, which include amortizable intangible and tangible assets. 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.

Table of Contents

Revenue Recognition

The Company's revenue consists of product revenue resulting from the sales of systems, instruments and accessories, and service revenue. The Company recognizes revenue when all four revenue recognition criteria have been met: 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 revenue recognition policy generally results in revenue recognition at the following points:

System sales. For system sales directly to end customers, revenue is recognized when acceptance occurs, which is deemed to have occurred upon the receipt by the Company of a form executed by the customer acknowledging delivery and/or installation. For system sales through distributors, revenue is recognized upon transfer of title and risk of loss, which is generally at the time of shipment. Distributors do not have price protection rights. The Company's system contracts do not allow rights of return. The Company's system revenue contains a software component. Since the *da Vinci* System's software and non-software elements function together to deliver the System's essential functionality, they are considered to be one deliverable that is excluded from the software revenue recognition guidance.

Instruments and accessories. Revenue from sales of instruments and accessories is recognized when the product has been shipped. The Company records an allowance on instruments and accessories sales returns based on historical returns experience.

Service. 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 determined that its multiple-element arrangements are generally comprised of the following elements that would qualify as separate units of accounting: system sales, service contracts and instruments and accessories sales.

In September 2009, the Financial Accounting Standards Board (FASB) amended the accounting standards related to revenue recognition for arrangements with multiple deliverables and arrangements that include software elements (new accounting principles). The new accounting principles permit prospective or retrospective adoption, and the Company elected prospective adoption at the beginning of the first quarter of 2010.

For multiple-element arrangements (which are generally comprised of system sales and service contracts) entered into prior to January 1, 2010, revenue was allocated to each element based on the relative fair value of each element. Fair value is generally determined by vendor specific objective evidence (VSOE) which is based on the price charged when each element is sold separately. The Company's systems sales generally include a first year service obligation. The Company typically does not sell the systems on a stand-alone basis and therefore does not have VSOE for its systems. The Company has established VSOE for services. When the fair value of a delivered element had not been established, but fair value existed for the undelivered elements, prior to January 1, 2010, the Company used the residual method to recognize revenue. Under the residual method, the fair value of the undelivered elements was deferred and the remaining portion of the arrangement fee was allocated to the delivered elements.

Subsequent to the adoption of the new revenue accounting principles, for multiple-element arrangements entered into on or after January 1, 2010, revenue is allocated to each element based on their relative selling prices. Relative selling prices are based first on VSOE, then on third-party evidence of selling price (TPE) when VSOE does not exist, and then on estimated selling price (ESP) when VSOE and TPE do not exist.

Because the Company has neither VSOE nor TPE for its systems, the allocation of revenue has been based on the Company's ESPs. The objective of ESP is to determine the price at which the Company would transact a sale if the product was sold on a stand-alone basis. The Company determines ESP for its systems by considering

Table of Contents

multiple factors including, but not limited to, features and functionality of the system, geographies, type of customer, and market conditions. The Company regularly reviews ESP and maintains internal controls over the establishment and updates of these estimates.

Had the new accounting guidance been applied to revenue at the beginning of 2009, the resultant revenue for the year ended December 31, 2009 would have been substantially the same.

Stock-Based Compensation

The Company accounts for stock-based employee compensation plans under the fair value recognition and measurement provisions under U.S. GAAP. It requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options. 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. U.S. GAAP 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.

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.

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.

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

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.

U.S. GAAP 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 additional-paid-in-capital (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.

Table of Contents

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, costs of prototypes, salaries, benefits and other headcount related costs, contract and other outside service fees, and facilities and overhead costs.

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.

The Company uses derivatives to partially offset its business exposure to foreign currency exchange risk. The Company enters into foreign currency forward contracts with one to seven month terms. The Company typically hedges portions of its forecasted foreign currency exposure associated with revenue. The Company may also enter into foreign currency forward contracts to offset the foreign currency exchange gains and losses generated by re-measurement of certain assets and liabilities denominated in non-functional currencies. The hedging program is not designated for trading or speculative purposes.

The Company's accounting policies for these instruments are based on whether the instruments are designated as hedge or non-hedge instruments. The Company records all derivatives on the Condensed Consolidated Balance Sheets at fair value. The effective portions of cash flow hedges are recorded in other comprehensive income (OCI) until the hedged item is recognized in earnings. Derivative instruments designated as cash flow hedges are de-designated as hedges when it is probable the forecasted hedged transaction will not occur in the initially identified time period or within a subsequent two month time period. Deferred gains and losses in OCI associated with such derivative instruments are reclassified immediately into earnings through interest and other income, net. Any subsequent changes in fair value of such derivative instruments also are reflected in current earnings.

Derivatives that are not designated as hedging instruments and the ineffective portions of cash flow hedges are adjusted to fair value through earnings in interest and other income, net.

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.

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, 2010 and 2009, over 98% of all long-lived assets were maintained in the United States. For the years ended December 31, 2010, 2009 and 2008, 80%, 79% and 78%, respectively, of net revenue were generated in the United States.

Table of Contents**Recent Accounting Pronouncements***Adopted Accounting Pronouncements*

In September 2009, the Financial Accounting Standards Board (FASB) amended the accounting standards related to revenue recognition for arrangements with multiple deliverables and arrangements that include software elements (new accounting principles). The new accounting principles permit prospective or retrospective adoption, and the Company elected prospective adoption at the beginning of the first quarter of 2010. See Revenue Recognition section above for more details on the related accounting.

Effective January 1, 2010, the Company adopted revised guidance intended to improve disclosures related to fair value measurements, issued by FASB. This guidance requires the Company to separate information about significant transfers in and out of Level 1 and Level 2 and the reason for such transfers, and also requires information related to purchases, sales, issuances, and settlements information of Level 3 financial assets to be included in the rollforward of activity. The guidance also requires the Company to provide certain disaggregated information on the fair value of financial assets and requires disclosure on valuation techniques and inputs used for both recurring and nonrecurring fair value measurements of Level 2 and Level 3 financial assets. The Company's policy is to recognize transfers into or out of levels as of the actual date of the event or change in circumstances that caused the transfer.

NOTE 3. CASH, CASH EQUIVALENTS & INVESTMENTS

The following tables summarize the Company's cash, cash equivalents and investments as of December 31, 2010 and 2009 (in millions):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2010				
Cash and cash equivalents:				
Cash	\$ 20.1	\$	\$	\$ 20.1
Cash equivalents	259.7			259.7
Total cash and cash equivalents	\$ 279.8	\$	\$	\$ 279.8
Available-for-sale investments:				
Short-term				
Commercial paper	\$ 79.0	\$	\$	\$ 79.0
Municipal notes	111.8	0.4		112.2
U.S. corporate debt	174.1	1.3		175.4
U.S. treasuries	76.3			76.3
U.S. government agencies	187.4	0.3		187.7
Total short-term	\$ 628.6	\$ 2.0	\$	\$ 630.6
Long-term				
Municipal notes	\$ 143.4	\$ 0.3	\$ (4.3)	\$ 139.4
U.S. corporate debt	300.4	1.8	(0.9)	301.3
U.S. treasuries	39.9	0.1		40.0
U.S. government agencies	196.7	0.3	(0.4)	196.6
Non-U.S. government securities	21.2	0.1	(0.1)	21.2
Total long-term	\$ 701.6	\$ 2.6	\$ (5.7)	\$ 698.5
Total cash, cash equivalents and available-for-sale investments	\$ 1,610.0	\$ 4.6	\$ (5.7)	\$ 1,608.9

Table of Contents

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2009				
Cash and cash equivalents:				
Cash	\$ 28.6	\$	\$	\$ 28.6
Cash equivalents	192.8			192.8
Total cash and cash equivalents	\$ 221.4	\$	\$	\$ 221.4
Available-for-sale investments:				
Short-term				
Commercial paper	\$ 13.1	\$	\$	\$ 13.1
Municipal notes	21.3	0.2		21.5
U.S. corporate debt	150.5	1.3		151.8
U.S. treasuries	31.6	0.2		31.8
U.S. government agencies	45.5	0.5		46.0
Total short-term	\$ 262.0	\$ 2.2	\$	\$ 264.2
Long-term				
Municipal notes	\$ 161.0	\$ 1.5	\$ (4.5)	\$ 158.0
U.S. corporate debt	222.5	2.1	(0.1)	224.5
U.S. treasuries	29.5		(0.2)	29.3
U.S. government agencies	204.6	0.6	(0.4)	204.8
Total long-term	\$ 617.6	\$ 4.2	\$ (5.2)	\$ 616.6
Total cash, cash equivalents and available-for-sale investments	\$ 1,101.0	\$ 6.4	\$ (5.2)	\$ 1,102.2
Other securities (included in short-term investments):				
Trading securities, auction rate securities	\$ 62.2	\$	\$	\$ 62.2
Put option	7.6			7.6
Total cash, cash equivalents and investments	\$ 1,170.8	\$ 6.4	\$ (5.2)	\$ 1,172.0

The following table summarizes the maturities of the Company's cash equivalents and available-for-sale investments at December 31, 2010 (in millions):

	Amortized Cost	Fair Value
Mature in less than one year	\$ 888.3	\$ 890.3
Mature in one to five years	679.0	679.9
Mature in more than five years	22.6	18.6
Total	\$ 1,589.9	\$ 1,588.8

During the years ended December 31, 2010, 2009 and 2008, realized gains or losses recognized on the sale of investments were not significant. As of December 31, 2010 and 2009, unrealized gain on investments, net of tax, of \$1.3 million and \$0.9 million, respectively, were included in accumulated other comprehensive income in the accompanying Consolidated Balance Sheets.

Table of Contents

The following tables present the breakdown of the available-for-sale investments with unrealized losses at December 31, 2010 and 2009 (in millions):

	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, 2010						
Municipal notes	\$ 57.5	\$ (0.3)	\$	\$	\$ 57.5	\$ (0.3)
Auction rate securities			18.6	(4.0)	18.6	(4.0)
U.S. corporate debt	135.7	(0.9)			135.7	(0.9)
Government agencies	180.9	(0.5)			180.9	(0.5)
	\$ 374.1	\$ (1.7)	\$ 18.6	\$ (4.0)	\$ 392.7	\$ (5.7)
December 31, 2009						
Municipal notes	\$ 16.6	\$	\$	\$	\$ 16.6	\$
Auction rate securities.			19.0	(4.5)	19.0	(4.5)
U.S. corporate debt	56.7	(0.1)			56.7	(0.1)
U.S. treasuries	29.8	(0.2)			29.8	(0.2)
U.S. government agencies	109.0	(0.4)			109.0	(0.4)
	\$ 212.1	\$ (0.7)	\$ 19.0	\$ (4.5)	\$ 231.1	\$ (5.2)

The unrealized losses on the available-for-sale investments in ARS. The Company determined these unrealized losses to be temporary and recorded no other-than-temporary impairments. 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.

NOTE 4. FAIR VALUE MEASUREMENTS

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 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 or discounted cash flow techniques.

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.

Table of Contents

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, 2010 and 2009 (in millions):

Assets	Fair Value Measurements at December 31, 2010 Using			Total
	Level 1	Level 2	Level 3	
Available-for-sale securities				
Money Market funds	\$ 211.2	\$	\$	\$ 211.2
U.S. treasuries	116.3			116.3
Commercial paper		122.5		122.5
Corporate debt		476.8		476.8
U.S. government agencies		389.2		389.2
Non-U.S. government securities		21.1		21.1
Municipal notes		233.1	18.6	251.7
Total available-for-sale securities	\$ 327.5	\$ 1,242.7	\$ 18.6	\$ 1,588.8
Foreign currency derivatives	\$	\$ 0.2	\$	\$ 0.2
Total assets measured at fair value	\$ 327.5	\$ 1,242.9	\$ 18.6	\$ 1,589.0
Liabilities				
Foreign Currency Derivatives	\$	\$ 2.1	\$	\$ 2.1
Total liabilities measured at fair value	\$	\$ 2.1	\$	\$ 2.1

Assets	Fair Value Measurements at December 31, 2009 Using			Total
	Level 1	Level 2	Level 3	
Municipal notes trading security	\$	\$	\$ 62.2	\$ 62.2
Put option			7.6	7.6
Available-for-sale securities				
Money Market funds	175.7			175.7
U.S. treasuries	61.1			61.1
Commercial paper		27.4		27.4
Corporate debt		379.0		379.0
U.S. government agencies		250.9		250.9
Municipal notes		160.4	19.1	179.5
Total available-for-sale securities	\$ 236.8	\$ 817.7	\$ 19.1	\$ 1,073.6
Total assets measured at fair value	\$ 236.8	\$ 817.7	\$ 88.9	\$ 1,143.4
Liabilities				
Foreign Currency Derivatives	\$	\$ 0.4	\$	\$ 0.4
Total liabilities measured at fair value	\$	\$ 0.4	\$	\$ 0.4

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, 2010 (in millions):

	Fair Value Measurements at Reporting Date Using Significant Unobservable Inputs (Level 3)		
	Put Option	ARS	Total
Balance at January 1, 2010	\$ 7.6	\$ 81.3	\$ 88.9
Purchases			
Sales/Maturities		(70.7)	(70.7)
Total gains or (losses):			
Included in other comprehensive income (loss)		0.4	0.4
Included in earnings	(7.6)	7.6	
Balance at December 31, 2010	\$	\$ 18.6	\$ 18.6

The Company's derivative instruments are primarily classified as Level 2 as they are not actively traded and are valued using pricing models that use observable market inputs. There have been no transfers between Level 1 and Level 2 measurements during the year ended December 31, 2010, and there were no changes in the Company's valuation technique. The Company recognizes transfers into or out of Level 3 classification as of the actual date of the event or change in circumstances that caused the transfer. 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. 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. On June 30, 2010, pursuant to the terms of the UBS rights offering, the Company exercised its right to sell all ARS subject to the rights offering to UBS at the par value of \$34.4 million. As a result on July 1, 2010, the Company received the full par value in cash from UBS.

The remainder of the Company's ARS investment portfolio of \$18.6 million, is reflected as long-term available-for-sale investments on the Company's Consolidated Balance Sheet as of December 31, 2010. The Company has valued the ARS using a discounted cash flow model based on Level 3 assumptions, including estimates of, based on data available as of December 31, 2010, interest rates, timing and amount of cash flows, credit and liquidity premiums and expected holding periods of the ARS.

Foreign currency derivative*Cash Flow Hedges*

The Company enters into currency forward contracts as cash flow hedges to hedge certain forecasted revenue transactions denominated in currencies other than the U.S. dollar, primarily the Euro and GBP.

As of December 31, 2010, the Company had the notional amount of 21.0 million outstanding currency forward contracts that were entered into to hedge Euro denominated sales, compared to 19.5 million and £3.9 million at December 31, 2009. The amounts reclassified to revenue as the related hedged revenue transactions were recognized for the years ended December 31, 2010 and 2009 were not significant. Other impacts of derivative instruments designated as cash flow hedges were not significant for the years ended December 31, 2010 and 2009.

Other Derivatives Not Designated as Hedging Instruments

Other derivatives not designated as hedging instruments consist primarily of forward contracts that the Company uses to hedge intercompany balances and other monetary assets or liabilities denominated in currencies other than the U.S. dollar, primarily the Euro or GBP.

Table of Contents

As of December 31, 2010, the Company had the notional amount of 26.0 million and £2.2 million outstanding currency forward contracts that were entered into to hedge non-functional currency denominated net monetary assets, compared to 22.0 million and £4.5 million at December 31, 2009. For the year ended December 31, 2010, the Company had recognized gains of approximately \$3.1 million, in interest and other income, net related to derivative instruments used to hedge against balance sheet foreign currency exposures. This was offset by approximately \$2.6 million of net foreign exchange losses for the year ended December 31, 2010, respectively, primarily related to the re-measurement of non-functional currency denominated net monetary assets. Impacts of derivative instruments not designated as hedges were not significant for the year ended December 31, 2009.

NOTE 5. BALANCE SHEET DETAILS

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

	December 31,	
	2010	2009
Inventory:		
Raw materials	\$ 25.6	\$ 16.3
Work-in-process	2.5	2.5
Finished goods	58.7	38.8
Total	\$ 86.8	\$ 57.6
Property, plant and equipment, net:		
Land	\$ 41.8	\$ 41.8
Building and building/leasehold improvements	62.4	48.5
Machinery and equipment	57.4	45.2
Computer and Office equipment	12.3	9.5
Capitalized software	38.9	31.2
Construction-in-process	34.0	15.1
	246.8	191.3
Less accumulated depreciation	(87.0)	(65.6)
Total property, plant and equipment, net	\$ 159.8	\$ 125.7
Other accrued liabilities short term:		
Taxes payable	\$ 19.7	\$ 0.5
Other	29.0	25.5
Total other accrued liabilities short-term	\$ 48.7	\$ 26.0
Other long-term liabilities:		
Income taxes long term	\$ 78.4	\$ 67.6
Other long-term liabilities	0.8	2.0
Total other liabilities	\$ 79.2	\$ 69.6

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

The Company's gross carrying amount of goodwill was \$116.9 million and \$110.7 million as of December 31, 2010 and 2009, respectively.

Intangibles

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

The Company's gross carrying amount of total intangible assets, primarily representing purchased intellectual property, was \$119.3 million and \$92.8 million as of December 31, 2010 and 2009, respectively.

Table of Contents

Additions made to intellectual property during the years ended December 31, 2010 and 2009 were \$27.6 million and \$15.6 million, respectively. The weighted average useful life was six years for each of the years ended December 31, 2010 and 2009. Amortization expense related to intangible assets was \$16.7 million, \$15.6 million and \$10.5 million for the years ended December 31, 2010, 2009 and 2008, respectively. Accumulated amortization of intangible assets was \$52.9 million and \$36.3 million as of December 31, 2010 and 2009, respectively.

The estimated future amortization expense of intangible assets as of December 31, 2010 is as follows (in millions):

Fiscal Year	Amount
2011	\$ 16.1
2012	15.4
2013	11.3
2014	7.7
2015	7.7
2016 and thereafter	7.9
Total	\$ 66.1

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

The Company leases office space in China, Japan, Mexico, Switzerland and United States. The Company leases automobiles for certain sales and field service 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, 2010 are as follows (in millions):

2011	\$ 2.1
2012	1.3
2013	0.6
2014	0.3
2015 and beyond	0.5
	\$ 4.8

Other commitments include an estimated amount of approximately \$212.2 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, acquisition and licensing of intellectual property and commitment to purchase land and buildings in Sunnyvale, California.

CONTINGENCIES

On August 6, 2010, a purported class action lawsuit entitled *Perlmutter v. Intuitive Surgical et al.*, No. CV10-3451, was filed against the Company and seven of the Company's current and former officers and directors in the United States District Court for the Northern District of California. The lawsuit seeks unspecified damages on behalf of a putative class of persons who purchased or otherwise acquired the Company's common stock between February 1, 2008 and January 7, 2009. The complaint alleges that the defendants violated federal securities laws by making allegedly false and misleading statements and omitting certain material facts in the Company's filings with the Securities and Exchange Commission.

Table of Contents

On August 19, 2010, an alleged shareholder caused a purported shareholder's derivative lawsuit entitled *Himmel v. Smith et al.*, No. 1-10-CV-180416, to be filed in the Superior Court of California for the County of Santa Clara naming the Company as a nominal defendant, and naming 14 of the Company's current and former officers and directors as defendants. The lawsuit seeks to recover, for the Company's benefit, unspecified damages purportedly sustained by the Company in connection with allegedly misleading statements and/or omissions made in connection with the Company's financial reporting for the period between February 1, 2008 and January 7, 2009. It also seeks a series of changes to the Company's corporate governance policies and an award of attorneys' fees. On September 15, 2010, another purported shareholder filed an essentially identical lawsuit entitled *Applbaum v. Guthart et al.*, No. 1-10-CV-182645, in the same court against 15 of the Company's current and former officers and directors. On October 5, 2010 the court ordered that the two cases be consolidated for all purposes.

Due to the uncertainty surrounding the litigation process, the Company is unable to reasonably estimate the ultimate outcome of the above cases at this time, and therefore no amounts have been accrued related to the outcome of the cases above. Based on currently available information, the Company believes that it has meritorious defenses to the above actions and that the resolution of these cases is not likely to have a material adverse effect on the Company's business, financial position or future results of operations. The Company is also a party to various other legal actions that arose in the ordinary course of our business. The Company does not believe that any of these other legal actions will have a material adverse impact on its business, financial position or results of operations.

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. 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.

In July 2010, the Board authorized an additional \$150 million for share repurchase under the share repurchase program. During the year ended December 31, 2010, the Company repurchased and retired approximately 0.7 million shares of its common stock at an average purchase price of \$267.81 per share, for an aggregate purchase price of \$198.6 million, through open market transactions. As of December 31, 2010, the remaining authorized amount of share repurchases that may be made under the Board-authorized share repurchase program was approximately \$101.3 million.

The Company uses the par value method of accounting for its stock repurchases. As a result of the share repurchases during the year ended December 31, 2010, the Company reduced common stock and additional paid-in capital by an aggregate of \$24.0 million and charged \$174.6 million to retained earnings. During the year ended December 31, 2009, the Company reduced common stock and APIC by an aggregate of \$31.3 million and charged \$118.7 million to retained earnings.

Table of Contents

COMPREHENSIVE INCOME

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

	December 31,	
	2010	2009
Foreign currency translation gains	\$ 0.1	\$ 0.4
Accumulated net unrealized gains on derivatives, net of tax	0.2	
Accumulated net unrealized gains on available-for-sale securities, net of tax	1.3	0.9
 Total accumulated other comprehensive income	 \$ 1.6	 \$ 1.3

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

	Year Ended December 31,		
	2010	2009	2008
Net income	\$ 381.8	\$ 232.6	\$ 204.3
Foreign currency translation gains (losses)	(0.3)	0.2	0.1
Unrealized gains (losses) on derivative instruments, net of tax:			
Unrealized gains (losses) on derivative instruments	0.2	(1.1)	
Reclassification adjustment for (gains) losses on derivative instruments recognized during the period		1.1	
Unrealized gains (losses) on available-for-sale securities, net of tax:			
Unrealized gains (losses) arising during period	0.4	4.0	(15.2)
Reclassification adjustment for gains (losses) realized in net income			11.6
 Total other comprehensive income	 \$ 382.1	 \$ 236.8	 \$ 200.8

NOTE 9. STOCK-BASED COMPENSATION

STOCK OPTION PLANS

2010 Incentive Award Plan

In April 2010, the Company's stockholders approved the 2010 Incentive Award Plan (2010 Plan), which authorized approximately 1.3 million shares of common stock for issuance. Under this plan, the Company issues nonqualified stock options (NSOs) to employees and certain consultants. The 2010 Plan generally permits NSOs to be granted at no less than the fair market value of the common stock on the date of grant, with terms of 10 years from the date of grant. Options generally vest 12.5% upon completion of 6 months service and 1/48th per month thereafter; however, options may have different vesting terms as determined by the Board of Directors. The plan expires in 2020.

2009 Employment Commencement Incentive Plan

In October 2009, the Board of Directors adopted the 2009 Employment Commencement Incentive Plan (New Hire Plan) and reserved 300,000 shares for issuance under the plan. The New Hire Plan provides for the 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.

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

Table of Contents

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 expired in March 2010. However, options granted prior to the plan's expiration continue to vest or remain outstanding until their original expiration date.

2000 Non-Employee Directors' Stock Option Plan

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 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 10 years. Initial grants are vested over a three-year period with 33.3% of the shares vesting after 1 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. This plan expires in March 2013.

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 144,906, 92,433 and 85,850 shares under the ESPP, representing approximately \$14.3 million, \$8.0 million and \$8.9 million in employee contributions for the years ended December 31, 2010, 2009 and 2008, respectively. As of December 31, 2010, there were approximately 690,156 shares reserved for grant under this program.

Table of Contents

STOCK OPTION PLAN INFORMATION

Option activity during fiscal 2010 under all the stock plans were as follows (in millions, except per share amounts):

	Shares Available for Grant	Number Outstanding	STOCK OPTIONS OUTSTANDING Weighted Average Exercise Price Per Share
Balance at December 31, 2009 (with 2.3 options exercisable at a weighted-average exercise price of \$137.75 per share and with 4.4 options vested and expected to vest at a weighted-average exercise price of \$156.04 per share)	8.6	4.6	\$ 157.25
Options authorized	1.3		
Options granted	(1.4)	1.4	328.92
Options exercised		(1.0)	133.24
Options canceled/expired	(7.1)	(0.2)	222.01
 Balance at December 31, 2010 (with 2.5 options exercisable at a weighted-average exercise price of \$173.49 per share and with 4.7 options vested and expected to vest at a weighted-average exercise price of \$207.79 per share)	 1.4	 4.8	 \$ 209.03

The aggregate intrinsic value of options exercised under our stock option plans determined as of the date of option exercise was \$192.9 million, \$94.9 million, and \$140.9 million during the years ended December 31, 2010, 2009, and 2008, respectively. Cash received from option exercises and employee stock purchase plans for the years ended December 31, 2010, 2009 and 2008 was \$141.1 million, \$63.2 million and \$44.7 million, respectively.

The following table summarizes significant ranges of outstanding and exercisable options as of December 31, 2010:

Range of Exercise Prices	Number of Shares	Options Outstanding			Options Exercisable			Aggregate Intrinsic Value (1)
		Weighted Average Remaining Contractual Life	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (1)	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (1)	
\$0.00 107.27	1.7	6.49	\$ 88.59	1.0	76.97			
\$107.65 288.55	1.0	7.24	183.13	0.7	156.91			
\$288.79 333.37	1.0	7.51	307.54	0.5	304.32			
\$334.30 365.98	1.1	8.97	336.22	0.3	336.92			
TOTAL	4.8	7.42	\$ 209.03	\$ 372.3	2.5	6.44	\$ 173.49	\$ 257.2

(1) The aggregate intrinsic value represents the total pre-tax intrinsic value, based on the Company's closing stock price of \$257.75 as of December 31, 2010, which would have been received by the option holders had all in-the-money option holders exercised their options as of that date.

As of December 31, 2010, the shares vested and expected to vest had a weighted average remaining contractual life of 7.38 years and aggregate intrinsic value of \$367.5 million.

Table of Contents

STOCK-BASED COMPENSATION

The following table summarizes stock-based compensation charges:

	Year Ended December 31,		
	2010	2009	2008
Cost of sales - products	\$ 9.6	\$ 7.7	\$ 6.3
Cost of sales - services	8.4	6.6	5.1
Total cost of sales	18.0	14.3	11.4
Selling, general and administrative	77.0	61.3	48.1
Research and development	22.6	21.4	17.1
Stock-based compensation expense before income taxes	117.6	97.0	76.6
Income tax effect	39.2	26.5	23.2
Stock-based compensation expense after income taxes	\$ 78.4	\$ 70.5	\$ 53.4

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, 2010, 2009 and 2008, were based on estimates at the date of grant as follows:

STOCK OPTION PLANS	Year Ended December 31,		
	2010	2009	2008
Average risk free interest rate	2.24%	1.76%	2.79%
Average expected term (years)	4.80	5.28	5.03
Average volatility	36%	55%	52%
Weighted average fair value at grant date	\$ 111.84	\$ 59.53	\$ 138.33
Total stock-based compensation expense (in millions)	\$ 109.1	\$ 90.3	\$ 72.3
EMPLOYEE STOCK PURCHASE PLAN			
Average risk free interest rate	0.43%	0.63%	2.18%
Average expected term (years)	1.30	1.30	1.30
Average volatility	39%	56%	54%
Weighted average fair value at grant date	\$ 106.72	\$ 51.23	\$ 108.08
Total stock-based compensation expense (in millions)	\$ 8.5	\$ 6.7	\$ 4.3

As stock-based compensation expense recognized in the Consolidated Statements of Income during the years ended December 31, 2010, 2009 and 2008 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, 2010, there was \$216.3 million and \$4.1 million, of total unrecognized compensation expense related to non-vested stock options and employee stock purchases, respectively. The unrecognized compensation expenses are expected to be recognized over a weighted average period of 2.5 years for non-vested stock options and 1.2 years for employee stock purchases.

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 \$65.2 million, \$25.1 million, and \$53.3 million for the years ended December 31, 2010, 2009 and 2008 have been classified as a financing cash inflow. The total income tax benefit recognized in the income statement for stock-based compensation costs was \$39.2 million, \$26.5 million and \$23.2 million for the years ended December 31, 2010, 2009 and 2008, respectively.

Table of Contents**NOTE 10. INCOME TAXES**

Income before provision for income taxes for the years ended December 31, 2010, 2009 and 2008 consisted of the following (in millions):

	Year Ended December 31,		
	2010	2009	2008
U.S	\$ 438.7	\$ 334.5	\$ 284.5
Foreign	133.6	61.6	50.7
Total income before provision for income taxes	\$ 572.3	\$ 396.1	\$ 335.2

The provision for income taxes for the years ended December 31, 2010, 2009 and 2008 consisted of the following (in millions):

	Year Ended December 31,		
	2010	2009	2008
Current			
Federal	\$ 189.9	\$ 159.0	\$ 134.7
State	20.0	19.1	16.2
Foreign	2.1	1.0	0.6
	\$ 212.0	\$ 179.1	\$ 151.5
Deferred			
Federal	\$ (22.2)	\$ (16.0)	\$ (19.1)
State	0.5	0.3	(1.8)
Foreign	0.2	0.1	0.3
	\$ (21.5)	\$ (15.6)	\$ (20.6)
Total income tax expense	\$ 190.5	\$ 163.5	\$ 130.9

Income tax expense differs from amounts computed by applying the statutory rate of 35% for the years ended December 31, 2010, 2009 and 2008 as a result of the following (in millions):

	Year Ended December 31,		
	2010	2009	2008
Federal tax at statutory rate	\$ 200.3	\$ 138.6	\$ 117.3
Increase (reduction) in tax resulting from:			
State taxes, net of federal benefits	20.5	19.4	14.4
Foreign rate differential	(31.3)		
Research and development credit	(4.6)	(2.6)	(2.9)
Stock compensation not benefitted	4.8	3.9	2.8
Other	0.8	4.2	(0.7)
	\$ 190.5	\$ 163.5	\$ 130.9

Table of Contents

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 millions):

	December 31,	
	2010	2009
Deferred tax assets:		
Stock-based compensation expense	\$ 65.0	\$ 46.0
Expenses deducted in later years for tax purposes	21.1	15.8
Other	0.2	
Deferred tax assets	\$ 86.3	\$ 61.8
Deferred tax liabilities:		
Identified intangible assets related to acquisitions	\$	\$ (0.1)
Other	(4.5)	(1.0)
Deferred tax liabilities	\$ (4.5)	\$ (1.1)
Net deferred tax assets	\$ 81.8	\$ 60.7

The Company has not provided U.S. income taxes and foreign withholding taxes on the undistributed earnings of foreign subsidiaries as of December 31, 2010 because the Company intends to permanently reinvest such earnings outside the U.S. If these foreign earnings were to be repatriated in the future, the related U.S. tax liability may be reduced by any foreign income taxes previously paid on these earnings. As of December 31, 2010, the cumulative amount of earnings upon which U.S. income taxes have not been provided is approximately \$88.0 million. Determination of the amount of unrecognized deferred tax liability related to these earnings is not practicable. The Company has a tax holiday in effect for its business operations in Switzerland which will last till approximately year 2017. This tax holiday provides for a lower rate of taxation in Switzerland based on various thresholds of investment and employment in such jurisdiction. The Company has been in compliance with the terms of the holiday.

As of December 31, 2010, the Company had state net operating loss carry forwards of approximately \$0.7 million. If not utilized, the state loss carry forwards will begin to expire in 2017.

In December 2010, a retroactive two-year extension of federal R&D credit through the end of year 2011 was signed into law. The federal R&D credit has previously expired at the end year 2009. As a result of this change in federal tax law, the Company recorded a net federal R&D credit of \$4.6 million for the full year 2010 discretely in the fourth quarter of 2010.

The Company recorded a net increase of its gross unrecognized tax benefits of approximately \$8.9 million during the year ended December 31, 2010. The Company had gross unrecognized tax benefits of approximately \$78.9 million, \$70.0 million and \$42.0 million as of December 31, 2010, 2009 and 2008, respectively, of which \$74.7 million, 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, 2010, 2009 and 2008, respectively. The Company included interest expense and penalties accrued on unrecognized tax benefits as a component of its income tax expense. As of December 31, 2010, 2009 and 2008, gross interest related to unrecognized tax benefits accrued was approximately \$5.5 million, \$3.3 million and \$0.9 million, respectively, and an increase of \$2.2 million was included in our income tax expense for the year ended December 31, 2010. The Company classified its net unrecognized tax benefits and related interest in Other accrued liabilities on the Consolidated Balance Sheet.

Table of Contents

A reconciliation of the beginning and ending amounts of gross unrecognized income tax benefits for the years ended December 31, 2010, 2009 and 2008 are as follows (in millions):

	Year Ended December 31,		
	2010	2009	2008
Beginning balance	\$ 70.0	\$ 42.0	\$ 21.9
Additions for tax positions related to current year	9.1	24.9	20.2
Increase (decrease) for tax positions related to prior year	(0.2)	3.1	(0.1)
Ending balance	\$ 78.9	\$ 70.0	\$ 42.0

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 share (in millions, except per share amounts):

	Year Ended December 31,		
	2010	2009	2008
Net income	\$ 381.8	\$ 232.6	\$ 204.3
Basic:			
Weighted-average shares outstanding	39.2	38.3	38.9
Basic net income per share	\$ 9.74	\$ 6.07	\$ 5.26
Diluted:			
Weighted-average shares outstanding used in basic calculation	39.2	38.3	38.9
Add dilutive potential common shares	1.1	0.9	1.0
Weighted-average shares used in computing diluted net income per share	40.3	39.2	39.9
Diluted net income per share	\$ 9.47	\$ 5.93	\$ 5.12

Employee stock options to purchase approximately 1.3 million, 1.5 million and 1.2 million shares for the years ended December 31, 2010, 2009 and 2008, respectively, were outstanding, but were not included in the computation of diluted net income per share because the effect of including such shares would have been antidilutive in the periods presented.

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, 2010, 2009 and 2008.

Table of Contents**SELECTED QUARTERLY DATA****(UNAUDITED, IN MILLIONS, EXCEPT PER SHARE AMOUNTS)**

	2010			
	Q1	Q2	Q3	Q4
Revenue	\$ 328.6	\$ 350.7	\$ 344.4	\$ 389.3
Gross profit	\$ 240.5	\$ 256.8	\$ 250.6	\$ 282.1
Net income	\$ 85.3	\$ 88.7	\$ 86.6	\$ 121.2
Net income per common share				
Basic	\$ 2.20	\$ 2.26	\$ 2.20	\$ 3.10
Diluted	\$ 2.12	\$ 2.19	\$ 2.14	\$ 3.02
	2009			
	Q1	Q2	Q3	Q4
Revenue	\$ 188.4	\$ 260.6	\$ 280.1	\$ 323.1
Gross profit	\$ 128.7	\$ 190.2	\$ 199.0	\$ 233.2
Net income	\$ 28.1	\$ 62.4	\$ 64.6	\$ 77.5
Net income per common share				
Basic	\$ 0.72	\$ 1.65	\$ 1.69	\$ 2.02
Diluted	\$ 0.72	\$ 1.62	\$ 1.64	\$ 1.95

Table of Contents

SCHEDULE II

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

	Balance at Beginning of Year	Additions	Deductions (1)	Balance at End of Year
Allowance for doubtful accounts and sales returns				
Year ended December 31, 2010	\$ 4.3	11.3	(10.8)	\$ 4.8
Year ended December 31, 2009	\$ 4.1	10.2	(10.0)	\$ 4.3
Year ended December 31, 2008	\$ 3.8	12.0	(11.7)	\$ 4.1

(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, 2010.

The effectiveness of our internal control over financial reporting as of December 31, 2010 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, 2010.

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 Directors and Corporate Governance 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(4)	2009 Employment Commencement Incentive Plan adopted October 22, 2009.
10.6(5)	2010 Incentive Award Plan.
10.7(3)	Amended and Restated Investor Rights Agreement dated March 31, 1999.
10.8(6)	Severance Plan.
10.9(7)	Third Amendment effective as of July 1, 2010, to Employment Agreement between the Company and Lonnie M. Smith, dated February 28, 1997.
10.10(8)	Form of Intuitive Surgical, Inc. 2010 Equity Incentive Plan Stock Option Agreement (Incentive and Nonstatutory Stock Options).
21.1(9)	Intuitive Surgical, Inc. subsidiaries.
23.1(9)	Consent of Independent Registered Public Accounting Firm.
31.1(9)	Certification of Principal Executive Officer.
31.2(9)	Certification of Principal Financial Officer.
32.1(9)	Certification of Chief Executive Officer and 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(10)	The following materials from Intuitive Surgical, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2010, formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Income, (iii) Consolidated Statement of Stockholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements, tagged at Level I through IV.

(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 July 26, 2010 (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 10.10 filed with the Company's 2009 Annual Report on Form 10-K filed January 29, 2010 (File No. 000-30713).

Table of Contents

- (5) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed April 23, 2010 (File No. 000-30713).
- (6) 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).
- (7) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed July 26, 2010 (File No. 000-30713).
- (8) 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).
- (9) Filed herewith.
- (10) 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

February 1, 2011

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)	February 1, 2011
/s/ MARSHALL L. MOHR Marshall L. Mohr	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 1, 2011
/s/ LONNIE M. SMITH Lonnie M. Smith	Chairman of the Board of Directors	February 1, 2011
/s/ ROBERT W. DUGGAN Robert W. Duggan	Director	February 1, 2011
/s/ AMAL M. JOHNSON Amal M. Johnson	Director	February 1, 2011
/s/ ERIC H. HALVORSON Eric H. Halvorson	Director	February 1, 2011
/s/ ALAN J. LEVY, PH.D. Alan J. Levy, Ph.D.	Director	February 1, 2011
/s/ FLOYD D. LOOP, M.D.	Director	February 1, 2011

Edgar Filing: INTUITIVE SURGICAL INC - Form 10-K

Floyd D. Loop, M.D.

/s/ MARK J. RUBASH

Director

February 1, 2011

Mark J. Rubash

/s/ GEORGE STALK JR.

Director

February 1, 2011

George Stalk Jr.