INTUITIVE SURGICAL INC
Form 10-K
February 03, 2014
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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, 2013
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 ¨
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. ¨

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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, 2013, based upon the closing price of Common Stock on such date as reported by NASDAQ Global Select Market, was approximately $19,977,428,381. 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 17, 2014 was 38,171,349.

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 24, 2014, to be filed within 120 days of the registrant’s fiscal year ended December 31, 2013.

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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. Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as “estimates,” “projects,” “believes,” “anticipates,” “plans,” “expects,” “intend “may,” “will,” “could,” “should,” “would,” “targeted” and similar words and expressions are intended to identify forward-look statements. These forward-looking statements include, but are not limited to, statements related to our expected business, new product introductions, procedures and procedure adoption, results of operations, future financial position, our ability to increase our revenues, the mix of our revenues between product and service revenues, our financing plans and capital requirements, our costs of revenue, our expenses, our potential tax assets or liabilities, the effect of recent accounting pronouncements, our investments, cash flows and our ability to finance operations from cash flows and similar matters and include statements based on current expectations, estimates, forecasts and projections about the economies and markets in which we operate and our beliefs and assumptions regarding these economies and markets. These forward-looking statements should be considered in light of various important factors, including the following: the impact of 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 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; 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 expectation and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those risk factors described throughout this filing and particularly in Part I, “Item 1A. Risk Factors.” Our actual results may differ materially and adversely from those expressed in any forward-looking statements. We undertake no obligation to 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 Si-e™, EndoWrist® , EndoWrist® One™, EndoWrist® Stapler 45, Single-Site™, DVSTAT, 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 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.

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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 new 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 provides the filtering of 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 three generations of da Vinci 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 system, 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 Si, a surgeon sitting at a second console can view the same surgery as the primary surgeon and can be passed control of some or all of the da Vinci instruments during 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

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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 Si and da Vinci S Surgical Systems and is available as a field upgrade on three-arm standard da Vinci and three-arm da Vinci S Surgical Systems 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 S and da Vinci Si Surgical Systems.

da Vinci Skills Simulator. The Skills Simulator is a practice tool which began shipping in early 2011 for the da Vinci Si Surgical System that gives a user the opportunity to practice his or her facility with the surgeon console controls. The 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 Si Surgical System. Most da Vinci Skills Simulators have been sold in connection with new da Vinci Si Surgical System sales.

Firefly Fluorescence Imaging. In the first quarter of 2011, we launched our Firefly product for use with the da Vinci Si 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 2013, we discontinued sale of the standard da Vinci System. We intend to continue supporting the installed base of standard da Vinci Systems with existing service agreements, as well as the continued supply of instruments and accessories. During 2014, we will phase out the sale of all instrument, accessory and service offerings for the standard da Vinci 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 so 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 and accessories that allow da Vinci Si 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 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. In February 2013, we received FDA clearance to market our Single-Site instruments for benign hysterectomy and salpingo oophorectomy procedures. We believe that the da Vinci Single-Site has been positively received by hospitals, surgeons, and patients, with over 800 customers having purchased da Vinci Single-Site kits as of December 31, 2013. However, as these are our initial

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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.

EndoWrist One Vessel Sealer. In December 2011, we received FDA clearance for our 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. 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.

EndoWrist Stapler 45 Instrument. In October 2012, we received FDA clearance for our 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. We expect its initial surgical use to be directed towards colorectal procedures. During 2013, the EndoWrist Stapler was used by a limited and gradually increasing number of customers, primarily for colorectal procedures. Although our first customer experiences have been positive, we are in the early stages of selling EndoWrist Stapler 45 and while we expect to continue to expand to a broadening set of customers in 2014, 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 is 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 economic studies.

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

1. Convert Candidate 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.

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

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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 Myomectomy, da Vinci Sacrocolpopexy, da Vinci Mitral Valve Repair, da Vinci Lobectomy and da Vinci Transoral Robotic Surgery (for cancers of the throat). In 2013, we estimate that over 75% of the procedures performed were in the urologic and gynecologic specialties. 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.

Pyeloplasty. Pyeloplasty is the surgical reconstruction or revision of the renal pelvis to drain and decompress the kidney. In nearly all cases, the goal of pyeloplasty surgery is to relieve an uretero-pelvic junction obstruction. Excluding da Vinci surgery, there are two common surgical approaches to performing pyeloplasty: open surgical technique and laparoscopy. 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 pyeloplasty patients.

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), a vaginal approach, or MIS techniques, which include both 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 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. Single-Site instruments enable surgeons to perform surgery through a single port via the patient's belly button, resulting in virtually scarless patient outcomes. During the twelve months ended December 31, 2013, we experienced lower growth rates in the category of U.S. benign gynecologic procedures than in prior years. The slower 2013 growth rate in the category of U.S. benign gynecologic procedures reflected a number of factors including, but not limited to, apparent pressure on benign gynecology hospital admissions, negative media reports about da Vinci surgery and a trend by payers toward encouraging conservative disease management and treatment in outpatient settings. We believe there is still a significant remaining market opportunity in benign gynecologic procedures since a large number are still done via open technique. However, as we penetrate more deeply into benign gynecologic procedures, our pace of capturing or consolidating the remaining market is progressing at a slower rate than previously.

Myomectomy. Myomectomy, or removal of a myoma/fibroid, is a surgical procedure performed when uterine preservation is sought, typically to preserve fertility. Due to the substantial suturing required for this procedure, the

standard surgical approach remains an open incision. There are some highly skilled gynecological laparoscopists who perform laparoscopic myomectomies, but laparoscopic myomectomy has remained a minority of myomectomies performed. 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 myomectomy patients.

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

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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.

Endometriosis Resection. Endometriosis is a gynecological medical condition in which cells from the lining of the uterus (endometrium) migrate outside the uterus. Endometriosis can range from mild to severe, and in the worst cases, can infiltrate bowel, ureters, ovaries and other organs in the female pelvis. Because of the diffuse and extensive nature of severe endometriosis, it can be difficult to treat either pharmaceutically or surgically. A successful resection of endometriosis involves both seeing lesions and their careful resection. Surgeons have reported that da Vinci surgery may enable a larger number of women with endometriosis to receive an effective MIS approach to their endometriosis resection.

Cardiothoracic Surgery

Mitral Valve Repair. When patients are diagnosed with mitral valve disease, there are two surgical treatment options from which they can choose: mitral valve replacement or mitral valve repair. Mitral valve repairs are generally preferred over mitral valve replacement for a number of reasons, which include longevity and durability of the repaired valve over a replacement valve and the elimination or reduction of the patient's post-surgical pharmaceutical regimen. Since mitral valve repairs are considered to be more technically challenging than mitral valve replacements, they are only performed approximately 50% of the time. 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.

Gastric Bypass. A growing body of literature is 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.

Thyroidectomy. Thyroid cancer is most commonly treated by thyroidectomy, the removal of all or part of the thyroid gland. Complete resection of the cancer and surrounding gland is required for proper oncologic outcomes. Open surgery is an effective surgery in terms of oncologic control and has low complication rates. However, it leaves a prominent neck scar.

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Surgeons, predominantly in Asia, are now using the da Vinci Surgical System to perform thyroidectomies entering the body from the axilla (armpit) in order to avoid the visible scar on the neck. At this time, the procedure is not within the indications for use for the da Vinci System in the U.S.

Procedure Segmentation

Our procedure business is now splitting into two segments: (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. Our less complex segment has increased from approximately 40% to 60% of U.S. procedures between 2011 and 2013. The complex procedure segment represents the large majority of international procedures.

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, 2013, we had an installed base of 2,966 da Vinci Surgical Systems, including 2,083 in the U.S., 476 in Europe, 159 in Japan, and 248 in the rest of the world. During the year ended December 31, 2013, we estimate that surgeons using our technology completed approximately 523,000 surgical procedures of various types in hospitals throughout the world. Of those da Vinci procedures performed in 2013, we estimate that approximately 201,000 were dVH procedures and approximately 114,000 were dVP procedures.

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, have led to a decline in our dVP business. During 2013 U.S. dVP procedure volumes appear to have stabilized, with a gradually decreasing trend. These treatment patterns have also impacted our European dVP procedure volumes. dVP is at earlier market penetration stages in the European markets; therefore, 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.

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 and, beginning with our acquisition of our Korean distributor on January 11, 2012, Korea. Beginning in 2013, we also established a direct sales structure in the Czech Republic, Slovakia, and Hungary. Prior to 2013, these markets were served by a distributor. 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, 2013, 2012, and 2011.

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. As of December 31, 2013, we had approximately 120 capital sales employees, compared to 92 as of December 31, 2012.

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 in relation to growth in the installed base of da Vinci systems and the total number of procedures performed. As of December 31, 2013, we had 722 clinical sales employees, compared to 685 as of December 31, 2012. This organization is expected 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

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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. Benign procedures represented a higher percentage of our total procedures in the fourth quarter of 2013 compared to the fourth quarter of 2012. 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 $167.7 million, $170.0 million and $140.2 million of research and development expenses for the years ended December 31, 2013, 2012 and 2011, 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, 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. and Covidien plc. Furthermore, as da Vinci use increases, a number of companies may be compelled to enter the field of robotic surgery, including but not limited to Stryker Corporation, Covidien plc, Johnson & Johnson, and Olympus. The following companies have made explicit statements about their efforts to enter the field: MedRobotics Corp., meerecompany

Inc., 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.

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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, 2013, we held ownership or exclusive field-of-use licenses for more than 1,500 U.S. and foreign patents and more than 1,400 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.

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 30 days for “special” 510(k) submissions which have a more restrictive scope and generally 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-marketing

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

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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 501(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.

The FDA and the Federal Trade Commission ("FTC") also regulate the advertising claims 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 and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping, installation and service of a company's products. 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 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. These enforcement actions could include legal actions, including fines and total shutdown of production facilities, seizure of product, 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.

A FDA inspection of the Company's 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 their intent to perform a follow-up inspection. We have responded to the Warning Letter with plans for corrective action, and continue to provide supplemental responses with objective evidence of corrections as they are completed. 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. However, we cannot assure that, upon re-inspection, the FDA will find that our corrective actions are acceptable or that they have been adequately implemented. We also cannot assure that the FDA will not find other observations. The FDA previously inspected our Sunnyvale, CA facilities in January 2012 and did not issue a Form FDA 483 as a result of this inspection.

To 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 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.

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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 inspection 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.

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 November 2009, we received Shonin approval from the Japanese Ministry of Health, Labor, and Welfare ("MHLW") for our da Vinci S Surgical System in Japan. These sales were primarily made to early adopters. Since receiving the approval, we have been focusing our efforts on obtaining specific reimbursement for da Vinci procedures in Japan and building our own organization, Intuitive Surgical Japan. Prior to April 2012, we had partnered with the experienced regulatory team from Johnson & Johnson K.K. Medical Company ("JJKK") in our Japanese regulatory process. In April 2012, the Marketing Authorization Application for da Vinci products was transferred to Intuitive Surgical Japan from JJKK, and Intuitive Surgical Japan now has primary responsibility for regulatory support of our products in Japan. We continue to partner with Adachi Co., Ltd. as our separate independent distribution partner for marketing, selling, and servicing our products in Japan. Effective April 2012, we obtained national reimbursement for dVP procedures in Japan, our only reimbursed procedure to date. In October 2012, we obtained MHLW approval for da Vinci Si Surgical Systems in Japan. In Japan additional procedures are considered for reimbursed status in April of even numbered years as the MHLW considers recommendations and data brought forth from Japanese surgical societies. We do not expect any additional procedures to be granted reimbursement status in the April 2014 cycle. We are supporting the Japanese surgical societies to gather the necessary data 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 2012,

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. 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

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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.

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 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, 2014, 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. Additionally, health maintenance organizations are emerging in certain European countries. To effectively conduct our business, we may need to seek international reimbursement approvals, and we do not know if these required approvals will be obtained in a timely manner or at all. In April 2012, radical prostatectomy utilizing the da Vinci Surgical System was approved for reimbursement in Japan. We intend to seek reimbursement approvals from the Japanese government for additional procedures performed with our products. The timing of these approvals can vary significantly, and could significantly impact our ability to commercialize our products in Japan. In some countries, patients may be permitted to pay directly for surgical services; however, such "co-pay" practices are not common in 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 are expected to significantly impact healthcare providers, insurers, pharmaceutical and medical device manufacturers. One of the principal aims of the PPACA is to

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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 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. Starting in 2013, medical device manufacturers are 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 paid an excise tax of approximately 1% of total global revenue in 2013. The tax is included as a cost of revenue and a reduction of product gross 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 to Medicare payments to providers of up to 2% per fiscal year,, which went into effect on April 1, 2013. 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.

Employees

As of December 31, 2013, we had 2,792 employees, 325 of whom were engaged directly in research and development, 1,018 in manufacturing and service and 1,449 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. 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. Additionally, 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.

We operate our business as one segment as defined by generally accepted accounting principles. Our financial results for the year ended December 31, 2013, 2012, and 2011 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

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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 have destabilized certain European economies as well and thereby increased 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 on credit. There could be additional effects from the credit crisis on our business, including the insolvency of key suppliers or their inability to obtain credit to finance the development and/or manufacture of our products resulting in product delays, and the inability of our customers and distributors to obtain credit to finance purchases of our products. If conditions worsen or if the improved economic conditions are slower than anticipated, our forecasted demand may not materialize to the levels we require to achieve our anticipated financial results, which could in turn have a material adverse effect on our revenue, profitability and the market price of our stock.

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

da Vinci Surgery is a new technology that competes with established and emerging treatment options in both disease management and reconstructive medical procedures. These competitive treatment options include conventional MIS, open surgery, interventional approaches or pharmacological regimens. Some of these procedures are widely accepted in the medical community and in many cases have a long history of use. Technological advances could make such treatments more effective or less expensive than using our products, which could render our products obsolete or unmarketable. Studies could be published that show that other treatment options are more beneficial and/or cost-effective than da Vinci Surgery. We cannot be certain that physicians will use our products to replace or supplement established treatments or that our products will continue to be competitive with current or future technologies.

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. Our revenues may be reduced or eliminated if our competitors develop and market products that are more effective or less expensive than our products. If we are unable to compete successfully, our revenues will suffer. We may not be able to maintain or improve our competitive position against current or potential competitors, especially those with greater resources.

NEW PRODUCT INTRODUCTIONS MAY ADVERSELY IMPACT OUR FINANCIAL RESULTS.

We introduce new products with enhanced features and extended capabilities from time to time. Our products are subject to various regulatory processes, and we must obtain and maintain regulatory approvals in order to sell our new

products. If a potential purchaser believes that we plan to introduce a new product in the near future or if a potential purchaser is located in a country where a new product that we have introduced has not yet received regulatory approval, planned purchases may be deferred or delayed. As a result, new product introductions may adversely impact our financial results.

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

Our da Vinci Surgical System has a lengthy sales and purchase order cycle because it is a major capital item and its purchase generally requires the approval of senior management of hospitals, their parent organizations, purchasing groups, and government bodies, as applicable. This approval process can be lengthy. In addition, hospitals may delay or accelerate system purchases in

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conjunction with timing of their capital budget timelines. As a result, it is difficult for us to predict the length of capital sales cycles and, therefore, the exact timing of capital sales. Historically, our sales of da Vinci Surgical Systems have tended to be heaviest during the third month of each fiscal quarter, and lighter in the third and first fiscal quarters and heavier in the fourth fiscal quarter.

Recently, we have experienced procedure growth for a number of benign conditions, including hysterectomies for benign conditions, sacrocolpopexies, myomectomies, 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 quarter and higher procedure counts in the fourth fiscal quarter. Timing of procedures and changes in procedure growth directly affect the timing of instrument and accessory purchases and capital purchases.

The above factors may contribute to substantial fluctuations in our quarterly operating results. Because of these fluctuations, it is 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. In addition, the introduction of new products could adversely impact our sales cycle, as customers take additional time to assess the benefits and costs of such products.

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

Our business currently depends in part on our activities in international markets. Revenue from markets outside of the United States accounted for approximately 28%, 21%, and 22% of our revenue for the years ended December 31, 2013, 2012, and 2011, 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 of our ability to move goods across borders;
- the risks associated with foreign currency exchange rate fluctuations;
- the expense of establishing facilities and operations in new foreign markets; and
- building an organization capable of supporting geographically dispersed operations.

A large portion of our international sales are denominated in 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 Intuitive to re-establish market access or

regulatory compliance in such case.

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

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for the Euro and the British Pound. We regularly review our hedging program and make adjustments as necessary based on our assessment of the relevant risks, opportunities and expenses. Our hedging activities may not offset more than a portion of the adverse financial impact resulting from unfavorable movement in foreign currency exchange rates, which could adversely affect our financial condition or results of operations.

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

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

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

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 under Part I, "Item 3. Legal Proceedings," 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. In addition, 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 the Company.

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 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.

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 are described under Part I, “Item 3. Legal Proceedings.”

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

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.

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 we face in the United States are prevalent in many of the other countries in which we intend to sell our products and these efforts are expected to continue. Please see our risk factor below titled "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.

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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 are located in California, a seismically active region. 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.

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 purchased our Korean distributor in January 2012. 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 the fact 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 questioning of current practices may adversely affect our reported financial results or the way we conduct our business.

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 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

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

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

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

- the jurisdictions in which profits are determined to be earned and taxed;
- the resolution of issues arising from tax audits with various tax authorities;
- changes in valuation of our deferred tax assets and liabilities;
- increases in expenses not deductible for tax purposes, including write-offs of acquired intangibles and impairment of goodwill in connection with acquisitions;
- changes in available tax credits and deductions;
- changes in share-based compensation;
- changes in tax laws or the interpretation of such tax laws and changes in generally accepted accounting principles; and
- the repatriation of non-U.S. earnings for which we have not previously provided for U.S. taxes.

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

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.

We devote significant resources to network security, data encryption and other security measures to protect our systems and data, but 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 the

Company’s 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.

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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 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 up to 2% per fiscal year,, which went into effect on April 1, 2013. 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.

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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 certain metals used in manufacturing which may stem from minerals (so called “conflict minerals”) which originate in the Democratic Republic of the Congo or adjoining regions. These metals include tantalum, tin, gold and tungsten. 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. It is not possible to determine the source of the metals by analysis but instead a good faith description of the source of the intermediate components and raw materials must be obtained. The components which 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, and components and assemblies which 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 from intermediate producers who are unwilling or unable to provide this information or further identify their sources of supply or to notify us if these sources change. 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 recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. 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.

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 investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Device manufacturers were required to begin collecting data on August 1, 2013 and will be required to submit reports to CMS by March 31, 2014 and the 90th day of each subsequent 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

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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, or 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.

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.

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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.

A FDA inspection of the Company's 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 their intent to perform a follow-up inspection. We have responded to the Warning Letter with plans for corrective action, and continue to provide supplemental responses with objective evidence of corrections as they are completed. 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. However, we cannot assure that, upon re-inspection,

the FDA will find that our corrective actions are acceptable or that they have been adequately implemented. We also cannot assure that the FDA will not find other observations. The FDA previously inspected our Sunnyvale, CA 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 U.S. 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

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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.

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 US 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. This is expected to have little 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 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 have 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 approvals in Japan for a limited set of procedures and products. 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 da Vinci S system was approved in Korea in April 2007 and our SI system was approved in December 2009. Since that time, we have received regulatory approvals for additional instruments and accessories from these regulatory agencies. 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.

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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. Our last FDA inspection occurred in January 2012. The FDA did not issue a Form FDA 483, also known as a Notice of Inspectional Observations, and the Establishment Inspection Report, dated February 29, 2012 has been received. In 2010 the FDA issued a Form FDA 483 listing deficiencies under the QSR relating to complaint handling and manufacturing/inspection handling. We responded to each observation with proposed corrective actions which were thereafter completed and verified.

In April of 2013, the FDA conducted an inspection of our facilities which resulted in the issuance of a Form FDA 483 on May 30, 2013. The Form FDA 483 listed deficiencies in the areas of reporting of Field Actions, the documentation of our Letter to File process and specific observations about Design Inputs. On July 16, 2013, FDA issued a Warning Letter to Intuitive expanding on two of the four observations in the Form FDA 483 issued May 30, 2013. We responded to the FDA Form 483 observations and Warning Letter citations with plans for corrective action and objective evidence of corrections as they are completed. The receipt of a Warning Letter places certain limits on the ability to obtain FDA issued CFGs used for new and re-registration of products in certain foreign countries. In addition, it creates a limitation on the use of so-called "special 510(k)" regulatory submissions which have a shorter review cycle than "traditional" 510(k)'s. These limitations are expected to result in delays in the registration of some products in a small number of foreign countries and lengthen the submission cycle for simple changes which are subject to 510(k) clearance.

Although we have made the closure of the Warning Letter a top priority and have engaged additional highly qualified outside experts to thoroughly examine and assist in the remediation of the areas cited by the FDA in the Form FDA 483 and Warning Letter, there can be no guarantee of the timing to clear the Warning Letter or preclude additional FDA requirements or enforcement actions.

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.

In January 2013, we leased additional manufacturing space in Mexicali, Mexico and we are in the process of installing manufacturing lines in this new space as well as making changes to the configurations of existing manufacturing

space. Such changes require various types of regulatory notifications and approvals depending on the country where product manufactured in these buildings is shipped. The process for obtaining those approvals and providing notifications or registrations is underway but delays or limitations could adversely affect our ability to deliver products to certain countries until all required regulatory authorizations are in place. This facility will be subject to the same types of periodic inspections and compliance requirements described above.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

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

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. If we fail to obtain adequate protection of our intellectual

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property, or if any protection we obtain is reduced or eliminated, our ability to prevent others from using our intellectual property could be adversely affected, resulting in harm to our business.

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

Our commercial success will depend in part on obtaining patent and other intellectual property protection for the technologies contained in our products, and on successfully defending our patents and other intellectual property against third-party challenges. We will incur substantial costs in obtaining patents and, if necessary, defending our proprietary rights. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. We do not know whether we will obtain the patent protection we seek, or that the protection we do obtain will be found valid and enforceable if challenged. We also do not know whether we will be able to develop additional patentable proprietary technologies. 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

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to maintain these licenses could prevent or delay further development or commercialization of our products, which would have a material adverse effect on our results of operations.

RISKS RELATING TO OUR TRADING MARKETS

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

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

- the extent to which our products gain market acceptance;
- actions relating to regulatory matters;
- our timing and ability to develop our manufacturing and sales and marketing capabilities;
- demand for our products;
- the size and timing of particular sales and any collection delays related to those sales;
- 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 2010, the NASDAQ closing price of one share of our common stock reached a high of $388.01 and a low of $247.50, during fiscal 2011, it 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, and during fiscal 2013, it reached a high of $583.67 and a low of $355.93. 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, 2013, we owned approximately 899,000 square feet of space on 55 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 of space is currently leased to third parties and will be used for the future expansion of our East Coast sales and training campus. In Aubonne, Switzerland, we owned 15,000 square feet of space on 1.5 acres, which is used for our international headquarters. We leased approximately 5,000 square feet of space for research and development in Milford, Connecticut, approximately 17,000 square feet in Georgia for which we are currently looking for a sublease tenant and 74,000 square feet in Mexicali, Mexico where we manufacture most of our EndoWrist instruments. We also leased facilities for sales and operations in Tokyo, Japan, Shanghai, China, and Seoul, Korea.

ITEM 3. LEGAL PROCEEDINGS

We are involved in a variety of claims, lawsuits, investigations and proceedings relating to securities laws, product liability, patent infringement, contract disputes and other matters relating to various claims that arise in the normal course of our business. Certain of these lawsuits and claims are described in further detail below. We do not know whether we will prevail in these matters nor can we assure that any remedy could be reached on commercially reasonable terms, if at all. It is not possible to predict the outcome of the pending or threatened litigation matters currently disclosed. We have therefore determined that an estimate of possible loss or range of loss cannot be determined as of December 31, 2013. 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 our business, financial condition, and results of operations or cash flows.

In accordance with U.S. generally accepted accounting principles, we record a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. These provisions are reviewed at least quarterly and adjusted to reflect the impacts of negotiations, settlements, rulings, advice of legal counsel, and other information and events pertaining to a particular case.

Purported Shareholder Class Action Lawsuit filed August 6, 2010

On August 6, 2010, a purported class action lawsuit entitled Perlmutter v. Intuitive Surgical et al., No. CV10-3451, was filed against seven of our current and former officers and directors in the United States District Court for the Northern District of California. The lawsuit seeks unspecified damages on behalf of a putative class of persons who purchased or otherwise acquired our common stock between February 1, 2008 and January 7, 2009. The complaint alleges that the defendants violated federal securities laws by making allegedly false and misleading statements and omitting certain material facts in our filings with the Securities and Exchange Commission. 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, we filed a motion 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 are substantially similar to the allegations in the prior complaint. We filed a motion to dismiss the amended complaint. A hearing occurred on February 16, 2012, and on May 22, 2012 our motion was granted. The complaint was dismissed with prejudice, and a final judgment was entered in our 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 is 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. We filed an answering brief on November 13, 2012, and plaintiffs filed a reply brief on December 17, 2012. No oral argument date has been set, and the appeal remains pending. Based on currently available information, we do not believe the resolution of this matter will have a material adverse effect on our business, financial position or future results of operations.

Purported Derivative Actions

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 us as a nominal defendant, and naming 14 of our current and former officers and directors as defendants. The lawsuit seeks to recover, for our benefit, unspecified damages purportedly sustained by us in connection with allegedly misleading statements and/or omissions made in connection with our financial reporting for the period between February 1, 2008 and January 7, 2009. It also seeks a series of changes to our corporate governance policies and an award of 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 our 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 the plaintiffs, all activity in the case has been stayed pending the results of the appeal in the purported shareholder class action lawsuit discussed above. Based on currently available information, we do not believe the resolution of this matter will have a material adverse effect on our business, financial position or future results of operations.

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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 our 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.

On October 15, 2013 the plaintiffs in the Abrams matter filed an amended complaint. The case has since been re-titled In re Intuitive Surgical Securities Litigation. The plaintiffs seek unspecified damages on behalf of a putative class of persons who purchased or otherwise acquired our 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 our filings with the Securities and Exchange Commission. On November 18, 2013 the Court appointed Employees' Retirement System of the State of Hawaii as lead plaintiff and appointed lead counsel. We filed a motion to dismiss the amended complaint on December 16, 2013. We anticipate a hearing on our motion in May 2014. Based on currently available information, we do not believe the resolution of this matter will have a material adverse effect on our business, financial position or future results of operations.

Product Liability Litigation

We are currently named as a defendant in about 76 individual product liability lawsuits filed in various state and federal courts by plaintiffs who allege that they 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. In addition, we have been 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 cases raise a variety of allegations including, to varying degrees, that the plaintiffs' injuries resulted from purported defects in the da Vinci Surgical System and/or failure on our part to provide adequate training resources to the healthcare professionals who performed plaintiffs' surgeries. The cases further allege that we 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. Except for a few cases, including the Taylor case described below, these cases generally are in the early stages of pretrial activity.

Plaintiffs' attorneys continue to engage in well-funded national advertising campaigns soliciting clients who have undergone da Vinci surgery and claim to have suffered an injury. The plaintiffs' attorneys are now alleging that we are liable for those injuries under products liability theories. We continue to receive claims as a result of these advertising efforts; however, we have not received detailed information regarding all claims. In an effort to provide an orderly process for evaluating claims before they result in costly litigation, we have entered into tolling agreements with certain plaintiffs' counsel acting on behalf of such claimants. The tolling agreements provide that the statute of limitations for each individual will be tolled for a certain period in exchange for the individual's agreement that, if he or she ultimately files a lawsuit, it will be filed in certain agreed upon venues. A substantial number of claims have been added to the tolling agreements, which provide the parties and their legal counsel with additional time to evaluate the claims, and to explore whether the claims have merit and whether they can be resolved through mediation without litigation. As of result of these discussions, plaintiffs' counsel have voluntarily removed a sizable number of claims from the tolling agreements and notified the Company that they no longer intend to pursue these claims. Nonetheless, we do not currently know how many individuals will ultimately file lawsuits or how many additional individuals will decide not to pursue their claims, nor are we able at this time to reasonably estimate the financial impact of their claims or predict the final disposition of such claims. Based on currently available information, we believe that we have meritorious defenses and although we continue to explore means of resolving individual claims or aggregate groups of claims without litigation, we intend to assert such defenses vigorously in the lawsuits that are currently pending and any future lawsuits. We are not at present able to determine whether the resolution of these matters will have a material adverse effect on our business, financial position or future results of operations.

In February 2011, we were 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 the 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 us, 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 our 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 we were not negligent. Judgment was entered in our favor on June 7, 2013. Plaintiff has filed a notice of appeal.

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False Claims Act Litigation

In October 2013, we were 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 twenty-one states and of the District of Columbia. Broadly, he alleges that he has first-hand knowledge of a fraudulent scheme, involving kickbacks paid in exchange for referrals and surgical procedures, and first-hand knowledge of off-label usage of our products. The complaint was filed under seal on November 27, 2012, and was provided to the Department of Justice and the twenty-one states and the District of Columbia. The United States Government declined to intervene on October 8, 2013. The twenty-one states and the District of Columbia declined to intervene on November 21, 2013. Based on currently available information, we believe that we have meritorious defenses in this action and intend to assert them vigorously. Based on currently available information, we do not believe the resolution of this matter will have a material adverse effect on our business, financial position or future results of operations.

Insurance Litigation

In October 2013, we were 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 us, which provides coverage for products liability claims first made against us during the policy period March 1, 2013 to March 1, 2014. In December 2013, we were 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 us for products liability claims first made against us during the policy period March 1, 2013 to March 1, 2014 should be rescinded. Both Plaintiffs generally allege that we did not disclose the existence of tolling agreements and the number of claimants incorporated within those agreements, and that those agreements were material to Plaintiffs' underwriting processes. We intend to vigorously defend these actions. Based on currently available information, we do not believe the resolution of this matter will have a material adverse effect on our business, financial position or future results of operations.

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.

	2013		2012	
Fiscal	High	Low	High	Low
First Quarter	$583.67	$459.44	$546.31	$440.00
Second Quarter	$513.49	$470.30	$588.28	$503.01
Third Quarter	$504.01	$363.89	$566.61	$472.48
Fourth Quarter	$401.68	$355.93	$551.19	$479.50

As of January 17, 2014, there were 241 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, 2013 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	4,756,443	$371.06	2,099,621
Equity compensation plans not approved by security holders	802,746	$437.87	219,860
Total	5,559,189	$380.71	2,319,481

RECENT SALES OF UNREGISTERED SECURITIES

None.

ISSUER PURCHASES OF EQUITY SECURITIES

The table below summarizes our stock repurchase activity during the fiscal quarter ended December 31, 2013 (in millions, except per share amounts):

Fiscal Period	Total Number of Shares Repurchased	Average Price Paid Per Share	Total Number of Shares Purchased As Part of a Publicly Announced Program	Approximate Dollar Amount of Shares That May Yet be Purchased Under the Program
October 1, 2013 to October 31, 2013	—	$—	—	$ 1,000.0
November 1, 2013 to November 30, 2013	—	$—	—	$ 1,000.0
December 1, 2013 to December 31,2013	—	$—	—	$ 1,000.0
Total during quarter ended December 31, 2013	—	$—	—	$ 1,000.0

Since March 2009, we have had an active stock repurchase program. The most recent Board authorizations were in March 2013 and July 2013 when the Board increased the authorization for stock repurchases by $1.0 billion and $0.8 billion. During the period from March 2009 to December 2013, we repurchased a total of 6.2 million shares of our

common stock at a total of $2.0 billion. As of December 31, 2013, the remaining authorized amount of stock repurchases that may be made under the Board-authorized stock repurchase program was $1.0 billion.

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STOCK PERFORMANCE GRAPH

The graph set forth below compares the cumulative total stockholder return on our common stock between December 31, 2008 and December 31, 2013, 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, 2008 in our common stock, the S&P Healthcare Index, the Nasdaq Composite Index, and the S&P 500 Index and assumes the reinvestment of dividends, if any. We included the comparison with the S&P 500 Index because our Company became a component of the S&P 500 Index on June 2, 2008.

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

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

	December 31,					
	2008	2009	2010	2011	2012	2013
Intuitive Surgical, Inc.	$100.00	$238.94	$202.97	$364.60	$386.15	$302.45
NASDAQ Composite	$100.00	$143.89	$168.22	$165.19	$191.47	$264.84
S&P 500 Healthcare Index	$100.00	$117.07	$117.90	$129.89	$152.58	$207.42
S&P 500 Index	$100.00	$123.45	$139.23	$139.23	$157.90	$204.63

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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.

	Years Ended December 31,				
	2013	2012	2011	2010	2009
	(In millions, except per share amounts and headcount)				
Revenue	$2,265.1	$2,178.8	$1,757.3	$1,413.0	$1,052.2
Gross profit	$1,594.2	$1,570.3	$1,273.8	$1,030.0	$751.1
Net income [(1)]	$671.0	$656.6	$495.1	$381.8	$232.6
Net income per common share:					
Basic	$17.12	$16.50	$12.63	$9.74	$6.07
Diluted	$16.73	$15.98	$12.32	$9.47	$5.93
Shares used in computing basic and diluted net income per share:					
Basic	$39.2	$39.8	$39.2	$39.2	$38.3
Diluted	$40.1	$41.1	$40.2	$40.3	$39.2
Cash, cash equivalents and investments	$2,753.9	$2,920.5	$2,171.8	$1,608.9	$1,172.0
Total assets	$3,950.3	$4,059.2	$3,063.1	$2,390.4	$1,809.7
Other long-term liabilities	$68.0	$77.5	$96.9	$79.2	$69.6
Stockholders' equity	$3,501.4	$3,580.1	$2,645.6	$2,037.4	$1,537.3
Total headcount	2,792	2,362	1,924	1,660	1,263

(1) Net income for the years ended December 31, 2013, 2012, 2011, 2010, and 2009 included share-based compensation expense of $110.4 million, $105.8 million, $93.5 million, $78.4 million and $70.5 million, respectively, net of tax, related to employee stock options and employee stock purchases. Net income for the years ended December 31, 2013, 2012, 2011, 2010, and 2009 included amortization of purchased intellectual property of $21.3 million, $23.1 million, $17.8 million, $16.7 million, and $15.6 million, respectively. The 2013 tax provision included discrete tax benefits of $26.7 million associated with the reversal of unrecognized tax benefits resulting from expiration of statutes of limitations in multiple jurisdictions. In addition, the 2013 tax provision included a net tax benefit of $8.2 million related to 2012 federal R&D tax credit. The 2012 tax provision includes discrete tax benefits totaling $46.5 million, which is comprised of $38.0 million associated with the third quarter reversal of unrecognized tax benefits in conjunction with the expiration of certain statutes of limitations, and $8.5 million of benefits associated with certain previously unrecognized tax benefits as a result of new IRS guidance issued in the first quarter. The 2012 tax provision excludes a federal R&D tax credit due to its expiration at the end of 2011. There were no significant discrete tax benefits for years ended December 31, 2009 through December 31, 2011.

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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 MIS, where MIS is available. Over the past two decades, MIS has reduced trauma to the patient by allowing selected surgeries to be performed through small ports rather than large incisions. MIS has been widely adopted for certain surgical procedures, but it has not been widely adopted for complex reconstructive surgeries.

The da Vinci Surgical System enables 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 the da Vinci system operate while seated comfortably at a console viewing a Three Dimensional ("3-D"), 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 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 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 products fall into four broad categories - 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 three generations of da Vinci Surgical Systems; the first is our standard da Vinci Surgical System, first commercialized in 1999, the second is our da Vinci S Surgical System, commercialized in 2006, and the third and most current is our da Vinci Si Surgical System, commercialized in 2009. Systems include a surgeon's console (or consoles), imaging electronics, a patient-side cart and computational hardware and software.

Instruments and accessories are used with systems to allow surgeons the 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 in cholecystectomy procedures utilizing the da Vinci Si Surgical System. During the first quarter of 2013, Single-Site instruments were FDA cleared in the U.S. for use in benign hysterectomies and salpingo oophorectomies. Single-Site instruments enable surgeons to perform surgery through a single port via the patient's belly button, resulting in virtually scarless patient outcomes. Single-Site instruments were Conformité Européenne ("CE") marked and introduced in Europe in the first quarter of 2011. 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.

Worldwide Procedures

The adoption of da Vinci surgery has the potential to grow for those procedures that offer greater patient value than non da Vinci alternatives. 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. In 2013, da Vinci was used primarily in gynecology, urology, general surgery, cardiothoracic surgery and head and neck surgery. Target procedures in gynecology include da Vinci Hysterectomy ("dVH"), sacrocolpopexy, myomectomy and endometriosis resection. Target procedures in urology include da Vinci Prostatectomy ("dVP"), partial nephrectomy and pyeloplasty. Target procedures in general surgery include Single-Site Cholecystectomy, colorectal procedures, and a

broad base 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 da Vinci Trans-oral Robotic-Assisted Surgery ("TORS") for throat and base of tongue cancers.

In 2013, approximately 523,000 surgical procedures were performed with the da Vinci Surgical System, compared to approximately 450,000 and 359,000 procedures performed in 2012 and 2011, respectively. The growth in our overall procedure volume in 2013 was driven by the growth in U.S. general surgery procedures, U.S. gynecologic procedures and urology procedures outside of the U.S.

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U.S. Procedures

Overall U.S. procedure volume grew to approximately 422,000 in 2013, compared to approximately 367,000 in 2012, and 292,000 in 2011.

Gynecology is our largest U.S. surgical specialty. Overall U.S. gynecology procedure volume grew from approximately 170,000 cases in 2011 to approximately 222,000 in 2012 and to approximately 240,000 in 2013. The growth was driven by adoption of dVH, our highest volume procedure, and other gynecologic procedures, including sacrocolpopexy and myomectomy. U.S. dVH procedure volume grew from approximately 140,000 cases in 2011 to approximately 176,000 cases in 2012 to approximately 191,000 cases in 2013, of which approximately 41,000 were for the treatment of cancer and approximately 150,000 were related to benign conditions. The lower 2013 U.S. gynecology procedure growth rate reflected a number of factors including, but not limited to, dVH for cancer approaching standard of care penetration levels, apparent pressure on benign gynecology hospital admissions, negative media reports, and a trend by payers toward encouraging conservative disease management and treatment in outpatient settings. We estimate the total annual U.S. addressable robotic hysterectomy market to consist of approximately 300,000 procedures previously performed via open surgery, of which approximately 50,000 are for cancer.

Based upon procedure run rates exiting 2013, general surgery is now our second largest and fastest growing specialty in the U.S. Overall U.S. general surgery procedure volume grew from approximately 15,000 cases in 2011 to approximately 42,000 in 2012 and to approximately 81,000 in 2013. Over 800 customers have purchased da Vinci Single-Site instrumentation through the end of 2013.

U.S. urology procedure volume was approximately 85,000 in 2013, compared to approximately 88,000 in 2012, and 93,000 in 2011. We consider dVP to be the standard of care for the surgical treatment of prostate cancer in the U.S. About 58,000 dVPs were performed in 2013, compared to 62,000 in 2012, and 73,000 in 2011. The approximately 15% reduction in 2012 dVP procedures in the U.S. were caused by the U.S. Preventive Services Task Force recommendation against prostate-specific antigen (“PSA”) screening, as well as changes in treatment pattern for low risk prostate cancer away from definitive treatment. U.S. dVP volumes appear to have stabilized throughout 2013.

International Procedures

Overall international procedure volume grew to approximately 101,000 in 2013, compared to approximately 83,000 in 2012 and 68,000 in 2011. dVP accounted for the majority of international procedures, having grown from about 40,000 in 2011, to 47,000 in 2012, and to 56,000 in 2013. Growth in international dVP was driven by higher procedure volumes in Japan, Italy, the United Kingdom and Australia.

Procedure Seasonality

The majority of da Vinci procedures performed are now for benign conditions, most notably benign hysterectomies. The proportion of these benign procedures is growing in relation to the total number of procedures performed. Hysterectomies for benign conditions 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. Third quarter activity is also slower given vacation periods, particularly in Europe. As we achieve deeper penetration in certain procedures, seasonality has a more substantial impact on our business.

Business Model

We generate revenue from both the initial capital sales of da Vinci Surgical Systems as well as recurring revenue, derived from sales of instruments, accessories and service. The da Vinci Surgical System generally sells for between $1.0 million and $2.3 million, depending 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 instruments 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. We also 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 the rate of growth of system revenue. Recurring revenue increased from $979.5 million, or 56% of total revenue in 2011 to $1,245.9 million, or 57% of total revenue in 2012 to $1,430.2 million, or 63% of total revenue in 2013. The increase in recurring revenue relative to system revenue reflects lower 2013 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 2,966 at December 31, 2013, compared with 2,585 at December 31, 2012, and 2,132 at December 31, 2011.

We provide our products through a direct sales organization in the U.S. and in Europe, excluding Spain, Italy, Greece and Eastern European countries. In January 2012, we acquired our Korean distributor and began selling directly to Korean customers.

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Beginning in 2013, we began to provide our products through a direct sales organization in the Czech Republic, Slovakia and Hungary, whereas prior to 2013, these markets were served by a distributor. In the remainder of our world markets, we provide our products through distributors.

Regulatory Activities

We believe that we have obtained the clearances required to market our multiport products to our targeted surgical specialties within the U.S. and most of Europe. As we make additions to target procedures 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. FDA clearance for Single-Site Cholecystectomy was received in December 2011.

In September 2013, we received FDA clearance to expand the indication for use for Firefly to include visual assessment of at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common heptatic duct), using near infrared imaging. Fluorescence imaging of biliary ducts with the da Vinci Fluorescence Imaging Vision System 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 November 2009, we received Shonin approval from the Japanese Ministry of Health, Labor, and Welfare (“MHLW”) for our da Vinci S Surgical System in Japan. Until April 2012, we had partnered with the experienced regulatory team from Johnson & Johnson K.K. Medical Company (“JJKK”) to assist in navigating the Japanese regulatory process. In April 2012, the Marketing Authorization Application for da Vinci products was transferred to Intuitive Surgical Japan from JJKK, and Intuitive Surgical Japan now has primary responsibility for regulatory support of our products in Japan. We continue to partner with Adachi Co., Ltd as our separate independent distribution partner for marketing, selling, and servicing our products in Japan. Effective April 2012, we obtained national reimbursement for the dVP procedures in Japan, our only reimbursed procedure to date. In Japan additional procedures are considered for reimbursed status in April of even numbered years as the MHLW considers recommendations and data brought forth from Japanese surgical societies. We do not expect any additional procedures to be granted reimbursement status in the April 2014 cycle. We are supporting the Japanese surgical societies to gather the necessary data for MHLW consideration for reimbursement of additional procedures in the April 2016 cycle. In October 2012, we obtained MHLW approval for da Vinci Si Surgical Systems in Japan. 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.

FDA Inspection

A FDA inspection of the Company’s 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 their intent to perform a follow-up inspection. We have responded to the Warning Letter with plans for corrective action, and continue to provide supplemental responses with objective evidence of corrections as they are completed. 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. However, we cannot assure that, upon re-inspection, the FDA will find that our corrective actions are acceptable or that they have been adequately implemented. We also cannot assure that the FDA will not find other observations. The FDA previously inspected our Sunnyvale, CA 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 used for new and re-registration of products in certain foreign countries.

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, which contain allegations of patient injury, are required to be investigated. In those cases in which da Vinci was used and the system cannot yet be ruled out as a cause of the alleged injury, these cases are reported to the FDA as MDRs. This has led to increases in MDRs.

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We will continue to work with the FDA, CDRH and OSB to establish agreement on reporting criteria and to complete any retrospective reporting that may be required as a result of new criteria. We cannot predict when this work will be completed as it is highly dependent on FDA questions and the acceptance of our responses and data.

Recalls and Corrections

Medical device companies have regulatory obligations to correct or remove medical devices in the field which have factors which 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, 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 some cases actions taken us that we believed to be routine or not reportable may be retrospectively classified by regulators as reportable, resulting in the reporting of additional field actions, which in some cases may have already been completed. 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 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 to complete field actions.

2013 Business Events and Trends

Procedures

Overall. During the year ended December 31, 2013, total da Vinci procedures grew approximately 16% compared with 2012, driven by growth in general surgery and gynecology procedures in the U.S. and international urology procedures, partially offset by an approximately 6% reduction in dVP procedures in the U.S.

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, have led to a decline in our dVP business. During 2013, U.S. dVP procedure volumes appear to have stabilized, with a gradually decreasing trend. These treatment patterns have also impacted our European dVP procedure volumes. dVP is at earlier market penetration stages in the European markets; therefore, 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, 2013, we experienced lower growth rates in the category of U.S. benign gynecologic procedures than in prior years. The slower 2013 growth rate in the category of U.S. benign gynecologic procedures reflected a number of factors including, but not limited to, apparent pressure on benign gynecology hospital admissions, negative media reports, and a trend by payers toward encouraging conservative disease management and treatment in outpatient settings. We still have a significant remaining market opportunity in benign gynecologic procedures since a large number are still done via open technique. However, as we penetrate more deeply into benign gynecologic procedures, our pace of capturing or consolidating the remaining market is progressing at a slower rate than previously.

Monopolar Curved Scissors Field Action. During early May 2013, we issued a field notice informing customers of the potential for micro-crack formations in certain of our EndoWrist Monopolar Curved Scissors (“MCS”). We decided to stop shipment of these versions until a replacement product was made available. However, as the risk of injury to patients from the recalled product was extremely low, customers were notified that they could continue to use the recalled product; which most did. To date, we have no confirmed evidence of patient injury attributable to this issue. The replacement MCS product began shipping on May 31, 2013. We do not believe that this field action materially impacted our 2013 procedure volume and customer returns of the recalled product have not been material.

Environment and Demand for Our Products

During the year ended December 31, 2013, there have been a number of factors that have resulted in slowing growth rates in U.S. benign gynecologic procedures as noted previously. We expect growth in benign procedures to continue at a level below 2012 and could decline further depending on changes in hospital admissions, payer behavior, the impact of the Affordable Care Act and other factors. In the future, demand for da Vinci systems will be impacted by factors including procedure growth rates, 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 the time until potential additional da Vinci procedures will be considered for reimbursement, anticipated in 2016, and changing economic and geopolitical factors. The European credit

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and sovereign debt issues have slowed capital sales and curtailed procedure growth during 2012 and through 2013. European uncertainties could adversely impact demand for our products globally.

New Product Introductions

da Vinci Single-Site Instruments. da Vinci Single-Site is a set of non-wristed instruments 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 U.S. 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. We are encouraged by hospital, surgeon, and patient interest in da Vinci Single-Site, with over 800 U.S. customers having purchased da Vinci Single-Site kits as of December 31, 2013. 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. 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. 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.

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. We expect its initial surgical use to be directed towards colorectal procedures. During fiscal 2013, the EndoWrist Stapler was used by a limited and gradually increasing number of customers. We expect to continue to expand to a broadening set of customers in 2014. Although our first 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.

Recent Media and Lawsuits

Prior to and during the twelve months ended December 31, 2013, 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, the adequacy of surgeon training, and the Company’s sales and marketing practices. In addition, as further described below in “Part I, Item 3. Legal Proceedings,” we are currently

named as a defendant in about 76 individual product liability lawsuits. Plaintiffs' attorneys are 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 the training we provide to surgeons helps to ensure that they are able to operate our systems with the requisite skill and expertise. 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. We are not able at this time to reasonably estimate the financial impact of this recent negative media publicity.

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2013 Financial Highlights

- Total revenue increased 4% to $2,265.1 million during the year ended December 31, 2013, from $2,178.8 million during the year ended December 31, 2012.
- Approximately 523,000 da Vinci procedures were performed during the year ended December 31, 2013, up approximately 16% from the year ended December 31, 2012.
- Instruments and accessories revenue increased 14% to $1,032.9 million during the year ended December 31, 2013 from $903.3 million during the year ended December 31, 2012.
- Recurring revenue increased 15% to $1,430.2 million during the year ended December 31, 2013, representing 63% of total revenue, from $1,245.9 million during the year ended December 31, 2012, representing 57% of total revenue.
- We sold 546 da Vinci Surgical Systems during the year ended December 31, 2013, compared with 620 for the year ended December 31, 2012.
- System revenue decreased 11% to $834.9 million during the year ended December 31, 2013 from $932.9 million during the year ended December 31, 2012.
- As of December 31, 2013, we had a da Vinci Surgical System installed base of 2,966 systems - 2,083 in the U.S., 476 in Europe, 159 in Japan and 248 in the rest of the world.
- Operating income decreased 3% to $852.5 million during the year ended December 31, 2013 compared with $878.1 million during the year ended December 31, 2012. Operating income included $168.9 million and $153.3 million during the years ended December 31, 2013 and 2012, respectively, of share-based compensation expense related to employee stock programs.
- We ended fiscal 2013 with $2,753.9 million in cash, cash equivalents and investments. Cash, cash equivalents, and investments decreased by $166.6 million during 2013 driven by $1,109.2 million used to repurchase and retire 2.6 million shares of common stock and $104.6 million used for capital expenditures, partially offset by cash flow from operations and $160.6 million generated from employee stock programs.
- We ended fiscal 2013 with 2,792 employees, compared to 2,362 at the end of fiscal 2012. Headcount additions were made predominantly to our manufacturing, R&D organizations and field sales organizations.

Technology and Other Acquisitions

We continue to make strategic acquisitions of intellectual property and related technologies. Total investments in intellectual property and related technologies during the year ended December 31, 2013 were $2.0 million, compared with $41.6 million during the year ended December 31, 2012. Amortization expense related to purchased intellectual property for the years ended December 31, 2013 and 2012 were $21.3 million and $23.1 million, respectively.

On January 11, 2012, we completed the acquisition of our Korean distributor. The total purchase consideration of the acquisition was not material, and the acquisition has not had a material impact on the results of our operations.

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Results of Operations

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

	Years Ended December 31,							
	2013	% of total revenue		2012	% of total revenue		2011	% of total revenue	
Revenue:									
Product	$1,867.8	82	%	$1,836.2	84	%	$1,478.9	84	%
Service	397.3	18	%	342.6	16	%	278.4	16	%
Total revenue	2,265.1	100	%	2,178.8	100	%	1,757.3	100	%
Cost of revenue:									
Product	543.4	24	%	495.3	23	%	382.3	22	%
Service	127.5	6	%	113.2	5	%	101.2	6	%
Total cost of revenue	670.9	30	%	608.5	28	%	483.5	28	%
Product gross profit	1,324.4	58	%	1,340.9	61	%	1,096.6	62	%
Service gross profit	269.8	12	%	229.4	11	%	177.2	10	%
Gross profit	1,594.2	70	%	1,570.3	72	%	1,273.8	72	%
Operating expenses:									
Selling, general and administrative	574.0	25	%	522.2					