INTUITIVE SURGICAL INC
Form 10-K
February 06, 2015
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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, 2014
OR
.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM TO
COMMISSION FILE NUMBER 000-30713

Intuitive Surgical, Inc.

(Exact name of Registrant as Specified in its Charter)

DELAWARE	77-0416458
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)
1020 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 x 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 x
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 x No ¨

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates on June 30, 2014, based upon the closing price of Common Stock on such date as reported by NASDAQ Global Select Market, was approximately $14,639,055,551. 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 16, 2015, was 36,599,799.

DOCUMENTS INCORPORATED BY REFERENCE

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 23, 2015, to be filed within 120 days of the registrant's fiscal year ended December 31, 2014.

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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 (the "Exchange Act"). Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as “estimates,” “projects,” “believes,” “anticipates,” “plans,” “expects,” “intends,” “may,” “will,” “could,” “should,” “would,” “targeted” and similar words and expressions are inte 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, future results of operations, future financial position, our ability to increase our revenues, the anticipated mix of our revenues between product and service revenues, our financing plans and future capital requirements, anticipated costs of revenue, anticipated expenses, our potential tax assets or liabilities, the effect of recent accounting pronouncements, our investments, anticipated 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 global and regional economic and credit market conditions on health care spending; health care reform legislation in the United States and its impact on hospital spending, reimbursement, insurance deductibles, and fees which will be levied on certain medical device revenues; decreases in hospital admissions and actions by payers to limit or manage surgical procedures; timing and success of product development and market acceptance of developed products; procedure counts; regulatory approvals, clearances and restrictions, or any dispute that may occur with any regulatory body; 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 we operate; unanticipated manufacturing disruptions; the inability to meet demand for products; the results of legal proceedings to which we are or may become a party; product liability and other litigation claims; adverse publicity regarding our Company and safety of our products and the adequacy of training; our ability to expand in foreign markets; and other risk factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which are based on current expectations 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 publicly update or release any revisions to these forward-looking statements, except as required by law.

PART I

ITEM 1. BUSINESS

In this report, “Intuitive Surgical,” “Intuitive,” the “Company,” “we,” “us,” and “our” refer to Intuitive Surgical, Inc. and its wholly-owned subsidiaries. Intuitive®, Intuitive Surgical®, da Vinci®, da Vinci® S®, da Vinci® Si HD Surgical System™, da Vinci S HD Surgical System®, da Vinci® Si™, da Vinci Xi™, da Vinci Si-e™, da Vinci SP™, EndoWrist®, EndoWrist® One™, EndoWrist® Stapler 45, Single-Site®, Firefly™, InSite®, and da Vinci® Connect® are trademarks of Intuitive Surgical, Inc.

Company Background

Intuitive designs, manufactures and markets da Vinci Surgical Systems and related instruments and accessories, which taken together, are advanced surgical systems that we consider an advanced generation of surgery. This advanced generation of surgery, which we call da Vinci surgery, combines the benefits of minimally invasive surgery (“MIS”) for patients with the ease of use, precision and dexterity of open surgery. A da Vinci Surgical System consists of a surgeon’s console, a patient-side cart, and a high performance vision system. The da Vinci Surgical System translates a 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. The da Vinci Surgical System is designed to provide its operating surgeons with intuitive control, range of motion, fine tissue manipulation capability and Three Dimensional (“3-D”), High-Definition (“HD”) vision while simultaneously allowing surgeons to work through the small ports enabled by MIS procedures.

da Vinci Surgery

da Vinci Surgery utilizes computational, robotic and imaging technologies to enable improved patient outcomes compared to other surgical and non-surgical therapies. da Vinci Surgery is aimed towards advancing the critical surgical ideals of entering the body less invasively, seeing anatomy more clearly, interacting with tissue more precisely and building surgical skills. The da Vinci Surgical System enables surgeons to avail or improve the benefits of MIS to many patients who would otherwise undergo a more invasive surgery. Surgeons using the da Vinci system operate while seated comfortably at a console viewing a 3-D, HD image of the surgical field. This immersive visualization connects surgeons to the surgical field and their instruments. While seated at the console, the surgeon manipulates instrument controls in a natural manner, similar to the more intuitive open surgery technique. Our multi-port technology is designed to provide surgeons with a range of motion in the surgical field analogous to the motions

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of a human wrist, while filtering out the tremor inherent in a surgeon's hand. In designing our products, we focus on making our technology easy to use.

Our systems provide the following features and benefits to surgeons:

Immersive 3-D Visualization. Our vision system includes a 3-D endoscope with two independent vision channels linked to two separate color monitors through sophisticated image processing electronics. The da Vinci Surgical System provides visualization of target anatomy with natural depth-of-field, enhanced contrast and magnification that is intended to facilitate accurate tissue identification and tissue layer differentiation. With our Firefly Fluorescence Imaging upgrade, surgeons can use specialized imaging hardware in combination with an injectable fluorescent dye to visualize vasculature or biliary imaging in cholecystectomy beneath tissue surfaces in real-time.

Precise and Tremor-Free Endoscope Control. Our imaging 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. Surgeons can reposition the surgical camera quickly with foot controls or zoom in, out, up, down, left and right by moving their hands while maintaining a stable image.

Intuitive Instrument Movements. Our technology is designed to 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 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. 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. Most of 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.

Scaled, Tremor Filtered Instrument 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 precision and control for delicate tasks. In addition, our technology filters the tremor inherent in a surgeon's hands.

Improved Surgeon Ergonomics. The da Vinci Surgical System is designed to allow surgeons to operate while seated, which may be clinically advantageous because of reduced surgeon fatigue. The da Vinci Surgical System's design provides natural hand-eye alignment at the surgeon's console. Because the da Vinci Surgical System's robotic arms hold the camera and instruments steady, there is less surgeon and assistant fatigue.

Multi-Specialty Surgical Platform. The da Vinci Surgical System is designed to enable surgeons to perform a wide range of surgical procedures, within our targeted gynecologic, urologic, general surgery, cardiothoracic and head and neck specialties. To date, surgeons have used the da Vinci Surgical System to perform dozens of different types of surgical procedures. While we do not expect all of these different types of procedures to become widely adopted, they demonstrate the flexibility of the da Vinci Surgical System in approaching anatomy.

Advanced Training Tools. Surgeons can efficiently train and improve their da Vinci Surgery skills with a group of tools unique to robotic surgery, including our da Vinci Skills Simulator for software based skills practice and assessment, our da Vinci dual console for inter-operative collaboration, and our da Vinci Connect networking technology for on-line proctoring.

Products:

da Vinci Surgical System

We have commercialized four generations of da Vinci Surgical System— the da Vinci Xi Surgical System, the da Vinci Si Surgical System, the da Vinci S Surgical System and the standard da Vinci Surgical System. da Vinci Surgical Systems are comprised of the following components:

Surgeon's Console. The da Vinci Surgical System allows surgeons to operate while comfortably seated at an ergonomic console viewing a 3-D image of the surgical field. The surgeon's fingers grasp instrument controls below the display with the surgeon's hands naturally positioned relative to his or her eyes. Using electronic hardware,

software, algorithms and mechanics, our technology translates the surgeon's hand movements into precise and corresponding real-time micro movements of the EndoWrist instruments positioned inside the patient. On our most current systems, da Vinci Xi and da Vinci Si, a second surgeon's console may be used in two possible ways: to provide assistance to the primary surgeon during surgery or to act as an active aid during surgeon-proctor training sessions. With the da Vinci Xi and 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

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the da Vinci instruments during the surgery. In addition, surgeons can control 3-D virtual pointers to augment the dual surgeon experience.

Patient-Side Cart. The patient-side cart holds electromechanical arms that manipulate the instruments inside the patient. Up to four arms attached to the cart can be positioned as appropriate, and then locked into place. At least two arms hold our EndoWrist instruments, one representing the surgeon's left hand and one representing the surgeon's right hand. A third arm positions the endoscope, allowing the surgeon to easily move, zoom and rotate his or her field of vision. An optional fourth instrument arm extends surgical capabilities by enabling the surgeon to add a third EndoWrist instrument to perform additional tasks. The fourth instrument arm is a standard integrated feature on the da Vinci Xi, Si, and S Surgical Systems and is available as an upgrade on three-arm da Vinci S Surgical Systems and da Vinci Si-e 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 image processing hardware. The resulting 3-D image has high resolution, high contrast, low flicker and low cross fading. A digital zoom feature in the 3-D, HD vision system allows surgeons to magnify the surgical field of view without adjusting the endoscope position and thereby reduces interference between the endoscope and instruments. The 3-D, HD vision is a standard integrated feature on da Vinci Xi, Si, and S Surgical Systems.

da Vinci Skills Simulator. The Skills Simulator is a practice tool that gives a user the opportunity to practice his or her facility with the surgeon console controls. The Skills Simulator incorporates 3-D, 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. Upon completion of a skills exercise, the Skills 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 Xi and Si Surgical Systems. Most da Vinci Skills Simulators have been sold in connection with new da Vinci Xi and Si Surgical Systems.

Firefly Fluorescence Imaging. In the first quarter of 2011, we launched our Firefly product for use with the da Vinci Si Surgical System. Firefly is a standard feature of the da Vinci Xi Surgical System. This imaging capability combines a fluorescent dye with a specialized da Vinci camera head, endoscope and laser-based illuminator to allow surgeons to identify vasculature in three dimensions beneath tissue surfaces to visualize critical anatomy. Adoption of Firefly is progressing with use across the categories of urology, gynecology and general surgery. In September 2013, we received U.S. Food and Drug Administration ("FDA") 510(k) clearance to market our Firefly fluorescence imaging product for real-time imaging of bile ducts (cystic duct, common bile duct and common hepatic duct).

Standard da Vinci System. During 2014, we phased out the sale of all instrument, accessory and service contract offerings for the standard da Vinci Surgical System.

Instruments and Accessories

EndoWrist Instruments. We manufacture a variety of instruments, most of which incorporate wrist joints for natural dexterity, with tips customized for various surgical procedures. EndoWrist instruments are offered in a variety of sizes, of which 5mm and 8mm diameter sizes are the most commonly sold. At their tips, the various EndoWrist instruments include forceps, scissors, electrocautery, scalpels, and other surgical tools that are familiar to the surgeon from open surgery and conventional MIS. A variety of EndoWrist instruments are selected and used interchangeably during a surgery. Our 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. In addition, the chip will not allow the instrument to be used for more than the prescribed number of procedures to help ensure that its performance meets specifications during each procedure. We typically develop new types of EndoWrist instruments to support additional types of surgical procedures.

da Vinci Single-Site. da Vinci Single-Site is a set of non-wristed instruments (except for wristed needle driver discussed below) and accessories that allow Surgical Systems to work through a single incision, typically in the umbilicus, rather than multiple incisions. Single incision surgery is intended to minimize trauma to patients by reducing the number of ports required to enter the body and is typically utilized for less complex surgery than multi-port surgery. Non-robotic single incision surgery today is typically performed with modified laparoscopic

instruments. Early clinical adoption of this manual technique has been mostly positive; however, physicians have reported that manual single incision surgery is technically and ergonomically challenging. da Vinci Single-Site instruments and accessories were designed to address these issues. In February 2011, we received the CE mark for our da Vinci Single-Site instrument kit for da Vinci Si Surgical Systems and began selling these new products in Europe. The majority of da Vinci Single-Site procedures performed in Europe to date has been cholecystectomies. In December 2011, we received FDA regulatory clearance to market our Single-Site instrumentation in the U.S. for laparoscopic cholecystectomy procedures for da Vinci Si Surgical Systems. In February 2013, we received FDA clearance to market our da Vinci Single-Site instruments for benign hysterectomy and salpingo oophorectomy procedures. In September 2014, we received FDA clearance to market the wristed version of our da Vinci

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Single-Site needle driver product for use on benign hysterectomy, cholecystectomy, and salpingo-oophorectomy procedures on da Vinci Si Surgical Systems. We are encouraged by hospital, surgeon, and patient interest in da Vinci Single-Site, and believe this instrument may have particular utility in benign hysterectomy procedures. However, these are our first products targeted towards procedures already highly penetrated by manual MIS techniques, and we are not able to predict the extent or pace that da Vinci Single-Site may be adopted.

EndoWrist One Vessel Sealer. In December 2011, we received FDA clearance for our EndoWrist One Vessel Sealer for da Vinci Si Surgical Systems. The EndoWrist One Vessel Sealer is a wristed, single-use instrument intended for bipolar coagulation and mechanical transection of vessels up to 7 mm in diameter and tissue bundles that fit in the jaws of the instrument. This instrument enables surgeons to fully control vessel sealing, while providing the benefits of da Vinci surgery. This instrument is designed to enhance surgical efficiency and autonomy in a variety of general surgery and gynecologic procedures. Clinical response to the EndoWrist One Vessel Sealer has been encouraging, with positive commentary on precision, articulation, vessel sealing quality and thermal spread, and we expect applications for the EndoWrist One Vessel Sealer to be centered on general surgery and gynecologic oncology procedures. EndoWrist One Vessel Sealer utilization rates have increased steadily in 2013 and 2014. In June 2014, we received FDA clearance for the da Vinci Xi version of the EndoWrist One Vessel Sealer.

EndoWrist Stapler 45 Instrument. In October 2012, we received FDA clearance for our EndoWrist Stapler 45 Instrument with Blue and Green 45 mm reloads for da Vinci Si Surgical Systems. The EndoWrist Stapler 45 is a wristed, stapling instrument intended for resection, transection and/or creation of anastomoses in general, gynecologic and urologic surgery. This instrument enables surgeons to precisely position and fire the stapler. Its initial surgical use has been directed towards colorectal procedures. During 2013, the EndoWrist Stapler was used by a limited and gradually increasing number of customers. In 2014, we expanded the availability of the EndoWrist Stapler to a broadening set of customers. In September 2014, we notified our customers to suspend the use of the EndoWrist Stapler 45 (see Recalls and Corrections section for additional discussion). Although our early customer experiences have been positive, we are in the early stages of selling EndoWrist Stapler 45, and we are not able to predict the extent to which the instrument may be adopted.

Accessory Products. We sell various 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 items that facilitate use of the system.

Business Strategy

Our objective is to bring the benefits of MIS to as many patients as possible through the use of computer aided robotic technologies. 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 = Procedure Efficacy/Invasiveness. We define procedure efficacy as a measure of the success of the surgery in resolving the underlying disease and invasiveness as how disruptive and painful the treatment is itself. When the patient value of a da Vinci procedure is deemed higher than alternate treatment options, patients may seek out surgeons and hospitals that offer that specific da Vinci procedure, potentially resulting in a local market share shift for the specific treatment. Adoption occurs procedure by procedure, and is driven by the relative patient value of da Vinci procedures compared to alternative treatment options for the same disease state. We believe 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 products to surgeons who in turn provide patients with procedure options that are both highly effective and less invasive than other surgical options.
2. Surgeon Value. We train surgeons on the use of our da Vinci Surgical System and assist them in building their practices by their delivery of superior patient value. We provide an ergonomic platform for surgeons to perform their procedures. We seek to provide surgeons with reliable and easy to use products.
3. Hospital Value. We assist hospitals in building value by offering patient value using da Vinci thereby increasing surgical revenue and reducing costs through lower complication rates and reduced length of patient stay. da Vinci Surgery is a cost effective approach to many surgeries as compared to alternative treatment options as demonstrated in many published studies.

Given the priorities above, our strategy is to improve our target surgical procedures in one or more of the following ways:

1. Convert Target Open Procedures to da Vinci Surgery. We believe that our technology has the potential to convert a significant percentage of our targeted open procedures to da Vinci Surgery.
2. Facilitate Difficult MIS Operations. We believe that several surgical procedures that are seldom performed today using conventional MIS techniques can be performed more routinely using da Vinci Surgery. Some procedures have been adopted using 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 such procedures.

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3. Offer a Less Invasive Single Port Surgical Option. We believe that our da Vinci Single Site technology has the potential to convert target procedures typically performed via multiport laparoscopic technique to single port da Vinci Surgery, offering patients less invasive, improved cosmetic outcomes.

Clinical Applications

We are the beneficiaries of productive collaborations with leading surgeons in exploring and developing new techniques and applications for da Vinci surgery—an important part of our creative process. We primarily focus our development efforts on those procedures in which we believe our products bring the highest patient value, surgeon value, and hospital value. We currently focus on five surgical specialties: urologic surgery, gynecologic surgery, general surgery, cardiothoracic surgery, and head and neck surgery. Key procedures which we are focused on include da Vinci Prostatectomy ("dVP"), da Vinci Hysterectomy ("dVH"), da Vinci Cholecystectomy, da Vinci Colon and Rectal procedures, da Vinci Partial Nephrectomy, da Vinci Sacrocolpopexy, da Vinci Mitral Valve Repair, da Vinci Lobectomy, and da Vinci Transoral Robotic Surgery (for cancers of the throat). In 2014, total U.S. procedure volume was approximately 449,000, of which 20% was in urology, 52% was in gynecology, and 24% was in general surgery. International procedure volume was approximately 121,000 in 2014, of which most procedures were in urology. Representative surgical applications are described below.

Urologic Surgery

Prostatectomy. Radical prostatectomy is the removal of the prostate gland in patients diagnosed with clinically localized prostate cancer. The standard approach to removal of the prostate has been via an open surgical procedure. The conventional laparoscopic approach is an option, but is difficult and poses challenges to even the most skilled urologist. 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.

Partial Nephrectomy. Partial nephrectomy is the removal of a small portion of a kidney (typically, an area of the kidney containing a tumor). Partial nephrectomies are most commonly performed in patients diagnosed with clinically localized renal cancer. Excluding da Vinci surgery, there are three common surgical approaches to performing partial nephrectomies: open surgical technique, laparoscopy, and hand assisted laparoscopy, which is a hybrid of open and laparoscopic technique. Surgeons have reported that the da Vinci Surgical System's capabilities may enable a large number of these procedures to be performed through a minimally invasive technique, conferring the benefits of MIS to a broader range of partial nephrectomy patients. Treatment guidelines for patients with localized renal cancer recommend partial nephrectomy due to the benefits nephron-sparing surgery has in long-term patient outcomes. Published clinical literature has shown that the presence of a da Vinci Surgical System is associated with a higher-proportion of patients receiving guideline-recommended partial nephrectomy.

Gynecologic Surgery

Hysterectomy. Removal of the uterus is one of the most commonly performed surgeries in gynecology and is performed for a variety of underlying benign and malignant conditions. Hysterectomies can be performed using open surgery (laparotomy), or MIS techniques, which include vaginal, laparoscopic, and robotic approaches. Despite the availability of non-robotic MIS approaches to hysterectomy, most hysterectomies performed prior to da Vinci Surgery were open surgeries. da Vinci Surgery has enabled a large number of women to receive a minimally invasive treatment as an alternative to an open hysterectomy. During the first quarter of 2013, Single-Site instruments were FDA cleared in the U.S. for use in benign hysterectomies and salpingo oophorectomies. In September 2014, we received FDA clearance to market the wristed version of our Single-Site needle driver product for use on benign hysterectomy, cholecystectomy, and salpingo-oophorectomy procedures. Single-Site instruments enable surgeons to perform surgery through a single port via the patient's belly button, allowing for virtually scarless results.

Sacrocolpopexy. The abdominal (open) sacrocolpopexy is one of the most successful operations for vaginal vault prolapse. Sacrocolpopexy involves suturing a synthetic mesh that connects and supports the vagina to the sacrum (tailbone). A sacrocolpopexy can be performed using conventional laparoscopic technique; however, it is generally described as difficult and cumbersome to perform. Surgeons have reported that the da Vinci Surgical System's capabilities may enable a large number of these procedures to be performed through a minimally invasive technique, conferring the benefits of MIS to a broader range of sacrocolpopexy patients.

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. Because mitral valve repairs are considered to be more technically challenging than mitral valve replacements, they are only performed

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approximately 50% of the time. Several of our surgeon customers have reported an improvement in their mitral valve repair rates over mitral valve replacements when using the da Vinci Surgical System.

Thoracic Surgery. Conventional approaches to surgical procedures in the thorax include both open and video-assisted thoracoscopic approaches. Procedures performed via these methods include pulmonary wedge resection, pulmonary lobectomy, thymectomy, mediastinal mass excision, and esophagectomy. Many thoracic procedures remain open procedures. Surgeons have reported that the use of the da Vinci Surgery System in thoracic surgery has enabled them to offer MIS approaches to a broader range of thoracic surgery patients.

General Surgery

Cholecystectomy. Cholecystectomy, or the surgical removal of the gall bladder, is a commonly performed general surgery procedure. Cholecystectomy is the primary method for the treatment of gallstones and other gall bladder diseases. Most cholecystectomies are performed using multi-port MIS techniques, although some surgeons choose to perform cholecystectomy using manual single-port instrumentation. With the 2011 European introduction of da Vinci Single-Site instruments followed by the U.S. introduction in 2012, Single-Site robotic cholecystectomies are now being performed. Using da Vinci Single-Site instruments, many of the technical challenges of manual single-port MIS are reduced as surgeons benefit from additional precision, control, and improved ergonomics. Multi-port robotic cholecystectomies are also being performed.

Colorectal Surgery. These procedures typically involve benign or cancerous conditions of the lower digestive system, in particular the rectum or colon. Common procedures in this area include hemicolectomy, sigmoidectomy, low anterior resection, and abdominoperineal resection. Conventional laparoscopy is not widely employed to treat these types of diseases, due to their high degree of difficulty. Surgeons have reported that the use of the da Vinci Surgery System in colorectal surgery has enabled them to offer MIS approaches to a broader range of colorectal surgery patients.

Hernia Repair. A hernia occurs when an organ or fatty tissue squeezes through a weak spot in a surrounding muscle or connective fascia tissue. During a hernia repair surgery, the weakened abdominal wall tissue is secured and defects are repaired. Common types of hernia are ventral and inguinal. Ventral, or abdominal hernia, may occur through a scar after surgery in the abdomen. Inguinal hernia is a bulge in the groin and is more common in men. Hernia repair can be performed using traditional open surgery or minimally invasive surgery. There is a wide-range of complexity in hernia repair surgeries and the benefits of minimally invasive and robotic surgery varies by patient. da Vinci hernia repair is associated with low rates of recurrence, pain, and conversion to open surgery as well as shorter hospital stays.

Gastric Bypass. A body of literature has emerged pointing to the benefit of surgery to treat patients for morbid obesity and its secondary effects, such as diabetes. Laparoscopic roux-en-Y gastric bypass (“LRYGB”) is the most commonly performed surgical procedure for morbid obesity in the U.S. The LRYGB can be a technically challenging procedure because of the suturing, stapling, and tissue (bowel) manipulation that is required. Surgeons using the da Vinci Surgical System have reported a reduction in a critical complication (anastomotic leaks) relative to LRYGB.

Head and Neck Surgery

Transoral Surgery. Head and neck cancers are typically treated by either surgical resection or chemo-radiation, or a combination of both. Surgical resection performed by an open approach may require a “jaw-splitting” mandibulotomy. This procedure, while effective in treating cancer, is traumatic and disfiguring to the patient. MIS approaches via the mouth (transoral surgery) are challenged by line-of-sight limitations dictated by conventional endoscopic tools. Chemo-radiation as a primary therapy does allow patients to avoid traumatic surgical incisions; however, literature suggests that this modality diminishes patients’ ability to speak and swallow normally. Surgeons have reported that da Vinci Transoral Surgery allows them to treat cancers occurring in the oropharynx (e.g., tonsil and base of tongue) and larynx via the mouth and to overcome some of the line-of-sight limitations of conventional transoral surgery.

Procedure Mix

Our procedure business is now splitting into two categories: (1) cancer and other highly complex procedures and (2) less complex benign procedures. Our strategy is to provide hospitals with attractive clinical and economic solutions in each of these categories. More fully featured products targeted towards the more complex procedure segment include 4-arm, dual console, firefly enabled systems and advanced instruments including vessel sealing and stapler. Lower priced products targeted towards the less complex segment of procedures include the three-arm da Vinci Si-e System

and lower priced Single-Site instruments.

Clinical Summary

We believe there are numerous additional applications that can be addressed with the da Vinci Surgical System and we work closely with our surgeon customers to refine and explore new techniques in which da Vinci may bring value. As of December 31, 2014, we had an installed base of 3,266 da Vinci Surgical Systems, including 2,223 in the U.S., 549 in Europe, 193 in Japan, and

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301 in the rest of the world. We estimate that surgeons using our technology completed approximately 570,000 surgical procedures of various types in hospitals throughout the world during the year ended December 31, 2014. Of those da Vinci procedures performed in 2014, we estimate that approximately 203,000 were dVH procedures and approximately 125,000 were dVP procedures.

Sales and Customer Support

Sales Model

We provide our products through a direct sales organization in the U.S.; most of Western Europe excluding Spain, Portugal, Italy and Greece; Japan and Korea. Beginning in 2013, we established a direct sales structure in the Czech Republic, Slovakia, and Hungary. Beginning in June 2014, we also established a direct sales structure in Japan. These markets were served by distributors prior to us establishing direct sales structures. In the remainder of our world markets, we provide our products through distributors. No one customer accounted for more than 10% of revenue during the years ended December 31, 2014, 2013, and 2012.

Our direct sales organization is composed of a capital sales team, responsible for selling da Vinci Surgical Systems, and a clinical sales team, responsible for supporting da Vinci Surgical System use in surgical procedures performed at our hospital accounts. The initial da Vinci Surgical System sale into an account is viewed as a major capital equipment purchase by our customers and typically has a lengthy sales cycle that can be affected by macroeconomic factors, capital spending prioritization, and the timing of budgeting cycles. Capital sales activities include educating surgeons and hospital staff across multiple surgical specialties on the benefits of da Vinci Surgery and the clinical applications that our technology enables. We also train our sales organization 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, surgeon recruitment, and volume.

Our clinical sales team works on site at the hospitals, interacting with surgeons, operating room staff, and hospital administrators to develop and sustain successful robotics surgery programs. They assist the hospital in identifying surgeons who have an interest in robotic surgery delivering da Vinci’s benefits. Our clinical sales team provides the current clinical information on robotic surgery practices and new product applications to the hospital teams and has grown with the expanded installed base of da Vinci Surgical Systems and the total number of procedures performed. We expect this organization to continue to grow as our business expands.

Our customers place orders to replenish their supplies of instruments and accessories on a regular basis. Orders received are typically shipped within one business day. Direct customers who purchase a new da Vinci Surgical System typically place an initial stocking order of 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, lighter in the first and third fiscal quarters and heavier in the fourth fiscal quarter. In addition, we have historically experienced lower procedure volume in the first and third fiscal quarters and higher procedure volume in the second and fourth fiscal quarter. Procedures treating benign conditions are typically higher in the fourth quarter and lower in the first quarter. Timing of procedures and changes in procedure growth impact the timing of instrument and accessory and capital purchases.

Customer Support and Training Programs

We have a network of field service engineers across the U.S., 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, surgical assistants, and operating room nurses. We have established training centers where initial system training and ongoing surgical procedural training are provided, the latter led by expert surgeons. Surgeons may also practice their robotic surgery technique using our da Vinci Skills Simulator. In addition, we help facilitate the proctoring of surgeons who are new to da Vinci Surgery by experienced da Vinci Surgical System users. Proctors

provide training to other surgeons on how to perform certain surgical procedures with da Vinci Surgical Systems.

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 MIS procedures with less difficulty. We employ research and development and engineering staff responsible for product design and engineering. We invested $178.0 million, $167.7 million, and $170.0 million of research and development expenses for the years ended December 31, 2014, 2013, and 2012, respectively.

We establish strategic alliances with other medical device and technology based companies to complement our research and development effort. To date, these alliances have taken several forms, including cooperation in the areas of product development,

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training, procedure development, and marketing activities. We have formed alliances with several companies, including, but not limited to, Erbe Elektromedizin GMBH, Johnson & Johnson, Olympus/Gyrus, Novadaq Technologies, Inc., and Mimic Technologies, Inc.

Manufacturing

We manufacture our da Vinci Surgical Systems at our facility in Sunnyvale, California. We manufacture our instruments at our Sunnyvale facility and Mexicali, Mexico facility.

We purchase both custom and off-the-shelf components from a large number of suppliers and subject them to stringent quality specifications and processes. 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 the majority of our components and major assemblies 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 results associated with da Vinci Surgery and its value relative to other techniques. We also face competition from several companies that are developing new approaches and products for the MIS market. We believe that many 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 prove complementary to some of these new technologies.

Moreover, as we add new robotically controlled products (e.g., Single-Site, stapler, and vessel sealer) that compete with product offerings traditionally within the domains of open surgery and/or conventional MIS, we face greater competition from larger and well established companies such as Ethicon Endo-Surgery, Inc.

Furthermore, as da Vinci use increases, a number of companies may be compelled to enter the field of robotic surgery. The following companies have made explicit statements about their efforts to enter the field: Johnson & Johnson, MedRobotics Corp., meerecompany Inc., Medtronic PLC, Olympus Corp., SOFAR S.p.A., IMRIS Inc., TransEnterix, Inc., and Titan Medical, Inc. Companies with substantial experience in industrial robotics could potentially expand into the field of surgical robotics and become a competitor. In addition, research efforts utilizing computers and robotics in surgery are underway at various companies and research institutions. 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 intellectual property laws, as well as confidentiality procedures and contractual provisions, to protect our proprietary technology. For example, we have trademarks, both registered and unregistered, that provide distinctive identification of our products in the marketplace. We also have exclusive and non-exclusive patent licenses with various third parties to supplement our own large and robust patent portfolio.

As of December 31, 2014, we held ownership or exclusive field-of-use licenses for more than 1,700 U.S. and foreign patents and more than 1,500 U.S. and foreign patent applications. We intend to continue filing new patent applications in the U.S. and foreign jurisdictions to seek protection for our technology.

Patents are granted for finite terms and eventually expire. Upon expiration, the inventions claimed in a patent enter the public domain. While our patents are an important element of our success, our business as a whole is not significantly dependent on any one patent.

Government Regulation

Our products and operations are subject to extensive and rigorous regulation by the FDA, the State of California and countries or regions in which we market our products. In addition, our products must meet the requirements of a large and growing body of international standards which govern the design, manufacture, materials content and sourcing, testing, certification, packaging, installation, use and disposal of our products. We must continually keep abreast of these standards and requirements and integrate compliance to these with the development and regulatory

documentation for our products. Failure to meet these standards could limit the ability to market our products in those regions which require compliance to such standards. Examples of groups of such standards are electrical safety standards such as those of the International Electrotechnical Commission (e.g. IEC 60601-ss series of standards) and composition standards such as the Reduction of Hazardous Substances (“RoHS”) and Waste Electrical and Electronic Equipment (“WEEE”) Directives.

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United States

The FDA regulates the development, testing, manufacturing, labeling, storage, recordkeeping, promotion, marketing, distribution, and service of medical devices in the U.S. 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 U.S. to international markets and the importation of medical devices manufactured abroad.

Under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 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 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. Unless a Class II device is exempt from premarket review, 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 device that has previously 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 in the U.S. The FDA has a statutory 90-day period to respond to a 510(k) submission, or a guidance-based 30-day period for "special" 510(k) submissions which have a more restrictive scope and generally involve more specific or very limited changes to a legally marketed device. 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 may deny the request for clearance. Although unlikely for the types of products marketed by us, the FDA may classify the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill more rigorous pre-market approval ("PMA") requirements. A PMA application, which is intended to demonstrate that a device is safe and effective, must be supported by extensive data, including data from preclinical studies and human clinical trials. The FDA, by statute and regulation, has 180 days to review a PMA application, though the review more often occurs over a significantly longer period of time, and can take up to several years. In approving a PMA application or clearing a 510(k) submission, the FDA may also require some form of post-market surveillance when necessary to protect the public health or to provide additional safety and effectiveness data for the device. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients.

After a device receives FDA 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 PMA application approval. The FDA requires each manufacturer to make the determination of whether a modification requires a new 510(k) notification or PMA application 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 or PMA approval for a particular change, the FDA may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease U.S. marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

In addition, after a device is placed on the market, numerous FDA and other regulatory requirements continue to apply. These include establishment registration and device listing with the FDA; compliance with medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and compliance with corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FFDCA that may present a risk to health. The FDA and the Federal Trade Commission ("FTC") also regulate the advertising and promotion of our products to ensure that the

claims we make are consistent with our regulatory clearances, that there is scientific data to substantiate the claims and that our advertising is neither false nor misleading. In general, we may not promote or advertise our products for uses not within the scope of our intended use statement in our clearances or make unsupported safety and effectiveness claims. Many regulatory jurisdictions outside of the U.S. have similar regulations to which we are subject.

Our manufacturing processes are required to comply with the FDA's Good Manufacturing Practice ("GMP") requirements contained in its Quality System Regulation ("QSR") and associated regulations and guidance. The QSR covers, among other things, the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all medical devices intended for human use. The QSR also requires maintenance of extensive records which demonstrate compliance with FDA regulation, the manufacturer's own procedures, specifications and testing as well as distribution and postmarket experience. Compliance with the QSR is necessary to receive FDA clearance or approval to market

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new products and is necessary for a manufacturer to be able to continue to market cleared or approved product offerings in the U.S. A company's facilities, records, and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA, which may issue reports known as Forms FDA 483 or Notices of Inspectional Observations which list instances where the FDA inspector believes the manufacturer has failed to comply with applicable regulations and/or procedures. If the observations are sufficiently serious or the manufacturer fails to respond appropriately, the FDA may issue Warning Letters, or Untitled Letters, which are notices of intended enforcement actions against the manufacturer. If a Warning Letter or Untitled Letter is not addressed to the satisfaction of the FDA, or if the FDA becomes aware of any other serious issue with a manufacturer's products or facilities, it could result in fines, injunctions, civil penalties, delays, suspension or withdrawal of clearances, seizures or recalls of products, operating restrictions, total shutdown of production facilities, prohibition on export or import and criminal prosecution. Such actions may have further indirect consequences for the manufacturer outside of the U.S., and may adversely affect the reputation of the manufacturer and the product. In the U.S., routine FDA inspections usually occur every two years, and may occur more often for cause.

An FDA inspection of our facilities occurred in April-May 2013 and the FDA issued a Form FDA 483 listing four observations relating to the reporting of field corrections, information which is to be included on reports of field corrections, written procedures for changes to certain product labeling, and design input documentation. We responded to each observation with corrective actions during the course of the inspection and provided additional evidence of corrective actions to the FDA in response to the Form FDA 483. The FDA issued a Warning Letter on July 16, 2013 related to two of the four Form FDA 483 observations asking for additional corrective actions, and its intent to perform a follow-up inspection. In addition, the FDA collected electronic samples of all our advertising and promotional material for review, and to date has taken no action in connection therewith. We responded to the Warning Letter, communicating corrective actions taken. The FDA re-inspected our facilities during February-March of 2014 to complete a general quality system audit as well as a review of the status of the Warning Letter and 483 remediation activities. At the end of the inspection, the FDA issued a Form FDA 483 listing five observations related to quality management system improvement opportunities. We responded to the FDA with a corrective action plan for those observations. On April 25, 2014, we received a closure letter from the FDA stating that the observations in the July 16, 2013 Warning Letter had been addressed, and on April 25, 2014, we also received an Establishment Inspection Report (EIR) confirming close-out of the FDA inspection. Although the FDA did not indicate whether it reviewed the promotional materials previously collected, we believe that the FDA's review of these materials and all other 2013 findings are now closed based on receipt of both the Warning Letter close-out and the EIR.

To a greater or lesser extent, most other countries require some form of quality system and regulatory compliance, which may include periodic inspections, inspections by third party auditors, and specialized documentation. Failure to meet all the requirements of these countries could jeopardize our ability to import, market, support and receive reimbursement for the use of our products in these countries.

In addition to the above, we may seek to conduct clinical research on products that have not yet been cleared or approved for particular indications in clinical studies or trials in the U.S. or other countries. Additional regulations govern the approval, initiation, conduct, documentation and reporting of clinical studies to regulatory agencies in the countries or regions in which they are conducted. Such investigational use is generally also regulated by local and institutional requirements and policies which usually include review by an ethics committee or institutional review board ("IRB"). Failure to comply with all regulations governing such studies could subject the company to significant enforcement actions and sanctions, including halting of the study, seizure of investigational devices or data, sanctions against investigators, civil or criminal penalties, and other actions. Without the data from one or more clinical studies, it may not be possible for us to secure the data necessary to support certain regulatory submissions, to secure reimbursement or demonstrate other requirements. We cannot assure that access to clinical investigators, sites and subjects, documentation and data will be available on the terms and timeframes necessary.

Products manufactured outside the U.S. by or for us are subject to U.S. Customs and FDA inspection upon entry into the U.S. We must demonstrate compliance of such products to U.S. regulations and carefully document the eventual distribution or re-exportation of such products. Failure to comply with all applicable regulations could prevent us from having access to products or components critical to the manufacture of finished products and lead to shortages and

delays.

California Regulation

The State of California requires that we obtain a license to manufacture medical devices and until 2012 conducted periodic inspections of medical device manufacturers. Our facilities and manufacturing processes were last inspected in July 2011 and were found to be in compliance. In accordance with the State of California regulations, the license to manufacture is renewed annually with any updated manufacturing information. Although the State of California has announced suspension of routine periodic inspections, there can be no assurance the State of California will not resume such inspections or conduct such inspections under specific circumstances which are not yet known.

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Foreign Regulation

In order for us to market our products in other countries, we must obtain regulatory approvals and comply with extensive product and quality system 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. Some countries have regulatory review processes which are substantially longer than U.S. processes. Failure to obtain regulatory approval in a timely manner and to meet all local requirements including language and specific safety standards in any foreign country in which we plan to market our products could prevent us from marketing products in such countries or subject us to sanctions and fines.

To be sold in Japan, most medical devices must undergo thorough safety examinations and demonstrate medical efficacy before they receive regulatory (“Shonin”) approval. In October 2012, we obtained from the Japanese Ministry of Health, Labor, and Welfare ("MHLW") approval for our da Vinci Si Surgical Systems. Effective April 2012, we obtained national reimbursement for dVP procedures, our only reimbursed procedure in Japan to date. We are currently seeking reimbursement for additional procedures through the MHLW's Senshin Iryo process as well as other alternative reimbursement processes. Such approvals require in-country clinical data and are considered for reimbursed status in April of even numbered years. No additional procedures were granted in the April 2014 cycle. We are currently working with the Japanese surgical societies to gather the necessary data on additional procedures for MHLW consideration in the April 2016 cycle. If we are not successful in obtaining additional regulatory clearances, importation licenses, and adequate procedure reimbursements for future products and procedures, then the demand for our products in Japan could be limited.

Commercialization of medical devices in Europe is regulated by the European Union (“EU”). The EU presently requires that all medical products bear the Conformité Européenne (“CE”) mark, for compliance with the Medical Device Directive (93/42/EEC) as amended. The CE mark is an international symbol of adherence to certain essential principles of safety and performance mandated in applicable European medical device directives, which once affixed, enables a product to be sold in member countries of the EU and those affiliated which accept the CE mark. 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 and design dossier for compliance with international and European requirements. We have received authorization from DGM Denmark A/S, a recognized European Notified Body and part of Nemko Presafe A/S, to affix the CE mark to our da Vinci Surgical System and EndoWrist instruments and accessories. To maintain authorization to apply the CE mark, we are subject to annual surveillance audits and periodic re-certification audits. As of 2014, Notified Bodies, including DGM, are also required to conduct periodic unannounced inspections.

If we modify our existing products or develop new products in the future, we may need to apply for authorization to affix the CE mark to such products. We do not know whether we will be able to obtain authorization to affix the CE mark for new or modified products or whether we will continue to meet the safety and performance standards required to maintain the authorizations we have already received. If we are unable to maintain authorizations to affix the CE mark to our products, we will no longer be able to sell our products in member countries of the EU or those whose marketing authorizations are based on the CE Mark.

Regulations in other countries, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. Certain countries have their own regulatory agencies, such as China and Korea. 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 negatively impact our ability to generate revenue and harm our business. In addition, local regulations may apply which govern the use of our products and which could have an adverse effect on our product utilization if they are unfavorable. All such regulations are revised from time to time and in general are increasing in complexity, and in the scope and degree of documentation and testing required. There can be no assurance the outcomes from such documentation and testing will be acceptable to any particular regulatory agency or will continue to be acceptable over time. There are further regulations governing the importation, marketing, sale, distribution, use and service as well as the removal and disposal of medical devices. Failure to comply with any of these regulations could result in

sanctions, fines and prevent us from marketing our products in these regions.

Other Healthcare Laws

We are also subject to federal and state healthcare laws and regulations pertaining to fraud and abuse, physician payment transparency and privacy and security laws and regulations. These laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting

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from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payors that are false or fraudulent;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners. Manufacturers are required to submit reports to CMS by the 90th day of each calendar year; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to violate any of the laws described above or any other laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to market our products and materially adversely affect our business, results of operations and financial condition. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Third-Party Coverage and Reimbursement

In the U.S. and most 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 procedure is considered medically necessary. In the U.S., the Centers for Medicare & Medicaid Services ("CMS") administers the Medicare and Medicaid programs (the latter, along with applicable State governments). Many other third-party payors model their reimbursement methodologies after the Medicare program. As the single largest payor, this program has a significant impact on other payors' payment systems.

Generally, reimbursement for professional services performed at a facility by physicians is reported under billing codes issued by the American Medical Association ("AMA"), known as Current Procedural Terminology ("CPT") codes. Physician reimbursement under Medicare generally is based on a fee schedule and determined by the relative values of the professional service rendered. In addition, CMS and the National Center for Health Statistics ("NCHS") are

jointly responsible for overseeing changes and modifications to billing codes known as ICD-9-CM procedural codes used by hospitals to report inpatient procedures. For Medicare, 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 ("MS-DRGs"). 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. Hospital outpatient services, reported by CPT codes, are assigned to clinically relevant Ambulatory Payment Classifications ("APCs") used to determine the payment amount for services provided.

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 Surgical System, U.S. hospitals are expected to report the

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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. At this time, it does not appear that these codes will be available after October 1, 2015, when the ICD-10 code sets are implemented. A surgical procedure, completed with or without robotic assistance, continues to be assigned to the clinically relevant MS-DRG.

Governments and insurance companies carefully review and increasingly challenge the prices charged for medical products and surgical services. Reimbursement rates from private companies vary depending on the procedure performed, the third-party payor, contract terms, and other factors. Because both hospitals and physicians may receive the same reimbursement for their respective services, with or without robotics, regardless of actual costs incurred by the hospital or physician in furnishing the care, including for 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 incurred when 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 U.S. by the FDA, coverage and reimbursement by payors are generally determined by the medical necessity of the primary surgical procedure. We believe that the additional procedures we intend to pursue are established surgical procedures that are generally already reimbursable by government agencies and insurance companies for appropriately selected patients. 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 countries outside the U.S., 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. In addition, 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 some countries, patients may be permitted to pay directly for surgical services; however, such "co-pay" practices are not common in most countries.

In March 2010, the U.S. President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, "the PPACA"), which makes changes that significantly impact healthcare providers, insurers, pharmaceutical and medical device manufacturers. One of the principal aims of the PPACA is to expand health insurance coverage to Americans who are currently uninsured. The consequences of these significant coverage expansions on the sales of our products are currently unknown. The PPACA contains a number of provisions designed to generate the revenues necessary to fund this coverage expansion, including, but not limited to new fees or taxes on certain health-related industries, including medical device manufacturers. Since 2013, medical device manufacturers have been required to pay an excise tax (or sales tax) of 2.3% on certain U.S. medical device revenues. Under this provision, the Company has incurred an excise tax of approximately $16 million in 2014. The tax is included as a cost of revenue and a reduction of product gross profit margin.

The PPACA also has provisions to study the comparative effectiveness of health care treatments and strategies. It remains unclear how this research will influence future Medicare coverage and reimbursement decisions, as well as influence other third-party payor coverage and reimbursement policies. As Congress and state governments determine how to implement the PPACA, the full impact of the PPACA on the medical device industry and the sale of our products is currently unknown. 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 business. The taxes imposed by PPACA and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits, lower reimbursement from payors for procedures that use our products and/or reduced procedural volumes, all of which may adversely affect our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. More recently, on August 2, 2011, the U.S. President signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress.

The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included aggregate reductions of 2% per fiscal year of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers.

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.

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Employees

As of December 31, 2014, we had 2,978 employees, 342 of whom were engaged directly in research and development, 1,106 in manufacturing and service and 1,530 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.

General

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 (the "SEC"). Our website address is www.intuitivesurgical.com and the reports are filed under “SEC Filings,” on the Company—Investor Relations portion of our website. Periodically, we webcast Company announcements, product launch events and executive presentations which can be viewed via our Investor Relations pages on our website. In addition, we provide notifications of our material news including SEC filings, investor events, and press releases as part of our Investor Relations website. The contents of these websites 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 websites are intended to be inactive textual references only. The public may read and copy any materials filed by the Company with the SEC at the SEC’s Public Reference Room at 100 F Street, NE, Room 1580, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. The contents of these websites are not incorporated into this filing. Further, references to the URLs for these websites are intended to be inactive textual references only.

We operate our business as one segment as defined by U.S. generally accepted accounting principles. Our financial results for the year ended December 31, 2014, 2013, and 2012 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.

Intuitive Surgical, Inc. was founded in 1995. We are a Delaware corporation with our corporate headquarters located at 1020 Kifer Road, Sunnyvale, California 94086. Our telephone number is (408) 523-2100, and our website address is www.intuitivesurgical.com.

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, customers 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 2008 and 2009, 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. More recently, credit and sovereign debt issues destabilized certain European economies and thereby contributed to global macroeconomic uncertainties. Uncertainty about current global economic conditions continue to pose a risk as customers may postpone or reduce spending in response to restraints

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on credit. There could be additional effects from adverse conditions in the credit markets 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 economic 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 relatively 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.

In addition, we may face competition from companies that develop wristed, robotic or computer-assisted surgical systems and products in the future. For example, SOFAR S.p.A, an Italian medical device company, supported by the European Commission's Joint Research Centre, has developed a telesurgical robot system. Other competitors have made explicit statements about their efforts to enter the field. 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 EXPECT GROSS PROFIT MARGINS TO VARY OVER TIME, AND CHANGES IN OUR GROSS PROFIT MARGINS COULD ADVERSELY AFFECT OUR FINANCIAL CONDITION OR RESULTS OF OPERATIONS.

Our gross profit margins have fluctuated from period to period, and we expect that they will continue to fluctuate in the future. Our gross profit margins may be adversely affected by numerous factors, including:

- changes in customer, geographic, or product mix, including mix of da Vinci Surgical System models sold;
- changes in the portion of sales involving a trade-in of another system and the amount of trade-in credits given;
- introduction of new products, which may have lower margins than our existing products;
- our ability to maintain or reduce production costs;
- changes to our pricing strategy;
- changes in competition;
- changes in production volume driven by demand for our products;
- changes in material, labor or other manufacturing-related costs;
- inventory obsolescence and product recall charges; and
- market conditions.

If we are unable to offset the unfavorable impact of the factors noted above by increasing the volume of products shipped, reducing product manufacturing costs or otherwise, our financial condition and results of operations may be

materially adversely affected.

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

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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. Further, 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. 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, lighter in the first and third 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, sacrocolpopexies, hernia repair, and certain other surgeries. 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 first and third fiscal quarters and higher procedure counts in the second and fourth fiscal quarters. Timing of procedures and changes in procedure growth directly affect the timing of instrument and accessory purchases and capital purchases by customers.

The above factors may contribute to substantial fluctuations in our quarterly operating results. Because of these fluctuations, it is possible 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.

INTERNATIONAL SALES 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 international markets. Revenue from markets outside of the United States accounted for approximately 30%, 28%, and 21% of our revenue for the years ended December 31, 2014, 2013, and 2012, respectively. We are subject to a number of challenges that specifically relate to our international business activities. These challenges include:

- failure to obtain the same degree of protection against infringement of our intellectual property rights as we have in the United States;
- protectionist laws and business practices that favor local competitors, which could slow our growth in international markets;
- local or national regulations that make it difficult or impractical to market or use our products;
- inability or regulatory limitations on our ability to move goods across borders;
- the risks associated with foreign currency exchange rate fluctuations;
- difficulty in establishing, staffing and managing non-U.S. operations;
- the expense of establishing facilities and operations in new foreign markets; and
- building and maintaining an organization capable of supporting geographically dispersed operations.

A large portion of our international sales are denominated in U.S. dollars. As a result, an increase in the value of the U.S. dollar relative to foreign currencies could 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, WHICH SUBJECTS US TO A NUMBER OF RISKS THAT COULD HARM OUR BUSINESS.

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. In addition, we may be named as a defendant in lawsuits against our distributors related to sales or service of our products performed by them. Please see our risk factor below titled “Unfavorable Results of Legal Proceedings Could Materially Adversely Affect Our Financial Condition.” The actions of our distributors may affect our ability to effectively market our products in certain foreign countries or regulatory jurisdictions if the distributor holds the regulatory authorization in such countries or within such regions and causes, by action or inaction, the suspension of such marketing authorization or sanctions for

non-compliance. It may be difficult, expensive and time consuming for us to re-establish market access or regulatory compliance in such case.

WE ARE EXPOSED TO THE CREDIT RISK OF SOME OF OUR CUSTOMERS, WHICH COULD RESULT IN MATERIAL LOSSES.

We believe customer financing through leasing is an important consideration for some of our customers and have experienced an increase in demand for customer financing. We may experience loss from a customer’s failure to make payments according to

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the contract terms. Our exposure to the credit risks relating to our lease financing arrangements may increase if our customers are adversely affected by changes in healthcare laws, coverage and reimbursement, economic pressures or uncertainty, or other customer-specific factors.

Although we have programs in place that are designed to monitor and mitigate the associated risk, there can be no assurance that such programs will be effective in reducing credit risks relating to these lease financing arrangements. Although we have not experienced significant credit losses to date, should the level of credit losses we experience in the future exceed our expectations, they could have a material adverse effect on our financial condition or results of operations.

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, Japanese Yen, Korean Won, 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 may contain errors or failures, especially when first introduced. In addition, new products or enhancements may contain undetected errors or performance problems that, despite testing, are discovered only after commercial shipment. Because our products are designed to be used to perform complex surgical procedures, we expect that our customers will have an increased sensitivity to such defects. In the past, we have voluntarily recalled certain products as a result of performance problems. We cannot assure that our products will not experience component aging, errors, or performance problems in the future. If we experience flaws or performance problems, any of the following could occur:

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

WE ARE SUBJECT TO PRODUCT LIABILITY AND NEGLIGENCE CLAIMS RELATING TO THE USE OF OUR PRODUCTS THAT COULD BE EXPENSIVE, DIVERT MANAGEMENT'S ATTENTION AND HARM OUR BUSINESS.

Our business exposes us to significant risks of product liability claims, which are inherent to the medical device industry. Product liability claims may be brought by individuals or by groups seeking to represent a class. We currently are subject to product liability claims, which are described in more detail in Note 7 to the Consolidated Financial Statements included in Part II, Item 8, and which have been brought by individuals alleging that they have sustained personal injuries and/or death as a result of purported product defects, the alleged failure to warn, and/or the alleged inadequate training by us of physicians regarding the use of the da Vinci Surgical System. The individuals who have brought the product liability claims seek recovery for the alleged personal injuries and in many cases, punitive damages. Current product liability claims have resulted in negative publicity regarding our Company, and these and any other product liability or negligence claims or product recalls also could harm our reputation. Please see

our risk factor below titled “Negative Publicity, Whether Accurate or Inaccurate, Concerning Our Products or Our Company Could Reduce Market Acceptance of Our Products and Could Result in Decreased Product Demand and a Decline in Revenues” for additional risks related to the potential effects of negative publicity on our business.

The outcome of product liability litigation is inherently uncertain and difficult to quantify, and the magnitude of potential damages, if any, may not be known for a substantial period of time. Although we maintain product liability insurance, the coverage limits of these policies may not be adequate to cover current or 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. In addition, current

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or future product liability claims, regardless of their merit or eventual outcome, could result in significant legal costs (including settlements, judgments, legal fees, and other related defense costs). It is possible that future legal costs could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

NEGATIVE PUBLICITY, WHETHER ACCURATE OR INACCURATE, CONCERNING OUR PRODUCTS OR OUR COMPANY COULD REDUCE MARKET ACCEPTANCE OF OUR PRODUCTS AND COULD RESULT IN DECREASED PRODUCT DEMAND AND A DECLINE IN REVENUES.

There have been articles published and papers written questioning patient safety and efficacy associated with da Vinci Surgery, the cost of da Vinci Surgery relative to other disease management methods, and the adequacy of surgeon training. Negative publicity, whether accurate or inaccurate, concerning our products or our Company could reduce market acceptance of our products and could result in decreased product demand and a decline in revenues. In addition, significant negative publicity could result in an increased number of product liability claims, regardless of whether these claims are meritorious. The number of claims could be further increased by plaintiffs' law firms that use a wide variety of media to advertise their services and solicit clients for product liability cases against us.

UNFAVORABLE RESULTS OF LEGAL PROCEEDINGS COULD MATERIALLY ADVERSELY AFFECT OUR FINANCIAL CONDITION.

We are and may become subject to various legal proceedings and claims that arise in or outside the ordinary course of business. Certain current lawsuits and pending proceedings, including purported class action and derivative lawsuits and product liability litigation, are described in Note 7 to the Consolidated Financial Statements included in Part II, Item 8.

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 related to these lawsuits and proceedings. In addition, as described in more detail in Note 7 to the Consolidated Financial Statements included in Part II, Item 8, certain product liability insurers have instituted legal proceedings to rescind the Company's products liability insurance. 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 and derivative lawsuit, product liability litigation, or other legal proceedings, we may be faced with significant monetary damages or injunctive relief against us that could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

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 other types of coverage that we do not maintain. 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 in recent 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 MAY ENCOUNTER MANUFACTURING PROBLEMS OR DELAYS THAT COULD RESULT IN LOST REVENUE.

Manufacturing our products is a complex process. We (or our critical suppliers) may encounter difficulties in scaling up or maintaining production of our products, including:

- problems involving production yields;
- quality control and assurance;
- component supply shortages;
- import or export restrictions on components, materials or technology;
- 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.

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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 generally purchase components through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of inventory. While alternative suppliers exist and could be identified for sole-sourced components, the disruption or termination of the supply of components could cause a significant increase in the costs of these components, which could affect our operating results. A disruption or termination in the supply of components could also result in our inability to meet demand for our products, which could harm our ability to generate revenues, lead to customer dissatisfaction and damage our reputation. Furthermore, if we are required to change the manufacturer of a key component of our products, we may be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could delay our ability to manufacture our products in a timely manner or within budget.

IF INSTITUTIONS OR SURGEONS ARE UNABLE TO OBTAIN 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 for 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 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 "Recently Enacted Healthcare Legislation Reforming the U.S. Healthcare System, as well as Future Reforms, May Have a Material Adverse Effect on Our Financial Condition and Results of Operations" 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, electronics, 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. For example, the March 2011 earthquake and tsunami in Japan and their aftermath created economic uncertainty and disrupted economic activities in Japan, including a reduction in hospital spending.

Our corporate headquarters and many of our operations, including certain of our manufacturing facilities, are located in California, a seismically active region. We do not have multiple-site capacity for all of the operations in the event

of a business disruption. A natural disaster in any of our major markets 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 similar events could have a material adverse impact on our operating results.

EPIDEMIC DISEASES OR THE PERCEPTION OF THEIR EFFECT COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS, OR CASH FLOWS. Outbreaks of pandemic or contagious diseases, such as the Ebola virus could divert medical resources and priorities towards the treatment of that disease. An outbreak of a contagious disease could also negatively affect hospital admission rates. This could negatively impact the number of da Vinci procedures performed and have a material adverse effect on our business, financial condition, results of operations or cash flow.

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IF WE FAIL TO SUCCESSFULLY ACQUIRE OR INTEGRATE NEW BUSINESSES, PRODUCTS AND TECHNOLOGY, WE MAY NOT REALIZE EXPECTED BENEFITS OR OUR BUSINESS MAY BE HARMED.

We need to grow our businesses in response to changing technologies, customer demands and competitive pressures. In some circumstances, we may decide to grow our business through the acquisition of complementary businesses, products or technologies rather than through internal development. For example, we acquired certain intellectual property, know-how, and employees from Luna Innovations, Inc. in January 2014 and reacquired the Japan distribution rights from our Japanese distributor in June 2014. If we are unable to effectively transition the sales, marketing, regulatory and other operational functions in Japan, our Japanese business could be disrupted.

Identifying suitable acquisition candidates can be difficult, time-consuming and costly, and we may not be able to identify suitable candidates or successfully complete identified acquisitions. In addition, completing an acquisition can divert our management and key personnel from our business operations, which could harm our business and affect our financial results. Even if we complete an acquisition, we may not be able to successfully integrate newly acquired organizations, products, technologies or employees into our operations, or may not fully realize some of the expected synergies. An acquired company may have deficiencies in product quality or regulatory marketing authorizations which are not detected during due diligence activities or which are unasserted at the time of acquisition. It may be difficult, expensive and time consuming for us to re-establish market access, regulatory compliance or cure such deficiencies in product quality in such cases.

Integrating an acquisition can also be expensive and time-consuming, and may strain our resources. In many instances, integrating a new business will also involve implementing or improving internal controls appropriate for a public company at a business that lacks them. In addition, we may be unable to retain the employees of acquired companies, or the acquired company's customers, suppliers, distributors or other partners for a variety of reasons, including that these entities may be our competitors or may have close relationships with our competitors.

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 reevaluation of current practices may adversely affect our reported financial results or the way we conduct our business.

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 may lead us to change our methods, estimates, and judgments. Changes in any of our assumptions may adversely affect our reported financial results.

In addition, we utilize methods for determining surgical market sizes and number of 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 number of 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 number of 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, from time to time, we may change the method for determining market sizes and number of da Vinci procedures, causing variation in our reporting.

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

A number of factors may impact our future effective tax rate 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 and deductions;
- changes in share-based compensation;

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- 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 rate could harm net income for future periods.

DISRUPTION OF CRITICAL INFORMATION SYSTEMS OR MATERIAL BREACHES IN THE SECURITY OF OUR SYSTEMS COULD HARM OUR BUSINESS, CUSTOMER RELATIONS 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 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 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.

Our business requires us to use and store customer, employee and business partner personally identifiable information ("PII"). This may include names, addresses, phone numbers, email addresses, contact preferences, tax identification numbers and payment account information. We require user names and passwords in order to access our information technology systems. We also use encryption and authentication technologies to secure the transmission and storage of data. These security measures may be compromised as a result of third-party security breaches, employee error, malfeasance, faulty password management or other irregularity, and result in persons obtaining unauthorized access to our data or accounts. Third parties may attempt to fraudulently induce employees or customers into disclosing user names, passwords or other sensitive information, which may in turn be used to access our information technology systems.

While we devote significant resources to network security, data encryption and other security measures to protect our systems and data, these security measures cannot provide absolute security. We may experience a breach of our systems and may be unable to protect sensitive data. The costs to us to eliminate or alleviate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and our efforts to address these problems may not be successful and could result in unexpected interruptions, delays, cessation of service and may harm our business operations. Moreover, if a computer security breach affects our systems or results in the unauthorized release of PII, our reputation and brand could be materially damaged and use of our products and services could decrease. We would also be exposed to a risk of loss or litigation and potential liability, which could result in a material adverse effect on our business, results of operations and financial condition.

RISKS RELATING TO OUR REGULATORY ENVIRONMENT

RECENTLY ENACTED HEALTHCARE LEGISLATION REFORMING THE U.S. HEALTHCARE SYSTEM, AS WELL AS FUTURE REFORMS, MAY HAVE A MATERIAL ADVERSE EFFECT ON OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

In March 2010, the U.S. President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education 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 manufacturers were required to pay an excise tax (or sales tax) of 2.3% of certain U.S. medical device revenues. Though there are some exceptions to the excise tax, this excise tax does apply to all or most of our products sold within the United States. The PPACA also establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness

research in an effort to coordinate and develop such research; implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models; and creates an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

The PPACA provisions on comparative clinical effectiveness research also extend the initiatives of the American Recovery and Reinvestment Act of 2009, 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 reviewing 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 taxes imposed by the PPACA and the expansion in the government’s role in the U.S. healthcare industry may result in decreased

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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.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. More recently, on August 2, 2011, the U.S. President signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect that additional state and federal health care reform measures may be adopted in the future, any of which 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 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. 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 policies, including policies stemming from legislation or regulations affecting our business may be proposed or enacted in the future; what effect such policies would have on our business; or the effect ongoing uncertainty about these matters will have on the purchasing decisions of our customers.

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

The Dodd-Frank Wall Street Reform and Consumer Protection Act requires us to track and disclose the source of any tantalum, tin, gold, and tungsten used in manufacturing which may originate in the Democratic Republic of the Congo or adjoining regions (so called "conflict minerals"). These metals are central to the technology industry and are present in some of our products as component parts. In most cases no acceptable alternative material exists which has the necessary properties. Because it is not possible to determine the source of the metals by analysis, we must obtain a good faith description of the source of the intermediate components and raw materials from parties in our supply chain. The components that incorporate those metals may originate from many sources and we purchase fabricated products from manufacturers who may have a long and difficult-to-trace supply chain. As the spot price of these materials varies, producers of the metal intermediates can be expected to change the mix of sources used. Accordingly, components and assemblies we buy may have a mix of sources as their origin. We are required to carry out a diligent effort to determine and disclose the source of these materials. There can be no assurance we can obtain this information accurately or reliably, or at all, from intermediate producers who may be unwilling or unable to provide this information or further identify their sources of supply or to notify us if these sources change. In addition, these metals are subject to price fluctuations and shortages which can affect our ability to obtain the manufactured materials we rely on at favorable terms or from consistent sources. These changes could have an adverse impact on our ability to manufacture and market our devices and products.

The Medicare and Medicaid anti-kickback laws, and several similar state laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, prohibit payments or other remuneration that could be considered 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 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. These laws may 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 exclusion from government 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.

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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. Such information must be made publicly available in a searchable format. In addition, device manufacturers will also be required to report and disclose any ownership or investment interests held by physicians and their immediate family members, as well as any transfers of value made to such physician owners and investors, 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. Device manufacturers will be required to submit reports to CMS by the 90th day of each calendar year.

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. Certain states mandate implementation of commercial compliance programs to ensure compliance with these laws, impose restrictions on device manufacturer marketing practices and/or require 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 be found out of compliance of one or more of the requirements, subjecting us to significant civil monetary penalties.

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 United States and/or abroad. These numerous and sometimes conflicting laws and regulations include U.S. laws such as the Foreign Corrupt Practices Act, and similar laws in foreign countries, such as the U.K. Bribery Act of 2010, which became effective on July 1, 2011. 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.

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

Our products and operations are subject to extensive regulation in the United States by the U.S. Food and Drug Administration ("FDA"). The FDA regulates the development, bench and clinical testing, manufacturing, labeling, storage, record keeping, promotion, sales, distribution and postmarket support and reporting 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 ("FFDCA"). Clearance under Section 510(k) requires demonstration that a new device is substantially equivalent to another device with 510(k) clearance or grandfathered ("pre-amendment") 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 ("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 grandfathered 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. For example, in 2011, the FDA announced a Plan of Action to modernize and improve the FDA's premarket review of medical devices, and has implemented, and continues to implement, reforms intended to streamline the premarket review process. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA"), Congress enacted several reforms entitled the Medical Device Regulatory Improvements and

additional miscellaneous provisions which will further affect medical device regulation both pre- and post-approval. 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, lengthy 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. In some cases such studies may be requested for a 510(k) as well. We may not be able to meet the requirements to obtain 510(k) clearance or PMA approval, in which case 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.

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In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a medical device, a company must, among other things, apply for and obtain Institutional Review Board ("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 ("IDE") application. Many of our products to date have been or would be 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 conduct studies which 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.

Certainty that clinical trials will meet desired endpoints, produce meaningful or useful data and be free of unexpected adverse effects, or that the FDA will accept the validity of foreign clinical study data cannot be assured, and such uncertainty could preclude or delay market clearance or authorizations resulting in significant financial costs and reduced revenue.

In addition, some products may be regulated by the FDA as drugs, biologics or combination devices which carry still greater requirements for clinical trials, regulatory submissions and approvals.

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 quality and postmarket regulatory requirements apply, including the following:

- continued compliance to the QSR, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the development and 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;
- stringent complaint reporting and Medical Device Reporting regulations, which requires that manufacturers keep detailed records of investigations or complaints against their devices and to 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;
- adequate use of the Corrective and Preventive Actions process to identify and correct or prevent significant systemic failures of products or processes or in trends which suggest same; and
- the reporting of Corrections and Removals, 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 FFDCA that may pose a risk to health.

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 inspectional observations (Form FDA 483) to a public Warning Letter to more severe civil and criminal sanctions including the seizure of our products and equipment or ban on the import or export of our products. 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.

Any modification or change of medical devices cleared for market requires the manufacturer to make a determination whether the change is significant enough to require new 510(k) clearance. We have created labeling, advertising and user training for the da Vinci Surgical System to describe specific surgical procedures that we believe are fully within the scope of our existing 510(k) indications for use stated in our 510(k) clearances. Although we have relied on expert in-house and external staff, consultants and advisors, many of whom were formerly employed by FDA and familiar with FDA requirements, 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 obtaining 510(k) clearance in ways that we do not believe require new 510(k) clearance. We cannot assure that the FDA would agree in all cases 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.

An FDA inspection of our facilities occurred in April-May 2013, and the FDA issued a Form FDA 483 listing four observations relating to the reporting of field corrections, information which is to be included on reports of field corrections, written procedures for changes to certain product labeling, and design input documentation. We responded to each observation with corrective actions

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during the course of the inspection and provided additional evidence of corrective actions to the FDA in response to the Form FDA 483. The FDA issued a Warning Letter, dated July 16, 2013, related to two of the four Form FDA 483 observations asking for additional corrective actions and indicated their intent to perform a follow-up inspection. In addition, the FDA collected electronic samples of all our advertising and promotional material for review, and to date have taken no action in connection therewith. We responded to the Warning Letter, communicating corrective actions taken. The FDA re-inspected our facilities during February-March of 2014 to complete a general quality system audit as well as a review of the status of the Warning Letter and 483 remediation activities. At the end of the inspection, the FDA issued a Form FDA 483 listing five observations related to quality management system improvement opportunities. We responded to the FDA with a corrective action plan for those observations. On April 25, 2014, we received a closure letter from the FDA stating that the observations in the July 16, 2013 Warning Letter have been addressed. However, we cannot assure that the FDA will not find other observations in future inspections. The FDA previously inspected our Sunnyvale, California facilities in January 2012 and did not issue a Form FDA 483 as a result of this inspection.

The receipt of a Warning Letter places certain limits on the ability to obtain FDA issued Certificates to Foreign Government ("CFGs") used for new and re-registration of products in certain foreign countries.

We have a wholly owned manufacturing facility located in Mexicali, Mexico which manufactures reusable and disposable surgical instruments. This facility is registered with the FDA as well as Mexican authorities. The facility is operated under U.S. and international quality system regulations including those applicable to Canada, the European Union and Japan among others. Our wholly owned manufacturing facility in Mexicali, Mexico has an FDA Establishment Registration but has not been FDA inspected to date. If the FDA were to determine non-conformances in our product documentation or quality system compliance, they could hold indefinitely the importation of instruments at the border which would deprive us of the ability to sell and supply the majority of our customers until the FDA requirements have been satisfied. Similar supply disruptions could occur if key suppliers outside of U.S. were to encounter non-conformances with their documentation or quality system compliance. Please see our risk factor below titled "If Our Manufacturing Facilities do not Continue to Meet Federal, State or Other Manufacturing Standards, We May Be Required to Temporarily Cease All or Part of Our Manufacturing Operations, Import/Export of Our Products and/or Recall Some Products Which Would Result in Significant Product Delivery Delays and Lost Revenue" for additional risks related to the potential effects of our expansion of our manufacturing space in Mexicali, Mexico.

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 PROVIDE OUR PRODUCTS IN FOREIGN COUNTRIES.

To be able to provide our products in other countries, we must obtain regulatory approvals and comply with the regulations of those countries which may differ substantially from those of the United States. 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 is complex, and we cannot be certain that we will receive regulatory approvals in any foreign country in which we plan to market our products, or to obtain such approvals on a favorable schedule. 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. In particular, if the FDA refuses to provide CFGs our ability to register products or renew such registrations may be delayed or denied.

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 authorization 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 and have maintained this authorization continuously since that time. From time to time we seek the authorization to affix the CE mark to new or modified products. Subsequent products and accessories have received marketing authorization by our Notified Body, DGM. In September 2013, we received notice that DGM

has changed their name to PreSafe following acquisition by a larger Notified Body. The change did not have a significant impact on our operations other than replacement of various quality system certificates with the new name. As we modify existing products or develop new products in the future, including new instruments, we currently plan to apply for authorization 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 authorizations we have already obtained including inspection of our compliance to required standards and directives to enable this path to CE marking. We cannot be certain we will be able to affix the CE mark for new or modified products or that we will continue to meet the quality and performance standards required to maintain the authorizations 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 and many affiliated countries that accept the CE mark, which would have a material adverse effect on our results of operations. Some member states of the European Union have additional requirements for registration and notification which may add to the time and effort to obtain market access. In addition, the regulations applied to end users

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of our products may increase over time, forcing us to provide additional solutions to regulations which do not apply directly to us, but which apply indirectly as they may limit our customers' ability to use our products.

In November 2009, we received Shonin approval from the Japanese Ministry of Health, Labor and Welfare ("MHLW") for our da Vinci S Surgical System and in October 2012, we received approval for our da Vinci Si system and various associated instruments and accessories for use in certain da Vinci 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, because only a subset of our instruments has received Shonin approval, and reimbursement is an additional process to generate market acceptance, it is possible that approved procedures will be adopted slowly or not at all. Sales of our products depend, in part, on the extent to which the costs of our products are reimbursed by governmental health administration authorities. To date, we have received reimbursement approval for prostatectomy in Japan. There are multiple pathways to obtain reimbursement for procedures including those require in-country clinical data and which are considered for reimbursed status in April of even numbered years. 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. In addition, in January 2012 we acquired certain assets of our distributor in Korea, Bio-Robotics. Our products are highly regulated in Korea and we face many of the same risks and limitations on the commercialization of our products as in Japan and the United States.

IF OUR MANUFACTURING FACILITIES DO NOT CONTINUE TO MEET FEDERAL, STATE OR OTHER MANUFACTURING STANDARDS, WE MAY BE REQUIRED TO TEMPORARILY CEASE ALL OR PART OF OUR MANUFACTURING OPERATIONS, IMPORT/EXPORT OF OUR PRODUCTS AND/OR RECALL SOME PRODUCTS WHICH WOULD RESULT IN SIGNIFICANT 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 and inspected by the FDA and other regulatory agencies for compliance with Good Manufacturing Practice requirements contained in the QSR and other regulatory requirements. We are also required to comply with International Organization for Standardization ("ISO") quality system standards as well as European Directives and norms in order to produce products for sale in the European Union. In addition, many countries such as Canada and Japan have very specific additional regulatory requirements for quality assurance and manufacturing. If we fail to continue to comply with Good Manufacturing Practice requirements, as well as ISO or other regulatory standards, we may be required to cease all or part of our operations until we comply with these regulations.

We continue to be subject to FDA and certain other 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 and other regulatory requirements in future inspections and audits by regulatory authorities.

Our Sunnyvale, California facility is licensed by the State of California to manufacture medical devices. We have been subject to periodic inspections by the California Department of Health Services Food and Drug Branch and, if we are unable to maintain this license following any future inspections, we will be unable to manufacture or ship some products, which would have a material adverse effect on our results of operations. In 2012 the State of California announced suspension of routine inspections but this policy could be modified or inspections could be resumed for specific circumstances. In addition, both our Sunnyvale, California and Mexicali, Mexico facilities are subject to periodic inspections by other regulatory bodies, including third party auditors on behalf of national regulatory authorities. Compliance with multiple regulatory standards is complex, difficult and costly to maintain, and material deficiencies could result in significant limitations on our ability to manufacture, transport and sell our products in one or more countries.

IF HOSPITALS AND OTHER SURGERY FACILITIES DO NOT CONTINUE TO MEET FEDERAL, STATE OR OTHER REGULATORY STANDARDS, THEY MAY BE REQUIRED TO TEMPORARILY CEASE ALL OR PART OF THEIR DA VINCI UTILIZATION.

Our global customers are subject to periodic inspection by regulatory authorities. Our customers are required to comply with applicable local and international regulations, including with respect to the reprocessing of da Vinci

instruments and accessories. Hospitals may not follow cleaning and sterilization instructions properly. Equipment used for cleaning and sterilization may malfunction or be used improperly. If our customers deviate from cleaning and sterilization instructions, regulatory authorities may require them to suspend use of da Vinci Surgical Systems.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

IF WE ARE UNABLE TO REPLACE OUR PATENTS BY THE TIME THEY EXPIRE OR TO FULLY PROTECT OUR INTELLECTUAL PROPERTY FROM USE BY THIRD PARTIES, OUR ABILITY TO COMPETE IN THE MARKET WILL BE HARMED.

We believe new competitors will emerge in medical robotics. We also do not know whether we will be able to develop additional patentable proprietary technologies as older patents expire. Our commercial success will depend in part on obtaining

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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. 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 U.S. and foreign patents issued to third parties that relate to our products. Some of these patents may be broad enough to cover one or more aspects of our present or 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 accusing us of infringing and/or 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 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.

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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 achieve and maintain market acceptance;
- actions relating to regulatory matters;
- our timing and ability to develop our manufacturing and sales and marketing capabilities;
- demand for our products;
- the size and timing of particular sales and any collection delays related to those sales;
- 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 2011, the NASDAQ closing price of one share of our common stock reached a high of $466.30 and a low of $267.40, during fiscal 2012, it reached a high of $588.28 and a low of $440.00, during fiscal 2013, it reached a high of $583.67 and a low of $355.93, and during fiscal 2014, it reached a high of $540.63 and a low of $352.35. 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 and enforcement actions;
- changes in product pricing policies;
- changes in earnings estimates by analysts or changes in accounting policies;
- 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 us, 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.

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ITEM 2. PROPERTIES

As of December 31, 2014, we owned approximately 918,000 square feet of space on 70 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 Norcross, Georgia, we owned approximately 92,000 square feet of space on ten acres, of which 50,000 square feet of space serves as our East Coast sales and training headquarters and 41,000 square feet of space was leased to third parties that will be used for future expansion of our East Coast sales and training campus. In Aubonne, Switzerland, we owned 35,000 square feet of space on 1.6 acres, which is used for our international headquarters and 5,000 square feet of space was leased to a third party. We leased 76,000 square feet in Mexicali, Mexico where we manufacture most of our EndoWrist instruments. We also leased facilities in Milford, Connecticut, and Blackburg, Virgina for research and development and other operations. We also leased facilities for sales and operations in Tokyo, Japan; Shanghai, China; Brazil; and Seoul, Korea.

ITEM 3. LEGAL PROCEEDINGS

The information included in Note 7 to the Consolidated Financial Statements included in Part II, Item 8 of this report is incorporated herein by reference.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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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.

	2014		2013	
Fiscal	High	Low	High	Low
First Quarter	$453.84	$370.94	$583.67	$459.44
Second Quarter	$540.63	$352.35	$513.49	$470.30
Third Quarter	$480.73	$380.26	$504.01	$363.89
Fourth Quarter	$533.84	$456.51	$401.68	$355.93

As of January 16, 2015, there were 215 stockholders of record of our common stock, although we believe that there are a significantly larger number of beneficial owners of our common stock.

DIVIDENDS

We have never declared or paid any cash dividends on our common stock. We intend to retain earnings for use in the operation and expansion of our business.

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The following table contains information as of December 31, 2014 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	4,458,082	$387.52	1,337,919
Equity compensation plans not approved by security holders	736,558	$446.83	107,255
Total	5,194,640	$395.85	1,445,174

RECENT SALES OF UNREGISTERED SECURITIES

None.

ISSUER PURCHASES OF EQUITY SECURITIES

Since March 2009, we have had an active stock repurchase program. The most recent authorizations occurred in March 2013 and July 2013 when the Board of Directors increased the authorization for stock repurchases by $1.0 billion and $0.8 billion, respectively. During the period from March 2009 to December 2014, we repurchased a total of 8.7 million shares of our common stock at a total of $3.0 billion. As of December 31, 2014, we had used all amounts authorized for stock repurchases under the stock repurchase program. We did not purchase any of our securities in the open market during the quarter ended December 31, 2014.

On January 29, 2015, our Board of Directors authorized the Company to repurchase up to $1.0 billion of our outstanding common stock.

STOCK PERFORMANCE GRAPH

The graph set forth below compares the cumulative total stockholder return on our common stock between December 31, 2009 and December 31, 2014, 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, 2009 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.

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

COMPARISON OF CUMULATIVE TOTAL RETURN AMONG INTUITIVE SURGICAL, NASDAQ COMPOSITE, S&P HEALTH CARE INDEX, AND S&P 500 INDEX

	December 31,					
	2009	2010	2011	2012	2013	2014
Intuitive Surgical, Inc.	$100.00	$84.95	$152.59	$161.61	$126.58	$174.32
NASDAQ Composite	$100.00	$118.02	$117.04	$137.47	$192.62	$221.02
S&P 500 Healthcare Index	$100.00	$102.81	$115.76	$136.26	$192.18	$240.44
S&P 500 Index	$100.00	$115.06	$117.49	$136.30	$180.44	$205.14

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ITEM 6. SELECTED 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.

	Fiscal Year				
	2014	2013	2012	2011	2010
	(In millions, except per share amounts and headcount)				
Revenue	$2,131.7	$2,265.1	$2,178.8	$1,757.3	$1,413.0
Gross profit	$1,413.8	$1,594.2	$1,570.3	$1,273.8	$1,030.0
Net income	$418.8	$671.0	$656.6	$495.1	$381.8
Net income per common share:					
Basic	$11.35	$17.12	$16.50	$12.63	$9.74
Diluted	$11.11	$16.73	$15.98	$12.32	$9.47
Shares used in computing basic and diluted net income per share:					
Basic	36.9	39.2	39.8	39.2	39.2
Diluted	37.7	40.1	41.1	40.2	40.3
Cash, cash equivalents and investments	$2,497.0	$2,753.9	$2,920.5	$2,171.8	$1,608.9
Total assets	$3,959.4	$3,950.3	$4,059.2	$3,063.1	$2,390.4
Other long-term liabilities	$78.8	$68.0	$77.5	$96.9	$79.2
Stockholders' equity	$3,379.4	$3,501.4	$3,580.1	$2,645.6	$2,037.4
Total headcount	2,978	2,792	2,362	1,924	1,660

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

Overview

Open surgery remains the predominant form of surgery and is used in almost every area of the body. However, the large incisions required for open surgery create trauma to the patient, typically resulting in longer hospitalization and recovery times, increased hospitalization costs, and additional pain and suffering relative to minimally invasive surgery ("MIS"), where MIS is available. For over two decades, MIS has reduced trauma to the patient by allowing selected surgeries to be performed through small ports rather than large incisions. MIS has been widely adopted for certain surgical procedures, but has not yet been widely adopted for reconstructive surgeries.

da Vinci Surgical Systems enable surgeons to extend the benefits of MIS to many patients who would otherwise undergo a more invasive surgery by using computational, robotic and imaging technologies to overcome many of the limitations of conventional MIS. Surgeons using a da Vinci Surgical System operate while seated comfortably at a console viewing a Three Dimensional ("3-D") representation of a High Definition ("HD") image of the surgical field. This immersive visualization connects surgeons to the surgical field and their instruments. While seated at the console, the surgeon manipulates instrument controls in a natural manner, similar to the open surgery technique. Our multi-port technology is designed to provide surgeons with a range of motion of MIS instruments 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 focus on making our technology easy and safe to use.

Our products fall into four broad categories - the da Vinci Surgical Systems, InSite and Firefly Fluorescence imaging systems ("Firefly"), instruments and accessories (e.g., EndoWrist, EndoWrist One Vessel Sealer, da Vinci Single-Site and EndoWrist Stapler 45) and training technologies. We have commercialized four generations of da Vinci Surgical Systems: the first is our da Vinci standard Surgical System, commercialized in 1999, the second is our da Vinci S Surgical System, commercialized in 2006, the third is our da Vinci Si Surgical System, commercialized in 2009, and the fourth is our da Vinci Xi Surgical System, launched in the second quarter of 2014 (see further description in New Product Introductions section below). Systems include a surgeon's console (or consoles), imaging electronics, a patient-side cart, and computational hardware and software.

We offer over 65 different da Vinci instruments enabling surgeons flexibility in choosing the types of tools needed in a particular surgery. In the fourth quarter of 2011, we introduced our Single-Site instruments in the U.S. for use with the da Vinci Si Surgical System and for use in cholecystectomy procedures. During the first quarter of 2013, Single-Site instruments were cleared by the U.S. Food and Drug Administration (the "FDA") in the U.S. for use in benign hysterectomies and salpingo-oophorectomies. Single-Site instruments enable surgeons to also perform surgery through a single port via the patient's belly button, resulting in the potential for virtually scarless results. The initial instrumentation set for single site surgery was not wristed. However, in September 2014, the FDA cleared our wristed needle driver, designed for Single-Site surgeries. We believe that the wristed needle driver will better enable single site surgeries requiring significant reconstruction, like hysterectomies.

Training technologies include our recently developed da Vinci Connect remote case observation and mentoring tool, our da Vinci Skills Simulator, and our dual console for use in surgeon proctoring and collaborative surgery.

Procedures

We model patient value as equal to procedure efficacy / invasiveness. In this equation procedure efficacy is defined as a measure of the success of the surgery in resolving the underlying disease and invasiveness is defined as a measure of patient pain and disruption of regular activities. When the patient value of a da Vinci procedure is greater than that of alternative treatment options, patients may benefit from seeking out surgeons and hospitals that offer da Vinci Surgery, which potentially could result in a local market share shift. Adoption occurs procedure by procedure, and is driven by the relative patient value of da Vinci procedures compared to alternative treatment options for the same disease state or condition.

Worldwide Procedures

da Vinci systems and instruments are regulated independently in various countries and regions of the world. The discussion of indications for use and representative or target procedures is intended solely to provide an understanding of the market for da Vinci products but is not intended to promote for sale or use any Intuitive Surgical product

outside of its licensed or cleared labeling and indications for use.

The adoption of da Vinci surgery has the potential to grow for those procedures that offer greater patient value than non da Vinci alternatives, while providing economic return to health care providers. We focus our organization and investments on developing, marketing and training for those products and procedures where da Vinci can bring significant patient value relative to alternative treatment options. da Vinci Surgical Systems are used primarily in gynecologic surgery, urologic surgery, general surgery, cardiothoracic surgery, and head and neck surgery. Principal target procedures in gynecology include da Vinci Hysterectomy ("dVH") and sacrocolpopexy. Target procedures in urology include da Vinci Prostatectomy ("dVP") and partial nephrectomy. Target procedures in general surgery include colorectal procedures, hernia repair, Single-Site Cholecystectomy, and a broad base

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of other general surgery procedures. In cardiothoracic surgery, target procedures include da Vinci Lobectomy and da Vinci Mitral Valve Repair. In head and neck surgery, target procedures include certain procedures resecting benign and malignant tumors classified as T1 and T2. Not all the indications, procedures or products described may be available in a given country or region or on all generations of da Vinci Surgical Systems. Please consult the product labeling in a specific country and for each product in order to determine the actual authorized uses, as well as important limitations, restrictions or contraindications.

In 2014, approximately 570,000 surgical procedures were performed with the da Vinci Surgical System, compared to approximately 523,000 and 450,000 procedures performed in 2013 and 2012, respectively. The growth in our overall procedure volume in 2014 was driven by the growth in U.S. general surgery procedures and worldwide urologic procedures.

U.S. Procedures

Overall U.S. procedure volume grew to approximately 449,000 in 2014, compared to approximately 422,000 in 2013, and 367,000 in 2012.

Gynecology is our largest U.S. surgical specialty. Overall U.S. gynecology procedure volume was approximately 235,000 2014 compared to 240,000 in 2013 and 222,000 in 2012. Our growth through 2013 was driven by adoption of dVH, our highest volume procedure, and other gynecologic procedures, including sacrocolpopexy and myomectomy largely resulting from capturing market share from open surgery techniques for these procedures. In 2014, our 2% U.S. gynecology procedure decline was driven primarily by fewer benign dVH procedures. As of 2014, we estimate that approximately 80% of total benign hysterectomies were performed via minimally invasive approaches, including robotic, endoscopic, and vaginal techniques. Given this high level of MIS penetration, we believe our benign hysterectomy volume largely declined with the overall market, which reflected payor trends encouraging more conservative non-surgical disease management approaches for certain uterine conditions. Our benign dVH procedure volumes were approximately 148,000, 150,000, and 138,000 in 2014, 2013, and 2012, respectively. We now consider robotic surgery to be the standard of care for hysterectomies for cancer. dVH for cancer procedure volumes were approximately 43,000, 41,000, and 38,000 in 2014, 2013, and 2012, respectively.

General surgery is our second largest and fastest growing specialty in the U.S. Overall U.S. general surgery procedure volume grew from approximately 42,000 cases in 2012 to approximately 81,000 in 2013 and to approximately 107,000 in 2014. Growth through 2013 was driven by rapid adoption of da Vinci Cholecystectomies, the first procedure to be FDA-cleared for Single-Site Surgery, and earlier stage growth in colorectal and several other general surgery procedures. In 2014, cholecystectomy growth moderated, and general surgery growth was driven by growth across a broad set of procedures, including ventral and inguinal hernia repair, colorectal, bariatric, cholecystectomy, foregut, and other procedures.

U.S. urology procedure volume was approximately 91,000 in 2014, compared to approximately 85,000 in 2013, and 88,000 in 2012. We consider dVP to be the standard of care for the surgical treatment of prostate cancer in the U.S. About 60,000 dVPs were performed in 2014, compared to 58,000 in 2013, and 62,000 in 2012.

International Procedures

Overall international procedure volume grew to approximately 121,000 in 2014, compared to approximately 101,000 in 2013 and 83,000 in 2012. International procedure growth was driven largely by dVP volume, which grew from approximately 47,000 in 2012, to 56,000 in 2013, to 65,000 in 2014. Partial nephrectomy, general surgery, and gynecologic oncology procedures also contributed to international procedure growth.

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 approximately between $0.6 million and $2.5 million, depending upon configuration and geography, and represents a significant capital equipment investment for our customers. We generate recurring revenue as our customers consume our EndoWrist and Single-Site instrument and accessory products used in performing procedures with the da Vinci Surgical System. Our 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. Also, we generate recurring revenue from ongoing system service. We typically enter into service contracts at the time systems are sold at an annual rate of approximately $100,000 to

$170,000 per year, depending upon the configuration of the underlying system. These service contracts have generally been renewed at the end of the initial contractual service periods.

Recurring revenue has generally grown at a faster rate than system revenue in the last few fiscal years. Recurring revenue increased from $1.2 billion, or 57% of total revenue in 2012 to $1.4 billion, or 63% of total revenue in 2013 to $1.5 billion, or 70% of total revenue in 2014. The increase in recurring revenue relative to system revenue reflects lower 2014 system sales and continuing adoption of procedures on a growing base of installed da Vinci Surgical Systems. The installed base of da Vinci Surgical Systems has grown to 3,266 at December 31, 2014, compared with 2,966 at December 31, 2013, and 2,585 at December 31, 2012.

We provide our products through direct sales organizations in the U.S., Japan, Korea, and Europe, excluding Spain, Portugal, Italy, Greece and Eastern European countries. In June 2014, we terminated our distribution relationship with Adachi Co., Ltd.

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("Adachi"), a Japanese distributor and now market, sell, and service our products directly in Japan. In the remainder of our world markets, we provide our products through distributors.

Regulatory Activities

Clearances and Approvals

We have obtained the clearances required to market our multiport products associated with the first three generations of our da Vinci Surgical Systems (Standard, S, and Si systems) for our targeted surgical specialties within the U.S. and most of Europe. As we expand indications and introduce new products, we will continue to seek necessary clearances. In February 2013, we received FDA clearance to market our Single-Site instruments for benign hysterectomy and salpingo-oophorectomy procedures. In September 2014, we received FDA clearance to market the wristed version of our Single-Site needle driver product for use in benign hysterectomy, cholecystectomy, and salpingo-oophorectomy procedures.

In March 2014, we received FDA clearance to market our da Vinci Xi System in the U.S. This is our fourth generation da Vinci Surgical System and is now available to U.S. customers (see the complete description of the da Vinci Xi Surgical System in the New Product Introductions Section). In June 2014, we received CE mark clearance for our da Vinci Xi Surgical System in Europe. In October 2014, we received regulatory clearance for our da Vinci Xi Surgical System in Korea. Regulatory submissions have been made for the da Vinci Xi Surgical System in Japan with the status currently pending. The regulatory status of the da Vinci Xi Surgical System in other international markets varies by country.

In April 2014, we received FDA clearance to market our da Vinci Single Port Surgical System in the U.S. for single-port urologic surgeries. However, we do not plan to commercialize the da Vinci Single Port Surgical System until it is further developed and cleared as an extension of the da Vinci Xi Surgical System dedicated to single port surgeries. We will seek additional FDA clearance(s) for the da Vinci Single Port Surgical System for procedure(s) in which a single small entry point to the body and parallel delivery of instruments is important. Such surgeries could include those performed through a natural orifice like the mouth for head and neck procedures or those performed through a single incision like prostate removal. We are in the process of modifying the da Vinci Single Port Surgical System to be compatible with the da Vinci Xi Surgical system and ready for commercialization.

In September 2013, we received FDA clearance to expand the indication for use of Firefly to include visual assessment of at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging. Fluorescence imaging of biliary ducts with Firefly is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization. We believe that the use of Firefly during cholecystectomy procedures will enhance the ability of surgeons to identify key anatomical structures during the surgery.

In October 2012, we obtained from the Japanese Ministry of Health, Labor, and Welfare ("MHLW") approval in Japan for our da Vinci Si Surgical Systems. Effective April 2012, we obtained national reimbursement for dVP procedures in Japan, our only broadly reimbursed procedure to date. We are currently seeking reimbursement for additional procedures through the MHLW's Senshin Iryo process as well as other alternative reimbursement processes. Such approvals require in-country clinical data and are considered for reimbursed status in April of even numbered years. No additional procedures were granted in the April 2014 cycle. Japanese surgeons have begun registering patients to gather clinical data for partial nephrectomy and gastrectomy surgeries. We also are continuing our discussions with the MHLW and surgical societies concerning the pathway to obtain reimbursement for several other procedures. The next cycle for MHLW reimbursement consideration is April 2016 and there can be no assurance that we will gain additional reimbursements at that time. If we are not successful in obtaining additional regulatory clearances, importation licenses, and adequate procedure reimbursements for future products and procedures, then the demand for our products in Japan could be limited. In June 2014 we terminated the distribution relationship with our Japanese distributor, Adachi, and now market, sell, and service our products directly in Japan. Prior to the acquisition, these functions were performed through Adachi. If we are unable to effectively transition the sales, marketing, regulatory and other operational functions from Adachi, our Japanese business could be disrupted.

FDA Inspection

An FDA inspection of our facilities occurred in April-May 2013 and the FDA issued a Form FDA 483 listing four observations relating to the reporting of field corrections, information which is to be included on reports of field corrections, written procedures for changes to certain product labeling, and design input documentation. We responded to each observation with corrective actions during the course of the inspection and provided additional evidence of corrective actions to the FDA in response to the Form FDA 483. The FDA issued a Warning Letter, dated July 16, 2013, related to two of the four Form FDA 483 observations asking for additional corrective actions and indicated its intent to perform a follow-up inspection. In addition, the FDA collected electronic samples of all our advertising and promotional material for review, and to date has taken no action in connection therewith. We responded to the Warning Letter, communicating corrective actions taken. The FDA re-inspected our facilities during February-March of 2014 to complete a general quality system audit as well as a review of the status of the Warning Letter and 483 remediation activities. At the end of the inspection, the FDA issued a Form FDA 483 listing five observations related to quality management

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system improvement opportunities. We responded to the FDA with a corrective action plan for those observations. On April 25, 2014, the Company received a closure letter from the FDA stating that the observations in the July 16, 2013 Warning Letter have been addressed.

Medical Device Reporting

In September of 2012 we contacted the Office of Surveillance and Biometrics ("OSB") in the FDA Center for Devices and Radiological Health ("CDRH") regarding proposed changes to our reporting practices for non-injury malfunction Medical Device Reports ("MDRs"). In addition we discussed summary reporting for well characterized events. As a result of the proposed changes, we have increased our reports of device malfunction MDRs, the vast majority of which are related to instruments and not to systems. By definition, none of these device malfunction MDRs involve reportable injuries or deaths. These MDRs are posted on the FDA Manufacturer and User Facility Device Experience ("MAUDE") database.

In addition, claims brought to our attention by plaintiffs' attorneys that contain allegations of patient injury are required to be investigated as complaints. In those cases in which da Vinci was used and the system cannot yet be ruled out as a cause or contributor of the alleged injury, these cases are reported to the FDA as MDRs. This has led to increases in MDRs. During the first quarter 2014, as agreed to by the FDA, MDR Policy Branch, we reported a summary level MDR for 1,406 events related to these claims. 1,387 of these events relate to allegations of injuries that had not previously been reported to us and, subsequently, we had not reported them to the FDA; the remaining 19 events are supplemental reports to events previously reported to the FDA. In the second quarter of 2014, we filed a second summary level MDR for 455 events related to legal claims. 219 of these events related to allegations of injuries that had not previously been reported to us and, subsequently, we had not reported them to the FDA; the remaining 236 events are supplemental reports to events previously reported to the FDA.

Recalls and Corrections

Medical device companies have regulatory obligations to correct or remove medical devices in the field that could pose a risk to health. The definition of "recalls and corrections" is expansive and includes repair, replacement, inspections, re-labeling and issuance of new, added or reinforcement of instructions for use and training when such actions are taken for specific reasons of safety or compliance. These field actions require stringent documentation, reporting and monitoring worldwide. There are other actions which a medical device manufacturer may take in the field without reporting, including routine servicing, the introduction of new products, and new indications for use and stock rotations.

As we determine whether a field action is reportable in any regulatory jurisdiction, we prepare and submit notifications to the appropriate regulatory agency for the particular jurisdiction. In general, upon submitting required notifications to regulators regarding a field action which is a recall or correction, we will notify customers regarding the field action, provide any additional documentation required in their national language, and arrange, as required, return or replacement of the affected product or a field service visit to perform the correction. In addition, regulators can require the expansion, reclassification, or change in scope and language of the field action. Field actions can result in adverse effects on our business, including damage to reputation, delays by customers of purchase decisions, reduction or stoppage of use of installed systems, and reduced revenue as well as increased expenses to complete field actions.

In September 2014, we stopped shipping the EndoWrist Stapler 45 for the da Vinci Si Surgical System and advised our customers to suspend use. While the observed failure rate in the field was low at 0.023%, based on the total number of staple fires, we believe that immediately suspending use was the best course of action in the interest of patients. Our investigation of the three failed EndoWrist Staplers uncovered two separate failure modes in the clamp mechanism: 1) a component failure in two instruments and 2) an assembly error in one instrument. Based on these findings, in December 2014, we voluntarily initiated a field recall related to the EndoWrist Stapler 45 instrument for the da Vinci Si Surgical System. We have refined the relevant design elements and manufacturing processes to address these failure modes and have begun shipping replacement instruments in early 2015.

Certain outcomes from any of the above regulatory activities may result in material adverse effects on the business, including damage to reputation, delays by customers of purchase decisions, reduction or stoppage of use of installed systems, and reduced revenue as well as increased expenses.

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2014 Business Events and Trends

Procedures

Overall. During the year ended December 31, 2014, total da Vinci procedures grew approximately 9% compared with 16% for the year ended December 31, 2013. Procedure growth during the year ended December 31, 2014 was driven by growth in general surgery in the U.S. and worldwide urologic procedures. The lower 2014 procedure growth rate was driven by continued pressure on U.S. benign gynecologic procedures and slowing growth in U.S. cholecystectomy procedures partially offset by growth in several multi-port general surgery procedures, including hernia repair, colorectal, and bariatric procedures and worldwide growth in urologic procedures.

dVP. We believe the U.S. Preventive Services Task Force recommendation against PSA screening, as well as changes in treatment patterns for low risk prostate cancer away from definitive treatment, contributed to a 15% decline in our dVP business in 2012 and a 6% decline in 2013. U.S. dVP procedures grew 2% for the full year 2014. Treatment patterns impacting the U.S. dVP market have likely also impacted our European dVP procedure volumes. As dVP is at earlier market penetration stages in the European markets, we are unable to precisely estimate the extent to which these recommendations and treatment pattern changes may have been adopted by governments or clinicians within non-U.S. jurisdictions.

Benign Gynecology Procedure Adoption Trends. During the year ended December 31, 2014, we experienced continued pressure on the category of U.S. benign gynecologic procedures. For the year ended 2014, U.S. benign gynecologic procedures reflected an approximately 3% decline compared to 2013. The pressure on U.S. benign gynecologic procedures reflected a macro trend of fewer benign gynecologic procedures caused by a number of factors including, but not limited to, apparent pressure on benign gynecology hospital admissions, larger patient deductibles and co-pays associated with the Affordable Care Act, a trend by payers toward encouraging conservative disease management, and FDA actions regarding the use of power morcellation in uterine surgeries which mostly impacted da Vinci myomectomy procedures (see more detailed description of the FDA Actions Concerning Morcellation below). Minimally invasive surgery is presently approaching 80% penetration of the U.S. benign hysterectomy market, causing the rate of migration from open surgeries to minimally invasive surgeries to slow. Combined with the dispersion of the remaining open procedures among hospitals and surgeons, we believe the number of da Vinci hysterectomies performed for benign conditions has moved roughly in-line with the gradually decreasing surgical market in 2014.

Cholecystectomy. In December 2011, we received FDA clearance for Single-Site Cholecystectomy, our first procedure cleared for Single-Site instruments. Since then, da Vinci Cholecystectomy has grown into our third largest procedure, after hysterectomy and prostatectomy. da Vinci Cholecystectomies are performed with either Single-Site instruments or multiport instruments. In many cases, surgeons performing multiport cholecystectomies are using that approach as a training pathway towards Single-Site Cholecystectomy or other more complex procedures. Cholecystectomy is a lower complexity procedure which can generally be executed in a minimally invasive manner via multiport laparoscopy and has lower reimbursement rates than more complex procedures. For these reasons, it is difficult to estimate to what degree we may capture these procedures. During 2014, total U.S. cholecystectomies grew at a lower percentage than in previous periods.

Procedure Seasonality. More than half of da Vinci procedures performed are for benign conditions, most notably benign hysterectomies and cholecystectomies. The proportion of these benign procedures has grown over time in relation to the total number of procedures performed. Hysterectomies for benign conditions, cholecystectomies, hernia repairs, and other short-term elective procedures tend to be more seasonal than cancer operations and surgeries for other life threatening conditions. Seasonality for these benign procedures results in higher fourth quarter procedure volume when more patients have met annual deductibles and lower first quarter procedure volume when deductibles are reset. We experienced lower seasonality in 2014 which could be reflective of higher deductible insurance plans required by PPACA. It is possible that in the first quarter 2015, benign procedures will decline at a similar or greater rate than first quarter 2014 procedures declined from the fourth quarter of 2013 procedures. Third quarter activity has historically been seasonally lower due to summer vacations, particularly in Europe.

Procedure Mix. Our procedure business is now comprised of: (1) cancer and other highly complex procedures and (2) less complex benign procedures. Cancer and other highly complex procedures tend to be reimbursed at higher rates

than less complex benign procedures. Thus, hospitals are more sensitive to the costs associated with treating less complex benign conditions. Our strategy is to provide hospitals with attractive clinical and economic solutions in each of these procedure categories. More fully featured products, including 4-arm, dual console, Firefly enabled systems, and advanced instruments including vessel sealing and stapler are targeted towards more complex procedures. Lower priced products, including the three-arm da Vinci Si-e System and lower priced Single-Site instruments are targeted towards less complex procedures.

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FDA Actions Concerning Morcellation. In April 2014, the FDA announced that it discourages the use of power morcellators in the surgical removal of assumed benign fibroids. This statement was followed in July 2014 by an FDA panel discussion on the topic. In November 2014, the FDA issued specific contraindications for the use of laparoscopic power morcellation and required specific patient warning prior to its use in surgery. We do not manufacture or sell power morcellation products and power morcellators do not attach to da Vinci Surgical Systems. Minimally invasive da Vinci gynecologic surgeries are routinely performed without the use of power morcellators. However, we believe that these FDA actions likely created some uncertainty for surgeons and patients when choosing among minimally invasive surgical methods for removing fibroids that may have adversely impacted the number of da Vinci procedures performed. During the second, third, and fourth quarters of 2014 we experienced a decline in myomectomies that likely reflected the impact of the FDA actions. Myomectomies are not a significant portion of our business. It is difficult to gauge what impact the FDA actions may have had on benign dVH procedures.

System Demand

Future demand for da Vinci Surgical Systems will be impacted by factors including procedure growth rates, market response to our recently launched da Vinci Xi Surgical System, economic pressure and uncertainty at hospitals associated with the Affordable Care Act, evolving system utilization and point of care dynamics, likely variability in the timing of Japanese systems sales given that additional da Vinci procedures are considered for reimbursement only in even numbered years and the possible approval of the Xi System, the timing of when we receive regulatory clearance in our other international markets for our Xi System and related instruments, as well as other economic and geopolitical factors.

Recent Media and Lawsuits

Prior to and during the twelve months ended December 31, 2014, various print, television, and internet media have released pieces questioning the patient safety and efficacy associated with da Vinci Surgery, the cost of da Vinci Surgery relative to other disease management methods, and the adequacy of surgeon training and our sales and marketing practices. In addition, as further described in Note 7 to the Consolidated Financial Statements included in Part II, Item 8, we are currently named as a defendant in approximately 102 individual product liability lawsuits and a multi-plaintiff product liability lawsuit filed on behalf of 20 patients who underwent da Vinci Surgery. Plaintiffs' attorneys have been engaged in well-funded national advertising campaigns soliciting clients who have undergone da Vinci Surgery and claim to have suffered an injury, and we have seen a substantial increase in these claims. We believe that da Vinci Surgery continues to be a safe and effective surgical method, as supported by a substantial and growing number of scientific studies and peer reviewed papers. We also believe that we provide appropriate training on the use of the da Vinci Surgical System, consistent with our role as device manufacturer. However, the recent negative media publicity likely has and may continue to delay or adversely impact procedure adoption, system sales, and our revenue growth in future periods.

The increase in product liability claims coincided with national attorney advertising efforts seeking patients dissatisfied with da Vinci surgery. In an effort to avoid the expense and distraction of defending multiple lawsuits, we entered into tolling agreements to pause the applicable statutes of limitations for the claims, and engaged in mediation efforts. The attorneys for the patients agreed to collect and supply medical records, operative notes and other necessary information from these patients to us. Each claim was individually investigated. The collection and evaluation of the patients' medical information was laborious. For hundreds of the asserted claims, we have never received medical records. As patient records related to these claims were received, we and our legal counsel, assisted by independent medical consultants, reviewed and analyzed the large volumes of medical information that began to arrive in the fall of 2013. The completion of the evaluation of a significant number of these claims occurred during the first quarter of 2014 and continued throughout 2014.

During the year ended December 31, 2014, we recorded pre-tax charges of $82.4 million, of which $67.4 million, $9.6 million, and $5.4 million was recorded in the first, second, and fourth quarters of 2014, respectively, to reflect the estimated cost of settling a number of the product liability claims covered by the tolling agreements described below. The claims relate to alleged complications from surgeries performed with certain versions of Monopolar Curved Scissor (MCS) instruments that included an MCS tip cover accessory that was the subject of a market withdrawal in 2012 and MCS instruments that were the subject of a recall in 2013.

Our estimate of the anticipated cost of settling these claims is based on negotiations with attorneys for patients who have participated in a mediation process. To date, approximately 4,800 claims have been reviewed as part of that mediation process. Of those, however, a substantial number have already been removed from the tolling agreement that covers the claims in the mediation process and plaintiffs' counsels have indicated to us that they no longer intend to pursue these claims. Nonetheless, the claimants that have been removed from the tolling agreement remain free to pursue lawsuits against us and it is also possible that more claims will be made by other individuals who have undergone da Vinci surgery and allege that they suffered injuries. It is further possible that the claimants who participate in the mediations, as well as those claimants who have not participated in negotiations, will pursue greater amounts in mediation or in a court of law. Consequently, the final outcome of these claims is dependent on many variables that are difficult to predict and the ultimate cost associated with these product liability claims may be materially different than the amount of the current estimate and accruals and could have a material adverse effect on our business,

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financial condition, and results of operations or cash flows. Although there is a reasonable possibility that a loss in excess of the amount recognized exists, we are unable to estimate the possible loss or range of loss in excess of the amount recognized at this time. See Note 7 to the Consolidated Financial Statements included in Part II, Item 8 for further details.

We submit reports to the FDA for these claims as part of our post-market surveillance process. The FDA publicly reports these claims on its MAUDE database. On February 27, 2014, we submitted an Alternative Summary Report (ASR) to consolidate 1,406 of the product liability claims for surgeries spanning the period 2004 through the third quarter of 2013. On May 29, 2014, we submitted a second ASR to consolidate 219 initial claims and amend 236 previous claims for surgeries spanning the period 2005 through the fourth quarter of 2013. On August 27, 2014, we submitted a third ASR that included 441 initial claims and amended 204 previous claims for surgeries spanning from September 2005 through January 2014. During the time period of 2004 through December 2014, approximately 2.2 million surgeries were performed with the da Vinci Surgical System in the U.S.

MDR reporting criteria are described in FDA regulations at 21 CFR Part 806. An MDR report or any other information submitted by us to the FDA is not necessarily an admission that the device caused or contributed to the reportable event. The February 27, 2014 ASR contains information from attorneys who submitted claims of injury involving da Vinci use in surgery. The vast majority of the alleged injuries in the ASR are common complications associated with surgery, including minimally invasive and open surgical procedures. In the rare instances in which our records were able to confirm claims of a malfunction of the da Vinci Surgical System during a surgery, we filed a separate MDR. Where a claim indicated a patient death, we filed a separate MDR. The ASR excludes these individually reported death and malfunction events.

New Product Introductions

da Vinci Xi Surgical System. During April 2014, we launched our newest da Vinci model, the da Vinci Xi, in the U.S. The da Vinci Xi can be used across a wide spectrum of minimally invasive surgical procedures, and has been optimized for multi-quadrant surgeries. The da Vinci Xi expands upon core da Vinci features including wristed instruments, 3D-HD visualization, intuitive motion, and ergonomic design, while improving ease, and delivering several new features, including:

- A new overhead instrument arm architecture designed to facilitate anatomical access from virtually any position.
- A new endoscope digital architecture that creates a simpler, more compact design with improved vision definition and clarity.
- An ability to attach the endoscope to any arm, providing flexibility for visualizing the surgical site.
- Smaller, thinner arms with newly designed joints that offer a greater range of motion than ever before.
- Longer instrument shafts designed to give surgeons greater operative reach.

With the da Vinci Xi, we now offer hospitals a broader line of da Vinci Surgical Systems to match their surgical profile and patient care requirements. These include the da Vinci Si-e, a lower price system suited for surgeries requiring two instrument arms; the da Vinci Si, which has the capability of controlling three instrument arms; and the da Vinci Xi, which has four universal instrument arms that attach to a rotating overhead platform. We separately applied for FDA clearance for the da Vinci Xi Firefly, Vessel Sealer, and Stapler products and have received clearance for these products between June and August of 2014. Our Single Site line of instruments is only available for our da Vinci Si and da Vinci Si-e systems.

We CE marked the da Vinci Xi system in June 2014 and have begun sales and marketing activities in certain countries recognizing the CE mark. We are in various stages of applying for CE mark on other da Vinci Xi products, including Firefly, Vessel Sealer, and Stapler. We plan to bring these products to market upon receiving CE marks. In October 2014, we received regulatory clearance for our da Vinci Xi Surgical System in Korea. Regulatory submissions have been made for the da Vinci Xi Surgical System in Japan with the status currently pending. The regulatory status of the da Vinci Xi Surgical System in other international markets varies by country.

da Vinci Single-Site Instruments. da Vinci Single-Site consists of a set of non-wristed instruments (except for wristed needle driver discussed below) and accessories that allow the da Vinci Si systems to work through a single incision, typically in the umbilicus, rather than multiple incisions. Single incision surgery is intended to minimize invasiveness to patients by reducing the number of ports required to enter the body and is typically utilized for less complex

surgery than multi-port surgery. Non-robotic single incision surgery today is typically performed with modified laparoscopic instruments. Early clinical adoption of this manual technique has been mostly positive, although physicians have reported that manual single incision surgery is technically and ergonomically challenging. da Vinci Single-Site instruments and accessories were designed to address these issues. In February 2011, we received the CE mark for our da Vinci Single-Site instrument kit and began selling these new products in Europe. The majority of da Vinci Single-Site procedures performed in Europe to date have been cholecystectomies. In December 2011, we received FDA regulatory clearance to market our Single-Site instrumentation in the U.S. for laparoscopic cholecystectomy procedures. In February 2013, we received FDA clearance to market our Single-Site instruments for benign hysterectomy and salpingo-oophorectomy procedures. In September 2014, we received FDA clearance to market the wristed version of our Single-Site needle driver product for use on benign hysterectomy, cholecystectomy, and salpingo-oophorectomy procedures. We believe

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this instrument may have particular utility in benign hysterectomy procedures. However, as these are our initial products targeted towards procedures already highly penetrated by manual MIS techniques, we are not able to predict the extent or pace that da Vinci Single-Site may be adopted.

da Vinci Firefly Fluorescence Imaging. In the first quarter of 2011, we launched our Firefly product for use with the da Vinci Si Surgical System. Firefly is a standard feature of the da Vinci Xi Surgical System. This imaging capability combines a fluorescent dye with a specialized da Vinci camera head, endoscope and laser-based illuminator to allow surgeons to identify vasculature in three dimensions beneath tissue surfaces to visualize critical anatomy. Adoption of Firefly is progressing with use across the categories of urology, gynecology and general surgery. In September 2013, we received FDA 510(k) clearance to market our Firefly fluorescence imaging product for real-time imaging of bile ducts (cystic duct, common bile duct, and common hepatic duct). We believe that the use of Firefly during cholecystectomy procedures will enhance the ability of surgeons to identify key anatomical structures during the surgery.

EndoWrist One Vessel Sealer. In December 2011, we received FDA clearance for the EndoWrist One Vessel Sealer. The EndoWrist One Vessel Sealer is a wristed, single-use instrument intended for bipolar coagulation and mechanical transection of vessels up to 7 mm in diameter and tissue bundles that fit in the jaws of the instrument. This instrument enables da Vinci Si surgeons to fully control vessel sealing, while providing the benefits of da Vinci Surgery. This instrument is designed to enhance surgical efficiency and autonomy in a variety of general surgery and gynecologic procedures. Clinical response to the EndoWrist One Vessel Sealer has been encouraging, with positive commentary on precision, articulation, vessel sealing quality and thermal spread, and we expect applications for the EndoWrist One Vessel Sealer to be centered on general surgery and gynecologic oncology procedures. EndoWrist One Vessel Sealer utilization rates have increased steadily in 2013 and 2014. In June 2014, we received FDA clearance for the da Vinci Xi version of the EndoWrist One Vessel Sealer.

EndoWrist Stapler 45. In October 2012, we received FDA clearance for the EndoWrist Stapler 45 instrument with Blue and Green 45 mm reloads. The EndoWrist Stapler 45 is a wristed, stapling instrument intended for resection, transection and/or creation of anastomoses in general, gynecologic and urologic surgery. This instrument enables operators of the da Vinci Si to precisely position and fire the stapler. Its initial surgical use was directed towards colorectal procedures. During 2013, the EndoWrist Stapler was used by a limited and gradually increasing number of customers. In 2014, we expanded the availability of the EndoWrist Stapler to a broadening set of customers. In September 2014, we notified our customers to suspend the use of the EndoWrist Stapler 45 (see Recalls and Corrections section for additional discussion). In January 2015, we began to ship the replacement product. Although our early customer experiences have been positive, we are in the early stages of selling EndoWrist Stapler 45, and we are not able to predict the extent to which the instrument may be adopted.

2014 Financial Highlights

- Total revenue was $2.1 billion during the year ended December 31, 2014, compared to $2.3 billion during the year ended December 31, 2013.
- Approximately 570,000 da Vinci procedures were performed during the year ended December 31, 2014, up approximately 9% from the year ended December 31, 2013.
- Instruments and accessories revenue increased 4% to $1.1 billion during the year ended December 31, 2014, from $1.0 billion during the year ended December 31, 2013.
- Recurring revenue increased 5% to $1.5 billion during the year ended December 31, 2014, representing 70% of total revenue, from $1.4 billion during the year ended December 31, 2013, representing 63% of total revenue.
- We shipped 431 da Vinci Surgical Systems during the year ended December 31, 2014, compared with 546 for the year ended December 31, 2013.
- System revenue decreased 24% to $632.5 million during the year ended December 31, 2014, from $834.9 million during the year ended December 31, 2013.
- As of December 31, 2014, we had a da Vinci Surgical System installed base of 3,266 systems - 2,223 in the U.S., 549 in Europe, 193 in Japan and 301 in the rest of the world.
- Operating income decreased 36% to $544.8 million during the year ended December 31, 2014, compared with $852.5 million during the year ended December 31, 2013. Operating income included $169.1 million and $168.9 million

during the years ended December 31, 2014, and 2013, respectively, of share-based compensation expense related to employee stock plans. Operating income for the year ended December 31, 2014, also included a pre-tax charge of $82.4 million to reflect the estimated cost of settling a number of the product liability claims covered by the tolling agreements.

- We ended fiscal 2014 with $2.5 billion in cash, cash equivalents and investments. Cash, cash equivalents and investments decreased by $256.9 million compared to December 31, 2013, primarily due to $1.0 billion of cash used in share repurchases, partially offset by cash provided by operating activities.

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Technology and Other Acquisitions

We continue to make strategic acquisitions of intellectual property and related technologies. On January 17, 2014, we completed the acquisition of certain intellectual property, know-how, and retained employees from Luna Innovations, Inc. ("Luna"). On June 25, 2014, we terminated our distribution relationship with our Japanese distributor, Adachi, and now market, sell, and service our products directly in Japan. Both transactions, from an accounting perspective, met the definition of a business and were accounted for using the acquisition method of accounting. The purchase considerations were $19.9 million and $73.6 million for Luna and Adachi, respectively. Pro-forma results of operations related to the acquisitions have not been presented because the operating results of the acquired businesses are not material to the Company's consolidated financial statements.

Total investments in intellectual property and related technologies during the year ended December 31, 2013 were $2.0 million. Other than Luna and Adachi, there were no other intellectual property and related technologies acquired during the year ended December 31, 2014. Amortization expense related to purchased intellectual property for the years ended December 31, 2014, and 2013 were $22.4 million and $21.3 million, respectively.

Results of Operations

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

	Years Ended December 31,							
	2014	% of total revenue		2013	% of total revenue		2012	% of total revenue	
Revenue:									
Product	$1,702.7	80	%	$1,867.8	82	%	$1,836.2	84	%
Service	429.0	20	%	397.3	18	%	342.6	16	%
Total revenue	2,131.7	100	%	2,265.1	100	%	2,178.8	100	%
Cost of revenue:									
Product	569.9	27	%	543.4	24	%	495.3	23	%
Service	148.0	7	%	127.5	6	%	113.2	5	%
Total cost of revenue	717.9	34	%	670.9	30	%	608.5	28	%
Product gross profit	1,132.8	53	%	1,324.4	58	%	1,340.9	61	%
Service gross profit	281.0	13	%	269.8	12	%	229.4	11	%
Gross profit	1,413.8	66	%	1,594.2	70	%	1,570.3	72	%
Operating expenses:									
Selling, general and administrative	691.0	32	%	574.0	25	%	522.2	24	%
Research and development	178.0	8	%	167.7	7	%	170.0	8	%
Total operating expenses	869.0	40	%	741.7	32	%	692.2	32	%
Income from operations	544.8	26	%	852.5	38	%	878.1	40	%
Interest and other income, net	4.2	—	%	18.4	1	%	15.8	1	%
Income before taxes	549.0	26	%	870.9	39	%	893.9	41	%
Income tax expense	130.2	6	%	199.9	9	%	237.3	11	%
Net income	$418.8	20	%	$671.0	30	%	$656.6	30	%

Total Revenue

Total revenue decreased by 6% during the year ended December 31, 2014 from the year ended December 31, 2013, and increased by 4% during the year ended December 31, 2013, from the year ended December 31, 2012. Total revenue was $2.1 billion during the year ended December 31, 2014, compared to $2.3 billion during the year ended December 31, 2013, and $2.2 billion during the year ended December 31, 2012. The decline in total revenue for the year ended December 31, 2014, was driven by 24% lower sales of da Vinci Systems, largely reflecting lower system sales in the U.S. and Japan, partially offset by 5% higher recurring instruments, accessories, and services revenue, resulting primarily from an approximately 9% higher procedure volume. The increase in total revenue for the year ended December 31, 2013, was driven by 15% higher recurring instruments, accessories, and services revenue,

resulting primarily from approximately 16% higher procedure volume. The increase in recurring revenue during the year ended December 31, 2013 was partially offset by 11% lower sales of da Vinci Systems, largely reflecting lower da Vinci System sales in the U.S.

Revenue generated in the U.S. accounted for 70%, 72%, and 79% of total revenue during the years ended December 31, 2014, 2013, and 2012, respectively. We believe that domestic revenue has accounted for the large majority of total revenue due to patients

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ability to choose their provider and method of treatment in the U.S., reimbursement structures supportive of innovation and minimally invasive surgery, and initial investments focused on domestic infrastructure. Our international revenue has grown faster in proportion to U.S. revenue primarily due to higher procedure growth rates in international markets and lower U.S. system sales.

The following table summarizes our revenue and da Vinci Surgical System unit shipment information for the years ended December 31, 2014, 2013, and 2012, respectively (in millions, except unit sales and percentages):

	Years Ended December 31,					
	2014		2013		2012	
Revenue						
Instruments and accessories	$1,070.2		$1,032.9		$903.3	
Systems	632.5		834.9		932.9	
Total product revenue	1,702.7		1,867.8		1,836.2	
Services	429.0		397.3		342.6	
Total revenue	$2,131.7		$2,265.1		$2,178.8	
Recurring revenue	$1,499.2		$1,430.2		$1,245.9	
% of total revenue	70	%	63	%	57	%
Domestic	$1,490.9		$1,625.9		$1,726.9	
International	640.8		639.2		451.9	
Total revenue	$2,131.7		$2,265.1		$2,178.8	
% of Revenue—Domestic	70	%	72	%	79	%
% of Revenue—International	30	%	28	%	21	%
Unit Shipments by Region:						
Domestic unit shipments	238		342		476	
International unit shipments	193		204		144	
Total unit shipments*	431		546		620	
*Systems shipped on operating leases (included in total unit shipments)	14		—		—	
Unit Shipments by Model:						
da Vinci S unit shipments	10		6		40	
da Vinci Si-e - Single console unit shipments (3 arm)	29		30		26	
da Vinci Si - Single console unit shipments (4 arm)	143		365		449	
da Vinci Si - Dual console unit shipments	43		145		105	
da Vinci Xi - Single console unit shipments	157		—		—	
da Vinci Xi - Dual console unit shipments	49		—		—	
Total unit shipments*	431		546		620	
*Systems shipped on operating leases (included in total unit shipments)	14		—		—	
Unit Shipments involving System Trade-ins:						
Unit shipments involving trade-ins of da Vinci standard Surgical Systems	18		28		51	
Unit shipments involving trade-ins of da Vinci S Surgical Systems	82		126		116	
Unit shipments involving trade-ins of da Vinci Si Surgical Systems	31		—		—	
Total unit shipments involving trade-ins	131		154		167	
Unit shipments not involving trade-ins	300		392		453	
Total unit shipments	431		546		620	
Product Revenue						

Product revenue decreased to $1.7 billion during the year ended December 31, 2014, from $1.9 billion during the year ended December 31, 2013.

Instruments and accessories revenue increased to $1.1 billion for the year ended December 31, 2014, up 4% compared with $1.0 billion for the year ended December 31, 2013. The increase in revenue was driven by an approximate 9% increase in procedure volume, partially offset by lower initial instrument and accessory stocking orders associated with lower 2014 system unit sales.

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The growth in our overall procedure volume was driven by approximately 32% growth in U.S. general surgery procedures and approximately 12% growth in worldwide urologic procedures, partially offset by approximately 2% lower U.S. gynecologic procedures. Higher U.S. general surgery procedures reflected growth in hernia repair, colorectal, cholecystectomy, and several other procedures.

Systems revenue decreased to $632.5 million during the year ended December 31, 2014, down 24% from $834.9 million during the year ended December 31, 2013, primarily due to lower U.S. and Japanese da Vinci Surgical System unit shipments, partially offset by higher da Vinci Surgical System unit shipments into Europe and other international markets. During 2014, 238 systems were shipped into the U.S., 97 into Europe, 37 into Japan, and 59 into other markets, compared with 342 systems shipped into the U.S., 82 into Europe, 79 into Japan, and 43 into other markets in 2013. The demand for systems is ultimately driven by da Vinci surgical procedure volume and is highly sensitive to changes in procedure growth rates. The decline in U.S. system sales in 2014 was largely driven by moderating procedure growth (as described in the Procedures section) resulting in lower need for customers to expand capacity, economic pressure and uncertainty at hospitals associated with the Affordable Care Act, and evolving system utilization and point of care dynamics. The decrease in system sales in Japan likely reflect the fact that only prostatectomies are broadly reimbursed and the effect of a possible approval of the Xi System. The increase in system sales in Europe reflects continued procedure growth and investments we have made in our European sales and marketing organizations.

The da Vinci Surgical System average selling price ("ASP"), excluding the impact of units shipped under operating leases, was fairly consistent at $1.5 million for 2014 and 2013.

Product revenue increased to $1.9 billion during the year ended December 31, 2013, from $1.8 billion during the year ended December 31, 2012.

Instruments and accessories revenue increased to $1,032.9 million for the year ended December 31, 2013, up 14% compared with $903.3 million for the year ended December 31, 2012. The increase in revenue was driven by an approximate 16% increase in procedure volume and, to a lesser extent, higher initial instrument and accessory orders associated with recently released products, including da Vinci Single-Site, the EndoWrist One Vessel Sealer, and Firefly Fluorescence Imaging products, partially offset by lower initial instrument and accessory stocking orders associated with lower 2013 system units sales and procedure mix.

The growth in our 2013 overall procedure volume was driven by growth in U.S. general surgery procedures, U.S. gynecologic procedures and international urology procedures, partially offset by a decline of approximately 6% in U.S. dVP procedures.

Systems revenue decreased to $834.9 million during the year ended December 31, 2013, down 11% from $932.9 million during the year ended December 31, 2012, primarily due to lower U.S. da Vinci Surgical System unit sales, partially offset by higher international system unit sales. During 2013, 342 systems were sold into the U.S., 82 into Europe, 79 into Japan, and 43 into other markets, compared with 476 systems sold into the U.S., 64 into Europe, 40 into Japan, and 40 into other markets in 2012. The demand for systems is ultimately driven by da Vinci surgical procedure volume and is highly sensitive to changes in procedure growth rates. The decline in U.S. system sales in 2013 was largely driven by moderating growth in the category benign gynecologic procedures resulting in fewer systems sales required to be sold into the installed base to expand capacity. In addition, hospital capital spending appears to have been impacted by strategic uncertainties surrounding the Affordable Care Act, economic pressures, and negative media reports.

The da Vinci Surgical System ASP was fairly consistent at $1.5 million for 2013 and 2012.

Service Revenue

Service revenue, comprised primarily of system service and customer training, increased 8% to $429.0 million for the year ended December 31, 2014, from $397.3 million for the year ended December 31, 2013. Service revenue increased 16% to $397.3 million for the year ended December 31, 2013, from $342.6 million for the year ended December 31, 2012. We typically enter into multi-year service fixed annual rate contracts at the time systems are sold. These service contracts have been generally renewed at the end of the service periods. Higher service revenue in 2014 and 2013 was driven by a larger installed base of da Vinci Surgical Systems producing service contract revenue.

Gross Profit

Product gross profit during the year ended December 31, 2014, decreased 14% to $1.1 billion, or 66.5% of product revenue, compared with $1.3 billion, or 70.9% of product revenue, during the year ended December 31, 2013. The lower 2014 gross profit was driven by lower 2014 product revenue as described above and a lower 2014 gross product profit margin. The lower 2014 gross profit margin was driven by a higher proportion of 2014 sales of recently introduced products that yield lower gross margin percentages, including the da Vinci Xi Surgical System, as well as the EndoWrist One Vessel Sealer and the EndoWrist Stapler. Margins on newly launched products will typically be lower than our mature products reflecting vendor pricing on low volumes, temporary tooling costs and other start-up costs. Over time, as volumes increase, and we refine the manufacturing processes and products, we expect to see improvement in the margins of these newer products. However, gross margins may ultimately differ for these newer products relative to our previous products based on market conditions, volume, and complexity of the product.

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Other factors contributing to the lower 2014 product gross profit margin were a higher proportion of sales involving trade-in's and higher credits given for those trade-ins, higher 2014 incentive compensation, and higher product recall costs.

Product gross profit for the year ended December 31, 2014, and 2013 reflected share-based compensation expense of $19.1 million and $17.6 million, respectively. Product gross profit for the years ended December 31, 2014, and 2013 included $15.7 million and $21.0 million, respectively, related to the U.S. medical device excise tax, which became effective January 1, 2013.

Service gross profit during the year ended December 31, 2014, increased to $281.0 million, or 65.5% of service revenue, compared with $269.8 million, or 67.9% of service revenue during the year ended December 31, 2013. The higher 2014 service gross profit was driven by higher service revenue. The lower 2014 gross service profit margin was primarily driven by costs added to support the newly introduced da Vinci Xi system and higher incentive compensation. Service gross profit during the years ended December 31, 2014, and 2013, reflected share-based compensation expense of $13.5 million and $12.7 million, respectively.

Product gross profit during the year ended December 31, 2013, decreased 1% to $1.3 billion, or 70.9% of product revenue, compared with $1.3 billion, or 73.0% of product revenue, during the year ended December 31, 2012. The lower 2013 product gross margin largely reflected the impact of the new U.S. medical device excise tax and lower gross margins earned on recently released instrument and accessory products. 2013 product revenue included a higher proportion of recently introduced instrument and accessory products which yield lower gross margin percentages, particularly Single-Site Instruments and the EndoWrist One Vessel Sealer. Margins on newly launched products will typically be lower than our mature products reflecting vendor pricing on low volumes, temporary tooling costs and other start-up costs. Over time, as volumes increase, and we refine the manufacturing processes and products, we expect to see improvement in the margins of these newer products. However, gross margins may ultimately differ for these newer products relative to our previous products based market conditions, volume, and complexity of the product. Product gross profit for the year ended December 31, 2013 and 2012, reflected share-based compensation expense of $17.6 million and $14.1 million, respectively.

Service gross profit during the year ended December 31, 2013, increased to $269.8 million, or 67.9% of service revenue, compared with $229.4 million, or 67.0% of service revenue during the year ended December 31, 2012. The higher 2013 service gross profit was driven by higher service revenue as described above. The higher 2013 gross service profit margin was primarily driven by lower service parts consumption rates. Service gross profit during the years ended December 31, 2013 and 2012, reflected share-based compensation expense of $12.7 million and $12.9 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, 2014 increased 20% to $691.0 million compared to $574.0 million for the year ended December 31, 2013. The increase was primarily due to a pre-tax charge of $82.4 million of which $67.4 million, $9.6 million, and $5.4 million was recorded in the first, second, and fourth quarters of 2014, respectively, to reflect the estimated cost of settling a number of the product liability claims covered by tolling agreements outlined above. In addition, selling, general and administrative expenses for the year ended December 31, 2014, also increased due to higher legal costs related to the pending or threatened litigation, expansion of our Japanese and other international organizations, higher regulatory compliance costs, and higher incentive compensation. Share-based compensation expense charged to selling, general and administrative expenses during the years ended December 31, 2014, and 2013, were $99.0 million and $101.4 million, respectively.

Selling, general and administrative expenses for the year ended December 31, 2013, increased 10% to $574.0 million compared to $522.2 million for the year ended December 31, 2012. The increase was primarily due to organizational growth to support our expanding business, particularly in the clinical field sales function, regulatory activity, and higher legal costs related to pending or threatened litigation, and higher share-based compensation expenses, partially offset by lower employee incentive costs. Share-based compensation expense charged to selling, general and administrative expenses during the years ended December 31, 2013 and 2012 were $101.4 million and $93.1 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, 2014, increased 6% to $178.0 million compared to $167.7 million during the year ended December 31, 2013. The increase was driven by higher headcount and incentive compensation expenses. Share-based compensation expense charged to research and development expense during the years ended December 31, 2014, and 2013, were $37.5 million and $37.2 million, respectively. Amortization expense related to purchased intellectual property during the years ended December 31, 2014, and 2013, were $11.6 million and $10.8 million, respectively. We expect to continue

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to make substantial investments in research and development and anticipate that research and development expenses, including co-development arrangements with industry partners, will increase in the future.

Research and development expenses during the year ended December 31, 2013, decreased 1% to $167.7 million compared to $170.0 million during the year ended December 31, 2012. The decrease was due to lower 2013 incentive compensation, amortization of intangible assets, and prototype expenses, partly offset by higher share-based compensation. Share-based compensation expense charged to research and development expense during the years ended December 31, 2013 and 2012, was $37.2 million and $33.2 million, respectively. Amortization expense related to purchased intellectual property during the years ended December 31, 2013, and 2012, were $10.8 million and $13.8 million, respectively.

Interest and Other Income, Net

Interest and other income, net, was $4.2 million during the year ended December 31, 2014, compared to $18.4 million for the year ended December 31, 2013. Lower interest and other income, net for the year ended December 31, 2014, was driven by lower 2014 interest income on lower investment balances and $8.5 million in charges recorded related to the impairment of two equity investments.

Interest and other income, net, was $18.4 million during the year ended December 31, 2013, compared to $15.8 million for the year ended December 31, 2012. Higher interest and other income, net for the year ended December 31, 2013, was driven by higher 2013 interest income earned.

Income Tax Expense

Our income tax expense was $130.2 million, $199.9 million, and $237.3 million during the years ended December 31, 2014, 2013, and 2012, respectively. The effective tax rate for 2014 was approximately 23.7% compared with 23.0% for 2013, and 26.5% for 2012. Our tax rates for all these periods differed from the U.S. federal statutory rate of 35% due primarily to income earned by certain of our overseas entities being taxed at rates lower than the federal statutory rate and the reversal of unrecognized tax benefits, partially offset by state income taxes net of federal benefit. We intend to indefinitely reinvest all of our undistributed foreign earnings that were not previously subject to U.S. tax in activities outside the U.S. Our 2014, 2013, and 2012 tax provision reflected net tax benefits of $20.3 million, $26.7 million, and $38.0 million, respectively, associated with the reversal of unrecognized tax benefits and interests resulting from expiration of statutes of limitations in multiple jurisdictions and certain audit settlements. Our 2014 tax provision included a net tax benefit of $5.0 million related to the federal research and development (“R&D”) credit which was reinstated in December 2014. Our 2013 tax provision included a net tax benefit of $4.7 million for the 2013 federal R&D credit and a net tax benefit of $8.2 million related to 2012 federal R&D credit as the federal R&D credit was retroactively reinstated during the first quarter of 2013. Our 2012 tax provision did not reflect any benefit from federal R&D credit but reflected $8.5 million in benefits related to certain previously unrecognized tax benefits and associated interest as a result of new IRS guidance issued in the first quarter of 2012.

A valuation allowance has been recorded against our California deferred tax assets because it is more likely than not these deferred tax assets will not be realized as a result of the computation of California taxes under the single sales factor. We will continue to monitor and reassess the need for further increases or decreases to the valuation allowance. As of December 31, 2014, and 2013, we had valuation allowances of $9.5 million and $7.2 million, respectively, primarily on California deferred tax assets.

The U.S. Internal Revenue Service (“IRS”) completed its audit of our 2010 and 2011 federal income tax returns in December 2014. At the conclusion of the audit, the IRS provided its Revenue Agent’s Report to the Joint Committee of Taxation, which agreed with the IRS examiner’s Report with no exceptions. As a result, we released reserves in connection with years 2010 and 2011 in the fourth quarter of 2014, which were included in the $20.3 million reversal of unrecognized tax benefits and interests described above. In addition, we anticipate receiving a refund of $4.5 million in 2015 in connection with the conclusion of the audit.

We file federal, state and foreign income tax returns in many jurisdictions in the U.S. and abroad. Generally, years before 2010 are closed for most significant jurisdictions except for California, for which years before 2008 are considered closed. We are subject to the examination of our income tax returns by various tax authorities and the outcome of these audits cannot be predicted with certainty.

Certain of our unrecognized tax benefits could reverse based on the normal expiration of various statutes of limitations, which could affect our effective tax rate in the period in which they reverse. Management regularly assesses the likelihood of adverse outcomes resulting from these examinations to determine the adequacy of our provision for income taxes. If any issues addressed in our tax audits are resolved in a manner not consistent with management's expectations, we could be required to adjust our provision for income taxes in the period such resolution occurs.

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Liquidity and Capital Resources

Sources and Uses of Cash

Our principal source of liquidity is cash provided by operations and issuance of common stock through exercise of stock options and our employee stock purchase program. Cash and cash equivalents plus short and long-term investments decreased from $2.9 billion at December 31, 2012, to $2.8 billion at December 31, 2013, and to $2.5 billion at December 31, 2014. Cash generation is one of our fundamental strengths and provides us with substantial financial flexibility in meeting our operating, investing, and financing needs. The decreases in cash and investments generally reflect cash used for stock repurchases and capital expenditures partially offset by cash flow from operations.

As of December 31, 2014, $766.7 million of our cash, cash equivalents and investments were held by foreign subsidiaries. Amounts held by foreign subsidiaries are generally subject to U.S. income taxation on repatriation to the U.S. We currently have no plans to repatriate any foreign earnings back to the U.S. as we believe our cash flows provided by our U.S. operations will meet our U.S. liquidity needs.

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

Consolidated Cash Flow Data

	Years Ended December 31,		
	2014	2013	2012
	(in millions)		
Net cash provided by (used in)			
Operating activities	$665.1	$880.0	$814.2
Investing activities	(153.9)	259.0	(845.7)
Financing activities	(692.4)	(910.6)	119.2
Effect of exchange rates on cash and cash equivalents	(0.6)	—	0.2
Net increase (decrease) in cash and cash equivalents	$(181.8)	$228.4	$87.9

Operating Activities

During the year ended December 31, 2014, cash flow from operations of $665.1 million exceeded our net income of $418.8 million for two primary reasons:

1. Our net income included substantial non-cash charges primarily in the form of share-based compensation, amortization of intangible assets, taxes, and depreciation. These non-cash charges totaled $232.1 million during the year ended December 31, 2014.
2. Changes in operating assets and liabilities resulted in approximately $14.2 million in cash provided by operating activities during the year ended December 31, 2014.

Operating assets and liabilities are comprised primarily of accounts receivable, inventory, deferred revenue, other accrued liabilities, and prepaid expenses. Accrued liabilities increased by $63.4 million, mainly driven by an increase in product liability accruals. Deferred revenue, which includes deferred service revenue that is being recognized as revenue over the service contract period, increased by $19.8 million in 2014 primarily due to the increase in the number of installed systems for which service contracts existed. Also, accrued compensation and accounts payable increased by $39.1 million. The favorable impact of these items on cash provided by operating activities was partly offset by an increase in accounts receivable of $13.7 million in 2014 reflecting timing of our system sales and related collections, a net increase in inventory of $26.8 million primarily due to expanded product offerings, and an increase in prepaids and other assets of $67.6 million, primarily driven by timing of tax payments and an increase in lease receivables relating to sales-type lease arrangements entered into during fiscal 2014.

During the year ended December 31, 2013, cash flow from operations of $880.0 million exceeded our net income of $671.0 million for two primary reasons:

1. Our net income included substantial non-cash charges in the form of share-based compensation, amortization of intangible assets, taxes, and depreciation. These non-cash charges totaled $231.0 million during the year ended December 31, 2013.
2.

Changes in operating assets and liabilities resulting in cash used in operating activities during the year ended December 31, 2013 was approximately $22.0 million.

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Operating assets and liabilities are comprised primarily of accounts receivable, inventory, deferred revenue and other liabilities. Accounts receivable decreased by $68.9 million, or 19%, in 2013 reflecting timing of our system sales. Inventory increased by $58.1 million, or 48%, in 2013 due to expanded product offerings and safety stocks acquired for key components. Deferred revenue, which includes deferred service revenue that is being recognized as revenue over the service contract period, increased $15.3 million, or 8%, in 2013 primarily due 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 decreased by $35.1 million in 2013 primarily due to timing of vendor, tax and employee compensation payments during 2013.

During the year ended December 31, 2012, cash flow from operations of $814.2 million exceeded our net income of $656.6 million for two primary reasons:

1. Our net income included substantial non-cash charges in the form of share-based compensation, amortization of intangible assets, taxes and depreciation. These non-cash charges totaled $223.1 million during the year ended December 31, 2012.
2. Changes in operating assets and liabilities resulting in cash used in operating activities during the year ended December 31, 2012 was approximately $65.5 million.

Operating assets and liabilities are comprised primarily of accounts receivable, inventory, deferred revenue and other liabilities. Accounts receivable increased by $68.9 million, or 24%, in 2012 reflecting timing of our system sales. Inventory increased by $7.1 million, or 8%, in 2012 due to our business growth, expanded product offerings, and safety stocks acquired for key components. Deferred revenue, which includes deferred service contract revenue that is being amortized over the service contract period, increased $30.5 million, or 20%, in 2012 primarily due 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 by $17.1 million in 2012 primarily due to timing of vendor, tax and employee compensation payments during 2012.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2014, consisted primarily of cash used for purchases of property and equipment of $105.6 million and purchases of businesses of $84.3 million, partially offset by the proceeds from the sales and maturities of investments (net of purchases of investments) of $36.0 million. Purchases of property included the acquisition of approximately 15 acres of land in Sunnyvale, California for future expansion. During the year ended December 31, 2014, we acquired certain intellectual property, know-how, fixed assets, and employees from Luna and we reacquired the Japan distribution rights from Adachi.

Net cash provided by investing activities during the year ended December 31, 2013, consisted primarily of proceeds from the sales and maturities of investments (net of purchases of investments) of $363.6 million, less purchases of property and equipment and licensing of intellectual property of $104.6 million.

Net cash used in investing activities during the year ended December 31, 2012, consisted primarily of purchases of investments (net of proceeds from sales and maturities of investments) of $703.9 million less purchases of property and equipment and licensing of intellectual property of $114.2 million. 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, corporate notes and bonds, commercial paper, cash deposits and money market funds.

Financing Activities

Net cash used in financing activities in 2014 consisted primarily of $1.0 billion used for the repurchase of 2.5 million shares of our common stock through an accelerated share repurchase program, offset by proceeds from stock option exercises and employee stock purchases of $283.6 million and excess tax benefits of $24.0 million. Net cash used in financing activities in 2013 consisted primarily of $1.1 billion used for the repurchase of 2.6 million shares of our common stock, offset by proceeds from stock option exercises and employee stock purchases of $160.6 million and excess tax benefits of $38.0 million. Net cash proceeds provided by financing activities in 2012 consisted primarily of stock option exercises and employee stock purchases of $263.3 million and excess tax benefits of $94.2 million, offset by $238.3 million used for the repurchase of 0.4 million shares of our common stock through open market transactions.

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 devote substantial resources to expand procedure adoption and acceptance of our products. We have made substantial investments in our commercial operations, 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 beyond one year and for the foreseeable future.

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Contractual Obligations and Commercial Commitments

The following table summarizes our contractual obligations as of December 31, 2014 (in millions):

	Payments due by period			
	Total	Less than 1 year	1 to 3 years	3 to 5 years
Operating leases	$10.8	$5.1	$5.1	$0.6
Purchase commitments and obligations	251.5	250.0	1.5	—
Total contractual obligations	$262.3	$255.1	$6.6	$0.6

Operating leases. We lease office spaces in the U.S., Switzerland, Mexico, Japan, Brazil, China, and Korea. We also lease automobiles for certain sales and field service employees. Operating lease amounts include future minimum lease payments under all our non-cancellable operating leases with an initial term in excess of one year.

Purchase commitments and obligations. These amounts include an estimate of all open purchase orders and contractual obligations in the ordinary course of business, including commitments with contract manufacturers and suppliers, for which we have not received the goods or services and acquisition and licensing of intellectual property. A majority of these purchase obligations are due within a year. Although open purchase orders are considered enforceable and legally binding, the terms generally allow us the option to cancel, reschedule, and adjust our requirements based on our business needs prior to the delivery of goods or performance of services. 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, 2014, 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 U.S. generally accepted accounting principles ("U.S. GAAP"), which requires us to make judgments, estimates and assumptions. See "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," which describes our significant accounting policies and methods used in the preparation of our Consolidated Financial Statements. The methods, estimates and judgments that we use in applying our accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates regarding matters that are inherently uncertain. Our most critical accounting estimates include:

- the valuation and recognition of investments, which impacts our investment portfolio balance when we assess fair value, and interest and other income, net, when we record impairments;
- the valuation of revenue and allowance for sales returns and doubtful accounts, which impacts revenue;
- the estimation of transactions to hedge, which impacts revenue and other expense;
- the valuation of inventory, which impacts gross profit margins;
- the assessment of recoverability of intangible assets and their estimated useful lives, which primarily impacts gross profit margin or operating expenses when we record asset impairments or accelerate their amortization;
- the valuation and recognition of share-based compensation, which impacts gross profit margin and operating expenses;
- the recognition and measurement of current and deferred income taxes (including the measurement of uncertain tax positions), which impact our provision for taxes; and
- the estimate of probable loss associated with product liability claims, which impacts accrued liabilities and operating expenses.

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Investments Valuation

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 investments can be difficult and subjective. U.S. GAAP establishes three levels of inputs that may be used to measure fair value. 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. During the year ended December 31, 2014, the Level 3 securities were redeemed. There were no other Level 3 securities as of December 31, 2014.

Other-than-temporary impairment

After determining the fair value of our available-for-sales 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 we considered in classifying impairments as either temporary or 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.

During the year ended December 31, 2014, we recorded pre-tax losses of $8.5 million related to a decline in the value of two equity investments that we concluded were other-than-temporary. No significant impairment charges were recorded during the years ended December 31, 2013, and 2012. As of December 31, 2014, and 2013, net unrealized losses on investments of $0.2 million, net of tax and net unrealized gains on investments of $1.7 million, net of tax, respectively, were included in accumulated other comprehensive income (loss).

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, we make estimates of the collectibility of accounts receivable, especially analyzing the aging and nature of 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 an 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.

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 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 OCI to net income.

Inventory valuation. Inventory is stated at the lower of cost or market, with cost determined on a first-in, first-out basis. The cost basis of our inventory is reduced for any products that are considered excessive or obsolete based upon

assumptions about future demand and market conditions. If actual future demand or market conditions are less favorable than those projected by management, additional inventory write-downs may be required, which could have a material adverse effect on the results of our operations.

Intangible Assets. Our intangible assets include identifiable intangibles and goodwill. Identifiable intangibles include developed technology, patents, distribution rights, customer relationships, 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.

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Identifiable intangible assets with finite lives are subject to impairment testing and are reviewed for impairment when events or circumstances indicate that the carrying value of an asset is not recoverable and its carrying amount exceeds its fair value. We evaluate the recoverability of the carrying value of these identifiable intangible assets 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.

The valuation and classification of intangible assets and goodwill and the assignment of useful lives for purposes of amortization 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 the assumptions made. When we determine that the useful lives of assets are shorter than we had originally estimated, we accelerate the rate of amortization over the assets' new, shorter useful lives. No impairment charge or accelerated amortization was recorded for the years ended December 31, 2014, 2013, and 2012. 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. Our system sale arrangements contain multiple elements, including system(s), system accessories, instruments, accessories, and system service. We generally deliver all of the elements, other than service, within days of entering into the system sale arrangement. Each of these elements is a separate unit of accounting. System accessories, instruments, accessories, and service are also sold on a stand-alone basis.

For multiple-element arrangements, revenue is allocated to each unit of accounting based on their relative selling prices. Relative selling prices are based first on vendor specific objective evidence of fair value ("VSOE"), then on third-party evidence of selling price ("TPE") when VSOE does not exist, and then on management's best estimate of the selling price ("ESP") when VSOE and TPE do not exist.

Our system sale arrangements generally include a one-year period of free service, and the right for the customer to purchase service annually after that for up to four years at a stated service price. The revenue allocated to the free service period is deferred and recognized ratably over the free service period.

Because we have neither VSOE nor TPE for our systems, the allocation of revenue is based on ESP for the systems sold. The objective of ESP is to determine the price at which we would transact a sale, had the product been 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 regularly review ESP and maintain internal controls over establishing and updating these estimates.

Accounting for stock options. We account for share-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 most significantly affect the grant date fair value of stock options. Changes in expected risk-free rate of return do not significantly impact the calculation of fair value, and determining this input is not highly subjective.

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

- the sufficiency of the trading volume of freely traded options;
- the ability to reasonably match the terms, such as the date of the grant and the exercise price of the freely traded options to options granted; and
- the length of the term of the freely traded options used to derive implied volatility.

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 exercise. We determine expected term based on historical exercise patterns and our expectation of the time it will take for employees to exercise options still outstanding.

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.

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Changes in these subjective assumptions can materially affect the estimate of fair value of stock options and, consequently, the related amount of share-based compensation expense 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. As of December 31, 2014, we believe it is more likely than not that our deferred tax assets ultimately will be recovered with the exception of our California deferred tax assets. We believe that due to the computation of California taxes under the single sale factor, it is more likely than not that our California deferred tax assets will not be realized. Should there be a change in our ability to recover our deferred tax assets, our tax provision would be affected 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 re-evaluate these uncertain tax positions on a quarterly basis. This evaluation is based on factors including, but not limited to, changes in facts or circumstances, changes in tax law, effective settlement of audit issues, and new audit activity. Such a change in recognition or measurement would result in the recognition of a tax benefit or an additional charge to the tax provision.

Accounting for legal contingencies. We are involved in a number of legal proceedings involving product liability, intellectual property, shareholder derivative actions, securities class actions, and other matters. We record a liability and related charge to earnings in our consolidated financial statements for legal contingencies when the loss is considered probable and the amount can be reasonably estimated. Our assessment is reevaluated each accounting period and is based on all available information, including discussion with any outside legal counsel that represents us. If a reasonable estimate of a known or probable loss cannot be made, but a range of probable losses can be estimated, the low-end of the range of losses is recognized if no amount within the range is a better estimate than any other. If a loss is reasonably possible, but not probable and can be reasonably estimated, the estimated loss or range of loss is disclosed in the notes to the consolidated financial statements.

When determining the estimated probable loss or range of losses, significant judgment is required to be exercised in order to estimate the amount and timing of the loss to be recorded. Estimates of probable losses resulting from litigation are inherently difficult to make, particularly when the matters are in early procedural stages with incomplete facts and information. The final outcome of legal proceedings is dependent on many variables difficult to predict, and therefore, the ultimate cost to entirely resolve such matters may be materially different than the amount of current estimates. Consequently, new information or changes in judgments and estimates could have a material adverse effect on our business, financial condition, and results of operations or cash flows. See Note 7 Commitments and Contingencies for discussion of the charges recorded during fiscal 2014 related to our best estimate of probable loss associated with product liability claims.

RECENT ACCOUNTING PRONOUNCEMENTS

See “Note 2. 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 estimated effects, if any on our consolidated financial statements.

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. The securities are classified as available-for-sale and consequently are recorded 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 as of December 31, 2014 was approximately 1.4 years. If interest rates rise, the market value of our investments may decline,

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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 $7.5 million as of December 31, 2014. We do not utilize derivative financial instruments to manage our interest rate risks.

The uncertain financial markets have 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.

Foreign Exchange Risk

The majority of our revenue, expense, and capital purchasing activities are transacted in U.S. dollars. However, we sell in local currency in most of the European markets where we sell direct, as well as in Japan, and in Korea. We operate in a number of markets on a direct sales basis and incur operating expenses in local currencies in Europe, Japan, and Korea. We also purchase certain product components from non-U.S. suppliers in local currency. As a result, because a portion of our operations consist of sales activities outside of the U.S., we have foreign exchange exposures to non-U.S. dollar revenues, operating expenses, accounts receivable, accounts payable, and foreign currency bank balances.

For the year ended December 31, 2014, sales denominated in foreign currencies (Euro, British Pound, Japanese Yen, and Korean Won) were approximately 16% of total revenue. The objective of our hedging program is 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, 2014, our revenue would have decreased by approximately $3.6 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 to which we have exposure, after taking into account hedges and offsetting positions as of December 31, 2014, would have resulted in a $7.2 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 ongoing assessment of counterparty risk, we will adjust our exposure to various counterparties.

Although we sell to distributors outside the U.S. in U.S. dollars, strengthening of the dollar can impact our distributors' margins and could impact the end customers' ability to purchase our product if our distributors seek to recover the impact of the change in the dollar by increasing product and service prices. Less than 10% of our revenue is conducted through distributors outside the U.S. Strengthening of the dollar relative to non-U.S. currencies could have an adverse impact on our business.

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.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index To Consolidated Financial Statements

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Intuitive Surgical, Inc.

In our opinion, the accompanying consolidated balance sheet of Intuitive Surgical, Inc. as of December 31, 2014 and the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for the year then ended present fairly, in all material respects, the financial position of Intuitive Surgical, Inc. and its subsidiaries at December 31, 2014, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule for the year ended December 31, 2014 listed in the accompanying index presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements, on the financial statement schedule and on the Company's internal control over financial reporting based on our integrated 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 the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audit of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

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 (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 (iii) 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.

/s/ PricewaterhouseCoopers LLP

San Jose, California
February 5, 2015

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REPORT OF ERNST & YOUNG - INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheet of Intuitive Surgical, Inc. as of December 31, 2013, and the related consolidated statements of income, comprehensive income, stockholders' equity, and cash flows for the two years ended December 31, 2013. 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, 2013, and the consolidated results of its operations and its cash flows for the two years ended December 31, 2013, 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.

/s/ ERNST & YOUNG LLP

San Francisco, California
February 5, 2015

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

	December 31, 2014	2013
ASSETS		
Current assets:		
Cash and cash equivalents	$600.3	$782.1
Short-term investments	632.2	621.4
Accounts receivable, net of allowances of $0.3 and $0.5 at December 31, 2014 and 2013, respectively	315.1	301.4
Inventories	181.7	179.6
Prepaids and other current assets	82.6	38.3
Deferred tax assets	35.1	9.6
Total current assets	1,847.0	1,932.4
Property, plant and equipment, net	387.4	309.9
Long-term investments	1,264.5	1,350.4
Long-term deferred tax asset	136.2	126.1
Intangible and other assets, net	126.3	94.1
Goodwill	198.0	137.4
Total assets	$3,959.4	$3,950.3
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$61.6	$46.2
Accrued compensation and employee benefits	96.2	70.7
Deferred revenue	216.6	200.1
Other accrued liabilities	126.8	63.9
Total current liabilities	501.2	380.9
Other long-term liabilities	78.8	68.0
Total liabilities	580.0	448.9
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, 2014 and December 31, 2013, respectively	—	—
Common stock, 100.0 shares authorized, $0.001 par value, 36.6 shares and 38.2 shares issued and outstanding as of December 31, 2014 and December 31, 2013, respectively	—	—
Additional paid-in capital	2,896.8	2,519.9
Retained earnings	487.7	979.4
Accumulated other comprehensive income (loss)	(5.1)	2.1
Total stockholders' equity	3,379.4	3,501.4
Total liabilities and stockholders' equity	$3,959.4	$3,950.3

See accompanying Notes to Consolidated Financial Statements.

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

	Years Ended December 31,		
	2014	2013	2012
Revenue:			
Product	$1,702.7	$1,867.8	$1,836.2
Service	429.0	397.3	342.6
Total revenue	2,131.7	2,265.1	2,178.8
Cost of revenue:			
Product	569.9	543.4	495.3
Service	148.0	127.5	113.2
Total cost of revenue	717.9	670.9	608.5
Gross profit	1,413.8	1,594.2	1,570.3
Operating expenses:			
Selling, general and administrative	691.0	574.0	522.2
Research and development	178.0	167.7	170.0
Total operating expenses	869.0	741.7	692.2
Income from operations	544.8	852.5	878.1
Interest and other income, net	4.2	18.4	15.8
Income before taxes	549.0	870.9	893.9
Income tax expense	130.2	199.9	237.3
Net income	$418.8	$671.0	$656.6
Net income per share:			
Basic	$11.35	$17.12	$16.50
Diluted	$11.11	$16.73	$15.98
Shares used in computing net income per share:			
Basic	36.9	39.2	39.8
Diluted	37.7	40.1	41.1

See accompanying Notes to Consolidated Financial Statements.

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INTUITIVE SURGICAL, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(IN MILLIONS)

	Years Ended December 31,		
	2014	2013	2012
Net income	$418.8	$671.0	$656.6
Other comprehensive income (loss):			
Change in foreign currency translation gains (losses)	(2.5)	—	0.6
Available-for-sale investments:			
Change in unrealized gains (losses), net of tax	(3.9)	(3.9)	5.0
Less: Reclassification adjustment for net gains (losses) on investments recognized during the year, net of tax	2.0	(0.6)	0.1
Net change, net of tax effect	(1.9)	(4.5)	5.1
Derivative instruments:			
Change in unrealized gains (losses)	8.6	(1.8)	(1.1)
Less: Reclassification adjustment for gains (losses) on derivative instruments recognized during the year, net of tax	(7.5)	1.8	1.1
Net change, net of tax effect	1.1	—	—
Employee benefit plans:			
Change in unrealized losses	(4.2)	—	—
Less: Reclassification adjustment for gains (losses) on employee benefit plans recognized during the year, net of tax	0.3	—	—
Net change, net of tax effect	(3.9)	—	—
Other comprehensive income (loss)	(7.2)	(4.5)	5.7
Total comprehensive income	$411.6	$666.5	$662.3

See accompanying Notes to Consolidated Financial Statements.

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INTUITIVE SURGICAL, INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(IN MILLIONS)

	Common Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income (loss)	Total
	Shares	Amount				
Balances at December 31, 2011	39.3	$—	$1,742.8	$901.9	$ 0.9	$2,645.6
Issuance of common stock upon exercise of options and under stock purchase plan	1.3		263.3			263.3
Income tax benefit from employee stock plans			93.9			93.9
Share-based compensation expense related to employee stock plans			153.3			153.3
Repurchase and retirement of common stock	(0.4)		(13.2)	(225.1)		(238.3)
Net income				656.6		656.6
Other comprehensive income					5.7	5.7
Balances at December 31, 2012	40.2	$—	$2,240.1	$1,333.4	$ 6.6	$3,580.1
Issuance of common stock upon exercise of options and under stock purchase plan	0.6		160.6			160.6
Income tax benefit from employee stock plans			34.5			34.5
Share-based compensation expense related to employee stock plans			168.9			168.9
Repurchase and retirement of common stock	(2.6)		(84.2)	(1,025.0)		(1,109.2)
Net income				671.0		671.0
Other comprehensive loss					(4.5)	(4.5)
Balances at December 31, 2013	38.2	$—	$2,519.9	$979.4	$ 2.1	$3,501.4
Issuance of common stock upon exercise of options and under stock purchase plan	0.9		283.6			283.6
Income tax benefit from employee stock plans			13.9			13.9
Share-based compensation expense related to employee stock plans			168.9			168.9

Repurchase and retirement of common stock	(2.5)		(89.5)	(910.5)		(1,000.0)
Net income				418.8		418.8
Other comprehensive loss					(7.2)	(7.2)
Balances at December 31, 2014	36.6	$—	$2,896.8	$487.7	$ (5.1)	$3,379.4

See accompanying Notes to Consolidated Financial Statements.

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

	Years Ended December 31,		
	2014	2013	2012
Operating activities:			
Net income	$418.8	$671.0	$656.6
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	52.0	46.0	34.7
Amortization of intangible assets	22.4	21.3	23.1
Loss of investment, accretion of discounts and amortization of premiums on investments, net	33.9	36.8	33.1
Deferred income taxes	(35.0)	(38.5)	(20.8)
Income tax benefits from employee stock plans	13.9	34.5	93.9
Excess tax benefit from employee stock plans	(24.0)	(38.0)	(94.2)
Share-based compensation expense	168.9	168.9	153.3
Changes in operating assets and liabilities, net of effects of acquisition:			
Accounts receivable	(13.7)	68.9	(68.9)
Inventories	(26.8)	(70.0)	(7.1)
Prepaids and other assets	(67.6)	(5.0)	(37.1)
Accounts payable	17.7	(8.9)	8.4
Accrued compensation and employee benefits	21.4	(33.3)	21.0
Deferred revenue	19.8	15.2	30.5
Other liabilities	63.4	11.1	(12.3)
Net cash provided by operating activities	665.1	880.0	814.2
Investing activities:			
Purchase of investments	(1,344.6)	(1,443.7)	(1,833.9)
Proceeds from sales of investments	665.9	984.9	329.8
Proceeds from maturities of investments	714.7	822.4	800.2
Purchase of property, plant and equipment, intellectual property	(105.6)	(104.6)	(114.2)
Acquisition of business, net of cash acquired	(84.3)	—	(27.6)
Net cash provided by (used in) investing activities	(153.9)	259.0	(845.7)
Financing activities:			
Proceeds from issuance of common stock	283.6	160.6	263.3
Excess tax benefit from employee stock plans	24.0	38.0	94.2
Repurchase and retirement of common stock	(1,000.0)	(1,109.2)	(238.3)
Net cash (used in) provided by financing activities	(692.4)	(910.6)	119.2
Effect of exchange rate changes on cash and cash equivalents	(0.6)	—	0.2
Net increase (decrease) in cash and cash equivalents	(181.8)	228.4	87.9
Cash and cash equivalents, beginning of year	782.1	553.7	465.8
Cash and cash equivalents, end of year	$600.3	$782.1	$553.7

See accompanying Notes to Consolidated Financial Statements.

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INTUITIVE SURGICAL, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. DESCRIPTION OF THE BUSINESS

Intuitive Surgical, Inc. designs, manufactures, and markets da Vinci® Surgical Systems and related instruments and accessories, which taken together, are advanced surgical systems, The Company believes these surgical systems enable a new generation of surgery. This advanced generation of surgery, which the Company calls da Vinci Surgery, combines the benefits of minimally invasive surgery ("MIS") for patients with the ease of use, precision and dexterity of open surgery. A da Vinci Surgical System consists of a surgeon's console, a patient-side cart and a high performance vision system. The da Vinci Surgical System translates a 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. The da Vinci Surgical System is designed to provide its operating surgeons with intuitive control, range of motion, fine tissue manipulation capability and Three Dimensional ("3-D"), High-Definition ("HD") vision while simultaneously allowing surgeons to work through the small ports enabled by MIS procedures.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying 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 the 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, revenue recognition, the valuation and recognition of share-based compensation, the recognition and measurement of current and deferred income tax assets and liabilities, and the legal contingencies estimate. 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 throughout the world. 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, 2014, and 2013, 64% and 66%, respectively, of accounts receivable were from domestic customers. No single customer represented more than 10% of net accounts receivable as of December 31, 2014, and 2013.

During the years ended December 31, 2014, 2013, and 2012, domestic revenue accounted for 70%, 72%, and 79%, respectively, of total revenue, while international revenue accounted for 30%, 28%, and 21%, respectively, of total revenue for each of the years then ended. No single customer represented more than 10% of total revenue for the years ended December 31, 2014, 2013, and 2012.

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, 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

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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 extent and length of time the investment's fair value has been lower than its 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 prior the expected recovery of the investment's amortized cost basis. During the year ended December 31, 2014, the Company recorded pre-tax other-than-temporary losses of $8.5 million related to equity investments, while there were no such charges during the years ended December 31, 2013, and 2012.

Fair Value Measurements

The Company measures the fair value of money market funds, corporate equity securities and certain debt securities based on quoted prices in active markets for identical assets as Level 1 securities. Marketable securities, measured at fair value using Level 2 inputs, are primarily comprised of U.S. government agencies and FDIC guaranteed securities and corporate debt securities. The Company reviews trading activity and pricing for these investments as of the measurement date. When sufficient quoted pricing for identical securities is not available, the Company uses market pricing and other observable market inputs for similar securities obtained from various third party data providers. These inputs either represent quoted prices for similar assets in active markets or have been derived from observable market data. This approach results in the Level 2 classification of these securities within the fair value hierarchy. Where Level 1 and Level 2 inputs are not available, the Company used a discounted cash flow model based on data available, including interest rates, timing and amount of cash flows, credit and liquidity premiums, and expected holding period for Level 3 securities. The only Level 3 securities consist of municipal bonds with auction rate securities ("ARS") whose underlying assets are student loans which are substantially backed by the federal government. Because the auctions for these securities have continued to fail since February 2008, these investments were not actively traded and therefore did not have a readily determinable market value. During the year ended December 31, 2014, the ARS were redeemed at par value.

Inventories

Inventory is stated at the lower of cost or market on a first-in, first-out basis. Inventory costs include direct materials, direct labor, and normal manufacturing overhead. The cost basis of the Company's inventory is reduced for any products that are considered excessive or obsolete based upon assumptions about future demand and market conditions.

Property, Plant and Equipment

Property, plant and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed 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, 2014, 2013, and 2012 was $52.0 million, $46.0 million, and $34.7 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 $12.0 million and $6.6 million during the years ended December 31, 2014 and 2013, respectively. Upon being placed in service, these costs are depreciated over an estimated useful life of up to 5 years.

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Goodwill and Intangible Assets

Goodwill and intangible assets with indefinite useful lives are not amortized, but are tested for impairment at least annually during the fourth fiscal quarter, or as circumstances indicate their value may no longer be recoverable. Goodwill represents the excess of the purchase price over the fair value of net tangible and identifiable intangible assets. 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, 2014, there has been no impairment of goodwill.

The Company does not have intangible assets with indefinite useful lives other than goodwill. 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 on a straight-line basis over the intangible assets' useful lives, which range from approximately 1 to 9 years.

Impairment of Long-lived assets

The Company evaluates long-lived assets, which include amortizable intangible and tangible 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 material impairment losses were incurred in the periods presented.

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 persuasive evidence of an arrangement exists, delivery has occurred or service has been rendered, the price is fixed or determinable, and collectability is reasonably assured. Revenue is presented net of taxes collected from customers that are remitted to government authorities. The Company generally recognizes revenue at the following points in time:

•System sales. For systems sold directly to end customers, revenue is recognized when acceptance occurs, which is deemed to have occurred upon customer acknowledgment of delivery or installation, depending on the terms of the arrangement. For systems sold through distributors, revenue is recognized when title and risk of loss has transferred, which generally occurs at the time of shipment. Distributors do not have price protection rights and the Company's system arrangements generally do not provide a right of return. The da Vinci Surgical Systems are delivered with a software component. However, because the software and non-software elements function together to deliver the system's essential functionality, the Company's arrangements are excluded from being accounted for under software revenue recognition guidance.

•Instruments and accessories. Revenue from sales of instruments and accessories is generally recognized at the time of shipment. The Company allows its customers in the normal course of business to return unused products for a limited period of time subsequent to initial purchase and records an allowance against revenue recognized based on historical experience.

•Service. Service 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 offers its customers the opportunity to trade in their older systems for credit towards the purchase of a newer generation system. The Company generally does not provide specified price trade-in rights or upgrade rights at the time of system purchase. Such trade-in or upgrade transactions are separately negotiated based on the circumstances at the time of the trade-in or upgrade, based on the then fair value of the system, and are generally not based on any pre-existing rights granted by the Company. Accordingly, such trade-ins and upgrades are not considered as separate deliverables in the arrangement for a system sale.

As part of a trade-in transaction, the customer receives a new generation system in exchange for its pre-owned system. The trade-in credit is negotiated at the time of the trade-in and is applied towards the purchase price of the new generation unit. Traded-in systems can be reconditioned and resold. The Company accounts for trade-ins consistent with the guidance in AICPA Technical Practice Aid 5100.01, Equipment Sales Net of Trade-Ins ("TPA 5100.01"). The Company applies the accounting guidance by crediting system revenue for the negotiated price of the new generation system, while the difference between (a) the trade-in allowance and (b) the net realizable value of the traded-in system

less a normal profit margin is treated as a sales allowance. The value of the traded-in system is determined as the amount, after reconditioning costs are added, that will allow a normal profit margin on the sale of the reconditioned unit to be generated. When there is no market for the traded-in units, no value is assigned. Traded-in units are reported as a component of inventory until reconditioned and resold, or otherwise disposed.

In addition, customers may also have the opportunity to upgrade their systems, for example, by adding a fourth arm to a three-arm system, adding a second surgeon console for use with the da Vinci Si™ and Xi™ Surgical System or adding new vision systems to the standard da Vinci and da Vinci S™ Surgical Systems. Such upgrades are performed by completing component level upgrades at the customer's site. Upgrade revenue is recognized when the component level upgrades are complete and all revenue recognition criteria are met.

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The Company's system sale arrangements contain multiple elements including a system(s), system accessories, instruments, accessories, and system service. The Company generally delivers all of the elements, other than service, within days of entering into the system sale arrangement. Each of these elements is a separate unit of accounting. System accessories, instruments, accessories and service are also sold on a stand-alone basis.

For multiple-element arrangements, revenue is allocated to each unit of accounting based on their relative selling prices. Relative selling prices are based first on vendor specific objective evidence of fair value (“VSOE”), then on third-party evidence of selling price (“TPE”) when VSOE does not exist, and then on management's best estimate of the selling price (“ESP”) when VSOE and TPE do not exist.

The Company’s system sale arrangements generally include a one-year period of free service, and the right for the customer to purchase service annually after that for up to four years at a stated service price. The revenue allocated to the free service period is deferred and recognized ratably over the free service period.

Because the Company has neither VSOE nor TPE for its systems, the allocation of revenue is based on ESP for the systems sold. The objective of ESP is to determine the price at which the Company would transact a sale, had the product been sold on a stand-alone basis. The Company determines ESP for its systems by considering 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 establishing and updating these estimates.

Leases

The Company enters into sales-type lease and operating lease arrangements with certain qualified customers to purchase or rent its systems. Sales-type leases have on average a 5-year term and are usually collateralized by a security interest in the underlying assets. Revenue related to multiple-element arrangements are allocated to lease and non-lease elements based on their relative selling prices as prescribed by the Company's revenue recognition policy. Lease elements generally include a da Vinci Surgical System, while non-lease elements generally include service, instruments and accessories. In determining whether a transaction should be classified as a sales-type or operating lease, the Company considers the following terms: (1) whether title of the system transfers automatically or for a nominal fee at the end of the term of the lease, (2) whether the present value of the minimum lease payments are equal to or greater than 90% of the fair market value of the system at the inception of the lease, (3) whether the life of the lease exceeds 75% of the life of the asset, and (4) whether there is an option to purchase the asset at a "bargain price" at the end of the lease term.

The Company generally recognizes revenue from sales-type lease arrangements at the time the system is accepted by the customer, assuming all other revenue recognition criteria have been met. Revenue from sales-type leases is presented as product revenue. Revenue from operating lease arrangements is recognized as earned over the lease term, which is generally on a straight-line basis and is presented as product revenue. Revenue from operating lease arrangements was not material in any of the periods presented.

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

Share-Based Compensation

The Company accounts for share-based employee compensation plans using the fair value recognition and measurement provisions under U.S. GAAP. The Company’s share-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.

Expected Term: The expected term represents the weighted-average period that the stock options are expected to be outstanding prior to being exercised. The Company determines expected term based on historical exercise patterns and its expectation of the time it will take for employees to exercise options still outstanding.

Expected Volatility: The Company uses market-based implied volatility for purposes of valuing options granted. Market-based implied volatility is derived based on at least one-year traded options on the Company's common stock. The extent to which the Company relies on market-based volatility when valuing options, depend among other things, on the availability of traded options on the Company's stock and the term of such options. Due to sufficient volume of the traded options, the Company used 100% market-based implied volatility to value options granted, which the Company believes is more representative of future stock price trends than historical volatility.

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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.

The fair value of restricted stock units is determined based on the closing quoted price of the Company's common stock on the day of the grant. See “Note 9. Share-Based Compensation,” for a detailed discussion of the Company's share-based employee compensation plans and share-based compensation expense.

Computation of Net Income per Share

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

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.

Research and Development Expenses

Research and development 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 period. 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 Consolidated Balance Sheets at fair value. The effective portions of cash flow hedges are recorded in other comprehensive income (loss) (“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.

The Company recognizes tax benefits from uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such positions are then measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement.

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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, 2014 and 2013, 93% and 94% of all long-lived assets were in the United States. For the years ended December 31, 2014, 2013, and 2012, 70%, 72%, and 79%, respectively, of net revenue were generated in the United States.

Legal Contingencies

The Company is involved in a number of legal proceedings involving product liability, intellectual property, shareholder derivative actions, securities class actions, and other matters. A liability and related charge are recorded to earnings in the Company's consolidated financial statements for legal contingencies when the loss is considered probable and the amount can be reasonably estimated. The assessment is reevaluated each accounting period and is based on all available information, including discussion with outside legal counsel. If a reasonable estimate of a known or probable loss cannot be made, but a range of probable losses can be estimated, the low-end of the range of losses is recognized if no amount within the range is a better estimate than any other. If a loss is reasonably possible, but not probable and can be reasonably estimated, the estimated loss or range of loss is disclosed in the notes to the consolidated financial statements. The Company expenses legal fees as incurred.

When determining the estimated probable loss or range of losses, significant judgment is required to be exercised in order to estimate the amount and timing of the loss to be recorded. Estimates of probable losses resulting from litigation are inherently difficult to make, particularly when the matters are in early procedural stages with incomplete facts and information. The final outcome of legal proceedings is dependent on many variables difficult to predict, and therefore, the ultimate cost to entirely resolve such matters may be materially different than the amount of current estimates. Consequently, new information or changes in judgments and estimates could have a material adverse effect on the Company's business, financial condition, and results of operations or cash flows.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Updates No. 2014-09, Revenue from Contracts with Customers, requiring an entity to recognize the amount of revenue to which it expects to be entitled to for the transfer of promised goods or services to customers. The updated standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. Early adoption is not permitted. The updated standard becomes effective for the Company in the first quarter of fiscal year 2017. The Company has not yet selected a transition method and is currently evaluating the effect that the updated standard will have on the Consolidated Financial Statements and related disclosures.

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NOTE 3. FINANCIAL INSTRUMENTS

Cash, Cash Equivalents and Investments

The following tables summarize the Company's cash and available-for-sale securities' amortized cost, gross unrealized gains, gross unrealized losses, and fair value by significant investment category recorded as cash and cash equivalents or short-term or long-term investments as of December 31, 2014, and 2013 (in millions):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Cash and Cash Equivalents	Short-term Investments	Long-term Investments
December 31, 2014							
Cash	$227.7	$—	$—	$227.7	$227.7	$—	$—
Level 1:							
Money market funds	324.4	—	—	324.4	324.4	—	—
U.S. treasuries & corporate equity securities	46.1	—	(0.1)	46.0	—	19.3	26.7
Subtotal	370.5	—	(0.1)	370.4	324.4	19.3	26.7
Level 2:							
Commercial paper	120.5	—	—	120.5	48.2	72.3	—
Corporate securities	904.8	1.3	(1.6)	904.5	—	241.7	662.8
U.S. government agencies	446.0	0.3	(0.4)	445.9	—	105.6	340.3
Non-U.S. government securities	42.2	—	(0.1)	42.1	—	26.1	16.0
Municipal securities	385.4	0.7	(0.2)	385.9	—	167.2	218.7
Subtotal	1,898.9	2.3	(2.3)	1,898.9	48.2	612.9	1,237.8
Total assets measured at fair value	$2,497.1	$2.3	$(2.4)	$2,497.0	$600.3	$632.2	$1,264.5

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Cash and Cash Equivalents	Short-term Investments	Long-term Investments
December 31, 2013							
Cash	$247.8	$—	$—	$247.8	$247.8	$—	$—
Level 1:							
Money market funds	516.2	—	—	516.2	516.2	—	—
U.S. treasuries & corporate equity securities	65.4	—	(0.3)	65.1	—	25.5	39.6
Subtotal	581.6	—	(0.3)	581.3	516.2	25.5	39.6
Level 2:							
Commercial paper	100.2	—	—	100.2	18.1	82.1	—
Corporate securities	844.7	2.9	(1.9)	845.7	—	227.7	618.0
U.S. government agencies	352.2	0.7	(0.7)	352.2	—	84.7	267.5
Non-U.S. government securities	67.7	0.2	(0.1)	67.8	—	41.2	26.6
Municipal securities	550.1	1.5	(0.1)	551.5	—	160.2	391.3
Subtotal	1,914.9	5.3	(2.8)	1,917.4	18.1	595.9	1,303.4
Level 3:							
Auction rate securities	8.0	—	(0.6)	7.4	—	—	7.4
Subtotal	8.0	—	(0.6)	7.4	—	—	7.4
Total assets measured at fair value	$2,752.3	$5.3	$(3.7)	$2,753.9	$782.1	$621.4	$1,350.4

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The following table summarizes the contractual maturities of the Company's cash equivalents and available-for-sale investments (excluding cash and money market funds), at December 31, 2014 (in millions):

	Amortized Cost	Fair Value
Mature in less than one year	$676.7	$677.4
Mature in one to five years	1,265.4	1,264.5
Mature in after five years	—	—
Total	$1,942.1	$1,941.9

Realized gains and losses, net of tax, were not material for any of the periods presented.

As of December 31, 2014, and 2013, net unrealized loss on investments of $0.2 million, net of tax, and net unrealized gains on investments of $1.7 million, net of tax, were included in accumulated other comprehensive income (loss) in the accompanying Consolidated Balance Sheets.

The following tables present the breakdown of the available-for-sale investments with unrealized losses at December 31, 2014, and 2013 (in millions):

	Unrealized losses less than 12 months		Unrealized losses 12 months or greater		Total	
December 31, 2014	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate securities	$456.7	$(1.3)	$16.9	$(0.2)	$473.6	$(1.5)
U.S. government and agency securities	239.1	(0.4)	31.8	(0.2)	270.9	(0.6)
Municipal securities	91.3	(0.2)	—	—	91.3	(0.2)
Non-U.S. government securities	20.9	(0.1)			20.9	(0.1)
	$808.0	$(2.0)	$48.7	$(0.4)	$856.7	$(2.4)
December 31, 2013						
Corporate securities	$245.3	$(1.9)	$9.5	$—	$254.8	$(1.9)
U.S. government and agency securities	142.8	(1.0)	—	—	142.8	(1.0)
Municipal securities	37.6	(0.1)	—	—	37.6	(0.1)
Non-U.S. government securities	18.7	(0.1)	—	—	18.7	(0.1)
Auction rate securities	—	—	7.4	(0.6)	7.4	(0.6)
	$444.4	$(3.1)	$16.9	$(0.6)	$461.3	$(3.7)

The unrealized losses on the available-for-sale investments are related to corporate securities and government securities. The Company determined these unrealized losses to be temporary. Factors considered in determining whether a loss is temporary included the length of time and extent to which the investment's 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.

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The following table provides reconciliation for all assets measured at fair value using significant unobservable Level 3 inputs for the years ended December 31, 2014, 2013, and 2012 (in millions):

	Fair Value Measurements at Reporting Date Using Significant Unobservable Inputs (Level 3)
	Auction rate securities
Balance at January 1, 2012	$ 16.4
Sales	(12.0)
Total gains:	
Included in other comprehensive income	3.0
Included in earnings	—
Balance at December 31, 2012	$ 7.4
Sales	—
Total gains:	
Included in other comprehensive income	—
Included in earnings	—
Balance at December 31, 2013	$ 7.4
Sales	(8.0)
Total gains:	
Included in other comprehensive income	0.6
Included in earnings	—
Balance at December 31, 2014	$ —

There were no transfers between Level 1 and Level 2 measurements during the year ended December 31, 2014, and there were no changes in the valuation techniques used. The Level 3 assets consisted of municipal bonds with auction rate securities ("ARS") that were sold at par value of $8.0 million in April 2014.

Foreign currency derivative

The objective of the Company’s hedging program is to mitigate the impact of changes in currency exchange rates on net cash flow from foreign currency denominated sales and intercompany balances and other monetary assets or liabilities denominated in currencies other than the U.S. dollar ("USD"). The derivative assets and liabilities are measured using Level 2 fair value inputs.

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 USD, primarily the European Euro (“EUR”), the British Pound (“GBP”), the Japanese Yen (“JPY”), and the Korean Won (“KRW”).

For these derivatives, the Company reports the after-tax gain or loss from the hedge as a component of accumulated other comprehensive income (loss) in stockholders' equity and reclassifies into earnings in the same period in which the hedge transaction affects earnings. The Company reclassified net gains of $7.5 million to revenue related to the hedged revenue transactions for the years ended December 31, 2014, while the net gains/losses reclassified for the year ended December 31 2013, and 2012 were not significant.

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 USD, primarily the EUR, GBP, JPY, KRW, and the Swiss Franc (“CHF”).

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Derivative instruments used to hedge against balance sheet foreign currency exposures at the end of each period were as follows (in millions):

	Years Ended December 31,		
	2014	2013	2012
Recognized gains (losses) in interest and other income, net	$5.7	$(3.4)	$(0.3)
Foreign exchange gains (losses) related to re-measurement	$(6.9)	$3.1	$0.7

The notional amounts for derivative instruments provide one measure of the transaction volume. Total gross notional amounts (in USD) for derivatives and aggregate gross fair value outstanding at the end of each period were as follows (in millions):

	Derivatives Designated as Hedging Instruments		Derivatives Not Designated as Hedging Instruments	
	December 31, 2014	December 31, 2013	December 31, 2014	December 31, 2013
Notional amounts:				
Forward contracts	$7.9	$85.6	$102.1	$119.6
Gross fair value recorded in:				
Prepaid and other current assets	1.1	—	7.9	—
Other accrued liabilities	$—	$—	$0.1	$3.8

NOTE 4. BALANCE SHEET DETAILS AND OTHER FINANCIAL INFORMATION

The following table provides details of the inventories (in millions):

	December 31, 2014	2013
Inventories:		
Raw materials	$60.0	$67.2
Work-in-process	8.7	12.6
Finished goods	113.0	99.8
Total inventories	$181.7	$179.6

The following table provides details of the property, plant and equipment, net (in millions):

	December 31, 2014	2013
Property, plant and equipment, net:		
Land	$131.7	$84.7
Building and building/leasehold improvements	159.0	151.9
Machinery and equipment	181.6	137.2
Computer and office equipment	31.3	27.1
Capitalized software	77.9	66.9
Construction-in-process	28.8	16.4
Gross property, plant and equipment	610.3	484.2
Less: Accumulated depreciation	(222.9)	(174.3)
Total property, plant and equipment, net	$387.4	$309.9

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The following table provides details of the other accrued liabilities—short term (in millions):

	December 31,	
	2014	2013
Other accrued liabilities—short term:		
Taxes payable	$7.4	$5.1
Tolled product liability claims accrued	49.5	—
Other accrued liabilities	69.9	58.8
Total other accrued liabilities—short-term	$126.8	$63.9

The following table provides details of the other long-term liabilities balance sheet item (in millions):

	December 31,	
	2014	2013
Other long-term liabilities:		
Income taxes—long term	$61.8	$64.5
Other long-term liabilities	17.0	3.5
Total other long-term liabilities	$78.8	$68.0

Supplemental Cash flow Information

The following table provides supplemental cash flow information (in millions):

	Years Ended December 31,		
	2014	2013	2012
Income taxes paid	$176.8	$194.1	$226.1
Supplemental non-cash investing activities:			
Equipment transfers from inventories to property, plant and equipment	$27.2	$13.1	$22.3

NOTE 5. LEASE RECEIVABLES

Lease receivables relating to sales-type lease arrangements are presented on the Consolidated Balance Sheets as follows (in millions):

	December 31,	
	2014	2013
Gross lease receivables	$40.4	$10.1
Unearned income	(2.2)	(0.6)
Allowance for credit loss	—	—
Net investment in sales-type leases	38.2	9.5
Reported as:		
Prepaids and other current assets	5.8	1.9
Intangible and other assets, net	32.4	7.6
Total, net	$38.2	$9.5

Contractual maturities of gross lease receivables at December 31, 2014, are as follows (in millions):

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	Amount
2015	7.4
2016	10.4
2017	10.3
2018	9.1
2019	3.2
Thereafter	—
Total	$40.4

NOTE 6. GOODWILL AND INTANGIBLE ASSETS

On January 17, 2014, the Company acquired certain intellectual property, know-how, fixed assets, intangible assets, and employees from Luna Innovations, Inc. (“Luna”). On June 25, 2014, the Company reacquired the Japan distribution rights and intangible assets from Adachi Co., Ltd. (“Adachi”). The acquisition of Japan distribution rights enhances the Company's ability to directly interact with customers, surgical societies, and government agencies in Japan. In both transactions, the assets acquired met the definition of a business and were accounted for using the acquisition method of accounting for financial reporting purposes.

In connection with the Luna acquisition, the Company recognized goodwill of $10.1 million and intangible assets of $9.5 million, which are being amortized over nine years.

In connection with the acquisition of Japan distribution rights, the Company recognized goodwill of $50.5 million, intangible assets related to reacquired distribution rights of $5.5 million, and customer relationships of $17.2 million, which are being amortized over a weighted average period of 1.1 years and 7.0 years, respectively. The purchase consideration consisted of cash of $71.8 million and contingent payments of $1.8 million. Goodwill related to the acquisitions in 2014 is deductible for tax purposes.

Pro forma results of operations related to the acquisitions have not been presented because the operating results of the acquired businesses are not material to the Company's consolidated financial statements.

Goodwill

The Company’s gross carrying amount of goodwill was $198.0 million and $137.4 million as of December 31, 2014, and 2013, respectively.

Intangibles

The following table summarizes the components of gross intangible asset, accumulated amortization, and net intangible asset balances as of December 31, 2014, and 2013 (in millions):

	December 31, 2014			December 31, 2013		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents and developed technology	$162.1	$ (116.8)	$45.3	$155.7	$ (104.5)	$51.2
Distribution rights and others	12.7	(6.5)	6.2	11.2	(6.4)	4.8
Customer relationships	30.0	(7.4)	22.6	12.8	(4.5)	8.3
Total intangible assets	$204.8	$ (130.7)	$74.1	$179.7	$ (115.4)	$64.3

Amortization expense related to intangible assets was $22.4 million, $21.3 million, and $23.1 million for the years ended December 31, 2014, 2013, and 2012, respectively.

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The estimated future amortization expense of intangible assets as of December 31, 2014 is as follows (in millions):

Fiscal Year	Amount
2015	$24.4
2016	18.2
2017	12.4
2018	8.6
2019	3.6
2020 and thereafter	6.9
Total	$74.1

NOTE 7. COMMITMENTS AND CONTINGENCIES

OPERATING LEASES

The Company leases office space in Brazil, China, Japan, Korea, 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, 2014, are as follows (in millions):

Years	Amount
2015	$5.1
2016	3.5
2017	1.6
2018	0.6
2019	—
2020 and thereafter	—
Total	$10.8

Other commitments include an estimated amount of approximately $251.5 million of all open cancellable purchase orders and contractual obligations that occur in the ordinary course of business, including commitments with suppliers, for which we have not received the goods or services.

CONTINGENCIES

The Company is involved in a variety of claims, lawsuits, investigations and proceedings relating to securities laws, product liability, false claims, insurance, and contract disputes. Certain of these lawsuits and claims are described in further detail below. It is not possible to predict what the outcome of these matters will be and the Company cannot guarantee that any resolution will be reached on commercially reasonable terms, if at all. With the exception of the charges recorded related to the Company’s estimate of the probable loss associated with the tolled product liability claims described below, the Company has determined that an estimate of probable loss or range of loss related to material pending or threatened litigation matters cannot be determined as of December 31, 2014. Nevertheless, it is possible that future legal costs (including settlements, judgments, legal fees and other related defense costs) could 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 arise in the ordinary course of business and does not believe that any of these other legal actions will have a material adverse impact on the Company's business, financial position, or future results of operations.

In accordance with U.S. GAAP, the Company records a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. These provisions are reviewed at least quarterly and adjusted to reflect the impact 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 7 of the Company's current and former officers and directors in the United States District Court for the Northern District of California. The lawsuit sought 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 alleged that the defendants

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violated federal securities laws by making allegedly false and misleading statements and omitting certain material facts in filings with the SEC. On February 15, 2011, the Police Retirement System of St. Louis was appointed lead plaintiff in the case pursuant to the Private Securities Litigation Reform Act of 1995. An amended complaint was filed on April 15, 2011, making allegations substantially similar to the allegations described above. On May 23, 2011, a motion was filed to dismiss the amended complaint. On August 10, 2011, that motion was granted and the action was dismissed; the plaintiffs were given 30 days to file an amended complaint. On September 12, 2011, plaintiffs filed their amended complaint. The allegations contained therein were substantially similar to the allegations in the prior complaint. The Company filed a motion to dismiss the amended complaint on October 13, 2011. A hearing occurred on February 16, 2012, and on May 22, 2012, the court granted the Company's motion. The complaint was dismissed with prejudice and a final judgment was entered in the Company's favor on June 1, 2012. On June 20, 2012, plaintiffs filed a notice of appeal with the United States Court of Appeals for the Ninth Circuit. The appeal was styled Police Retirement System of St. Louis v. Intuitive Surgical, Inc. et al., No. 12-16430. Plaintiffs filed their opening brief on September 28, 2012. The Company filed an answering brief on November 13, 2012, and plaintiffs filed a reply brief on December 17, 2012. Oral argument was held on March 14, 2014, and the matter was taken under submission. On July 16, 2014, the Ninth Circuit published an opinion affirming the district court's order dismissing the amended complaint with prejudice. Plaintiffs declined to seek any further review of the decision and the matter is now at an end.

Purported Derivative Actions filed August 19, 2010

On August 19, 2010, an alleged stockholder caused a purported stockholder'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 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 stockholder filed a substantially identical lawsuit entitled Applebaum 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. By agreement with plaintiffs, all activity in the case was stayed pending final resolution of the appeal in the purported shareholder class action lawsuit discussed above. On October 23, 2014, the plaintiffs voluntarily dismissed the consolidated cases. The matter is now at an end.

Purported Shareholder Class Action Lawsuits filed April 26, 2013 and May 24, 2013

On April 26, 2013, a purported class action lawsuit entitled Abrams v. Intuitive Surgical, et al., No. 5-13-cv-1920, was filed against several of the Company's current and former officers and directors in the United States District Court for the Northern District of California. A substantially identical complaint, entitled Adel v. Intuitive Surgical, et al., No. 5:13-cv-02365, was filed in the same court against the same defendants on May 24, 2013. The Adel case was voluntarily dismissed without prejudice on August 20, 2013. The matter is now at an end.

On October 15, 2013, plaintiffs in the Abrams matter filed an amended complaint. The case has since been re-titled In re Intuitive Surgical Securities Litigation, No. 5:13-cv-1920. The plaintiffs seek unspecified damages on behalf of a putative class of persons who purchased or otherwise acquired the Company's common stock between February 6, 2012, and July 18, 2013. The amended complaint alleges that the defendants violated federal securities laws by making allegedly false and misleading statements and omitting certain material facts in certain public statements and in the Company's filings with the SEC. On November 18, 2013, the Court appointed Employees' Retirement System of the State of Hawaii as lead plaintiff and appointed lead counsel. The Company filed a motion to dismiss the amended complaint on December 16, 2013, which was granted in part and denied in part on August 21, 2014. The plaintiffs have elected not to further amend their complaint. On October 22, 2014, the court granted the Company's motion for leave to file a motion for reconsideration of the court's August 21, 2014, order. The Company filed its motion for reconsideration on November 5, 2014, the plaintiffs filed their opposition on November 19, 2014, and the Company filed its reply on November 26, 2014. The court denied the motion for reconsideration on December 15, 2014. The

case will move forward on the claims that remain. No trial date has been set. Based on currently available information, the Company does not believe the resolution of this matter will have a material adverse effect on the Company's business, financial position or future results of operations.

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Purported Derivative Actions filed on February 3, 2014, February 21, 2014, March 21, 2014, and June 3, 2014

On February 3, 2014, an alleged stockholder caused a purported stockholder's derivative lawsuit entitled Berg v. Guthart et al., No. 4:14-CV-00515, to be filed in the United States District Court for the Northern District of California. It names the Company as a nominal defendant and names 16 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 2012 and the present. It also seeks a series of changes to the Company's corporate governance policies and an award of attorneys' fees. On April 3, 2014, it was related to In re Intuitive Surgical Securities Litigation. On July 30, 2014 the court granted Robert Berg's motion to be appointed lead plaintiff, denied the City of Birmingham's motion seeking such appointment (see below for additional description), and re-titled the matter In re Intuitive Surgical, Inc. Shareholder Derivative Litigation, No. 4:14-CV-00515. On August 13, 2014, Berg filed a consolidated complaint, making allegations substantially similar to the allegations in his original complaint. On September 12, 2014, the Company filed a motion to dismiss the consolidated complaint. Berg filed his opposition on October 9, 2014, and the Company filed its reply on October 30, 2014. The motion remains pending. Based on currently available information, the Company does not believe the resolution of this matter will have a material adverse effect on the Company's business, financial position or future results of operations.

On February 21, 2014, a second alleged stockholder caused a substantially similar purported stockholder's derivative lawsuit entitled Public School Teachers' Pension and Retirement Fund of Chicago v. Guthart et al., No. CIV 526930, to be filed in the Superior Court of the State of California, County of San Mateo, against the same parties and seeking the same relief. On March 26, 2014, the case was removed to the United States District Court for the Northern District of California, where it was related to In re Intuitive Surgical Securities Litigation and Berg v. Guthart on April 30, 2014. The district court remanded the case back to San Mateo County Superior Court on June 30, 2014, where it remains pending. On August 28, 2014 the Company filed a motion seeking to stay the case in favor of the federal action and asking that the plaintiff be required to post a bond because the action was duplicative and was not in the Company's best interests. On November 13, 2014, the superior court entered an order denying the Company's bond request and denying in part the Company's motion to stay. On November 18, 2014, the Company petitioned the First Appellate District of the California Court of Appeal for a writ of mandate directing the superior court to stay the case in its entirety. At the same time, the Company requested an immediate stay of proceedings pending resolution of the petition. On November 19, 2014, the Court of Appeal granted the Company's request for an immediate stay and set a briefing schedule for the petition. The plaintiff filed its opposition to the petition on December 8, 2014, and the Company filed its reply on December 22, 2014. The petition was denied on January 8, 2015. On January 20, 2015, the Company demurred (moved to dismiss) the complaint. A hearing is set for February 11, 2015. Based on currently available information, the Company does not believe the resolution of this matter will have a material adverse effect on the Company's business, financial position or future results of operations.

On March 21, 2014, a third alleged stockholder caused a substantially similar purported stockholder's derivative lawsuit entitled City of Birmingham Relief and Retirement System v. Guthart et al., No. 5-14-CV-01307, to be filed in the United States District Court for the Northern District of California against the same parties and seeking the same relief. On April 8, 2014, it was related to In re Intuitive Surgical Securities Litigation and Berg v. Guthart. On July 30, 2014, the court consolidated the case with Berg v. Guthart and, as noted above, granted Berg's motion to be appointed lead plaintiff and denied the City of Birmingham's motion seeking such appointment. This effectively ends the City of Birmingham's involvement in this matter. Based on currently available information, the Company does not believe the resolution of this matter will have a material adverse effect on the Company's business, financial position or future results of operations.

On June 3, 2014, a fourth alleged stockholder caused a substantially similar purported stockholder's derivative lawsuit entitled City of Plantation Police Officers' Employees' Retirement System v. Guthart et al., C.A. No. 9726-CB, to be filed in the Court of Chancery of the State of Delaware. The Company filed a Motion to Stay Proceedings in favor of the earlier-filed stockholder derivative lawsuits pending in federal and state courts in California. In light of the Company's motion, the plaintiff agreed to a stay of all proceedings in the case in favor of the earlier-filed actions.

Based on currently available information, the Company does not believe the resolution of this matter will have a material adverse effect on the Company's business, financial position or future results of operations.

Product Liability Litigation

The Company is currently named as a defendant in approximately 102 individual product liability lawsuits filed in various state and federal courts by plaintiffs who allege that they or a family member underwent surgical procedures that utilized the da Vinci Surgical System and sustained a variety of personal injuries and, in some cases, death as a result of such surgery. The Company has also received a large number of product liability claims from plaintiffs' attorneys that are part of certain tolling agreements further discussed below. The Company has also been named as a defendant in a multi-plaintiff lawsuit filed in Missouri state court. On November 26, 2014, plaintiffs amended their complaint to add three additional plaintiffs. In total, plaintiffs seek damages on behalf of 20 patients who had da Vinci Surgeries in 13 different states. The cases raise a variety of allegations including, to varying degrees, that plaintiffs' injuries resulted from purported defects in the da Vinci Surgical System and/or failure on the Company's part to provide adequate training resources to the healthcare professionals who performed plaintiffs' surgeries. The

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cases further allege that the Company failed to adequately disclose and/or misrepresented the potential risks and/or benefits of the da Vinci Surgical System. Plaintiffs also assert a variety of causes of action, including for example, strict liability based on purported design defects, negligence, fraud, breach of express and implied warranties, unjust enrichment, and loss of consortium. Plaintiffs seek recovery for alleged personal injuries and, in many cases, punitive damages. The Company has reached confidential settlements in many of the filed cases. With certain exceptions, including the Taylor case described below, the remaining filed cases generally are in the early stages of pretrial activity.

The Company previously reported that it was named as a defendant in a purported class action filed in Louisiana state court, and removed to federal court, seeking damages on behalf of all patients who were allegedly injured by the da Vinci Surgical System at a single hospital in Louisiana. The Company settled this case and it was dismissed with prejudice on October 20, 2014. The settlement did not have a material adverse effect on the Company’s business, financial position or results of operations.

Plaintiffs’ attorneys have engaged in well-funded national advertising efforts seeking patients dissatisfied with da Vinci surgery. Among the allegations, a substantial number of claims relate to alleged complications from surgeries performed with certain versions of Monopolar Curved Scissor (“MCS”) instruments that included an MCS tip cover accessory that was the subject of a market withdrawal in 2012 and MCS instruments that were the subject of a recall in 2013. The Company has received a significant number of claims from plaintiffs’ attorneys that it believes are as a result of these advertising efforts. In an effort to avoid the expense and distraction of defending multiple lawsuits, the Company entered into tolling agreements to pause the applicable statutes of limitations for these claims and engaged in confidential mediation efforts. The attorneys for the patients agreed to collect and supply medical records, operative notes and other necessary information from these patients to the Company. Each claim was individually investigated. The collection and evaluation of the patients’ medical information was laborious. For hundreds of the asserted claims, the Company has never received medical records. As patient records related to these claims were received, the Company, assisted by independent medical consultants, reviewed and analyzed the large volumes of medical information that began to arrive in the fall of 2013. The completion of the legal and medical evaluation of a significant number of these claims occurred during the first quarter of 2014 and continued throughout the remainder of 2014. After an extended confidential mediation process with legal counsel for many of the claimants covered by the tolling agreements, the Company determined during the first quarter of 2014 that, while it denies any and all liability, in light of the costs and risks of litigation, settlement of certain claims may be appropriate. During the year ended December 31, 2014, the Company recorded pre-tax charges of $82.4 million to reflect the estimated cost of settling a number of the product liability claims covered by the tolling agreements. The Company’s estimate of the anticipated cost of resolving these claims is based on negotiations with attorneys for patients who have participated in the mediation process. To date, approximately 4,800 claims have been added to the tolling agreements and/or submitted into the mediation program. Of those, however, over 3,100 claims have voluntarily been removed from the tolling agreements and/or mediation program and plaintiffs’ counsels have indicated to the Company that they no longer intend to pursue these claims. Nonetheless, the claimants that have been removed from the tolling agreement remain free to pursue lawsuits against the Company and it is also possible that more claims will be made by additional individuals who have undergone da Vinci surgery and allege that they suffered injuries. It is further possible that the claimants who participate in the mediations, as well as those claimants who have not participated in negotiations, will choose to pursue greater amounts in a court of law. Consequently, the final outcome of these claims is dependent on many variables that are difficult to predict and the ultimate cost associated with these product liability claims may be materially different than the amount of the current estimate and accruals and could have a material adverse effect on the Company's business, financial position, and future results of operations. Although there is a reasonable possibility that a loss in excess of the amount recognized exists, the Company is unable to estimate the possible loss or range of loss in excess of the amount recognized at this time. As of December 31, 2014, a total of $49.5 million of the charges recorded during 2014 was included in other accrued liabilities in the accompanying Consolidated Balance Sheets related to the tolled product liability claims.

In February 2011, the Company was named as a defendant in a product liability action that had originally been filed in Washington State Superior Court for Kitsap County against the healthcare providers and hospital involved in plaintiff's decedent's surgery (Josette Taylor, as Personal Representative of the Estate of Fred E. Taylor, deceased; and on behalf of the Estate of Fred E. Taylor v. Intuitive Surgical, Inc., No. 09-2-03136-5). In Taylor, plaintiff asserted wrongful death and product liability claims against the Company, generally alleging that the decedent died four years after surgery as a result of injuries purportedly suffered during the surgery, which was conducted with the use of the da Vinci Surgical System. The plaintiff in Taylor asserted that such injuries were caused, in whole or in part, by the Company's purported failure to properly train, warn, and instruct the surgeon. The lawsuit sought unspecified damages for past medical expenses, pain and suffering, loss of consortium as well as punitive damages. A trial commenced in the action on April 15, 2013. On May 23, 2013, the jury returned a defense verdict, finding that the Company was not negligent. Judgment was entered in the Company's favor on June 7, 2013. Plaintiff has filed a notice of appeal.

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False Claims Act Litigation

In October 2013, the Company was served in a case entitled Rose v. Intuitive Surgical, Inc., No. 12-cv-1812, in the Middle District of Florida. Relator Bryan Rose, a former employee of Intuitive Surgical, brought the action on behalf of the United States of America, alleging violations of the False Claims Act, 31 U.S.C. § 3729 et seq., and the analogous false-claims statutes of 21 states and of the District of Columbia. The parties reached a settlement in the case and the court granted their joint motion for dismissal on May 21, 2014. The settlement did not have a material adverse effect on the Company's business, financial position or results of operations.

Insurance Litigation

In October 2013, the Company was named as a defendant in an insurance action entitled Illinois Union Insurance Co. v. Intuitive Surgical, Inc., No. 3:13-cv-04863-JST, filed in the Northern District of California. Plaintiff Illinois Union Insurance Co. seeks to rescind the Life Sciences Products-Completed Operations Liability Policy issued by plaintiff to the Company, which provides coverage for products liability claims first made against the Company during the policy period March 1, 2013 to March 1, 2014. In December 2013, the Company was named as a defendant in another insurance action entitled Navigators Specialty Insurance Co. v. Intuitive Surgical, Inc., No. 5:13-cv-05801-HRL, filed in the Northern District of California. Plaintiff Navigators Insurance Co. alleges that the Follow Form Excess Liability Insurance Policy issued by plaintiff to the Company for product liability claims first made against the Company during the policy period March 1, 2013 to March 1, 2014, should be rescinded. Both plaintiffs generally allege that the Company did not disclose the existence of tolling agreements, the number of claimants incorporated within those agreements, and that those agreements were material to plaintiffs' underwriting processes. The Company intends to vigorously defend these actions. Based on currently available information, the Company does not believe the resolution of this matter will have a material adverse effect on the Company's business, financial position or future results of operations.

NOTE 8. STOCKHOLDERS' EQUITY

STOCK REPURCHASE PROGRAM

The Company's Board of Directors has authorized an aggregate of $3.0 billion of funding for the Company's common stock repurchase program (the "Repurchase Program") since originally established in March 2009. As of December 31, 2014, the Company had used all amounts authorized for stock repurchases under the Repurchase Program.

On January 29, 2015 subsequent to the end of fiscal year 2014, the Company's Board of Directors authorized the Company to repurchase up to $1.0 billion of the Company's outstanding common stock.

On May 2, 2014, the Company entered into an accelerated share repurchase program (the "2014 ASR Program") with Goldman, Sachs & Co. ("Goldman") to repurchase $1.0 billion of the Company's common stock under the Repurchase Program. Under the 2014 ASR Program, the Company made an up-front payment of $1.0 billion to Goldman and received and retired approximately 2.5 million shares of its common stock. On September 19, 2014, Goldman exercised its early termination option under the 2014 ASR Program and the pricing period was closed. No additional shares were received by the Company.

On July 29, 2013, the Company entered into an accelerated share repurchase program (the "2013 ASR Program") with Goldman to repurchase $500.0 million of the Company's common stock under the Repurchase Program. Under the 2013 ASR Program, the Company made an up-front payment of $500.0 million to Goldman and received and retired an initial delivery of approximately 1.2 million shares of its common stock. On September 11, 2013, Goldman exercised its early termination option under the 2013 ASR Program and the pricing period was closed. Based on the settlement price, the final number of shares repurchased by the Company and delivered by Goldman under the 2013 ASR Program was 1.3 million shares. The Company received the additional 0.1 million shares from Goldman on September 16, 2013 to settle the difference between the initial share delivery and the total number of shares repurchased. Remaining shares were repurchased in the open market for the year ended December 31, 2013.

The following table provides the stock repurchase activities during the years ended December 31, 2014, 2013, and 2012 (in millions, except per share amounts):

	Years Ended December 31,		
	2014	2013	2012
Shares repurchased	2.5	2.6	0.4

Average price per share	$397.52	$429.09	$503.05
Value of shares repurchased	$1,000.0	$1,109.2	$238.3

The Company uses the par value method of accounting for its stock repurchases. As a result of the share repurchases during the years ended December 31, 2014, 2013, and 2012, the Company reduced common stock and additional paid-in capital by an aggregate of $89.5 million, $84.2 million, and $13.2 million, respectively, and charged $910.5 million, $1,025.0 million, $225.1 million, respectively, to retained earnings.

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ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

The components of accumulated other comprehensive income (loss) net of tax, for the years ended December 31, 2014, and 2013 are as follows (in millions):

	Year Ended December 31, 2014				
	Gains (Losses) on Hedge Instruments	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Translation Gains (Losses)	Employee Benefit Plans	Total
Beginning balance	$—	$ 1.7	$0.4	$—	$2.1
Other comprehensive income before reclassifications	8.6	(3.9)	(2.5)	(4.2)	(2.0)
Reclassified from accumulated other comprehensive income (loss)	(7.5)	2.0	—	0.3	(5.2)
Net current-period other comprehensive income (loss)	1.1	(1.9)	(2.5)	(3.9)	(7.2)
Ending balance	$1.1	$ (0.2)	$(2.1)	$(3.9)	$(5.1)

	Year Ended December 31, 2013				
	Gains (Losses) on Hedge Instruments	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Translation Gains (Losses)	Employee Benefit Plans	Total
Beginning balance	$—	$ 6.2	$0.4	$—	$6.6
Other comprehensive income before reclassifications	(1.8)	(3.9)	—	—	(5.7)
Reclassified from accumulated other comprehensive income (loss)	1.8	(0.6)	—	—	1.2
Net current-period other comprehensive income (loss)	—	(4.5)	—	—	(4.5)
Ending balance	$—	$ 1.7	$0.4	$—	$2.1

NOTE 9. SHARE-BASED COMPENSATION

Stock Plans

2010 Incentive Award Plan

In April 2010, the Company’s stockholders approved the 2010 Incentive Award Plan (“2010 Plan”). 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. The 2010 Plan expires in 2020. On April 25, 2013, the Company's stockholders approved an amended and restated 2010 Incentive Award Plan (“2010 Plan”) to provide for an increase in the number of shares of common stock reserved for issuance from 3,650,000 to 4,850,000. As of December 31, 2014, approximately 1.0 million shares were reserved for future issuance under the 2010 Plan.

2009 Employment Commencement Incentive Plan

In October 2009, the Board of Directors adopted the 2009 Employment Commencement Incentive Plan (“New Hire Plan”). The New Hire Plan provides for the shares to be used exclusively for the grant of NSOs to new employees (“New Hire Options”), who were not previously employees or non-employee directors of the Company. The Compensation Committee approves all equity awards under the New Hire Plan, which are granted to newly-hired employees once a month on the fifth business day of each month after their hire. 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.

In May 2013, the Board of Directors amended and restated the New Hire Plan to provide for an increase in the number of shares of common stock authorized for issuance pursuant to awards granted under the New Hire Plan from 855,000 to 1,155,000. As of December 31, 2014, approximately 0.1 million shares were reserved for future issuance under the New Hire Plan.

2000 Equity Incentive Plan

In March 2000, the Board of Directors adopted the 2000 Equity Incentive Plan ("2000 Plan"), which took effect upon the closing of the Company's initial public offering. Under this plan, certain employees, consultants and non-employee directors

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could 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. The 2000 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.

Employee Option Vesting

Prior to 2012, annual stock options were granted to employees on February 15 of each year or the next business day if the date was not a business day ("Annual Grant"). The grants generally vested 6/48 upon completion of 6 months service and 1/48 per month thereafter. Beginning in 2013, the Company split the annual grant into a grant on February 15 (or the next business day if the date is not a business day) and a separate grant on August 15 (or the next business day if the date is not a business day). The February 15 grants vest 6/48 upon completion of 6 months service and 1/48 per month thereafter. The August 15 stock option grants vest 7/48 at the end of one month and 1/48 per month thereafter through a 3.5 year vesting period.

Prior to 2014, New Hire Options generally vested 6/48 upon completion of 6 months service and 1/48 per month thereafter. Beginning in 2014, New Hire Options generally vest 12/48 upon completion of one year service and 1/48 per month thereafter. Option vesting terms are determined by the Board of Directors and, in the future, may vary from past practices.

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 stock option grants are vested over a three-year period with 12/36 of the shares vesting after one year from the date of grant and 1/36 of the shares vesting monthly thereafter. Annual stock option grants are vested one year from the date of the grant. Beginning in 2014, equity awards granted to non-employee directors include a mix of stock options and RSUs. Initial RSU grants are vested in one-third increments over a three-year period while annual RSU grants are vested one year from the date of grant. As of December 31, 2014, approximately 58,000 shares were reserved for future issuance under the Directors' Plan.

2000 Employee Stock Purchase Plan

In March 2000, the Board of Directors adopted the 2000 Employee Stock Purchase Plan (ESPP). 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 24 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 first or last day of the purchase period 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 0.1 million, 0.1 million and 0.1 million shares under the ESPP, representing approximately $29.4 million, $28.8 million, and $27.8 million in employee contributions for the years ended December 31, 2014, 2013, and 2012, respectively. As of December 31, 2014, there were approximately 0.3 million shares reserved for grant under the ESPP.

Restricted Stock Units

Beginning in 2014, equity awards granted to employees include a mix of stock options and RSUs. The RSUs vest in 1/4 increments annually over a four-year period. The number of shares issued on the date the RSUs vest is net of the

minimum statutory tax withholdings, which are paid in cash to the appropriate taxing authorities on behalf of the Company's employees.

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Stock Option Information

Option activity during fiscal 2014 under all the stock plans was as follows (in millions, except per share amounts):

	Stock Options Outstanding	
	Number Outstanding	Weighted Average Exercise Price Per Share
Balance at December 31, 2013	5.6	$ 380.71
Options granted	0.7	$ 446.91
Options exercised	(0.9)	$ 296.77
Options forfeited/expired	(0.4)	$ 478.19
Balance at December 31, 2014	5.0	$ 395.85

The aggregate intrinsic value of options exercised under our stock plans determined as of the date of option exercise was $146.2 million, $130.2 million, and $375.7 million during the years ended December 31, 2014, 2013, and 2012, respectively. Cash received from option exercises and employee stock purchase plans for the years ended December 31, 2014, 2013, and 2012 was $283.6 million, $160.6 million, and $263.3 million, respectively.

The following table summarizes significant ranges of outstanding and exercisable options as of December 31, 2014 (number of shares in millions):

	Options Outstanding				Options Exercisable			
Range of Exercise Prices	Number of Shares	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (1)	Number of Shares	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (1)
$47.86 - $333.42	1.0	3.38	$ 200.98		1.0		$ 200.82	
$334.30 - $358.40	1.0	5.62	$ 339.17		0.9		$ 338.96	
$358.57 - $451.50	1.0	8.51	$ 403.95		0.4		$ 397.19	
$459.14 - $517.31	1.4	7.78	$ 498.68		0.8		$ 505.75	
$518.29 - $579.24	0.6	7.83	$ 564.92		0.3		$ 564.70	
TOTAL	5.0	6.62	$ 395.85	$ 683.1	3.4	5.77	$ 363.03	$ 573.1

(1) The aggregate intrinsic value represents the total pre-tax intrinsic value, based on the Company's closing stock price of $528.94 at December 31, 2014, 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, 2014, a total of 4.8 million shares vested and expected to vest had a weighted average remaining contractual life of 6.5 years, an aggregate intrinsic value of $672.2 million, and a weighted average exercise price of $393.76.

Restricted Stock Units Information

RSU activity for the year ended December 31, 2014, was as follows (in millions, except per share amounts):

	Shares	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2013	—	$ —
Granted	0.2	$ 441.36
Vested	—	$ —
Canceled	0.0	$ 443.99

Unvested balance at December 31, 2014	0.2	$ 441.07

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Share-Based Compensation Expense

The following table summarizes share-based compensation expense (in millions):

	Years Ended December 31,		
	2014	2013	2012
Cost of sales—products	$19.1	$17.6	$14.1
Cost of sales—services	13.5	12.7	12.9
Total cost of sales	32.6	30.3	27.0
Selling, general and administrative	99.0	101.4	93.1
Research and development	37.5	37.2	33.2
Share-based compensation expense before income taxes	169.1	168.9	153.3
Income tax effect	53.5	58.5	47.5
Share-based compensation expense after income taxes	$115.6	$110.4	$105.8

The Black-Scholes option pricing model is used to estimate the fair value of stock options granted under the Company's share-based compensation plans and rights to acquire stock granted under the Company's employee stock purchase plan. The weighted average estimated fair values of stock options, the rights to acquire stock granted, and the weighted average assumptions used in calculating those fair values during the years ended December 31, 2014, 2013, and 2012, were as follows:

	Years Ended December 31,					
STOCK OPTION PLANS	2014		2013		2012	
Average risk free interest rate	1.5	%	1.2	%	0.8	%
Average expected term (years)	4.3		4.5		4.3	
Average volatility	31	%	30	%	33	%
Weighted average fair value at grant date	$122.39		$126.50		$146.26	
EMPLOYEE STOCK PURCHASE PLAN						
Average risk free interest rate	0.2	%	0.2	%	0.2	%
Average expected term (years)	1.2		1.3		1.3	
Average volatility	33	%	34	%	32	%
Weighted average fair value at grant date	$124.60		$153.33		$138.61	

As share-based compensation expense recognized in the Consolidated Statements of Income during the years ended December 31, 2014, 2013, and 2012 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Share-based 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, 2014, there were a total of $177.1 million, $65.9 million, and $7.3 million, of total unrecognized compensation expense related to non-vested stock options, non-vested restricted stock units, and employee stock purchases, respectively. The unrecognized compensation expense is expected to be recognized over a weighted average period of 2.3 years for non-vested stock options, 3.2 years for non-vested restricted stock units, and 0.7 years for rights granted to acquire stock under the ESPP.

Excess tax benefits are realized tax deductions for exercised options in excess of the deferred tax assets attributable to share-based compensation expense for such options. Excess tax benefits of $24.0 million, $38.0 million, and $94.2 million for the years ended December 31, 2014, 2013, and 2012, respectively, have been classified as a financing cash inflow. The total income tax benefit recognized in the consolidated statements of income for share-based compensation expense was $53.5 million, $58.5 million, and $47.5 million for the years ended December 31, 2014, 2013, and 2012, respectively.

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NOTE 10. INCOME TAXES

Income before provision for income taxes for the years ended December 31, 2014, 2013, and 2012 consisted of the following (in millions):

	Years Ended December 31,		
	2014	2013	2012
U.S	$353.0	$612.5	$718.5
Foreign	196.0	258.4	175.4
Total income before provision for income taxes	$549.0	$870.9	$893.9

The provision for income taxes for the years ended December 31, 2014, 2013, and 2012 consisted of the following (in millions):