INTUITIVE SURGICAL INC
Form 10-K
February 02, 2018
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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, 2017
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. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See definition of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth 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	¨
		Emerging growth company	¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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, 2017, based upon the closing price of Common Stock on such date as reported on the NASDAQ Global Select Market, was approximately $34,385,417,181. 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 as of January 19, 2018, was 112,298,504.

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 19, 2018, to be filed within 120 days of the registrant’s fiscal year ended December 31, 2017.

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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, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as "estimates," "projects," "believes," "anticipates," "plans," "expects," "intends," "may," "will," "could," "should," "would," "targeted" and similar word expressions are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements related to provisional income tax expense related to the Tax Cuts and Jobs Act, the potential impact of the final resolution of provisional estimates and potential subsequent adjustments due to additional guidance from and interpretations by regulatory and standard-setting bodies and changes in assumptions, our expected business, new product introductions, procedures and procedure adoption, future results of operations, future financial position, our ability to increase our revenues, the anticipated mix of our revenues between product and service revenues, our financing plans and future capital requirements, anticipated costs of revenue, anticipated expenses, our potential tax assets or liabilities, the effect of recent accounting pronouncements, our investments, anticipated cash flows, our ability to finance operations from cash flows and similar matters, and 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, therefore, be considered in light of various important factors, including, but not limited to, the following: the impact of global and regional economic and credit market conditions on healthcare spending; healthcare reform legislation in the U.S. and its impact on hospital spending, reimbursement and fees levied on certain medical device revenues; changes in hospital admissions and actions by payers to limit or manage surgical procedures; the timing and success of product development and market acceptance of developed products; the results of any collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships; procedure counts; regulatory approvals, clearances and restrictions or any dispute that may occur with any regulatory body; guidelines and recommendations in the healthcare 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 or 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 us and the safety of our products and adequacy of training; our ability to expand into foreign markets; the impact of changes to tax legislation, guidance, and interpretations; and other risk factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which are based on current expectations and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those risk factors described throughout this filing and particularly in Part I, "Item 1A. Risk Factors." Our actual results may differ materially and adversely from those expressed in any forward-looking statement. We undertake no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.

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PART I

ITEM 1. BUSINESS

In this report, “Intuitive Surgical,” “Intuitive,” the “Company,” “we,” “us,” and “our” refer to Intuitive Surgical, Inc. and its wh
and majority-owned subsidiaries. Intuitive®, Intuitive Surgical®, da Vinci®, da Vinci S®, da Vinci S HD Surgical System®, da Vinci Si®, da Vinci Si HD Surgical System®, da Vinci Xi®, da Vinci SP®, EndoWrist®, Firefly®, InSite®, da Vinci Connect®, Intuitive Surgical EcoSystem®, and da Vinci X® 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 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 and safe to use.

Our systems provide the following features and benefits to surgeons:

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

EndoWrist Instruments. Our instruments are modeled after the human wrist, offering a greater range of motion than the human hand. 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.

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 that environment.

Scaled, Tremor Filtered Instrument Movement. With our technology, a surgeon can also use "motion scaling," a feature that translates, for example, a three-millimeter hand movement outside the patient's body into a one-millimeter instrument movement in the surgical field inside the patient's body. Motion scaling is designed to allow precision and control for delicate tasks. In addition, our technology filters the tremor inherent in a surgeon's hands.

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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 Systems

We have commercialized the following four generational platforms of da Vinci Surgical Systems: our fourth generation da Vinci X and da Vinci Xi Surgical Systems, our third generation da Vinci Si Surgical System, our second generation da Vinci S Surgical System, and our first generation da Vinci standard Surgical System. da Vinci Surgical Systems are comprised of the following components:

Surgeon's Console. The da Vinci Surgical System allows surgeons to operate while comfortably seated at an ergonomic console viewing a 3-D image of the surgical field. The surgeon's fingers grasp instrument controls below the display with the surgeon's hands naturally positioned relative to his or her eyes. Using electronic hardware, software, algorithms, and mechanics, our technology translates the surgeon's hand movements into precise and corresponding real-time micro movements of the EndoWrist instruments positioned inside the patient. On our most current systems, da Vinci X, da Vinci Xi, and da Vinci Si, a second surgeon's console may be used in two possible ways: to provide assistance to the primary surgeon during surgery or to act as an active aid during surgeon-proctor training sessions. With da Vinci X, da Vinci Xi, and da Vinci Si, a surgeon sitting at a second console can view the same surgery as the primary surgeon and can be passed control of some or all of the da Vinci instruments during the surgery. In addition, surgeons can control 3-D virtual pointers to augment the dual surgeon experience.

Patient-Side Cart. The patient-side cart holds electromechanical arms that manipulate the instruments inside the patient. Up to four arms attached to the cart can be positioned as appropriate, and then locked into place. At least two arms hold our EndoWrist instruments, one representing the surgeon's left hand and one representing the surgeon's right hand. A third arm positions the endoscope, allowing the surgeon to easily move, zoom, and rotate his or her field of vision. A 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 da Vinci X, Xi, and Si Surgical Systems, and is available as an upgrade on three-arm Si-e Surgical System.

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 X, Xi, Si, and S Surgical Systems.

da Vinci Skills Simulator. The Skills Simulator is a practice tool that gives a user the opportunity to practice his or her facility with the surgeon console controls. The Skills Simulator incorporates 3-D, physics-based computer simulation technology to immerse the user within a virtual environment. The user navigates through the environment and completes exercises by controlling virtual instruments from the surgeon console. Upon completion of a skills exercise, the Skills Simulator provides a quantitative assessment of user performance based on a variety of task-specific metrics. The Skills Simulator is intended to augment, not replace, existing training programs for the da Vinci X, Xi, and Si Surgical Systems. Most da Vinci Skills Simulators have been sold in connection with our da Vinci X, Xi, and

Si Surgical Systems.

da Vinci Xi Integrated Table Motion. Integrated Table Motion coordinates the movements of the da Vinci robot arms with an advanced operating room table, the TruSystem® 7000dV sold by Trumpf Medical™, to enable shifting a patient's position in real-time while the da Vinci surgical robotic arms remain docked. This gives operating room teams the capabilities to optimally position the operating table so that gravity exposes anatomy during multi-quadrant da Vinci System procedures, maximize reach and access to target anatomy enabling surgeons to interact with tissue at an ideal working angle, and reposition the table during the procedure to enhance anesthesiologists' care of the patient.

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Firefly Fluorescence Imaging. Firefly is a standard feature of the da Vinci X and Xi Surgical System and available on our 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, tissue perfusion, or biliary ducts in three dimensions beneath tissue surfaces to visualize critical anatomy. Firefly is generally used across the categories of urology, gynecology, and general surgery.

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 may be selected and used interchangeably during a surgery. Our EndoWrist instruments are sterilizable at the hospital or provided sterile, 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 da Vinci system and instruments work together. In addition, the chip will generally not allow the instrument to be used for more than the prescribed number of procedures to help ensure that its performance meets specifications during each procedure.

da Vinci Single-Site. da Vinci Single-Site is a set of non-wristed and wristed instruments and accessories that allow da Vinci 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.

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 7mm in diameter and tissue bundles that fit in the jaws of the instrument. This instrument enables surgeons to fully control vessel sealing, while providing the benefits of da Vinci Surgery. This instrument is designed to enhance surgical efficiency and autonomy in a variety of general surgery and gynecologic procedures.

EndoWrist Stapler. The EndoWrist Stapler is a wristed, stapling instrument intended for resection, transection, and/or creation of anastomoses. This instrument enables operators to precisely position and fire the stapler. We market two types of staplers: the EndoWrist Stapler 45 and 30 where the numeric designation indicates the length of the staple line. The EndoWrist Stapler 45 is used in general, gynecologic, and urologic surgery. The EndoWrist Stapler 30, available with the da Vinci X and Xi Surgical System, is intended to deliver particular utility with fine tissue interaction in lobectomy and other thoracic procedures.

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 help 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 da Vinci Surgical System.

Business Strategy

Our goal is to fundamentally improve surgery and maximize the number of patients who can derive the benefits of MIS. Through the use of computer-aided robotic technologies our objective is to create value for patients, surgeons, and hospitals as summarized below:

Patient Value. We believe that the value of a surgical procedure to a patient can be defined as: Patient Value = Procedure Efficacy/Invasiveness. We define procedure efficacy as a measure of the success of the surgery in resolving the underlying disease and invasiveness as how disruptive and painful the treatment is itself. When the patient value of a da Vinci procedure is deemed higher than alternate treatment options, patients may seek out surgeons and hospitals that offer that specific da Vinci procedure, potentially resulting in a local market share shift for the specific treatment. da Vinci procedure adoption occurs procedure by procedure, and is driven by the relative patient value and total treatment costs 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.

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 high 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.

Hospital Value. We assist hospitals in building value by offering patient value using da Vinci products, thereby increasing surgical revenue and reducing costs through lower complication rates and reduced length of patient stay. We believe da

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Vinci Surgery is a cost effective approach to many surgeries as compared to alternative treatment options, as recognized in many published studies.

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: gynecologic surgery, urologic 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"), hernia repair, da Vinci Colon and Rectal procedures, da Vinci Partial Nephrectomy, da Vinci Sacrocolpopexy, da Vinci Mitral Valve Repair, da Vinci Lobectomy, and da Vinci Transoral Robotic Surgery. Representative surgical applications are described below.

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 cancerous conditions. Hysterectomies can be performed using open surgery (laparotomy), or MIS techniques, which include vaginal, laparoscopic, and robotic approaches. Prior to the clearance of da Vinci Surgery for use in gynecological procedures in 2005, the majority of hysterectomies performed were open surgeries. We believe that da Vinci Surgery provides a large number of women the opportunity to receive a minimally invasive treatment as an alternative to an open hysterectomy. Hysterectomies for benign conditions can be performed using either multi-port or Single-Site technology and we estimate that a majority of da Vinci Surgery is performed using multi-port techniques. Single-Site instruments enable surgeons to perform surgery through a single port via the patient's belly button, allowing for virtually scarless results.

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

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 was 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 the open and laparoscopic techniques. Surgeons have reported that the da Vinci Surgical System's capabilities may enable a large number of these procedures to be performed through a minimally invasive technique, conferring the benefits of MIS to a broader range of partial nephrectomy patients. Treatment guidelines for patients with localized renal cancer recommend partial nephrectomy due to the benefits nephron-sparing surgery has in long-term patient outcomes. Published clinical literature has shown that the presence of a da Vinci Surgical System is associated with a higher-proportion of patients receiving a guideline-recommended partial nephrectomy.

General Surgery

Hernia Repair. A hernia occurs when an organ or other tissue squeezes through a weak spot in a surrounding muscle or connective tissue. During a hernia repair surgery, the weakened tissue is secured and defects are repaired. Common types of hernia are ventral and inguinal. Ventral, or abdominal hernia, may occur through a scar after surgery in the abdomen. Inguinal hernia is a bulge in the groin and is more common in men. Hernia repair can be performed using

traditional open surgery or MIS. There is a wide-range of complexity in hernia repair surgeries and varying surgeon opinion regarding optimal surgical approach. The benefits of minimally invasive and robotic hernia repair surgery vary by patient.

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. Surgeons have reported that the use of the da Vinci Surgery System and our latest technologies, such as the da Vinci Xi Surgical System, EndoWrist Stapler, and EndoWrist Vessel Sealer, have enabled them to offer MIS approaches to a broader range of colorectal surgery patients.

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. 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 da Vinci techniques are also being used for certain cases, and Firefly technology can be used to visualize biliary anatomy in three dimensions beneath tissue surfaces during Single-Site and multi-port da Vinci cholecystectomies.

Bariatric Surgery. A body of literature points to the benefit of surgery to treat patients for morbid obesity and its secondary effects, such as diabetes. Sleeve gastrectomy and roux-en-Y gastric bypass (“RYGB”) are commonly performed surgical procedures for morbid obesity in the U.S. The body habitus of morbidly obese patients can make laparoscopic surgery physically challenging for the surgeon, and certain surgeons have found value in using the da Vinci Surgical System to improve upon the ergonomics when performing MIS in morbidly obese patients. In addition, RYGB 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 laparoscopic RYGB.

Cardiothoracic Surgery

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 and improved clinical outcomes compared to open and video-

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assisted thoracic surgery in published single-center, multi-center and national database clinical studies. We believe the EndoWrist Stapler 30 may have particular utility in thoracic procedures.

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

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 potentially 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 operate on tumors occurring in the oropharynx (e.g., tonsil and base of tongue) and larynx via the mouth and to overcome some of the line-of-sight limitations of conventional transoral surgery.

Procedure Mix

Our procedure business is broadly split into two categories: (1) cancer and other highly complex procedures and (2) less complex procedures for benign conditions. Cancer and other highly complex procedures tend to be reimbursed at higher rates than less complex procedures for benign conditions. Thus, hospitals are more sensitive to the costs associated with treating less complex benign conditions. Our strategy is to provide hospitals with attractive clinical and economic solutions in each of these categories. Our fully featured da Vinci Xi system with advanced instruments including the EndoWrist One Vessel Sealer, EndoWrist Stapler products, and our Table Motion product target the more complex procedure segment. Lower priced products, including the three-arm da Vinci Si-e System, refurbished da Vinci Si, and lower priced Single-Site instruments are targeted towards less complex procedures. Our da Vinci X Surgical System is priced between the da Vinci Si and Xi Surgical Systems and offers customers access to many of the da Vinci Xi features, including da Vinci Xi advanced instrumentation and imaging systems, at a lower price point.

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, 2017, we had an installed base of 4,409 da Vinci Surgical Systems, including 2,862 in the U.S., 742 in Europe, 579 in Asia, and 226 in the rest of the world. We estimate that surgeons using our technology completed approximately 877,000 surgical procedures of various types in hospitals throughout the world during the year ended December 31, 2017.

Sales and Customer Support

Sales Model

We provide our products through direct sales organizations in the U.S., Japan, South Korea, and Europe, excluding Spain, Portugal, Italy, Greece, and Eastern European countries. In the remainder of our markets outside of the U.S. ("OUS"), we provide our products through distributors. No single customer accounted for more than 10% of revenue during the years ended December 31, 2017, 2016, and 2015. During the years ended December 31, 2017, 2016, and 2015, domestic revenue accounted for 73%, 72%, and 71%, respectively, of total revenue, while revenue from our OUS markets accounted for 27%, 28%, and 29%, respectively. As of December 31, 2017, and 2016, 88% and 86% of all long-lived assets were in the U.S., respectively.

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. Our hospital accounts include both individual hospitals and health care facilities and hospitals and health care facilities that are part of an integrated delivery network ("IDN groups"). The initial da Vinci Surgical System sale into an account as a major capital equipment purchase by our customers typically has a lengthy sales cycle that can be affected by macroeconomic factors, capital spending prioritization, timing of budgeting cycles, and competitive bidding processes. Capital sales activities include educating surgeons and hospital staff across multiple surgical specialties on the benefits of da Vinci Surgery, total treatment costs, 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, potential reductions in complications and length of stay, and the resulting potential for increased patient satisfaction, surgeon recruitment, and procedure volume.

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

Our customers place orders to replenish their supplies of instruments and accessories on a regular basis. Orders received are typically shipped within one business day. New direct customers who purchase a new da Vinci Surgical System typically place an initial stocking order of instruments and accessories soon after they receive 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 fiscal quarter and heavier in the fourth fiscal quarter. In addition, we have historically experienced lower procedure volume in the first and third fiscal quarters and higher procedure volume in the second and fourth fiscal quarters. Procedures treating benign conditions are typically higher in the fourth quarter and lower in the first quarter. The timing of procedures and changes in procedure volume 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 offers a full complement of services for our customers, including 24/7 support, installation, repair, and maintenance. 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.

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Research and Development

We focus our research and development efforts on innovating products and product improvements that align with our mission to provide more effective, less invasive, and easier care options for physicians, patients and their families. We employ research and development and engineering staff responsible for product design and engineering. We invested $328.6 million, $239.6 million, and $197.4 million of research and development expenses for the years ended December 31, 2017, 2016, and 2015, 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, 3D Systems, Inc., Erbe Elektromedizin GmbH, InTouch Technology Inc., Johnson & Johnson, JustRight Surgical, LLC, Mimic Technologies, Inc., Novadaq Technologies, Inc., Olympus Corporation, Schoelly Fiberoptic GmbH, and Trumpf Medical (a division of Hill-Rom Holdings, Inc.).

In 2017, our majority-owned joint venture with Shanghai Fosun Pharmaceutical (Group) Co., Ltd. (“Fosun Pharma”), a subsidiary of Fosun International Limited, was legally formed. The joint venture was formed to research, develop, manufacture, and sell robotic-assisted catheter-based medical devices. See “Item 7. Management’s Discussion and Analysis” for further details on the joint venture with Fosun Pharma.

Manufacturing

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

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 face competition in the forms of 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 companies 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 Systems may prove complementary to some of these new technologies.

Moreover, as we add new robotically controlled products (e.g. Single-Site, EndoWrist Stapler, and EndoWrist One 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 Medtronic PLC.

Furthermore, a number of companies have introduced products in the field of robotic surgery or have made explicit their intention to enter the field of robotic surgery, including: Auris Surgical Robotics, Inc.; Avatera Medical GmbH; Cambridge Medical Robotics Ltd; Johnson & Johnson and Google Inc. and their joint venture, Verb Surgical Inc.; Medicaroid Inc.; MedRobotics Corp.; Medtronic PLC; meerecompany Inc.; Olympus Corp.; Samsung Corporation; Smart Robot Technology Group Co. Ltd.; Titan Medical Inc.; and TransEnterix Inc. Other 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 as our competitors announce their intent to enter our markets and as our customers anticipate the availability of competing products.

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, 2017, we held ownership or exclusive field-of-use licenses for more than 2,750 U.S. and foreign patents and more than 1,900 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.

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Patents are granted for finite terms. Upon expiration, the inventions claimed in a patent enter the public domain.

Government Regulation

Our products and operations are subject to 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 our compliance into the development and regulatory documentation for our products. Failure to meet these standards could limit our ability to market our products in those regions which require compliance to such standards. Examples of standards to which we are subject include 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 the 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 markets outside of the U.S. 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 I and 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:

- 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
- a device that has previously been cleared through the 510(k) process.

If the FDA agrees that the device is substantially equivalent to a predicate device, it will grant clearance to commercially market the device in the U.S. The FDA has a statutory 90-day period to respond to a 510(k) submission, or a guidance-based 30-day period for "special" 510(k) submissions which have a more restrictive scope and generally involve more specific or very limited changes to a legally marketed device. As a practical matter, clearance often takes longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not "substantially equivalent," the FDA may deny the request for clearance. Although unlikely for the types of products marketed by us, the FDA may classify the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill more rigorous pre-market approval ("PMA") requirements. A PMA application, which is intended to demonstrate that a device is safe and effective, must be supported by extensive data, including data from preclinical studies and human clinical trials. The FDA, by statute and regulation, has 180 days to review a PMA application, though the review more often occurs over a significantly longer period of time, and can take up to several years. In approving a PMA application or clearing a 510(k) submission, the FDA may also require some form of post-market surveillance when necessary to protect the public health or to provide additional safety and effectiveness data for the device. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients.

After a device receives FDA 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA application approval. The FDA requires each manufacturer to make the determination of whether a

modification requires a new 510(k) notification or PMA application in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance or PMA approval for a particular change, the FDA may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease U.S. marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

In addition, after a device is placed on the market, numerous FDA and other regulatory requirements continue to apply. These include establishment registration and device listing with the FDA; compliance with medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and compliance with corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FFDCA that may present a risk to health. The FDA and the Federal Trade Commission ("FTC") also regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, that there is scientific data to substantiate the claims and that our advertising is neither false nor misleading. In general, we may not promote or advertise our products for uses not within the scope of our intended use statement in our clearances or make unsupported safety and effectiveness claims. Many regulatory jurisdictions outside of the U.S. have similar regulations to which we are subject.

Our manufacturing processes are required to comply with the FDA's Good Manufacturing Practice ("GMP") requirements contained in its Quality System Regulation ("QSR") and associated regulations and guidance. The QSR covers, among other things, the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all medical devices intended for human use. The QSR also requires maintenance of extensive records which demonstrate compliance with FDA regulation, the manufacturer's own procedures, specifications, and testing as well as distribution and post-market 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 potential enforcement actions against the manufacturer. If a Warning Letter or Untitled Letter is not addressed to the satisfaction of the FDA, or if the FDA becomes aware of any other serious issue with a manufacturer's products or facilities, it could result in fines, injunctions, civil penalties, delays, suspension or withdrawal of clearances, seizures or recalls of products, operating restrictions, total shutdown of production facilities, prohibition on export or import and criminal prosecution. Such actions may have further indirect consequences for the manufacturer outside of the U.S., and may adversely affect the reputation of the manufacturer and the product. In the U.S., routine FDA inspections usually occur every two years, and may occur more often for cause.

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

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

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

California Regulation

The State of California requires that we obtain a license to manufacture medical devices and until 2012 conducted periodic inspections of medical device manufacturers. Our facilities and manufacturing processes were last inspected in July 2011 and were found to be in compliance. In accordance with the State of California regulations, our 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 countries outside the United States, 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 approval. We obtained from the Japanese Ministry of Health, Labor, and Welfare ("MHLW") approval for our da Vinci Si Surgical Systems in October 2012 and approval for our da Vinci Xi Surgical Systems in March 2015. National reimbursement status was received in Japan for dVP procedures, effective April 2012 and for da Vinci partial nephrectomy procedures in April 2016. We are currently seeking reimbursement for additional procedures through the MHLW's Senshin Iryo processes as well as alternative reimbursement processes. Our Senshin Iryo approvals require in-country clinical data and are considered for reimbursed status in April of even numbered years.

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 countries 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 Presafe Denmark A/S (formerly 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. In September 2013, the European Commission adopted a recommendation indicating that all Notified Bodies, including Presafe, should carry out unannounced audits, at least once every third year, of the manufacturers whose medical devices they have certified. These unannounced audits can also extend to the manufacturer's critical suppliers or sub-contractors (those that supply a critical input or perform a critical function for the manufacturer).

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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.

In April 2017, the Medical Device Regulation was adopted to replace the Medical Device Directive (93/42/EEC) as amended. The Medical Device Regulation will apply after a three-year transition period and imposes stricter requirements for the marketing and sale of medical devices and grants Notified Bodies increased post-market surveillance authority. We may be subject to risks associated with additional testing, modification, certification, or amendment of our existing market authorizations, or we may be required to modify products already installed at our customers' facilities to comply with the official interpretations of these revised regulations.

Regulations in other countries, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. Certain countries, such as China and South Korea, have their own regulatory agencies. These countries 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. Our system sales into China are also dependent on obtaining importation authorizations and hospitals completing a central purchasing tender process under the authorization, the most recent of which expired at the end of 2015. In addition, local regulations may apply which govern the use of our products and which could have an adverse effect on our product utilization if they are unfavorable. All such regulations are revised from time to time and in general are increasing in complexity, and in the scope and degree of documentation and testing required. There can be no assurance the outcomes from such documentation and testing will be acceptable to any particular regulatory agency or will continue to be acceptable over time. There are further regulations governing the importation, marketing, sale, distribution, use, and service as well as the removal and disposal of medical devices in the regions in which we operate and market our products. Failure to comply with any of these regulations could result in sanctions or fines, and could prevent us from marketing our products in these regions.

Other Healthcare Laws

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payors that are false or fraudulent;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;

the federal Physician Payment Sunshine Act, which requires (i) manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, and (ii) applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians described above

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and their immediate family members, and payments or other "transfers of value" to such physician owners. Manufacturers are required to submit reports to CMS by the 90th day of each calendar year; and

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other "transfers of value" to physicians and other healthcare providers or marketing expenditures and pricing information; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

Third-Party Coverage and Reimbursement

In the U.S. and most markets OUS 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., 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 used by hospitals to report inpatient procedures, known as ICD-9-CM procedural codes prior to October 1, 2015, and ICD-10-PCS codes on and after October 1, 2015. 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

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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." The purpose of the ICD-9-CM family of procedure codes, 17.4X, was to gather data on robotic assisted surgical procedures. Since October 1, 2015, a new family of ICD-10-PCS codes can be used-in conjunction with other applicable procedure codes-to describe various robotic assisted procedures. An inpatient 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 various third-party payors, such as Medicare, Medicaid, and other government programs and private insurance plans for the primary surgical procedure that includes our products. Because our da Vinci Surgical System has been cleared for commercial distribution in the U.S. by the FDA, coverage and reimbursement by payors are generally determined by the medical necessity of the primary surgical procedure. We believe that the additional procedures we intend to pursue are established surgical procedures that are generally already reimbursable by government agencies and insurance companies for appropriately selected patients. If hospitals do not obtain sufficient reimbursement from third-party payors for procedures performed with our products, or if governmental and private payors' policies do not cover surgical procedures performed using our products, we may not be able to generate the revenues necessary to support our business.

In countries outside the U.S., reimbursement is obtained from various sources, including governmental authorities, private health insurance plans, and labor unions. In most foreign countries, private insurance systems may also offer payments for some therapies. In addition, health maintenance organizations are emerging in certain European countries. To effectively conduct our business, we may need to seek OUS reimbursement approvals, and we do not know if these required approvals will be obtained in a timely manner or at all. In some countries, patients may be permitted to pay directly for surgical services; however, such "co-pay" practices are not common in most countries.

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "PPACA"), was enacted. The PPACA made changes that have significantly impacted healthcare providers, insurers, and pharmaceutical and medical device manufacturers. The PPACA contained a number of provisions designed to generate the revenues necessary to fund health insurance coverage expansion, including, but not limited to fees or taxes on certain health-related industries, including medical device manufacturers. For sales between January 1, 2013 and December 31, 2015, medical device manufacturers were required to pay an excise tax (or sales tax) of 2.3% on certain U.S. medical device revenues. Under this provision, we incurred Medical Device Excise Tax ("MDET") of approximately $17.0 million in 2015 which was included as a cost of revenue and a reduction of product gross profit margin. The Consolidated Appropriations Act, 2016 (the "Appropriations Act"), enacted in December 2015, included a two-year moratorium on MDET such that medical device sales in 2016 and 2017 were exempt from the MDET. New legislation was passed in January 2018 such that MDET will be delayed until January 1, 2020.

The PPACA also appropriated funding to research 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. 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. These changes included an aggregate reduction in Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers. The Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015 ("MACRA"), repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. Individual states in the U.S. have also become increasingly aggressive in passing legislation and implementing

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regulations designed to control product pricing, including price or patient reimbursement constraints and discounts, and require marketing cost disclosure and transparency measures.

There have also been judicial and congressional challenges to certain aspects of the PPACA, as well as efforts by the U.S. administration to modify, repeal, or otherwise invalidate all, or certain provisions of, the PPACA. Since January 2017, the U.S. President has signed two Executive Orders designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. The current U.S. administration has also announced that it will discontinue the payment of cost-sharing reduction ("CSR") payments to insurance companies until Congress approves the appropriation of funds for the CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the PPACA. A bipartisan bill to appropriate funds for CSR payments has been introduced in the Senate, but the future of that bill is uncertain. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the PPACA for plans sold through such marketplaces. Because of the Tax Cuts and Jobs Act enacted on December 22, 2017, the PPACA's individual mandate penalty for not having health insurance coverage will be eliminated starting in 2019. Further, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the PPACA. Although the majority of these measures have not been enacted by Congress to date, Congress will likely continue to consider other legislation to repeal or repeal and replace elements of the PPACA. 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 adversely affect our business, financial condition, and results of operations.

Employees

As of December 31, 2017, we had 4,444 employees, 597 of whom were engaged directly in research and development, 1,868 in manufacturing and service, and 1,979 in marketing, sales, and administrative activities. None of our employees are covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

General

We make our periodic and current reports, including our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, our Code of Business Conduct and Ethics Policy and any amendments to those reports, available free of charge, on our website as soon as practicable after such material is electronically filed or furnished with the Securities and Exchange Commission (the "SEC"). Our website address is www.intuitivesurgical.com and the reports are filed under "SEC Filings," on the Company—Investor Relations portion of our website. Periodically, we webcast Company announcements, product launch events, and executive presentations which can be viewed via our Investor Relations page on our website. In addition, we provide notifications of our material news including SEC filings, investor events, and press releases as part of our Investor Relations page on our website. The contents of our website are not intended to be incorporated by reference into this report or in any other report or document we file and any references to our website are intended to be inactive textual references only. The public may read and copy any materials filed by the Company with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. The contents of these websites are not incorporated into this filing. Further, references to the URLs for these websites are intended to be inactive textual references only.

We operate our business as one segment as defined by U.S. generally accepted accounting principles. Our financial results for the years ended December 31, 2017, 2016, and 2015 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 is crucial to our success. If our products fail to achieve market acceptance, customers will not purchase our products and we will not be able to generate the revenue necessary to support our business. We believe that physicians' and third-party payors' acceptance of the benefits of procedures performed using our products will be essential for acceptance of our products by patients. Physicians will

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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 and the evolving U.S. health care environment following the 2016 U.S. elections.

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.

Uncertainty about global economic conditions, including credit and sovereign debt concerns in certain European countries and concerns about slowed economic growth in China and other OUS markets, have caused and may continue to cause disruptions in the financial credit markets, 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. Customers and distributors may choose to postpone or reduce spending due to financial difficulties or may be unable to obtain credit to finance purchases of our products due to restraints on credit. There could be additional effects from adverse conditions in the credit markets on our business, including the insolvency of key suppliers or their inability to obtain credit to finance the development and/or manufacture of our products resulting in product delays.

In addition, our business is closely tied to the overall U.S. healthcare system, relating to which there are concerns and uncertainties as a result of efforts made by the U.S. federal government to modify, repeal, or otherwise invalidate all, or certain provisions of, the PPACA. In addition, the U.S. federal government has called for, or enacted, substantial changes to trade, fiscal, and tax policies, which may include changes to existing trade agreements, including, but not limited to, the North American Free Trade Agreement ("NAFTA"), and may have a significant impact on our operations. We cannot predict the impact, if any, that these changes could have on our business.

If economic conditions worsen or new legislation is passed related to the healthcare system, trade, fiscal or tax policies, customer demand may not materialize to the levels we require to achieve our anticipated financial results, which could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

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

da Vinci Surgery is a 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, and 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.

Additionally, we face or expect to face competition from companies that develop or have developed wristed, robotic, or computer-assisted surgical systems and products. The following companies have introduced products in the field of robotic surgery or have made explicit statements about their efforts to enter the field: Auris Surgical Robotics Inc.; Avatera Medical GmbH; Cambridge Medical Robotics Ltd; Johnson & Johnson and Google Inc. and their joint venture, Verb Surgical Inc.; Medicaroid Inc.; MedRobotics Corp.; meerecompany Inc.; Medtronic PLC; Olympus Corp.; Samsung Corporation; Smart Robot Technology Group Co. Ltd.; TransEnterix Inc.; and Titan Medical Inc. Other companies with substantial experience in industrial robotics could potentially expand into the field of surgical

robotics and become competitors. Our revenues may be reduced due to pricing pressure 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, which could have a material adverse effect on our business, financial condition, result of operations, or cash flows. We may not be able to maintain or improve our competitive position against current or potential competitors, especially those with greater resources.

In addition, third-party service providers that provide services to da Vinci Surgical System operators may emerge and compete with us on price or offerings. To date, substantially all of our customers have sourced services on their da Vinci Surgical Systems from us through service contract commitments or time and materials contracts. Furthermore, there are third-party service providers

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offering consulting services targeted at analyzing the cost-effectiveness of hospitals' robotic surgery programs, including procedures performed, placement of systems, and consumption of instruments and accessories. We currently provide similar services and analysis to our customers, but it is difficult to assess the impact that this may have on our business. If we are unable to compete successfully with any third-party service providers, our revenues may suffer.

OUR CUSTOMERS MAY USE UNAUTHORIZED OR UNAPPROVED INSTRUMENTS AND ACCESSORIES, WHICH WOULD RESULT IN REDUCED REVENUE AND LOSS OF MARKET SHARE.

A large portion of our revenue is generated through our sales of instruments and accessories. Third parties have attempted to and may discover ways to manufacture and sell counterfeit reprocessed instruments and/or alter instruments that are compatible and function with the da Vinci Surgical System, and such activities may reduce our market share. While our sales arrangements with customers generally prohibit the use of unauthorized or unapproved instruments and accessories with da Vinci Surgical Systems, warranties will be void if such instruments and accessories are used, and a programmed memory chip inside each instrument is designed to prevent the instrument from being used for more than the prescribed number of procedures to help ensure that its performance meets specifications during each procedure, these measures may not prevent the use of unauthorized or unapproved instruments and accessories by our customers. In addition to potential reductions to our revenues and market share, sales of unauthorized instruments and accessories by third parties may create safety and health risks to da Vinci patients and could cause negative publicity for us if these products cause injuries and/or do not function as intended when used with the da Vinci Surgical Systems, any of which could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

NEW PRODUCT DEVELOPMENTS AND INTRODUCTIONS MAY ADVERSELY IMPACT OUR FINANCIAL RESULTS.

We develop and introduce new products with enhanced features and extended capabilities from time to time. We may introduce new products that target different markets than what our existing products target. The success of new product introductions depends on a number of factors including, but not limited to, timely and successful research and development, regulatory clearances or approvals, pricing, competition, market and consumer acceptance, the effective forecasting and management of product demand, inventory levels, the management of manufacturing and supply costs, and the risk that new products may have quality or other defects in the early stages of introduction.

We invest substantially in various research and development projects to expand our product offerings. Our research and development efforts are critical to our success, and our research and development projects may not be successful. We may be unable to develop and market new products successfully, and the products we invest in and develop may not be well-received by customers or meet our expectations. Our research and development investments may not generate significant operating income or contribute to our future operating results for several years, and such contributions may not meet our expectations or even cover the costs of such investments. In addition, the introduction or announcement of new products or product enhancements may shorten the life cycle of our existing products or reduce demand for our current products, thereby offsetting any benefits of successful product introductions and potentially leading to challenges in managing inventory of existing products.

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 clearance, planned purchases may be deferred or delayed. We have in the past experienced a slowdown in demand for existing products in advance of new product introductions and may experience a slowdown in demand in the future as well. It is also possible that a new product introduction could cause downward pressure on the prices of our existing products or require us to change how we sell our products, either of which could have material adverse effect on our revenues.

If we fail to effectively develop new products and manage new product introductions in the future, our business, financial condition, results of operations, or cash flows could be materially adversely impacted.

WE EXPECT GROSS PROFIT MARGINS TO VARY OVER TIME, AND CHANGES IN OUR GROSS PROFIT MARGINS COULD ADVERSELY AFFECT OUR FINANCIAL CONDITION OR RESULTS OF OPERATIONS.

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

- changes in customer, geographic, or product mix, including mix of da Vinci Surgical System models sold;
- changes in the portion of sales involving a trade-in of another system and the amount of trade-in credits given;
- introduction of new products, which may have lower margins than our existing products;
- our ability to maintain or reduce production costs;
- changes to our pricing strategy;

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- changes in competition;
- changes in production volume driven by demand for our products;
- changes in material, labor, or other manufacturing-related costs, including the impact of foreign exchange rate fluctuations for foreign-currency denominated costs;
- changes to U.S. and foreign trade policies, including the enactment of tariffs on goods imported into the U.S., including but not limited to, goods imported from Mexico where we manufacture a majority of our instruments that we sell;
- inventory obsolescence and product recall charges; and
- market conditions.

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

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

The sales and purchase order cycle of our da Vinci Surgical System is lengthy 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. In addition, sales to some of our customers are subject to competitive bidding or public tender processes. These approval and bidding processes can be lengthy. As a result, hospitals may delay or accelerate system purchases in conjunction with timing of their capital budget timelines. Further, IDN groups are creating larger networks of da Vinci system operators with increasing purchasing power and are increasingly evaluating their da Vinci Surgery programs to optimize the efficiency of the da Vinci system operations. Further, the introduction of new products could adversely impact our sales cycle as customers take additional time to assess the benefits and costs of such products. As a result, it is difficult for us to predict the length of capital sales cycles and, therefore, the exact timing of capital sales. Historically, our sales of da Vinci Surgical Systems have tended to be heaviest during the third month of each fiscal quarter, lighter in the first fiscal quarter and heavier in the fourth fiscal quarter.

We have experienced procedure growth for a number of benign conditions, including hysterectomies for benign conditions, sacrocolpopexies, hernia repairs, cholecystectomies, 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 volume in the first and third fiscal quarters and higher procedure volume in the second and fourth fiscal quarters. Timing of procedures and changes in procedure growth directly affect the timing of instrument and accessory purchases and capital purchases by customers.

The above factors may contribute to substantial fluctuations in our quarterly operating results. Because of these fluctuations, it is possible that in future periods 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 our operating results in any particular period may not be relied upon as an indication of future performance.

WE ARE SUBJECT TO A VARIETY OF RISKS DUE TO OUR OPERATIONS OUTSIDE OF THE U.S.

We manufacture, perform research and development activities, and distribute our products in OUS markets. Revenue from OUS markets accounted for approximately 27%, 28%, and 29% of our revenue for the years ended December 31, 2017, 2016, and 2015, respectively. Our OUS operations are, and will continue to be, subject to a number of risks including:

- failure to obtain or maintain the same degree of protection against infringement of our intellectual property rights as we have in the U.S.;
- multiple OUS regulatory requirements that are subject to change and that could impact our ability to manufacture and sell our products;
- changes in tariffs, trade barriers, and regulatory requirements;
- protectionist laws and business practices that favor local competitors, which could slow our growth in OUS markets;

- local or national regulations that make it difficult or impractical to market or use our products;
- U.S. relations with the governments of the foreign countries in which we operate;
- inability or regulatory limitations on our ability to move goods across borders;
- the risks associated with foreign currency exchange rate fluctuations;
- difficulty in establishing, staffing, and managing OUS operations;
- the expense of establishing facilities and operations in new foreign markets;
- building and maintaining an organization capable of supporting geographically dispersed operations;

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- anti-corruption laws, such as the U.S. Foreign Corrupt Practices Act, and other local laws prohibiting corrupt payments to governmental officials;
- economic weakness, including inflation, or political instability in particular foreign economies and markets; and
- business interruptions due to natural disasters, outbreak of disease, and other events beyond our control.

On June 23, 2016, the United Kingdom (the "UK") held a referendum in which voters approved an exit from the European Union (the "EU"), commonly referred to as "Brexit." On March 29, 2017, the UK formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the UK from the EU will take effect either on the effective date of the withdrawal agreement or, in the absence of agreement, two years after the UK provided its notice of withdrawal. As a result of the referendum, the British government has begun negotiating the terms of the UK's future relationship with the EU, including the terms of trade between the UK and the EU. Although it is unknown what those terms will be, it is possible that there will be greater restrictions on imports and exports between the UK and EU countries, increased regulatory complexities, and economic and political uncertainty in the region.

In addition, the U.S. federal government has made recent proposals and explicit statements about its intention to make changes to U.S. trade policy, including signing an executive order to withdraw from the negotiating process of the Trans-Pacific Partnership, renegotiate the terms of NAFTA, and imposing border taxes on imports into the U.S. We manufacture a majority of the instruments we sell in Mexico and any legislation enacted that impacts the relationship between the U.S. and Mexico and/or the continuity of NAFTA could adversely affect our operations and financial results. If enacted, any legislation taken by the U.S. federal government that restricts trade, such as tariffs, trade barriers, and other protectionist or retaliatory measures taken by governments in Europe, Asia, and other countries, could adversely impact our ability to sell products and services in our OUS markets.

Furthermore, a large portion of our OUS 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 OUS markets.

If we are unable to meet and manage these risks, our OUS operations may not be successful, which would limit the growth of our business and could have a material adverse effect on our business, financial condition, result of operations, or cash flows.

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 sell or service our products in the markets 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 "We Are Subject to Product Liability and Negligence Claims Relating to the Use of Our Products and Other Legal Proceedings That Could Materially Adversely Affect Our Financial Condition, Divert Management's Attention, and Harm Our Business." The actions of our distributors may affect our ability to effectively market our products in certain foreign countries or regulatory jurisdictions if a distributor holds the regulatory authorization in such countries or within such regions and causes, by action or inaction, the suspension of such marketing authorization or sanctions for non-compliance. It may be difficult, expensive, and time consuming for us to re-establish market access or regulatory compliance in such case.

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

We believe customer financing through leasing is an important consideration for some of our customers and have experienced an increase in demand for customer financing. We may experience loss from a customer's failure to make payments according to the contractual lease terms. Our exposure to the credit risks relating to our lease financing arrangements may increase if our customers are adversely affected by changes in healthcare laws, coverage and reimbursement, economic pressures or uncertainty, or other customer-specific factors.

Although we have programs in place that are designed to monitor and mitigate the associated risk, there can be no assurance that such programs will be effective in reducing credit risks relating to these lease financing arrangements.

If the level of credit losses we experience in the future exceed our expectations, such losses could have a material adverse effect on our financial condition or results of operations.

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

Our operating results are subject to volatility due to fluctuations in foreign currency exchange rates. Our primary exposure to fluctuations in foreign currency exchange rates relates to revenue and operating expenses denominated in currencies other than the U.S. dollar. The weakening of foreign currencies relative to the U.S. dollar adversely affects our foreign currency-denominated revenue. Margins on OUS revenue could also be materially adversely affected by foreign currency exchange rate fluctuations as we may not be able to raise local prices to fully offset the strengthening of the U.S. dollar. Conversely, the strengthening of foreign

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currencies relative to the U.S. dollar, while generally beneficial to our foreign currency-denominated revenue and earnings, may cause us to reduce pricing on our products in our OUS markets and may cause us to incur losses on our foreign currency hedging instruments, thereby limiting the benefit that strengthened foreign currencies could have on our results of operations.

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. Although we have established a hedging program to partially hedge our exposure to foreign currency exchange rate fluctuations, primarily related to transactions denominated in the Euro, Japanese Yen, Korean Won, British Pound, and the Swiss Franc, and we regularly review our hedging program and make adjustments as necessary, our hedging activities may not offset more than a portion of the adverse financial impact caused by unfavorable movement in foreign currency exchange rates, which could materially adversely affect our financial condition or results of operations. See “Item 7A. Quantitative and Qualitative Disclosures About Market Risk” for additional discussion on the impact of foreign exchange risk.

WE ARE EXPOSED TO CREDIT RISK AND FLUCTUATIONS IN THE MARKET VALUE OF OUR INVESTMENTS.

Our investment portfolio includes both domestic and international investments. The credit ratings and pricing of our investments can be negatively affected by liquidity concerns, credit deterioration, financial results, economic risk, political risk, or other factors. As a result, the value and liquidity of our cash equivalents and marketable securities could fluctuate substantially. Our other income and expense could also vary materially from expectations depending on gains or losses realized on the sale or exchange of investments, impairment charges resulting from revaluations of debt and equity securities and other investments, changes in interest rates, increases or decreases in cash balances, volatility in foreign exchange rates, and changes in fair value of derivative instruments. Increased volatility in the financial markets and overall economic uncertainty could increase the risk that actual amounts realized on our investments may differ significantly from the fair values currently assigned to them.

While we have not realized any significant losses on our cash equivalents or marketable securities, future fluctuations in their value could have a material adverse impact on our business, financial condition, results of operations, or cash flows.

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 success depends on the quality and reliability of our products. While we subject components sourced and products manufactured to stringent quality specifications and processes, our products incorporate mechanical parts, electrical components, optical components, and computer software, any of which may contain errors or exhibit failures, especially when products are 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, due to the serious and costly consequences of product failure, we and our customers have an increased sensitivity to such defects. In the past, we have voluntarily recalled certain products. Although our products are subject to stringent quality processes and controls, we cannot provide assurance that our products will not experience component aging, errors, or performance problems. If we experience product flaws or performance problems, any or all 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.

Costs associated with product flaws or performance problems could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

WE ARE SUBJECT TO PRODUCT LIABILITY AND NEGLIGENCE CLAIMS RELATING TO THE USE OF OUR PRODUCTS AND OTHER LEGAL PROCEEDINGS THAT COULD MATERIALLY ADVERSELY AFFECT OUR FINANCIAL CONDITION, DIVERT MANAGEMENT'S ATTENTION, AND HARM OUR BUSINESS.

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 to which we are party, including purported class actions, derivative lawsuits, and product liability litigation, are described in Note 7 to the Consolidated Financial Statements included in Part II, Item 8.

In particular, our business exposes us to significant risks of product liability claims, which are inherent to the medical device industry. Product liability claims have been brought against us by or on behalf of individuals alleging that they have sustained

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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 their alleged personal injuries and in many cases, punitive damages. Current product liability claims have resulted in negative publicity regarding our Company, and these and any other product liability or negligence claims or product recalls also could harm our reputation. Please see our risk factor below titled “Negative Publicity, Whether Accurate or Inaccurate, Concerning Our Products or Our Company Could Reduce Market Acceptance of Our Products and Could Result in Decreased Product Demand and a Decline in Revenues” for additional risks related to the potential effects of negative publicity on our business.

The outcome of these product liability claims and other legal proceedings cannot be predicted with certainty. We currently self-insure our product liability risk and maintain third-party insurance coverage for certain other liabilities. However, we cannot determine whether our insurance coverage from third-party carriers, or our self-insurance of product liability risk, would be sufficient to cover the costs or potential losses related to these lawsuits and proceedings or otherwise be excluded under the terms of any third-party policy. Regardless of merit, litigation may be both time-consuming and disruptive to our operations and cause significant legal costs (including settlements, judgments, legal fees, and other related defense costs) and diversion of management attention. If we do not prevail in the purported class actions and derivative lawsuits, product liability litigation, or other legal proceedings, we may be faced with significant monetary damages or injunctive relief against us that could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

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

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

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 self-insure our product liability risks and we indemnify our directors and officers for third-party claims and do not carry insurance to cover that indemnity or the related underlying losses. We also do not carry, among other types of coverage, earthquake, and cyber insurance. 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 may not be available on acceptable terms, or at all. Because we retain some portion of our insurable risks, and in some cases we are self-insured completely, unforeseen or catastrophic losses in excess of insurance coverage could require us to pay substantial amounts, which may have a material adverse impact 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, which may have a material adverse impact on our business, financial condition, results of operations, or cash flows.

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

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

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 U.S., 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 OUS 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 OUS markets have government-managed healthcare systems that control reimbursement for new products and procedures. Other foreign markets have both private insurance systems and government-managed systems that control reimbursement for new products and procedures. Market acceptance of our products may depend on the availability and level of coverage and reimbursement in any country within a particular time. In addition, health care cost containment efforts similar to those in the U.S. 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 "Changes in Healthcare Legislation and Policy 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. For example, our product development plans depend, in part, on our ability to attract and retain engineers with experience in mechanics, electronics, software and optics. Attracting and retaining qualified personnel will be critical to our success, and competition for qualified personnel is intense. We may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among technology and healthcare companies and universities. The loss of any of these persons or our inability to attract and retain qualified personnel could harm our business and our ability to compete.

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

Natural disasters, terrorist activities, and other business disruptions, including but not limited to internet security threats, 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. Furthermore, our corporate headquarters and many of our operations, including certain of our manufacturing facilities, are located in California, which in the past

has experienced both severe earthquakes and other natural disasters. We do not have multiple-site capacity for all of our operations in the event of a business disruption. Furthermore, parties in our supply chain and our customers are similarly vulnerable to natural disasters or other sudden, unforeseen, and severe adverse events. A natural disaster in any of our major markets, or an unanticipated business disruption caused, for example, by internet security threats, damage to global communication networks, or similar events could have a material adverse impact on our business, financial condition, results of operations, or cash flows.

EPIDEMIC DISEASES OR THE PERCEPTION OF THEIR EFFECTS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS, OR CASH FLOWS.

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Outbreaks of pandemic or contagious diseases, such as the Ebola virus, Middle East Respiratory Syndrome, Severe Acute Respiratory Syndrome, or the H1N1 virus, could divert medical resources and priorities towards the treatment of that disease. An outbreak of a contagious disease could also negatively affect hospital admission rates. This could negatively impact the number of da Vinci procedures performed and have a material adverse effect on our business, financial condition, results of operations, or cash flows.

IF WE DO NOT SUCCESSFULLY MANAGE OUR COLLABORATION ARRANGEMENTS, LICENSING ARRANGEMENTS, JOINT VENTURES, STRATEGIC ALLIANCES, OR PARTNERSHIPS WITH THIRD PARTIES, WE MAY NOT REALIZE THE EXPECTED BENEFITS FROM SUCH ALLIANCES AND IT MAY HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS, OR CASH FLOWS.

From time to time, we enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships to complement or augment our research and development, product development, training, procedure development, and marketing efforts. For example, in 2016, we entered into an agreement to form a joint venture with Fosun Pharma to research, develop, manufacture, and sell robotic-assisted catheter-based medical devices. Proposing, negotiating, and implementing collaborations, in-licensing agreements, joint ventures, strategic alliances, or partnerships may be a lengthy and complex process. In addition, other companies, including those with substantially greater financial, marketing, sales, technology, or other business resources, may compete with us for these opportunities or arrangements. As a result, we may not identify, secure, or complete any such arrangements in a timely manner, on a cost-effective basis or on otherwise favorable terms, if it all.

There can be no assurance we will realize the expected benefits from these alliances. In addition, we may not be in a position to exercise sole decision making authority regarding any collaboration or other arrangement, which could create the potential risk of creating impasses on decisions, and our alliances may have economic or business interests that are, or that may become, inconsistent with our interests. It is possible that conflicts may arise in these relationships, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations, termination rights or the ownership or control of intellectual property developed during the collaboration. These alliances can be difficult to manage, given the potentially different interests of the parties involved, and we could suffer delays in product development or other operational difficulties.

The alliances may involve significant expense and divert the focus or attention of our management and other key personnel. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, or disrupt our ordinary business activities. Such arrangements may also expose us to numerous known and unknown risks, including unique risks with respect to the economic, political, and regulatory environment of any foreign entities with whom we partner, including Fosun Pharma. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, or cash flows.

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.

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, regulatory marketing authorizations, or intellectual property protections, 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 or intellectual property protection in such cases, which may have a material adverse impact on our financial condition and results of operations, or cash flows.

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

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

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

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

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

We utilize methods for determining surgical market sizes as well as the number and type (cancerous or benign) of certain da Vinci procedures performed that involve estimates and judgments, which are, by their nature, subject to substantial risks, uncertainties, and assumptions. Our estimates of surgical market sizes or the number and type of da Vinci procedures performed do not have an impact on our results of operations, but are used to estimate the progress of our business. Estimates and judgments for determining surgical market sizes and the number and type of da Vinci procedures and the accuracy of these estimates may be impacted over time with changes in treatment modalities, hospital reporting behavior, system internet connectivity, distributor 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 the number and type of da Vinci procedures, causing variation in our reporting.

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

We are subject to taxes in the U.S. and other jurisdictions. Tax rates in these jurisdictions may be subject to significant change due to economic and/or political conditions. A number of other factors may also impact our future effective tax rate including:

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

On December 22, 2017, the U.S. federal government enacted the Tax Cuts and Jobs Act (“2017 Tax Act”). The 2017 Tax Act significantly changed the existing U.S. corporate income tax laws by, among other things, lowering the corporate tax rate, implementing a territorial tax system, and imposing a one-time deemed repatriation toll tax on cumulative undistributed foreign earnings, for which we have not previously provided U.S. taxes. Given the timing, scope, and magnitude of the changes enacted by the 2017 Tax Act, along with on-going implementation efforts, guidance, and other developments from U.S. regulatory and standard-setting bodies, the completion of the accounting for certain tax items included in Note 10 to the Consolidated Financial Statements included in Part II, Item 8, that have been reported as provisional, or where no estimate of the impact was provided as a result of us not having the necessary information, may be subject to material change. Any significant changes to our future effective tax rate, including final resolution of provisional amounts relating to effects of the 2017 Tax Act, may result in a material adverse effect on our business, financial condition, results of operations, or cash flows.

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

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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 security breaches by unauthorized persons, 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. For example, our employees have received "phishing" emails and phone calls attempting to induce them to divulge passwords and other sensitive information.

In addition, unauthorized persons may attempt to hack into our products or systems to obtain personal data relating to patients or employees, our confidential or proprietary information or confidential information we hold on behalf of third parties. If the unauthorized persons successfully hack into or interfere with our connected products or services, they may create issues with product functionality that could pose a risk of loss of data, a risk to patient safety, and a risk of product recall or field activity. We have programs in place to detect, contain, and respond to data security incidents, and we make ongoing improvements to our information-sharing products in order to minimize vulnerabilities, in accordance with industry and regulatory standards. However, because the techniques used to obtain unauthorized access to or sabotage systems change frequently and may be difficult to detect, we may not be able to anticipate and prevent these intrusions or mitigate them when and if they occur.

We also rely on external vendors to supply and/or support certain aspects of our information technology systems. The systems of these external vendors may contain defects in design or manufacture or other problems that could unexpectedly compromise information security of our own systems, and we are dependent on these third parties to deploy appropriate security programs to protect their systems.

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

RISKS RELATING TO OUR REGULATORY ENVIRONMENT

CHANGES IN HEALTHCARE LEGISLATION AND POLICY MAY HAVE A MATERIAL ADVERSE EFFECT ON OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. In March 2010, the PPACA was enacted, which made changes that have impacted and are expected to significantly impact the pharmaceutical and medical device industries.

The PPACA contained a number of provisions designed to generate the revenues necessary to fund health insurance coverage expansions among other things. This includes fees or taxes on certain health-related industries, including medical device manufacturers. For sales between January 1, 2013, and December 31, 2015, 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 were some exceptions to the excise tax, this excise tax did apply to all or most of our products sold within the U.S. In December 2015, the former U.S. President signed into law the Appropriations Act. The Appropriations Act included a two-year moratorium on the medical device excise tax such that medical device revenues in 2016 and 2017 were exempt from the excise tax. New legislation was passed in January 2018 such that MDET will be delayed until January 1, 2020.

The PPACA also implemented a number of Medicare 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 appropriated funding for comparative effectiveness research.

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 have a material adverse impact on our business, financial condition, results of operations, or cash flows.

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Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA, as well as efforts by the current U.S. administration to modify, repeal or otherwise invalidate all, or certain provisions of, the PPACA. Since January 2017, the U.S. President has signed two Executive Orders designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. The current U.S. administration has also announced that it will discontinue the payment of cost-sharing reduction ("CSR") payments to insurance companies until Congress approves the appropriation of funds for the CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the PPACA. A bipartisan bill to appropriate funds for CSR payments has been introduced in the Senate, but the future of that bill is uncertain. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the PPACA for plans sold through such marketplaces. Because of the 2017 Tax Act, the PPACA's individual mandate penalty for not having health insurance coverage will be eliminated starting in 2019. It is unclear what impact the elimination of the individual mandate penalty will have on our business, financial condition, results of operations, or cash flows. Further, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the PPACA. Although the majority of these measures have not been enacted by Congress to date, Congress will likely continue to consider other legislation to repeal or repeal and replace elements of the PPACA.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of 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. MACRA repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what impact new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations, or cash flows. Individual states in the U.S. have also become increasingly aggressive in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, and discounts, and require marketing cost disclosure and transparency measures.

We expect additional state and federal health care reform measures to be adopted in the future that could have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to future reimbursement rates, or changes in hospital admission rates could impact our customers' demand for our products and services, which in turn could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

Further, the federal, state and local governments, Medicare, Medicaid, managed care organizations, and foreign governments have in the past considered, are 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. Future significant changes in the healthcare systems in the U.S. or other countries, including retroactive and prospective rate and coverage criteria changes, competitive bidding or tender processes for certain products and services, and other changes intended to reduce expenditures along with uncertainty about whether and how changes may be implemented, could have a negative impact on the demand for our products. We are unable to predict whether other healthcare policies, including policies stemming from legislation or regulations affecting our business may be proposed or enacted in the future; what effect such policies would have on our business; or the effect ongoing uncertainty about these matters will have on the purchasing decisions of our customers.

WE ARE SUBJECT TO FEDERAL, STATE AND FOREIGN LAWS GOVERNING OUR BUSINESS PRACTICES WHICH, IF VIOLATED, COULD RESULT IN SUBSTANTIAL PENALTIES. ADDITIONALLY, CHALLENGES

TO OR INVESTIGATION INTO OUR PRACTICES COULD CAUSE ADVERSE PUBLICITY AND BE COSTLY TO RESPOND TO AND THUS COULD HARM OUR BUSINESS.

The Dodd-Frank Wall Street Reform and Consumer Protection Act requires us to track and disclose the source of any tantalum, tin, gold, and tungsten used in manufacturing which may originate in the Democratic Republic of the Congo or adjoining regions (so called “conflict minerals”). These metals are central to the technology industry and are present in some of our products as component parts. In most cases no acceptable alternative material exists which has the necessary properties. Because it is not possible to determine the source of the metals by analysis, we must obtain a good faith description of the source of the intermediate components and raw materials from parties in our supply chain. The components that incorporate those metals may originate from many sources and we purchase fabricated products from manufacturers who may have a long and difficult-to-trace supply chain. As the spot price of these materials varies, producers of the metal intermediates can be expected to change the mix of sources used. Accordingly, components and assemblies we buy may have a mix of sources as their origin. We are required to carry out a diligent effort to determine and disclose the source of these materials. There can be no assurance we can obtain this information

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accurately or reliably, or at all, from intermediate producers who may be unwilling or unable to provide this information or further identify their sources of supply or to notify us if these sources change. In addition, these metals are subject to price fluctuations and shortages which can affect our ability to obtain the manufactured materials we rely on at favorable terms or from consistent sources. These changes could have an adverse impact on our ability to manufacture and market our devices and products.

The Medicare and Medicaid anti-kickback laws, and several similar state laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, prohibit payments, or other remuneration that could be considered to induce hospitals, physicians, or other potential purchasers of our products either to refer patients or to purchase, lease or order, or arrange for or recommend the purchase, lease or order, of healthcare products or services for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid and any other third-party payor programs. Further, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity does not need 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. Although we would not submit claims directly to government payors, manufacturers can be held liable under the federal false claim act if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label.

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 non-compliance. 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 are required to report and disclose any ownership or investment interests held by physicians and their immediate family members, as well as any transfers of value made to such physician owners and investors, during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $165,786 per year (and up to an aggregate of $1.105 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 are required to submit reports to CMS by the 90th day of each calendar year.

In addition, there has been 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 or marketing expenditures and pricing information. 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 OUS operations increases our cost of doing business in foreign jurisdictions and could expose us or our employees to fines and penalties in the U.S. and/or abroad. These numerous and sometimes conflicting laws and regulations include U.S. laws such as the Foreign Corrupt Practices Act, and similar laws in foreign countries, such as the U.K. Bribery Act of 2010, which became effective on July 1, 2011. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, prohibitions on the conduct of our business and damage to our reputation. Although we

have implemented policies and procedures designed to ensure compliance with these laws, there can be no assurance that our employees, contractors, or agents will not violate our policies.

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

Our products and operations are subject to extensive regulation in the U.S. by the FDA. The FDA regulates the development and clinical testing, manufacturing, labeling, storage, record keeping, promotion, sales, distribution, and post-market support and medical device reporting in the U.S. to ensure that medical products distributed domestically are safe and effective for their intended uses. In order for us to market products for use in the U.S., 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.

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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 U.S. In addition, if we develop products in the future that are not considered to be substantially equivalent to a device with 510(k) clearance or grandfathered status, we will be required to obtain FDA approval by submitting a PMA. A PMA 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. 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 the sale of new products in the U.S. Moreover, 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, results of operations, or cash flows.

In addition, the FDA or other regulatory agencies may change their policies, adopt additional regulations, or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. We may be found non-compliant as a result of future changes in, or interpretations of, regulations by the FDA or other regulatory agencies. We also cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation, administrative, or executive action. For example, certain policies of the current U.S. administration may impact our business and industry. Namely, the current U.S. administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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 U.S. for any new devices we intend to market in the U.S. in the future. If we obtain such approvals, we may not be able to conduct studies which comply with the IDE and other regulations governing clinical investigations or the data from any such trials may not support clearance or approval of the investigational device. Failure to obtain such approvals or to comply with such regulations could have a material adverse effect on our business, financial condition and results of operations. Certainty that clinical trials will meet desired endpoints, produce meaningful or useful data and be free of unexpected adverse effects, or that the FDA will accept the validity of foreign clinical study data cannot be assured, and such uncertainty could preclude or delay market clearance or authorizations resulting in significant financial costs and reduced revenue.

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

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

Because our products, including the da Vinci Surgical System, are commercially distributed, numerous quality and post-market regulatory requirements apply, including the following:

- continued compliance to the QSR, which requires manufacturers to follow 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 ("MDR") 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;

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- 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. The FDA has in the past issued and could in the future issue Warning Letters or other communications to us. If we fail to satisfy or remediate the matters discussed in any such Warning Letters or communications, the FDA could take further enforcement action, including prohibiting the sale or marketing of the affected product. 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. 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.

The FDA also strictly regulates labeling, advertising, promotion, and other activities relating to the marketing of our products. Medical devices may be promoted only for their cleared or approved indications and in accordance with the provisions of the cleared or approved label. It is possible that federal or state enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under a variety of statutory authorities, including under the FFDCA as well as laws prohibiting false claims for reimbursement.

In addition, 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, some of whom were formerly employed by FDA and familiar with FDA perspective, we cannot provide assurance 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. From time to time we modify our products, including the hardware and software in the da Vinci Surgical System, after we obtain 510(k) clearance from the FDA for the devices in ways that we do not believe require new 510(k) clearance. We cannot provide assurance that the FDA would agree in all cases with our determinations not to seek new 510(k) clearance for any of these changes. If the FDA disagrees with our assessments that a new 510(k) clearance was not required prior to commercializing the devices with these changes or modifications, then the FDA could impose enforcement sanctions and/or require us to obtain 510(k) clearance for any modification to our products. We may be prohibited from marketing the modified device until such 510(k) clearance is granted.

We have a wholly owned manufacturing facility located in Mexicali, Mexico which manufactures reusable and disposable surgical instruments. This facility is registered with the FDA as well as Mexican authorities. The facility is operated under U.S. and international quality system regulations including those applicable to Canada, the European Union, and Japan among others. Our wholly owned manufacturing facility in Mexicali, Mexico has an FDA Establishment Registration but has not been inspected by the FDA to date. If the FDA were to identify non-conformances in our product documentation or quality system compliance, it 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 the 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 U.S. These regulations, including the requirements for approvals and the time required for regulatory review, vary from country to country. Obtaining and maintaining foreign regulatory approvals is complex, and we cannot be certain that we will receive regulatory approvals in any foreign country in which we plan to market our products, or to obtain such approvals on a favorable schedule. If we fail to obtain or maintain regulatory approval in any foreign country in which we plan to market our products, our ability to generate revenue will be harmed. In particular, if the FDA refuses to provide CFGs our ability to register products or renew such registrations may be delayed or denied.

The EU requires that manufacturers of medical products obtain the right to affix the CE mark, for compliance with the Medical Device Directive (93/42/EEC), as amended, 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

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directives. In order to obtain the authorization to affix the CE mark to products, a manufacturer must obtain certification that its processes and products 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, PreSafe.

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 are 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. 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 EU 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 April 2017, the Medical Device Regulation was adopted to replace the Medical Device Directive (93/42/EEC), as amended. The Medical Device Regulation will apply after a three-year transition period and imposes stricter requirements for the marketing and sale of medical devices and grants Notified Bodies increased post-market surveillance authority. We may be subject to risks associated with additional testing, modification, certification, or amendment of our existing market authorizations, or we may be required to modify products already installed at our customers' facilities to comply with the official interpretations of these revised regulations.

To date, we received approvals from the Japanese Ministry of Health, Labor and Welfare ("MHLW") for our da Vinci S, Si, and Xi Surgical Systems and various associated instruments and accessories for use in certain da Vinci procedures. We may seek additional approvals for other products and/or indications; however, there can be no assurance that such approvals will be granted. In addition, because not all of our instruments have received product approvals, and reimbursement is an additional process to generate market acceptance, it is possible that procedures will be adopted slowly or not at all. Sales of our products depend, in part, on the extent to which the costs of our products are reimbursed by governmental health administration authorities. To date, we have received reimbursement approval for prostatectomy and partial nephrectomy procedures in Japan. There are multiple pathways to obtain reimbursement for procedures including those that require in-country clinical data and which are considered for reimbursed status in April of even numbered years. If we are not successful in obtaining the necessary reimbursement approvals or obtaining approvals for future products and procedures, then the demand for our products could be limited. These limitations could eliminate a significant market opportunity for our products in Japan.

Our capital sales in China are subject to importation authorizations and central purchasing tender processes. Therefore, future system sales and our ability to grow future procedure volumes are dependent on the completion of these central purchasing tender authorizations, the most recent of which expired at the end of 2015. The timing and magnitude of these future authorizations, which may determine our system placements in future years, is not certain and we expect to continue to experience variability in the timing of capital sales in China.

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 EU. In addition, many countries such as Canada and Japan have very specific additional regulatory requirements for quality assurance and manufacturing. If we fail to continue to comply with Good Manufacturing Practice requirements, as well as ISO or other regulatory standards, we may be required to cease all or part of our operations until we comply with these regulations.

We continue to be subject to FDA and certain other inspections at any time. Maintaining such compliance is difficult and costly. We cannot be certain that our facilities will be found to comply with Good Manufacturing Practice requirements or ISO standards and other regulatory requirements in future inspections and audits by regulatory authorities.

Our Sunnyvale, California facility is licensed by the State of California to manufacture medical devices. We have been subject to periodic inspections by the California Department of Health Services Food and Drug Branch and, if we are unable to maintain

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

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

Our global customers are subject to periodic inspection by regulatory authorities. Our customers are required to comply with applicable local and international regulations, including with respect to the reprocessing of da Vinci instruments and accessories. Hospitals may not follow cleaning and sterilization instructions properly, or equipment used for cleaning and sterilization may malfunction or be used improperly. If our customers deviate from cleaning and sterilization instructions, regulatory authorities may require them to suspend use of da Vinci Surgical Systems.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

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

Our commercial success depends in part on obtaining patent protection for the proprietary technologies contained in our products, and on successfully defending our patents against infringing products and/or services in litigation or administrative proceedings, including patent oppositions, reviews, or reexaminations. We will incur substantial costs in obtaining patents and, if necessary, defending our patent rights. We do not know whether we will be successful in obtaining the desired patent protection for our new proprietary technologies, or that the protection we do obtain will be found valid and enforceable when challenged. The success of defending our proprietary rights can be highly uncertain because it involves complex and often evolving legal issues and procedures that are dependent on particular facts of each case.

In addition to patents, we also rely on other intellectual property rights such as trade secret, copyright, and trademark laws to protect proprietary technologies. We further utilize nondisclosure agreements and other contractual provisions as well as technical measures to protect our proprietary technologies. Nevertheless, these measures may be inadequate in protecting our technologies. If these measures are proved to be inadequate in protecting our technologies, our competitive advantages may be reduced. Moreover, we may not have adequate remedies for potential breaches by employees, consultants, and others who participate in developing our proprietary technologies against their agreements with us regarding intellectual property. As a result, our trade secrets may be lost. 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 technologies without infringing any of our intellectual property which would harm our ability to compete in the market.

As foreign markets become more significant in revenue for us, our foreign operations and strategic alliances with foreign entities will likely increase. Our exposure to risks associated with these operations requires us to increase our reliance on protecting our intellectual property against infringing products and/or services in markets outside the U.S. The laws and judicial systems in these countries may introduce yet another level of uncertainty to our effort to obtain the desired protection as well as defending our rights.

OTHERS MAY BE SUCCESSFUL IN ASSERTING THAT OUR PRODUCTS INFRINGE THEIR INTELLECTUAL PROPERTY RIGHTS, WHICH MAY CAUSE US TO PAY SUBSTANTIAL DAMAGES AND/OR ENJOIN US FROM COMMERCIALIZING OUR PRODUCTS.

As we continue to introduce and commercialize new products and technologies, 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 products. 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 be certain 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, other parties may have filed or will file patent applications covering products that are similar or identical to ours. We cannot be certain that patents issuing from our own patent application covering our products will have a priority date over any patents issuing from applications filed by a third party.

The medical device industry has experienced extensive intellectual property litigation and administrative proceedings. If third parties assert infringement claims or institute administrative proceedings against us, our technical and management personnel will

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need to spend time and effort and we will incur large expenses in defending these attacks. We cannot be certain that we will prevail in infringement, invalidity or unenforceability claims against us. If plaintiffs in patent administrative proceedings are successful, our patent portfolio may be adversely affected. If plaintiffs in any patent action are successful, we may be enjoined from selling our products, we may have to pay substantial damages, including treble damages, or we may be required to obtain a license that requires us to pay substantial royalties. In addition, any public announcements related to litigation or administrative proceedings initiated or threatened against us could cause our stock price to decline.

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

We rely on technology that we license from others, including technology that is integral to our products. We have entered into license agreements with several industry partners. Any of these agreements may be terminated for breach. If any of these agreements are terminated, we may be unable to reacquire the necessary license on satisfactory terms, or at all. The loss or failure to maintain these licenses could prevent or delay further development or commercialization of our products, which may have a material adverse effect on our business, financial condition, results of operations, or cash flows.

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 maintain or grow our revenue. Our products typically have lengthy sales cycles. 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 may be materially adversely affected. Further, future revenue from sales of our products is difficult to forecast because the market for new surgical technologies is still evolving. Our results of operations will depend upon numerous factors, including:

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

Our operating results in any particular period will not be a reliable indication of our future performance. It is possible that in future periods 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 may fluctuate significantly in the future. For example, during fiscal 2015, it reached a high of $185.73 and a low of $151.62; during fiscal 2016, it reached a high of $241.61 and a low of $169.09; and during fiscal 2017, it reached a high of $403.70 and a low of $209.83, in each case after giving effect to the three-for-one stock split of our issued and outstanding common stock in October 2017. Our stock price can fluctuate for a number of reasons, including:

- announcements about us or our competitors;
- variations in operating results and financial guidance;
- introduction or abandonment of new technologies or products;

- regulatory approvals and enforcement actions;
- changes in product pricing policies;
- changes in earnings estimates by analysts;

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- changes in accounting policies;
- economic changes and overall market volatility;
- litigation; and
- political uncertainties.

In addition, stock markets generally have experienced, and in the future may experience significant price and volume volatility. This volatility has 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. Further, 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, it may have a material adverse impact on the market price of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of December 31, 2017, we own approximately 905,000 square feet of space on 81 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 own approximately 92,000 square feet of space on 10 acres which serves as our East Coast sales and training headquarters. In Aubonne, Switzerland, we own approximately 35,000 square feet of space on 2 acres, which is used for our headquarters outside of the U.S. and 15,000 square feet of space is leased to a third party. In Southaven, Mississippi, we lease 117,000 square feet of space for service operations and will be used for future expansion of our operations. In Tokyo, Japan and Seoul, South Korea, we lease 59,000 and 40,000 square feet, respectively, for our local training centers and sales operations. We lease 157,000 square feet in Mexicali, Mexico where we manufacture most of our EndoWrist instruments. We lease facilities in Milford, Connecticut; Raleigh, North Carolina; Blacksburg, Virginia; and San Francisco, California for research and development and other operations. We lease facilities for sales and operations in Osaka, Japan.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

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

All share and per share information presented have been retroactively adjusted to reflect the three-for-one stock split of our issued and outstanding common stock in October 2017.

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.

	2017		2016	
Fiscal	High	Low	High	Low
First Quarter	$255.77	$209.83	$201.02	$169.09
Second Quarter	$318.05	$253.11	$220.47	$202.17
Third Quarter	$348.79	$307.22	$241.61	$221.56
Fourth Quarter	$403.70	$353.49	$241.54	$206.34

As of January 19, 2018, there were 189 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, 2017 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	6,226,224	$ 162.17	7,920,163
Equity compensation plans not approved by security holders	979,614	$ 176.85	43,182
Total	7,205,838	$ 164.16	7,963,345

RECENT SALES OF UNREGISTERED SECURITIES

None.

ISSUER PURCHASES OF EQUITY SECURITIES

The table below summarizes our stock repurchase activity for the quarter ended December 31, 2017.

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 (1)
October 1 to October 31, 2017	—	$ ——		$ 991.6 million
November 1 to November 30, 2017	—	$ ——		$ 991.6 million
December 1 to December 31, 2017	—	$ ——		$ 717.5 million
Total during quarter ended December 31, 2017	—	$ ——		

(1) Since March 2009, we have had an active stock repurchase program. As of December 31, 2017, our Board of Directors (the "Board") had authorized an aggregate amount of up to $6.2 billion for stock repurchases, of which the

most recent authorization occurred in December 2016, when the Board increased the authorized amount available under our share repurchase program to $3.0 billion. In 2017, we entered into an accelerated share repurchase program (the “ASR Program”) with Goldman Sachs & Co.

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LLC (“Goldman”) and completed the ASR Program by making $2,274.0 million payment to Goldman for 7.3 million shares repurchased, including a final settlement payment of $274.0 million in December 2017. See “Note 8. Stockholders' Equity,” in Notes to the Consolidated Financial Statements, which is included in “Item 8. Financial Statements and Supplementary Data,” for further details on the ASR Program. The remaining $717.5 million represents the amount available to repurchase shares under the authorized repurchase program as of December 31, 2017. The authorized stock repurchase program does not have an expiration date.

STOCK PERFORMANCE GRAPH

The graph set forth below compares the cumulative total stockholder return on our common stock between December 31, 2012, and December 31, 2017, with the cumulative total return of (i) the NASDAQ Composite Index, (ii) the S&P Healthcare Index, and (iii) the S&P 500 Index over the same period. This graph assumes the investment of $100.00 on December 31, 2012 in our common stock, the NASDAQ Composite Index, the S&P Healthcare Index, and the S&P 500 Index, and assumes the re-investment of dividends, if any.

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,					
	2012	2013	2014	2015	2016	2017
Intuitive Surgical, Inc.	$100.00	$78.32	$107.87	$111.38	$129.32	$223.26
NASDAQ Composite	$100.00	$140.12	$160.78	$171.97	$187.22	$242.71
S&P 500 Healthcare Index	$100.00	$141.46	$177.30	$189.52	$205.65	$251.05
S&P 500 Index	$100.00	$132.39	$150.51	$152.59	$170.84	$208.14

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ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with our Consolidated Financial Statements and the accompanying Notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this report. The selected data in this section is not intended to replace the Consolidated Financial Statements.

	Fiscal Year (1)				
	2017 (2)	2016	2015	2014	2013
	(In millions, except per share amounts and headcount)				
Revenue	$3,128.9	$2,704.4	$2,384.4	$2,131.7	$2,265.1
Gross profit	$2,194.1	$1,890.1	$1,577.9	$1,413.8	$1,594.2
Net income	$660.0	$735.9	$588.8	$418.8	$671.0
Net income per common share:					
Basic	$5.91	$6.40	$5.29	$3.78	$5.71
Diluted	$5.67	$6.24	$5.18	$3.70	$5.58
Shares used in computing basic and diluted net income per share:					
Basic	111.7	114.9	111.3	110.7	117.6
Diluted	116.3	117.9	113.7	113.1	120.3
Cash, cash equivalents, and investments	$3,846.5	$4,837.9	$3,347.8	$2,497.0	$2,753.9
Total assets	$5,758.0	$6,486.9	$4,907.3	$3,959.4	$3,950.3
Other long-term liabilities	$327.1	$112.6	$95.9	$78.8	$68.0
Stockholders' equity	$4,726.8	$5,777.8	$4,319.5	$3,379.4	$3,501.4
Total headcount	4,444	3,755	3,211	2,978	2,792

(1) All share and per share information presented have been retroactively adjusted to reflect the three-for-one stock split of our issued and outstanding common stock in October 2017.

(2) Reflects the provisional estimated amounts recorded for the enactment of the 2017 Tax Act. See Note 10 to the Consolidated Financial Statements included in Part II, Item 8 of this report for further details.

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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 patients, typically resulting in longer hospitalization and recovery times, increased hospitalization costs, and additional pain and suffering relative to MIS, where MIS is available. For over three decades, MIS has reduced trauma to patients by allowing selected surgeries to be performed through small ports rather than large incisions. MIS has been widely adopted for certain surgical procedures.

da Vinci Surgical Systems enable surgeons to extend the benefits of MIS to many patients who would otherwise undergo a more invasive surgery by using computational, robotic and imaging technologies to overcome many of the limitations of conventional MIS. Surgeons using a da Vinci Surgical System operate while seated comfortably at a console viewing a 3-D representation of an HD image of the surgical field. This immersive visualization connects surgeons to the surgical field and their instruments. While seated at the console, the surgeon manipulates instrument controls in a natural manner, similar to the open surgery technique. Our technology is designed to provide surgeons with a range of motion of MIS instruments in the surgical field analogous to the motions of a human wrist, while filtering out the tremor inherent in a surgeon's hand. In designing our products, we focus on making our technology easy and safe to use.

Our products fall into four broad categories - the da Vinci Surgical Systems, InSite and Firefly Fluorescence imaging systems ("Firefly"), instruments and accessories (e.g., EndoWrist, EndoWrist Vessel Sealer, da Vinci Single-Site and EndoWrist Stapler), and training technologies. We have commercialized the following da Vinci Surgical Systems: the da Vinci standard Surgical System, commercialized in 1999, the da Vinci S Surgical System, commercialized in 2006, the da Vinci Si Surgical System, commercialized in 2009, the da Vinci Xi Surgical System, commercialized in 2014, and the da Vinci X Surgical System, commercialized in the second quarter of 2017. These systems include a surgeon's console (or consoles), imaging electronics, a patient-side cart, and computational hardware and software.

We offer over 80 different multi-port da Vinci instruments enabling surgeons' flexibility in choosing the types of tools needed in a particular surgery. These multi-port instruments are generally robotically controlled versions of surgical tools that surgeons would use in either open or laparoscopic surgery. We offer advanced instrumentation for the da Vinci Si, da Vinci Xi, and da Vinci X platforms, including the EndoWrist Vessel Sealer and EndoWrist Stapler products, to provide surgeons with sophisticated, computer-aided tools to precisely and efficiently interact with tissue. da Vinci X and da Vinci Xi Surgical Systems share the same instruments whereas da Vinci Si Surgical System uses different instruments.

We offer Single-Site instruments for use with the da Vinci Si, da Vinci Xi, and da Vinci X Surgical Systems. Single-Site instruments are most commonly used in cholecystectomy and hysterectomy procedures. Single-Site instruments enable surgeons to also perform surgery through a single port via the patient's belly button, resulting in the potential for virtually scarless results.

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

Business Model

Overview

We generate revenue from the initial capital sales of da Vinci Surgical Systems, including systems under sales-type lease arrangements, and revenue from operating lease arrangements and from the subsequent sales of instruments, accessories, and service. The da Vinci Surgical System generally sells for approximately between $0.5 million and $2.5 million, depending upon the model, configuration and geography, and represents a significant capital equipment investment for our customers. Our instruments and accessories have limited lives and will either expire or wear out as they are used in surgery, at which point they need to be replaced. We typically enter into service contracts at the time systems are sold at an annual rate of approximately $80,000 to $170,000, depending upon the configuration of the underlying system and composition of the services offered under the contract. These service contracts have generally been renewed at the end of the initial contractual service periods.

Recurring Revenue

Recurring revenue consists of instrument and accessory revenue, service revenue, and operating lease revenue. Recurring revenue increased to $2.2 billion, or 72% of total revenue in 2017, compared with $1.9 billion, or 71% of total revenue in 2016, and $1.7 billion, or 70% of total revenue in 2015.

Instrument and accessory revenue has generally grown at a faster rate than system revenue in the last few fiscal years. Instrument and accessory revenue increased to $1.6 billion in 2017, compared with $1.4 billion in 2016 and $1.2 billion in 2015. The growth of instrument and accessory revenue largely reflect continued procedure adoption.

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Service revenue growth has been driven by the growth of the base of installed da Vinci Surgical Systems. The installed base of da Vinci Surgical Systems grew 13% to approximately 4,409 at December 31, 2017; 9% to approximately 3,919 at December 31, 2016; and 10% to approximately 3,597 at December 31, 2015. Service revenue grew 13% to $581.8 million in 2017; 11% to $517.0 million in 2016; and 8% to $464.8 million in 2015.

Operating lease revenue has grown as a larger proportion of systems shipped are under operating lease arrangements. In the years ended December 31, 2017, 2016, and 2015, a total of 108, 62, and 43 of system placements were classified as operating leases, respectively. Revenue from operating lease arrangements is generally recognized on a straight-line basis over the lease term. Operating lease revenue for the years ended December 31, 2017, 2016, and 2015, was $25.9 million, $16.6 million and $7.0 million, respectively. As of December 31, 2017, a total of 164 da Vinci Surgical Systems were installed at customers under operating lease arrangements.

Intuitive Surgical da Vinci System Leasing

Since 2013, we have entered into sales-type and operating lease arrangements directly with certain qualified customers as a way to offer customers flexibility in how they acquire da Vinci Surgical Systems and expand da Vinci Surgery availability while leveraging our balance sheet. The leases generally have commercially competitive terms as compared with other third party entities that offer equipment leasing. We include both operating and sales-type leases in our system shipment and installed base disclosures. We exclude operating leases from our system average selling prices computations.

In the years ended December 31, 2017, 2016, and 2015, we shipped 139, 95, and 63 systems under lease arrangements, respectively, of which 108, 62, and 43 were classified as operating leases, respectively. Generally, the operating lease arrangements provide our customers with the right to purchase the leased system at some point during and/or at the end of the lease term. Revenue generated from customer purchases of systems under operating lease arrangements (“Lease Buyouts”) was $39.5 million, $38.2 million, and $9.4 million for the years ended December 31, 2017, 2016, and 2015, respectively. We expect that revenue recognized from customer exercises of the buyout options will fluctuate based on the timing of when, and if, customers choose to exercise their buyout options. We believe our leasing program has been effective and well-received, and we are willing to expand it based on customer demand, including offering more flexible options such as variable lease payments.

Systems Revenue

System placements are driven by procedure growth in most markets. In geographies where da Vinci procedure adoption is in an early stage, system sales will precede procedure growth. System placements also vary due to seasonality. System revenue grew 15% to $910.2 million in 2017; 10% to $791.6 million in 2016; and 14% to $721.9 million in 2015. System revenue is also affected by the proportion of systems placed that are under operating lease arrangements, recurring operating lease revenue, operating lease buyouts, product mix, ASPs, and trade-in activities.

Procedure Mix / Products

Our procedure business is primarily comprised of: (1) cancer and other highly complex procedures and (2) less complex procedures for benign conditions. Cancer and other highly complex procedures tend to be reimbursed at higher rates than less complex procedures for benign conditions. Thus, hospitals are more sensitive to the costs associated with treating less complex benign conditions. Our strategy is to provide hospitals with attractive clinical and economic solutions in each of these procedure categories. Our fully featured da Vinci Xi Surgical System with advanced instruments including the EndoWrist Vessel Sealer, EndoWrist Stapler products, and our Table Motion product target the more complex procedure segment. Lower priced products, including the three-arm da Vinci Si-e Surgical System, refurbished da Vinci Si Surgical System, and Single-Site instruments, are targeted towards less complex procedures. Our da Vinci X Surgical System is priced between the da Vinci Si and Xi Surgical Systems and offers customers access to many of the da Vinci Xi features, including da Vinci Xi advanced instrumentation and imaging systems, at a lower price point.

Procedure Seasonality

More than half of da Vinci procedures performed are for benign conditions, most notably benign hysterectomies, hernia repairs, and cholecystectomies. Hysterectomies for benign conditions, hernia repairs, cholecystectomies, and other short-term elective procedures tend to be more seasonal than cancer operations and surgeries for other life threatening conditions. Seasonality in the U.S. for these procedures for benign conditions typically results in higher

fourth quarter procedure volume when more patients have met annual deductibles and lower first quarter procedure volume when deductibles are reset. Seasonality outside the U.S. varies and is more pronounced around local holidays and vacation periods.

Distribution Channels

We provide our products through direct sales organizations in the U.S., Japan, South Korea, and Europe, excluding Spain, Portugal, Italy, Greece, and Eastern European countries. In the remainder of our OUS markets, we provide our products through distributors.

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Regulatory Activities

Clearances and Approvals

We have obtained the clearances required to market our multi-port products associated with all of our da Vinci Surgical Systems (Standard, S, Si, Xi, and X systems) for our targeted surgical specialties within the U.S., South Korea, and the European markets in which we operate.

In April 2017, we received CE mark clearance for our da Vinci X Surgical System in Europe. Following the CE mark, in May 2017, we received U.S. Food and Drug Administration ("FDA") clearance to market our da Vinci X Surgical System in the U.S. We received regulatory clearance for the da Vinci X Surgical System in South Korea in September 2017 (see the description of the da Vinci X Surgical System in the New Product Introductions section below). Regulatory clearances for da Vinci X Surgical System may be received in other markets over time.

In January 2016, we received FDA clearance for our Integrated Table Motion product. In March 2016, we received FDA 510(k) clearances in the U.S. and CE mark clearances in Europe for Single-Site instruments and the 30mm EndoWrist stapler products for the da Vinci Xi Surgical System (see the description of the EndoWrist Stapler 30 in the New Product Introductions section below).

In April 2014, we received FDA clearance to market our da Vinci Single Port Surgical System in the U.S. for single-port urologic surgeries. At the time, we decided not to market that version of the da Vinci Single Port Surgical System. We instead elected to pursue the necessary modifications to integrate it into our fourth generation da Vinci Xi/X product family as a dedicated single port patient console compatible with the existing da Vinci Xi/X surgeon console, vision cart, and other equipment. We have since completed these modifications and executed clinical evaluations of the product. In December 2017, we submitted our form 510(k) for this da Vinci Single Port Surgical System for certain urology procedures. In the future, we intend to file additional form 510(k)s for procedures in which a single small entry point to the body and parallel delivery of instruments is important. Such surgeries could include those performed through a natural orifice like the mouth for head and neck procedures or those performed through a single skin incision.

We obtained approval from the Japanese Ministry of Health, Labor, and Welfare ("MHLW") for our da Vinci Xi Surgical System in March 2015. National reimbursement status was received for dVP procedures in Japan effective April 2012 and for da Vinci partial nephrectomy procedures in April 2016. With our support, Japanese university hospitals and surgical societies are seeking reimbursement for additional procedures through the MHLW's Senshin Iryo (Advanced Medical Care) processes as well as alternative reimbursement processes. There are multiple pathways to obtain reimbursement for procedures including those that require in-country clinical data/economic data. Reimbursements are considered in April of even numbered years. In January 2018, a committee of the MHLW recommended 12 additional procedures for reimbursement. The reimbursement levels for each procedure is uncertain and may be inadequate for broad adoption. There can be no assurance that we will gain additional reimbursements for the procedures or at the times we have targeted. If we are not successful in obtaining additional regulatory clearances, and adequate procedure reimbursements for future products and procedures, then the demand for our products in Japan could be limited.

Recalls and Corrections

Medical device companies have regulatory obligations to correct or remove medical devices in the field that could pose a risk to health. The definition of "recalls and corrections" is expansive and includes repair, replacement, inspections, relabeling, and issuance of new or additional instructions for use or reinforcement of existing 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 a medical device manufacturer may take in the field without reporting, including, but not limited to, routine servicing 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. Regulators can require the expansion, reclassification, or change in scope and language of the field action. 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.

Field actions as well as certain outcomes from regulatory activities can result in adverse effects on our business, including damage to our reputation, delays by customers of purchase decisions, reduction or stoppage of the use of installed systems, and reduced revenue as well as increased expenses.

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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 could potentially result in a local market share shift. da Vinci procedure adoption occurs procedure by procedure, market by market, and is driven by the relative patient value and total treatment costs of da Vinci procedures as compared to alternative treatment options for the same disease state or condition.

Worldwide Procedures

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

The adoption of da Vinci Surgery has the potential to grow for those procedures that offer greater patient value than non-da Vinci alternatives, within the prevailing economics of healthcare providers. da Vinci Surgical Systems are used primarily in gynecologic surgery, general surgery, urologic surgery, cardiothoracic surgery, and head and neck surgery. We focus our organization and investments on developing, marketing, and training for those products and targeted procedures where da Vinci can bring patient value relative to alternative treatment options and/or economic benefit to healthcare providers. Target procedures in gynecology include da Vinci Hysterectomy (“dVH”), for both cancer and benign conditions, and sacrocolpopexy. Target procedures in general surgery include hernia repair (both ventral and inguinal) and colorectal procedures. Target procedures in urology include dVP and partial nephrectomy. In cardiothoracic surgery, target procedures include da Vinci Lobectomy and da Vinci Mitral Valve Repair. In head and neck surgery, target procedures include certain procedures resecting benign and malignant tumors classified as T1 and T2. Not all the indications, procedures, or products described may be available in a given country or region or on all generations of da Vinci Surgical Systems. Patients need to consult the product labeling in their specific country and for each product in order to determine the actual authorized uses, as well as important limitations, restrictions, or contraindications.

In 2017, approximately 877,000 surgical procedures were performed with the da Vinci Surgical Systems, compared with approximately 753,000 and 652,000 procedures performed in 2016 and 2015, respectively. The growth in our overall procedure volume in 2017 was driven by growth in U.S. general surgery procedures and worldwide urologic procedures.

U.S. Procedures

Overall U.S. procedure volume grew to approximately 644,000 in 2017, compared with approximately 563,000 in 2016, and approximately 499,000 in 2015. For 2017, general surgery was our fastest growing specialty in the U.S. with procedure volume that grew to approximately 246,000 in 2017, compared with approximately 186,000 in 2016 and 140,000 in 2015, and the second largest in procedure volume. For 2017, gynecology was our largest U.S. surgical specialty and the procedure volume was approximately 252,000 in 2017, compared with 246,000 in 2016 and 238,000 in 2015. U.S. urology procedure volume was approximately 118,000 in 2017, compared with approximately 109,000 in 2016, and 102,000 in 2015.

Procedures Outside of the U.S.

Overall OUS procedures grew to approximately 233,000 in 2017, compared with approximately 190,000 in 2016 and approximately 153,000 in 2015. Procedure growth in most OUS markets was driven largely by urology procedure volume, which grew to approximately 149,000 in 2017, compared with approximately 124,000 in 2016, and approximately 102,000 in 2015. General surgery, and gynecologic oncology procedures also contributed to OUS procedure growth.

Recent Business Events and Trends

Procedures

Overall. During the year ended December 31, 2017, total da Vinci procedures grew approximately 16% compared with 15% for the year ended December 31, 2016. U.S. procedure growth during the year ended December 31, 2017,

was approximately 14% compared with approximately 13% for the year ended December 31, 2016. The higher 2017 U.S. procedure growth was largely attributable to growth in general surgery procedures, most notably hernia repair and colorectal procedures, and thoracic procedures, as well as continued moderate growth in more mature gynecologic and urologic procedure categories.

Procedure volume OUS for the year ended December 31, 2017, grew approximately 23% compared with approximately 24% growth for the year ended December 31, 2016, driven by continued growth in dVP procedures and earlier stage growth in kidney cancer procedures, general surgery, and gynecology. We believe growth in these global markets is being driven by increased acceptance among surgeons and health systems, supported by expanded global evidence validating the clinical and economic value of da Vinci procedures.

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U.S. Gynecology. In 2017, gynecology was our largest U.S. surgical specialty and the procedure volume was approximately 252,000 in 2017, compared with 246,000 in 2016 and 238,000 in 2015. We believe that overall U.S. gynecologic surgery volume for benign conditions (robotic and other modalities) has been pressured in recent years by factors including, but not limited to, a trend by payers toward encouraging conservative disease management, trends towards higher patient deductibles and co-pays, and FDA actions regarding the use of power morcellation in uterine surgeries. Combining robotic, laparoscopic, and vaginal approaches, MIS represents about 80% of the U.S. hysterectomy market for benign conditions, and thus the rate of migration from open surgeries to MIS has slowed. We believe that our modest growth in gynecologic procedures over the past several years was primarily driven by consolidation of surgical volumes into surgeons that focus on cancer and complex surgeries, as well as higher sacrocolpopexy procedure volume.

U.S. General Surgery. In 2017, general surgery was our second largest and fastest growing specialty in the U.S. with procedure volume that grew to approximately 246,000 in 2017, compared with approximately 186,000 in 2016, and 140,000 in 2015. Ventral and inguinal hernia, combined, contributed to the most incremental growth in U.S. general surgery procedures in 2016 and 2017. We believe that growth in da Vinci hernia repair reflects improved clinical outcomes within certain patient populations, as well as potential cost benefits relative to certain alternative treatments. We believe hernia repair procedures represent a significant opportunity with the potential to drive growth in future periods. However, given the differences in complexity among hernia patient populations and varying surgeon opinion regarding optimal surgical technique, it is difficult to estimate the timing of and to what extent da Vinci hernia repair procedure volume will grow in the future. We expect a large portion of hernia repairs will continue to be performed via different modalities of surgery.

Adoption of da Vinci for colorectal procedures, which includes several underlying procedures including low anterior resections for rectal cancers and certain colon procedures for benign and cancerous conditions, has been ongoing for several years, and is supported by our recently launched technologies such as the da Vinci Xi Surgical System, EndoWrist Stapler, EndoWrist Vessel Sealer, and Integrated Table Motion. da Vinci use in cholecystectomy grew modestly in 2017 compared to a modest decline in 2016. 2017 cholecystectomy growth was driven by higher multi-port cholecystectomies, more than offsetting lower Single-Site cholecystectomy volume.

Global Urology. Along with U.S. general surgery, global urology procedures drove our recent procedure growth. dVP is the largest urology procedure in the U.S. and is at various stages of adoption in different areas of the world. We believe our growth in U.S. prostatectomy is largely aligned with new diagnoses of prostate cancer. As the U.S. standard of care for the surgical treatment of prostate cancer, we expect that the number of dVP procedures performed in the U.S. will largely fluctuate with the overall prostatectomy market. dVP is the largest overall OUS procedure. Kidney cancer procedures have also been a strong contributor to our recent global urology procedure growth. Clinical publications have demonstrated that the presence of a da Vinci system in a hospital or market increases the likelihood that a patient will receive nephron sparing surgery through a partial nephrectomy, which is typically surgical society guideline-recommended therapy.

OUS Procedures. The 2017 OUS procedure growth rate reflects continued da Vinci adoption in European and Asian markets. Growth was strong in Asia and varied by country in Europe. We experienced strong procedure growth in China as systems sold under a previous public hospital quota system have been installed and as utilization of those systems have increased. However, procedure growth is moderating in China. Future system placements and our ability to sustain procedure growth in China are dependent on obtaining additional importation authorizations or public hospital quotas, as well as on hospitals completing a central purchasing tender process under such authorizations. The most recent authorization expired at the end of 2015. The timing and magnitude of future authorizations that may enable future system placements is not certain. We have experienced strong procedure growth in Japan since receiving the national reimbursements, outlined above, for dVP and partial nephrectomy. However, as adoption for these procedures has progressed, procedure growth in Japan is slowing. Future procedure growth in Japan will likely be paced by the timing of procedure reimbursement approvals for procedures as well as the reimbursement levels for any of these procedures in addition to dVP and partial nephrectomy. In January 2018, a committee of the MHLW recommended 12 additional procedures for reimbursement. The reimbursement level for each procedure is uncertain at this time and may be insufficient for broad adoption. In addition, it is possible that procedures will be adopted

slowly or not at all, as there can be no assurance that the perceived value of da Vinci procedures is greater than alternative therapies.

System Demand

Future demand for da Vinci Surgical Systems will be impacted by factors including hospital response to the evolving health care environment under the current U.S. administration, procedure growth rates, hospital consolidation trends, evolving system utilization and point of care dynamics, capital replacement trends, additional reimbursements in various global markets, including Japan, the timing around governmental tenders and authorizations, including China, the timing of when we receive regulatory clearance in our other OUS markets for our Xi Surgical System, X Surgical System, and related instruments as well as other economic and geopolitical factors. Market acceptance of our recently launched X Surgical System may also impact future systems placement. Demand may also be impacted by robotic surgery competition, including from companies that have introduced products

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in the field of robotic surgery or have made explicit statements about their efforts to enter the field, including but not limited to: Auris Surgical Robotics, Inc.; Avatera Medical GmbH; Cambridge Medical Robotics Ltd.; Johnson & Johnson and Google Inc. and their joint venture, Verb Surgical Inc.; Medicaroid Inc.; MedRobotics Corp.; Medtronic PLC.; meerecompany Inc.; Olympus Corp.; Samsung Corporation; Smart Robot Technology Group Co. Ltd.; Titan Medical, Inc.; and TransEnterix, Inc.

New Product Introductions

da Vinci X Surgical System. In May 2017, we launched a new da Vinci model, the da Vinci X, in the U.S. The da Vinci X system provides surgeons and hospitals with access to some of the most advanced robotic-assisted surgery technology at a lower cost. The da Vinci X uses the same vision cart and surgeon console that are found on our flagship product, the da Vinci Xi system, giving our customers the option of adding advanced capabilities, and providing a pathway for upgrading should they choose to do so as their practices and needs grow.

The da Vinci X enables optimized, focused-quadrant surgery including procedures like prostatectomy, hernia repair, and benign hysterectomy, among others. The system features flexible port placement and 3-D digital optics, while incorporating the same advanced instruments and accessories as the da Vinci Xi. The new system drives operational efficiencies through set-up technology that uses voice and laser guidance, drape design that simplifies surgery preparations, and a lightweight, fully integrated endoscope.

da Vinci Xi Integrated Table Motion. In January 2016, we launched Integrated Table Motion in the U.S. Integrated Table Motion coordinates the movements of the da Vinci robot arms with an advanced operating room table, the TruSystem® 7000dV sold by Trumpf Medical™, to enable shifting a patient's position in real-time while the da Vinci surgical robotic arms remain docked. This gives operating room teams the capabilities to optimally position the operating table so that gravity exposes anatomy during multi-quadrant da Vinci System procedures, maximize reach and access to target anatomy enabling surgeons to interact with tissue at an ideal working angle, and reposition the table during the procedure to enhance anesthesiologists' care of the patient.

EndoWrist Stapler 30. In March 2016, we received FDA clearance in the U.S. for the EndoWrist Stapler 30 instrument with Blue, Green, White, and Gray 30mm reloads for use with the da Vinci Xi Surgical System. It is intended to deliver particular utility with fine tissue interaction in lobectomy and other thoracic procedures. The EndoWrist Stapler 30 is a wristed, stapling instrument intended for resection, transection, and/or creation of anastomoses. EndoWrist Stapler 30 broadens our existing stapler product line which includes EndoWrist Stapler 45 Blue, Green, and White reloads. Not all reloads or staplers are available for use on all systems or in all countries.

Intuitive Surgical-Fosun Medical Technology (Shanghai) Co., Ltd.

In September 2016, we agreed to establish a joint venture with Shanghai Fosun Pharmaceutical (Group) Co., Ltd. ("Fosun Pharma"), a subsidiary of Fosun International Limited, to research, develop, manufacture, and sell robotic-assisted catheter-based medical devices. The joint venture will initially produce products targeting early diagnosis and cost-effective treatment of lung cancer, one of the most commonly diagnosed forms of cancer in the world. The technology will be used in robotic-assisted medical devices based on catheters and incorporates proprietary intellectual property developed or owned by us. The joint venture is located in Shanghai, China, where it will perform research and development activities and manufacture catheter-based products for global distribution. Distribution in China will be conducted by the joint venture, while distribution outside of China will be conducted by us. The joint venture is owned 60% by us and 40% by Fosun Pharma. The companies will contribute up to $100 million as required by the joint venture, an arrangement representing a significant expansion of our relationship with Fosun Pharma. Since 2011, Chindex Medical Limited, a subsidiary of Fosun Pharma, has been our distribution partner for da Vinci Surgical Systems in China.

In the second quarter of 2017, the joint venture company was legally formed after receiving required approvals from the relevant PRC government authorities and administrative agencies. During the third quarter of 2017, the joint venture received contributions from us and Fosun Pharma. The joint venture also commenced hiring employees and began planning for the establishment of manufacturing infrastructure. For 2017, the joint venture did not have a material impact on our consolidated results. We expect that the joint venture will incur net losses before product commercialization and ramp up periods after commercialization, and that it will not generate revenue in 2018. Further, there can be no assurance that we and the joint venture can successfully complete the development of the

robotic-assisted catheter-based medical devices; that we and the joint venture will successfully commercialize such products; that the joint venture will not require additional contributions to fund its business; or that the joint venture will become profitable.

2017 Financial Highlights

- Total revenue increased by 16% to $3.1 billion for the year ended December 31, 2017, compared with $2.7 billion for the year ended December 31, 2016.
- Approximately 877,000 da Vinci procedures were performed during the year ended December 31, 2017, an increase of approximately 16% compared with approximately 753,000 for the year ended December 31, 2016.

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- Instrument and accessory revenue increased by 17% to $1.6 billion for the year ended December 31, 2017, compared with $1.4 billion for the year ended December 31, 2016.
- Systems revenue increased by 15% to $910.2 million for the year ended December 31, 2017, compared with 791.6 million for the year ended December 31, 2016. A total of 684 da Vinci Surgical Systems were shipped for the year ended December 31, 2017, compared with 537 for the year ended December 31, 2016.
- As of December 31, 2017, we had a da Vinci Surgical System installed base of approximately 4,409 systems, an increase of approximately 13% compared with the installed base as of December 31, 2016.
- Gross profit as a percentage of revenue increased to 70.1% for the year ended December 31, 2017, compared with 69.9% for the year ended December 31, 2016. Gross profit for the year ended December 31, 2017, was reduced by $7.8 million related to a litigation settlement charge. Gross profit for the year ended December 31, 2016, benefited from a $7.1 million Medical Device Excise Tax (“MDET”) refund.
- Operating income increased by 12% to $1,054.6 million for the year ended December 31, 2017, compared with $945.2 million for the year ended December 31, 2016. Operating income included $209.9 million and $178.0 million of share-based compensation expense related to employee stock plans for the years ended December 31, 2017, and 2016, respectively. Operating income for the year ended December 31, 2017, and 2016, also included pre-tax litigation charges of $25.3 million and $12.1 million, respectively.
- As of December 31, 2017, we had $3.8 billion in cash, cash equivalents, and investments. Cash, cash equivalents, and investments decreased by $1.0 billion compared with December 31, 2016, primarily as a result of the $2.3 billion accelerated share buyback executed and settled during 2017, partially offset by cash generated from operating activities and employee stock option exercises.

Results of Operations

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

	Years Ended December 31,								
	2017	% of total revenue		2016	% of total revenue		2015	% of total revenue	
Revenue:									
Product	$2,547.1	81	%	$2,187.4	81	%	$1,919.6	81	%
Service	581.8	19	%	517.0	19	%	464.8	19	%
Total revenue	3,128.9	100	%	2,704.4	100	%	2,384.4	100	%
Cost of revenue:									
Product	754.9	24	%	663.3	25	%	647.2	27	%
Service	179.9	6	%	151.0	5	%	159.3	7	%
Total cost of revenue	934.8	30	%	814.3	30	%	806.5	34	%
Product gross profit	1,792.2	57	%	1,524.1	56	%	1,272.4	54	%
Service gross profit	401.9	13	%	366.0	14	%	305.5	12	%
Gross profit	2,194.1	70	%	1,890.1	70	%	1,577.9	66	%
Operating expenses:									
Selling, general and administrative	810.9	25	%	705.3	26	%	640.5	27	%
Research and development	328.6	11	%	239.6	9	%	197.4	8	%
Total operating expenses	1,139.5	36	%	944.9	35	%	837.9	35	%
Income from operations	1,054.6	34	%	945.2	35	%	740.0	31	%
Interest and other income, net	41.9	1	%	35.6	1	%	18.5	1	%
Income before taxes	1,096.5	35	%	980.8	36	%	758.5	32	%
Income tax expense	436.5	14	%	244.9	9	%	169.7	7	%
Net income	$660.0	21	%	$735.9	27	%	$588.8	25	%

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Total Revenue

Total revenue increased by 16% to $3.1 billion for the year ended December 31, 2017, compared with $2.7 billion for the year ended December 31, 2016. Total revenue for the year ended December 31, 2016, increased by 13% compared with $2.4 billion for the year ended December 31, 2015. The increase in total revenue for the year ended December 31, 2017, reflects 17% higher instrument and accessory revenue driven by approximately 16% higher procedure volume, 15% higher systems revenue, and 13% higher service revenue. The increase in total revenue for the year ended December 31, 2016, reflects 17% higher instrument and accessory revenue driven by approximately 15% higher procedure volume, 10% higher systems revenue, and 11% higher service revenue.

Revenue denominated in foreign currencies was approximately 17%, 19%, and 19% of total revenue for the years ended December 31, 2017, 2016, and 2015, respectively. We sell our products and services in Euros and British Pounds in those European markets where we have direct distribution channels, and in Japanese Yen and Korean Won in Japan and South Korea, respectively. Foreign currency did not have a material impact on total revenue for the year ended December 31, 2017, as compared with 2016, or for the year ended December 31, 2016, as compared with 2015.

Revenue generated in the U.S. accounted for 73%, 72%, and 71% of total revenue during the years ended December 31, 2017, 2016, and 2015, respectively. We believe that U.S. revenue has accounted for the large majority of total revenue due to patients' ability to choose their provider and method of treatment in the U.S., reimbursement structures supportive of innovation and minimally invasive surgery, and initial investments focused on U.S. infrastructure. We have been investing in our business in the OUS market and our OUS procedures have grown faster in proportion to U.S. procedures. We expect that our OUS procedures and revenue will make up a greater portion of our business in the long term.

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The following table summarizes our revenue and da Vinci Surgical System unit shipments for the years ended December 31, 2017, 2016, and 2015, respectively (in millions, except percentages and unit shipments):

	Years Ended December 31,		
	2017	2016	2015
Revenue			
Instruments and accessories	$1,636.9	$1,395.8	$1,197.7
Systems	910.2	791.6	721.9
Total product revenue	2,547.1	2,187.4	1,919.6
Services	581.8	517.0	464.8
Total revenue	$3,128.9	$2,704.4	$2,384.4
United States	$2,279.8	$1,955.0	$1,695.8
OUS	849.1	749.4	688.6
Total revenue	$3,128.9	$2,704.4	$2,384.4
% of Revenue - U.S.	73 %	72 %	71 %
% of Revenue - OUS	27 %	28 %	29 %
Instruments and accessories	$1,636.9	$1,395.8	$1,197.7
Services	581.8	517.0	464.8
Operating lease (1)	25.9	16.6	7.0
Total recurring revenue (1)	$2,244.6	$1,929.4	$1,669.5
% of Total revenue	72 %	71 %	70 %
Unit Shipments by Region:			
U.S. unit shipments	417	338	298
OUS unit shipments	267	199	194
Total unit shipments*	684	537	492
*Systems shipped under operating leases (included in total unit shipments)	108	62	43
Unit Shipments involving System Trade-ins:			
Unit shipments involving trade-ins	163	156	151
Unit shipments not involving trade-ins	521	381	341

(1) Starting fourth quarter of 2017, we included operating lease revenue that is classified as systems revenue, as a component of total recurring revenue and revised prior years' total recurring revenue for comparability purposes.

Product Revenue

2016-2017

Product revenue increased by 16% to $2.5 billion for the year ended December 31, 2017, compared with $2.2 billion for the year ended December 31, 2016.

Instrument and accessory revenue increased by 17% to $1.6 billion for the year ended December 31, 2017, compared with $1.4 billion for the year ended December 31, 2016. The increase in instrument and accessory revenue was driven by procedure growth of approximately 16% and higher sales of our advanced instruments, partially offset by customer efficiency gains and timing of orders. U.S. procedure growth in 2017 was approximately 14% compared with 13% in 2016 and was driven by growth in general surgery procedures, most notably hernia repair and colorectal procedures; thoracic procedures; and a moderate growth in the more mature gynecologic and urologic procedure categories. OUS procedure growth was approximately 23% for 2017, compared with 24% for 2016, driven by continued growth in dVP procedures, earlier stage growth in kidney cancer procedures, general surgery, and gynecology. Geographically, OUS procedure growth for the year ended December 31, 2017, was driven by strong procedure expansion in Japan, China, and South Korea. Procedure growth varied by country in our European market.

Systems revenue increased by 15% to $910.2 million for the year ended December 31, 2017, compared with $791.6 million for the year ended December 31, 2016. Higher systems revenue was primarily driven by higher system shipments and partly offset

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by a higher number of system placements under operating lease arrangements and lower da Vinci Surgical System average selling price ("ASP").

During 2017, a total of 684 systems were shipped compared with 537 systems in 2016. By geography, 417 systems were shipped into the U.S., 108 into Asia, 122 into Europe, and 37 into other markets, compared with 338 systems shipped into the U.S., 96 into Asia, 79 into Europe, and 24 into other markets in 2016. During 2017, 108 of the 684 systems were shipped under operating lease arrangements compared with 62 of 537 systems shipped during 2016. The increase in systems shipments was primarily driven by procedure growth and the need for hospitals to expand or establish capacity.

Operating lease revenue was $25.9 million for the year ended December 31, 2017, compared with $16.6 million for the year ended December 31, 2016. Revenue from Lease Buyouts was $39.5 million for year ended December 31, 2017, compared with $38.2 million for the year ended December 31, 2016.

The da Vinci Surgical System ASP, excluding the impact of systems shipped under operating leases, was approximately $1.47 million and $1.52 million for 2017 and 2016, respectively. The lower 2017 ASP was driven by a higher proportion of systems sales into price sensitive market segments. ASPs fluctuate period to period based on geographic and product mix, product pricing, systems shipped involving trade-ins, and changes in foreign exchange rates.

2015-2016

Product revenue increased by 14% to $2.2 billion during the year ended December 31, 2016, from $1.9 billion during the year ended December 31, 2015.

Instrument and accessory revenue increased by 17% to $1.4 billion for the year ended December 31, 2016, compared with $1.2 billion for the year ended December 31, 2015. The increase in instrument and accessory revenue was driven by an approximate 15% increase in procedure volume, reflecting approximately 13% U.S. procedure growth and 24% OUS procedure growth, and higher sales of our advanced instruments, partially offset by customer buying patterns.

Systems revenue increased by 10% to $791.6 million during the year ended December 31, 2016, compared with $721.9 million during the year ended December 31, 2015. Higher systems revenue was driven by higher system shipments, higher number of Lease Buyouts, and higher revenue from our Integrated Table Motion product. Revenue from Lease Buyouts was $38.2 million for year ended December 31, 2016, compared with $9.4 million for the year ended December 31, 2015.

The da Vinci Surgical System ASP, excluding the impact of systems shipped under operating leases, was approximately $1.52 million and $1.54 million for 2016 and 2015, respectively.

Service Revenue

Service revenue increased by 13% to $581.8 million for the year ended December 31, 2017, compared with $517.0 million for the year ended December 31, 2016. Service revenue increased by 11% to $517.0 million for the year ended December 31, 2016, compared with $464.8 million for the year ended December 31, 2015. Higher service revenue in 2017 and 2016 was primarily driven by a larger installed base of da Vinci Surgical Systems producing service revenue.

Gross Profit

Product gross profit increased by 18% for the year ended December 31, 2017, to $1.8 billion, representing 70.4% of product revenue, compared with $1.5 billion, representing 69.7% of product revenue, for the year ended December 31, 2016. The higher 2017 product gross profit was primarily driven by higher product revenue.

The slightly higher product gross profit margin for the year ended December 31, 2017, as compared with the year ended December 31, 2016, was due to manufacturing efficiencies and product cost reductions on some of our newer products, partially offset by a $7.8 million litigation settlement charge related to a license and supply agreement recognized in cost of revenue during the first quarter of 2017, and a $7.1 million MDET refund in 2016. In December 2015, the Consolidated Appropriations Act, 2016 (the “Appropriations Act”) was signed into law. The Appropriations Act included a two-year moratorium on MDET such that medical device sales in 2016 and 2017 were exempt from the excise tax. New legislation was passed in January 2018 such that MDET will be delayed until January 1, 2020.

Product gross profit for the year ended December 31, 2016, increased by 20% to $1.5 billion, or 69.7% of product revenue, compared with $1.3 billion, or 66.3% of product revenue, for the year ended December 31, 2015. The higher

2016 product gross profit was primarily driven by higher product revenue and higher gross profit margin. The higher product gross profit margin for the year ended December 31, 2016, as compared with the year ended December 31, 2015, was driven by product cost reductions and manufacturing efficiencies on our da Vinci Xi System and other newer products, and favorable product mix, including higher sales of our da Vinci Xi Integrated Table Motion product. Product gross profit also included a $7.1 million MDET refund for the year ended December 31, 2016, while product gross profit for the year ended December 31, 2015, included $17.0 million of MDET expense, representing approximately 0.9% of total product revenue.

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Product gross profit for the year ended December 31, 2017, 2016, and 2015, included share-based compensation expense of $28.1 million, $25.2 million, and $22.8 million, respectively, and amortization expense of intangible assets of $5.4 million, $7.8 million, and $12.7 million, respectively.

Service gross profit for the year ended December 31, 2017, increased to $401.9 million, or 69.1% of service revenue, compared with $366.0 million, or 70.8% of service revenue, for the year ended December 31, 2016. The higher 2017 service gross profit was driven by higher service revenue, reflecting a larger installed base of da Vinci Surgical Systems, partially offset by lower service gross profit margin. The lower service gross profit margin for the year ended December 31, 2017, was primarily driven by higher costs associated with the repair of da Vinci Xi endoscope products.

Service gross profit for the year ended December 31, 2016, increased to $366.0 million, or 70.8% of service revenue, compared with $305.5 million, or 65.7% of service revenue, for the year ended December 31, 2015. The higher service gross profit margin for the year ended December 31, 2016, was primarily driven by improved efficiency and gains made in servicing the da Vinci Xi Surgical System.

Service gross profit for the years ended December 31, 2017, 2016, and 2015, included share-based compensation expense of $14.0 million, $12.4 million, and $12.9 million, respectively.

Selling, General and Administrative Expenses

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

Selling, general and administrative expenses for the year ended December 31, 2017, increased by 15% to $810.9 million, compared with $705.3 million for the year ended December 31, 2016. The increase was primarily due to higher variable compensation costs, higher OUS expenses associated with our expanded Asian and European teams, infrastructure to support our growth, higher headcount, and higher litigation charges. Selling, general and administrative expenses also included pre-tax litigation charges of $17.5 million and $12.1 million for the year ended December 31, 2017, and 2016, respectively.

Selling, general and administrative expenses for the year ended December 31, 2016, increased by 10% to $705.3 million compared with $640.5 million for the year ended December 31, 2015. The increase was primarily due to higher OUS expenses associated with our expanded Asian and European teams, infrastructure, higher headcount, and higher legal fees. Selling, general and administrative expenses also included pre-tax litigation charges of $12.1 million and $13.2 million for the years ended December 31, 2016, and 2015 respectively.

Share-based compensation expense charged to selling, general and administrative expenses during the years ended December 31, 2017, 2016, and 2015, was $111.8 million, $97.4 million, and $94.7 million, respectively.

Research and Development Expenses

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

Research and development expenses for the year ended December 31, 2017, increased by 37% to $328.6 million, compared with $239.6 million for the year ended December 31, 2016. The increase was primarily due to higher personnel and other project costs to support a broader set of product development initiatives, including our da Vinci Single Port Surgical System; robotic-assisted catheter-based medical devices; advanced imaging and analytics; advanced instrumentation; future generations of robotics; and expense related to licensed intellectual property.

Research and development expenses for the year ended December 31, 2016, increased by 21% to $239.6 million compared with $197.4 million for the year ended December 31, 2015. The increase was primarily due to higher personnel and other project costs to support a broader set of product development initiatives, including additional da Vinci Xi platform products; da Vinci Single Port Surgical System; our robotic-assisted catheter-based system; advanced imaging and analytics; advanced instrumentation; and next generation robotics.

Share-based compensation expense charged to research and development expense during the years ended December 31, 2017, 2016, and 2015, was $56.0 million, $43.0 million, and $37.7 million, respectively. Amortization expense related to intangible assets for the years ended December 31, 2017, 2016, and 2015, was $7.5 million, $10.4 million, and $11.7 million, respectively.

Research and development expenses fluctuate with project timing. Based upon our broader set of product development initiatives and the stage of the underlying projects, we expect to continue to make substantial investments in research and development and anticipate that research and development expenses will continue to increase in the future.

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Interest and Other Income, Net

Interest and other income, net, was $41.9 million for the year ended December 31, 2017, compared with $35.6 million for 2016 and $18.5 million for 2015. The increase in interest and other income, net, for the year ended December 31, 2017, was primarily driven by higher interest earned due to higher interest rates. The increase in interest and other income, net, for the year ended December 31, 2016, was primarily driven by higher interest earned on higher cash and investment balances.

Income Tax Expense

Our income tax expense was $436.5 million, $244.9 million, and $169.7 million for the years ended December 31, 2017, 2016, and 2015, respectively. The effective tax rate for 2017 was approximately 39.8% compared with 25.0% for 2016, and 22.4% for 2015. Our effective tax rate for 2017 differs from the U.S. federal statutory rate of 35% primarily due to the effect of the below mentioned one-time discrete items and state income taxes net of federal benefit, partially offset by income earned by certain of our overseas entities being taxed at rates lower than the federal statutory rate and reversal of certain unrecognized tax benefits. Our tax rates for 2016 and 2015 differ from the U.S. federal statutory rate of 35% primarily due to the effect of income earned by certain of our overseas entities being taxed at rates lower than the federal statutory rate and reversal of certain unrecognized tax benefits, partially offset by state income taxes net of federal benefit.

On December 22, 2017, the U.S. federal government enacted the 2017 Tax Act. The 2017 Tax Act includes a number of changes in existing tax law impacting businesses, including a one-time deemed repatriation of cumulative undistributed foreign earnings and a permanent reduction in the U.S. federal statutory rate from 35% to 21%, effective on January 1, 2018. Under U.S. GAAP, changes in tax rates and tax law are accounted for in the period of enactment and deferred tax assets and liabilities are measured at the enacted tax rate. Consistent with guidance issued by the Securities Exchange Commission (“SEC”), which provides for a measurement period of one year from the enactment date to finalize the accounting for effects of the 2017 Tax Act, we provisionally recorded an income tax expense of $317.8 million related to the 2017 Tax Act. Based on information available, we reflected a provisional estimate of $270.2 million of income tax expense related to the one-time deemed repatriation toll charge. As a result of the 2017 Tax Act, we can repatriate our cumulative undistributed foreign earnings back to the U.S. when needed with minimal U.S. income tax consequences other than the one-time deemed repatriation toll charge. In addition, we recorded a provisional estimate of $47.6 million income tax expense due to the re-measurement of our net deferred tax assets at a U.S. federal statutory rate of 21%. For the global intangible low-taxed income (“GILTI”) provisions of the 2017 Tax Act, a provisional estimate could not be made as we have not yet completed our assessment or elected an accounting policy to either recognize deferred taxes for basis differences expected to reverse as GILTI or to record GILTI as period costs if and when incurred.

In accordance with SEC guidance, provisional amounts may be refined as a result of additional guidance from, and interpretations by, U.S. regulatory and standard-setting bodies, and changes in assumptions. In the subsequent period, provisional amounts will be adjusted for the effects, if any, of interpretative guidance issued after December 31, 2017, by the U.S. Department of the Treasury. The effects of the 2017 Tax Act may be subject to changes for items that were previously reported as provisional amounts, as well as any element of the 2017 Tax Act that a provisional estimate could not be made, and such changes could result in a material effect on our future effective tax rate.

Our 2017, 2016, and 2015 tax provision reflected tax benefits of $62.4 million, $15.8 million, and $6.4 million, respectively, associated with the reversal of unrecognized tax benefits and interests resulting from expiration of statutes of limitations in multiple jurisdictions and certain audit settlements. Our 2017 tax provision also reflected excess tax benefits recognized in income tax expense under Accounting Standards Update (“ASU”) No. 2016-09, Improvements to Employee Share-based Payment Accounting. Our 2015 tax provision also reflected a $29.3 million tax benefit resulting from a U.S. Tax Court opinion involving an independent third party, issued in the third quarter of 2015. Based on the findings of the U.S. Tax Court, we were required to, and did, refund to our foreign subsidiaries the share-based compensation element of certain intercompany charges made in prior periods. Starting from 2015, share-based compensation has been excluded from intercompany charges.

In the first quarter of 2017, we adopted ASU No. 2016-09, which changes how the tax effects of share-based awards are recognized. ASU No. 2016-09 requires excess tax benefits and tax deficiencies associated with employee equity to

be recognized in the provision for income taxes as discrete items in the period when the awards vest or are settled, whereas previously such income tax effects were recorded as part of additional paid-in capital. Our provision for income taxes included excess tax benefits associated with employee equity plans of $102.8 million, which reduced our effective tax rate by 9.4 percentage points for the year ended December 31, 2017. The amount of excess tax benefits or deficiencies will fluctuate from period to period based on the price of our stock, the volume of share-based instruments settled or vested, and the value assigned to employee equity awards under U.S. GAAP. We expect that the adoption of this ASU will result in increased income tax expense volatility.

The tax holiday obtained in 2007 for our business operations in Switzerland ended on December 31, 2017. We received a new tax ruling in Switzerland for new business operations. The new tax ruling is effective for years 2018 through 2022, which will be extended for the next five years thereafter, to the extent certain terms and conditions continue to be met. The new ruling would allow for a reduced cantonal tax rate based on various thresholds of investment, including the ownership, development, and use of non-U.S. intellectual property rights and employment in such jurisdiction. The transfer of ownership of such intellectual

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property rights to our Swiss entity did not impact the Consolidated Financial Statements for the periods presented. We currently do not expect that the change will materially impact our future annual Swiss tax obligation.

We file federal, state, and foreign income tax returns in many jurisdictions in the U.S. and abroad. Years prior to 2014 are considered closed for most significant jurisdictions. Certain of our unrecognized tax benefits could reverse based on the normal expiration of various statutes of limitations, which could affect our effective tax rate in the period in which they reverse.

We are subject to the examination of our income tax returns by the Internal Revenue Service and other tax authorities. The outcome of these audits cannot be predicted with certainty. Management regularly assesses the likelihood of adverse outcomes resulting from these examinations to determine the adequacy of our provision for income taxes. If any issues addressed in our tax audits are resolved in a manner not consistent with management's expectations, we could be required to adjust our provision for income taxes in the period such resolution occurs.

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Liquidity and Capital Resources

Sources and Uses of Cash

Our principal source of liquidity is cash provided by operations and issuance of common stock through exercise of stock options and our employee stock purchase program. Cash and cash equivalents plus short- and long-term investments decreased by $1.0 billion to $3.8 billion as of December 31, 2017, from $4.8 billion as of December 31, 2016, primarily as a result of the $2.3 billion accelerated share buyback program executed and settled during 2017, partly offset by cash provided by our operations and employee stock option exercises. Cash and cash equivalents plus short- and long-term investments increased from $3.3 billion as of December 31, 2015, to $4.8 billion as of December 31, 2016, primarily as a result of cash provided by our operations and employee stock option exercises. Cash generation is one of our fundamental strengths and provides us with substantial financial flexibility in meeting our operating, investing, and financing needs.

As of December 31, 2017, $1,543.4 million of our cash, cash equivalents, and investments were held by foreign subsidiaries. Previously, amounts held by foreign subsidiaries were generally subject to U.S. income tax upon repatriation to the U.S. However, the 2017 Tax Act enacted in December 2017, requires us to pay a one-time deemed repatriation toll charge on cumulative undistributed foreign earnings for which we have not previously provided U.S. taxes. We estimated that our obligation associated with this one-time deemed repatriation toll charge to be $270.2 million, which will be paid in installments over eight years. As a result of the 2017 Tax Act, we can repatriate our cumulative undistributed foreign earnings back to the U.S. when needed with minimal U.S. income tax consequences other than the one-time deemed repatriation toll charge and do not expect other material non-U.S. tax consequences. We will continue to evaluate whether to repatriate all or a portion of the cumulative undistributed foreign earnings based on expansion needs and as circumstances change. We are still evaluating whether to change our indefinite reinvestment assertion in light of the 2017 Tax Act and consider that conclusion to be incomplete under guidance issued by the SEC. If we subsequently change our assertion during the measurement period, we will account for the change in assertion as part of the 2017 Tax Act enactment. We believe the cash flows provided by our operations will meet our liquidity needs for the foreseeable future.

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

Consolidated Cash Flow Data

	Years Ended December 31,		
	2017	2016	2015
(in millions)			
Net cash provided by (used in)			
Operating activities	$1,143.9	$1,087.0	$806.2
Investing activities	378.7	(1,279.4)	(849.5)
Financing activities	(1,913.1)	514.4	159.1
Effect of exchange rates on cash and cash equivalents	2.1	—	(1.5)
Net increase (decrease) in cash and cash equivalents	$(388.4)	$322.0	$114.3

Operating Activities

For the year ended December 31, 2017, cash provided by our operating activities of $1,143.9 million exceeded our net income of $660.0 million due to non-cash charges and changes in operating assets and liabilities as outlined below:

1. Our net income included non-cash charges, including share-based compensation of $209.1 million, depreciation and loss of disposal of property, plant, and equipment of $86.2 million, deferred income taxes of $62.9 million, investment related non-cash charges of $21.2 million, and amortization of intangible assets of $12.9 million.
2. Changes in operating assets and liabilities resulted in $91.6 million of cash provided by operating activities during the year ended December 31, 2017. Operating assets and liabilities are primarily comprised of accounts receivable, inventory, prepaid expenses and other assets, deferred revenue, and other accrued liabilities. Other accrued liabilities increased by $219.3 million, primarily due to an increase in income tax payable as a result of the 2017 Tax Act. Deferred revenue, which includes deferred service revenue that is being recognized as revenue over the service contract period, increased by $52.8 million primarily due to the higher number of installed systems for

which service contracts existed. Accrued compensation and employee benefits increased by $31.2 million. Accounts payable increased by $14.0 million. The favorable impact of these items on cash provided by operating activities was partly offset by an increase of $115.5 million in inventory, including the transfer of equipment from inventory to property, plant, and equipment; an increase of $81.7 million in accounts receivable; and an increase of $28.5 million in prepaids and other assets. The increase in accounts receivable was primarily driven by higher revenue and timing of collections. The increase in prepaids and other assets

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was primarily driven by higher lease receivable balances resulting from sales-type lease arrangement transactions entered into during the year ended December 31, 2017.

For the year ended December 31, 2016, cash provided by our operating activities of $1,087.0 million exceeded our net income of $735.9 million primarily due certain to non-cash charges as outlined below:

1. Our net income included non-cash charges including in the form of share-based compensation of $177.6 million; depreciation and loss of disposal of property, plant, and equipment of $73.9 million; investment related non-cash charges of $35.9 million; deferred income tax of $18.7 million; and amortization of intangible assets of $18.2 million.

2. The non-cash charges outlined above were partly offset by changes in operating assets and liabilities that resulted in $3.0 million of cash used by operating activities during the year ended December 31, 2016. Operating assets and liabilities are primarily comprised of accounts receivable, inventory, prepaid expenses, deferred revenue, and other accrued liabilities. Inventory, including the transfer of equipment from inventory to property, plant and equipment, increased by $46.7 million. Accounts receivable increased $35.9 million primarily driven by higher revenue and timing of collections. Prepaids and other assets increased $28.7 million primarily driven by higher lease receivable balances resulting from sales-type lease arrangement transactions entered into during year ended December 31, 2016. The unfavorable impact of these items on cash provided by operating activities was partly offset by a $53.8 million increase in other liabilities, primarily due to higher income tax payable, a $19.9 million increase in deferred revenue, an $18.7 million increase in accrued compensation and employee benefits, and a $15.9 million increase in accounts payable. Deferred revenue, which includes deferred service revenue that is being recognized as revenue over the service contract period, increased primarily due to the increase in the number of installed systems for which service contracts existed.

For the year ended December 31, 2015, cash provided by our operating activities of $806.2 million exceeded our net income of $588.8 million for two primary reasons:

1. Our net income included non-cash charges primarily in the form of share-based compensation of $167.9 million, depreciation and loss of disposal of property, plant, and equipment of $65.1 million, amortization of intangible assets of $24.4 million, and investment related non-cash charges of $26.4 million.

2. The non-cash charges outlined above were partly offset by changes in operating assets and liabilities that resulted in $92.5 million of cash used by operating activities. Operating assets and liabilities are primarily comprised of accounts receivable, inventory, deferred revenue, other accrued liabilities, and prepaid expenses. Accounts receivable increased $79.2 million in 2015 reflecting higher sales in 2015 and timing of sales and collections. Prepaids and other assets increased $10.5 million primarily driven by higher lease receivable balances resulting from sales-type lease arrangements entered into in 2015. Accrued liabilities decreased by $10.5 million mainly due to settlement payments made related to accrued product liability litigation. Other changes in operating assets and liabilities include an inventory increase of $10.7 million, net of equipment transfers from inventory to property, plant and equipment, and a decrease in accounts payable of $11.3 million also resulted in cash used by operating activities. The unfavorable impact of these items on cash provided by operating activities was partly offset by a $21.5 million increase in accrued compensation and employee benefits and an $8.2 million increase of deferred revenue.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2017, consisted of proceeds from the sales and maturities of investments (net of purchases of investments) of $569.4 million partly offset by purchases of property, plant, and equipment of $190.7 million.

Net cash used in investing activities for the year ended December 31, 2016, consisted of purchases of investments (net of the proceeds from the sales and maturities of investments) of $1.2 billion and purchases of property, plant, and equipment for $53.9 million.

Net cash used in investing activities for the year ended December 31, 2015, consisted of purchases of investments (net of the proceeds from the sales and maturities of investments) of $768.5 million and purchases of property, plant, and equipment for $81.0 million.

We invest predominantly in high quality, fixed income securities. Our investment portfolio may at any time contain investments in U.S. treasury and U.S. government agency securities, taxable and tax exempt municipal notes, corporate notes and bonds, commercial paper, non-U.S. government agency securities, cash deposits, and money market funds.

Financing Activities

Net cash used in financing activities during 2017 primarily consisted of $2,274.0 million related to an accelerated share buyback program executed and settled during 2017 that is further described in “Note 8. Stockholders' Equity” in the Notes to the Consolidated Financial Statements included in Item 8, and taxes paid on behalf of employees related to net share settlement of

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vested employee equity awards of $56.6 million. These uses partly offset by proceeds from stock option exercises and employee stock purchases of $415.5 million.

Net cash provided by financing activities in 2016 consisted primarily of proceeds from stock option exercises and employee stock purchases of $580.9 million, partly offset by $42.5 million used for the repurchase of 0.2 million shares of our common stock through open market transactions and taxes paid on behalf of employees related to net share settlement of vested employee equity awards of $24.0 million.

Net cash provided by financing activities in 2015 consisted primarily of proceeds from stock option exercises and employee stock purchases of $361.1 million, partly offset by $183.7 million used for the repurchase of 1.1 million shares of our common stock through open market transactions and taxes paid on behalf of employees related to net share settlement of vested employee equity awards of $11.0 million.

Our cash requirements depend on numerous factors, including market acceptance of our products, the resources we devote to developing and supporting our products, and other factors. We expect to continue to devote substantial resources to expand procedure adoption and acceptance of our products. We have made substantial investments in our commercial operations, product development activities, facilities, and intellectual property. Based upon our business model, we anticipate that we will continue to be able to fund future growth through cash provided from operations. We believe that our current cash, cash equivalents, and investment balances, together with income to be derived from the sale of our products, will be sufficient to meet our liquidity requirements beyond one year and for the foreseeable future.

Contractual Obligations and Commercial Commitments

The following table summarizes our contractual obligations and commercial commitments as of December 31, 2017 (in millions):

	Payments due by period				
	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Operating leases	$41.6	$ 8.2	$ 10.2	$ 6.4	$16.8
Purchase commitments and obligations	478.1	466.3	11.8	—	—
Other	270.2	21.6	43.2	43.2	162.2
Total	$789.9	$ 496.1	$ 65.2	$ 49.6	$179.0

Operating leases. We lease spaces for operations in the U.S. as well as in Japan, South Korea, Mexico, and other foreign countries. We also lease automobiles for certain sales and field service employees. Operating lease amounts include future minimum lease payments under all our non-cancellable operating leases with an initial term in excess of one year.

Purchase commitments and obligations. These amounts include an estimate of all open purchase orders and contractual obligations in the ordinary course of business, including commitments with contract manufacturers and suppliers, for which we have not received the goods or services and acquisition and licensing of intellectual property. A majority of these purchase obligations are due within a year. Although open purchase orders are considered enforceable and legally binding, the terms generally allow us the option to cancel, reschedule, and adjust our requirements based on our business needs prior to the delivery of goods or performance of services. In addition to the above, we have committed to make potential future milestone payments to third parties as part of licensing, collaboration and development arrangements. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory and/or commercial milestones. Because the achievement of these milestones is neither probable nor reasonably estimable, such contingencies have not been recorded on our Consolidated Balance Sheets and have not been included in the table above.

Other. We are unable to make a reasonably reliable estimate as to when payments may occur for our unrecognized tax benefits. Therefore, our liability for unrecognized tax benefits is not included in the table above. Due to the enactment of the 2017 Tax Act, we estimated a provisional obligation associated with a one-time deemed repatriation toll charge to be $270.2 million, which will be paid in installments over eight years. This provisional amount, as well as the current estimated timing of payments, is subject to change based on additional guidance from and interpretations by

U.S. regulatory and standard-setting bodies and changes in assumptions.

Off-Balance Sheet Arrangements

As of December 31, 2017, we did not have any significant off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K promulgated under the Exchange Act.

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Critical Accounting Estimates

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

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

Investments Valuation

Fair Value. Our investment portfolio may at any time contain investments in U.S. treasuries and U.S. government agency securities, non-U.S. government securities, taxable and/or tax exempt municipal notes, corporate notes and bonds, commercial paper, cash deposits, and money market funds. The assessment of the fair value of investments can be difficult and subjective. U.S. GAAP establishes three levels of inputs that may be used to measure fair value. Each level of input has different levels of subjectivity and difficulty involved in determining fair value. Valuation of Level 1 and 2 instruments generally do not require significant management judgment and the estimation is not difficult. Level 3 instruments include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The determination of fair value for Level 3 instruments requires the most management judgment and subjectivity. There were no Level 3 securities for the periods presented.

Other-than-temporary impairment. After determining the fair value of our available-for-sales instruments, gains or losses on these securities are recorded to other comprehensive income, until either the security is sold or we determine that the decline in value is other-than-temporary. The primary differentiating factors we considered in classifying impairments as either temporary or other-than-temporary impairments are our intent and ability to retain our investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value, the length of the time and the extent to which the market value of the investment has been less than cost, the financial condition and near-term prospects of the issuer. These judgments could prove to be wrong, and companies with relatively high credit ratings and solid financial conditions may not be able to fulfill their obligations.

No impairment charges were recorded during the years ended December 31, 2017, 2016, and 2015. As of December 31, 2017, and 2016, net unrealized losses on investments of $11.3 million and $8.6 million, net of tax, respectively, were included in accumulated other comprehensive loss.

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

Similarly, we make estimates of the collectability of accounts receivable, especially analyzing the aging and nature of accounts receivable and historical bad debts, customer concentrations, customer credit-worthiness, current economic trends, and changes in customer payment terms when evaluating the adequacy of the allowance for doubtful accounts. Credit evaluations are undertaken for all major sales transactions before shipment is authorized. On a quarterly basis, we evaluate aged items in the accounts receivable aging report and provide an allowance in an amount we deem adequate for doubtful accounts. If management were to make different judgments or utilize different estimates, material differences in the amount of our reported operating expenses could result.

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

Inventory valuation. Inventory is stated at the lower of standard cost, which approximates actual costs, or net realizable value, on a first-in, first-out basis. The cost basis of our inventory is reduced for any products that are considered excessive or obsolete based upon assumptions about future demand and market conditions. If actual future demand or market conditions are less favorable than those projected by management, additional inventory write-downs may be required, which could have a material adverse effect on the results of our operations.

Intangible Assets. Our intangible assets include identifiable intangibles and goodwill. Identifiable intangibles include developed technology, patents, distribution rights, customer relationships, and licenses. All of our identifiable intangibles have finite lives. Goodwill and intangible assets with indefinite lives are subject to an annual impairment review (or more frequent if impairment indicators arise) by applying a fair-value based test. There have been no impairments from the analysis required by U.S. GAAP.

Identifiable intangible assets with finite lives are subject to impairment testing and are reviewed for impairment when events or circumstances indicate that the carrying value of an asset is not recoverable and its carrying amount exceeds its fair value. We evaluate the recoverability of the carrying value of these identifiable intangible assets based on estimated undiscounted cash flows to be generated from such assets. If the cash flow estimates or the significant operating assumptions upon which they are based change in the future, we may be required to record additional impairment charges.

The valuation and classification of intangible assets and goodwill and the assignment of useful lives for purposes of amortization involves judgments and the use of estimates. The evaluation of these intangibles and goodwill for impairment under established accounting guidelines is required on a recurring basis. Changes in business conditions could potentially require future adjustments to the assumptions made. When we determine that the useful lives of assets are shorter than we had originally estimated, we accelerate the rate of amortization over the assets' new, shorter useful lives. No impairment charge or accelerated amortization was recorded for the years ended December 31, 2017, 2016, and 2015. A considerable amount of judgment is required in assessing impairment, which includes financial forecasts. If conditions are different from management's current estimates, material write-downs of long-lived assets may be required, which would adversely affect our operating results.

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

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

Our system sales arrangements generally include a one-year period of free service and four additional years of service that are generally billed for separately on an annual basis at a contractually stated price. The revenue allocated to the free service period is deferred and recognized ratably over the free service period. Amounts billed for the additional years of service are recorded into deferred revenue when they are billed and recognized ratably over the service period.

Because we have neither VSOE nor TPE for our systems, the allocation of revenue is based on ESP for the systems sold. The objective of ESP is to determine the price at which we would transact a sale, had the product been sold on a stand-alone basis. We determine ESP for our systems by considering multiple factors, including, but not limited to,

features and functionality of the system, geographies, type of customer, and market conditions. We regularly review ESP and maintain internal controls over establishing and updating these estimates.

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

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

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

The expected term represents the weighted-average period that our stock options are expected to be outstanding. The expected term is based on the observed and expected time to exercise. We determine expected term based on historical exercise patterns and our expectation of the time it will take for employees to exercise options still outstanding.

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

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

Accounting for income taxes. Significant management judgment is required in determining our provision for income taxes, deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets in accordance with U.S. GAAP. These estimates and judgments occur in the calculation of tax credits, benefits, and deductions, and in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes, as well as the interest and penalties related to uncertain tax positions. Significant changes to these estimates may result in an increase or decrease to our tax provision in the current or subsequent period.

We must assess the likelihood that we will be able to recover our deferred tax assets. If recovery is less than a 50% likelihood, we must increase our provision for taxes by recording a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be recoverable. As of December 31, 2017, we believe it is more likely than not that our deferred tax assets ultimately will be recovered with the exception of our California deferred tax assets. We believe that due to the computation of California taxes under the single sales factor, it is more likely than not that our California deferred tax assets will not be realized. Should there be a change in our ability to recover our deferred tax assets, our tax provision would be affected in the period in which such change takes place.

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

Accounting for legal contingencies. We are involved in a number of legal proceedings involving product liability, intellectual property, shareholder derivative actions, securities class actions, insurance, employee related, and other matters. We record a liability and related charge to earnings in our consolidated financial statements for legal

contingencies when the loss is considered probable and the amount can be reasonably estimated. Our assessment is reevaluated each accounting period and is based on all available information, including discussion with any outside legal counsel that represents us. If a reasonable estimate of a known or probable loss cannot be made, but a range of probable losses can be estimated, the low-end of the range of losses is recognized if no amount within the range is a better estimate than any other. If a loss is reasonably possible, but not probable and can be reasonably estimated, the estimated loss or range of loss is disclosed in the notes to the consolidated financial statements.

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

RECENT ACCOUNTING PRONOUNCEMENTS

See “Note 2. Summary of Significant Accounting Policies” of the Notes to Consolidated Financial Statements in “Item 8. Financial Statements and Supplementary Data” for a full description of recent accounting pronouncements including the respective expected dates of adoption and estimated effects, if any on our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate and Market Risk

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve this objective, we maintain our portfolio of cash equivalents and short- and long-term investments in a variety of high quality securities, including U.S. treasuries, U.S. government agencies, corporate debt, cash deposits, money market funds, commercial paper, non-U.S. government agency securities, and taxable or tax exempt municipal bonds. The securities are classified as available-for-sale and consequently are recorded at fair value with unrealized gains or losses reported as a separate component of accumulated other comprehensive loss. The weighted-average duration of our portfolio as of December 31, 2017, was approximately 0.9 years. If interest rates rise, the market value of our investments may decline, which could result in a realized loss if we are forced to sell an investment before its scheduled maturity. A hypothetical increase in interest rate by 25 basis points would have resulted in a decrease in the fair value of our net investment position of approximately $8.3 million as of December 31, 2017. We do not utilize derivative financial instruments to manage our interest rate risks.

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

Foreign Exchange Risk

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

For the year ended December 31, 2017, sales denominated in foreign currencies (Euro, British Pound, Japanese Yen, and Korean Won) were approximately 17% of total revenue. The objective of our hedging program is to mitigate the impact of changes in currency exchange rates on our net cash flow from foreign currency denominated sales. For the year ended December 31, 2017, our revenue would have decreased by approximately $28.8 million if the U.S. dollar exchange rate strengthened by 10%. We also hedge the net recognized non-functional currency balance sheet exposures with foreign exchange forward contracts to reduce the risk that our earnings and cash flows will be adversely affected by changes in exchange rates. A 10% strengthening of the U.S. dollar exchange rate against all currencies to which we have exposure, after considering foreign currency hedges and offsetting positions as of December 31, 2017, would have resulted in approximately $0.1 million decrease in the carrying amounts of those net assets. Actual gains and losses in the future may differ materially from the hypothetical gains and losses discussed above based on changes in the timing and amount of foreign currency exchange rate movements and our actual exposure and hedging transactions. Bank counterparties to foreign exchange forward contracts expose us to credit-related losses in the event of their nonperformance. To mitigate that risk, we only contract with counterparties

that meet certain minimum requirements under our counterparty risk assessment process. We monitor ratings and potential downgrades on at least a quarterly basis. Based on our ongoing assessment of counterparty risk, we will adjust our exposure to various counterparties.

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

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

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index To Consolidated Financial Statements

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Intuitive Surgical, Inc. and its subsidiaries as of December 31, 2017 and December 31, 2016, and the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2017, including the related notes and schedule of valuation and qualifying accounts for each of the three years in the period ended December 31, 2017 appearing under Item 8 (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and December 31, 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for certain elements of its employee share-based payments in 2017.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating

the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial

statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ PricewaterhouseCoopers LLP
San Jose, California
February 2, 2018

We have served as the Company's auditor since 2014.

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

	December 31,	
	2017	2016
ASSETS		
Current assets:		
Cash and cash equivalents	$648.2	$1,036.6
Short-term investments	1,312.4	1,518.0
Accounts receivable, net of allowances of $4.6 and $1.9 as of December 31, 2017, and 2016, respectively	511.9	430.2
Inventory	241.2	182.3
Prepaids and other current assets	97.2	83.3
Total current assets	2,810.9	3,250.4
Property, plant, and equipment, net	613.1	458.4
Long-term investments	1,885.9	2,283.3
Deferred tax assets	87.3	150.9
Intangible and other assets, net	159.7	142.8
Goodwill	201.1	201.1
Total assets	$5,758.0	$6,486.9
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$82.5	$68.5
Accrued compensation and employee benefits	167.6	136.4
Deferred revenue	284.5	240.6
Other accrued liabilities	169.5	151.0
Total current liabilities	704.1	596.5
Other long-term liabilities	327.1	112.6
Total liabilities	1,031.2	709.1
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, 2.5 shares authorized, $0.001 par value, issuable in series; no shares issued and outstanding as of December 31, 2017, and 2016	—	—
Common stock, 300.0 shares authorized, $0.001 par value, 112.3 shares and 116.4 shares issued and outstanding as of December 31, 2017, and 2016, respectively	0.1	—
Additional paid-in capital	4,679.2	4,211.8
Retained earnings	61.4	1,574.9
Accumulated other comprehensive loss	(15.5)	(8.9)
Total Intuitive Surgical, Inc. stockholders' equity	4,725.2	5,777.8
Noncontrolling interest in joint venture	1.6	—
Total stockholders' equity	4,726.8	5,777.8
Total liabilities and stockholders' equity	$5,758.0	$6,486.9

See accompanying Notes to Consolidated Financial Statements.

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

	Years Ended December 31,		
	2017	2016	2015
Revenue:			
Product	$2,547.1	$2,187.4	$1,919.6
Service	581.8	517.0	464.8
Total revenue	3,128.9	2,704.4	2,384.4
Cost of revenue:			
Product	754.9	663.3	647.2
Service	179.9	151.0	159.3
Total cost of revenue	934.8	814.3	806.5
Gross profit	2,194.1	1,890.1	1,577.9
Operating expenses:			
Selling, general and administrative	810.9	705.3	640.5
Research and development	328.6	239.6	197.4
Total operating expenses	1,139.5	944.9	837.9
Income from operations	1,054.6	945.2	740.0
Interest and other income, net	41.9	35.6	18.5
Income before taxes	1,096.5	980.8	758.5
Income tax expense	436.5	244.9	169.7
Net income	$660.0	$735.9	$588.8
Net income per share:			
Basic	$5.91	$6.40	$5.29
Diluted	$5.67	$6.24	$5.18
Shares used in computing net income per share:			
Basic	111.7	114.9	111.3
Diluted	116.3	117.9	113.7

See accompanying Notes to Consolidated Financial Statements.

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

	Years Ended December 31,		
	2017	2016	2015
Net income	$660.0	$735.9	$588.8
Other comprehensive income (loss):			
Change in foreign currency translation gains (losses)	3.6	2.0	(1.2)
Available-for-sale investments:			
Change in unrealized losses, net of tax	(2.7)	(4.6)	(3.2)
Less: Reclassification adjustment for net gains (losses) on investments recognized during the year, net of tax	—	0.2	(0.8)
Net change, net of tax effect	(2.7)	(4.4)	(4.0)
Derivative instruments:			
Change in unrealized gains (losses)	(8.6)	4.1	7.8
Less: Reclassification adjustment for gains (losses) on derivative instruments recognized during the year, net of tax	1.2	(0.6)	(7.4)
Net change, net of tax effect	(7.4)	3.5	0.4
Employee benefit plans:			
Change in unrealized losses, net of tax	(0.3)	(0.7)	(0.4)
Less: Reclassification adjustment for gains on employee benefit plans recognized during the year, net of tax	0.2	0.2	0.8
Net change, net of tax effect	(0.1)	(0.5)	0.4
Other comprehensive gains (losses)	(6.6)	0.6	(4.4)
Total comprehensive income	$653.4	$736.5	$584.4

See accompanying Notes to Consolidated Financial Statements.

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

	Common Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Total Intuitive Surgical, Inc. Stockholders' Equity	Non controlling Interest	Total Stockholders' Equity
	Shares	Amount						
Balances at December 31, 2014	36.6	$ —	$2,896.8	$487.7	$ (5.1)	$ 3,379.4	$ —	$ 3,379.4
Issuance of common stock through employee stock plans	1.2		361.1			361.1		361.1
Income tax benefit from employee stock plans			21.4			21.4		21.4
Shares withheld related to net share settlement of equity awards			(1.1)	(9.9)		(11.0)		(11.0)
Share-based compensation expense related to employee stock plans			167.9			167.9		167.9
Repurchase and retirement of common stock	(0.4)		(16.3)	(167.4)		(183.7)		(183.7)
Net income				588.8		588.8		588.8
Other comprehensive loss					(4.4)	(4.4)		(4.4)
Balances at December 31, 2015	37.4	$ —	$3,429.8	$899.2	$ (9.5)	$ 4,319.5	$ —	$ 4,319.5
Issuance of common stock through employee stock plans	1.5		580.9			580.9		580.9
Income tax benefit from employee stock plans			29.8			29.8		29.8
Shares withheld related to net share settlement of equity awards			(2.2)	(21.8)		(24.0)		(24.0)
Share-based compensation expense related to employee stock plans			177.6			177.6		177.6
Repurchase and retirement of common stock	(0.1)		(4.1)	(38.4)		(42.5)		(42.5)
Net income				735.9		735.9		735.9
Other comprehensive income					0.6	0.6		0.6
Balances at December 31, 2016	38.8	$ —	$4,211.8	$1,574.9	$ (8.9)	$ 5,777.8	$ —	$ 5,777.8
Three-for-one stock split	77.6	0.1	(0.1)			—		—
Capital contribution from noncontrolling interest						—	2.0	2.0
Issuance of common stock through employee stock plans	3.4		415.5			415.5		415.5
Shares withheld related to net share settlement of equity	(0.2)		(5.1)	(51.5)		(56.6)		(56.6)

awards								
Share-based compensation expense related to employee stock plans			209.1			209.1		209.1
Repurchase and retirement of common stock	(7.3)		(152.0)	(2,122.0)		(2,274.0)		(2,274.0)
Net income				660.0		660.0		660.0
Other comprehensive loss					(6.6)	(6.6)		(6.6)
Loss in noncontrolling interest							(0.4)	(0.4)
Balances at December 31, 2017	112.3	$ 0.1	$4,679.2	$61.4	$ (15.5)	$ 4,725.2	$ 1.6	$ 4,726.8

See accompanying Notes to Consolidated Financial Statements.

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

	Years Ended December 31,		
	2017	2016	2015
Operating activities:			
Net income	$660.0	$735.9	$588.8
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and loss on disposal of property, plant, and equipment, net	86.2	73.9	65.1
Amortization of intangible assets	12.9	18.2	24.4
Loss on investment, accretion of discounts, and amortization of premiums on investments, net	21.2	35.9	26.4
Deferred income taxes	62.9	18.7	4.6
Income tax benefits from employee stock plans	—	29.8	21.5
Share-based compensation expense	209.1	177.6	167.9
Changes in operating assets and liabilities, net of effects of acquisition:			
Accounts receivable	(81.7)	(35.9)	(79.2)
Inventory	(115.5)	(46.7)	(10.7)
Prepaids and other assets	(28.5)	(28.7)	(10.5)
Accounts payable	14.0	15.9	(11.3)
Accrued compensation and employee benefits	31.2	18.7	21.5
Deferred revenue	52.8	19.9	8.2
Other liabilities	219.3	53.8	(10.5)
Net cash provided by operating activities (1)	1,143.9	1,087.0	806.2
Investing activities:			
Purchase of investments	(1,995.0)	(2,585.5)	(1,827.4)
Proceeds from sales of investments	1,861.3	389.9	233.1
Proceeds from maturities of investments	703.1	970.1	825.8
Purchase of property, plant and equipment, and intellectual property	(190.7)	(53.9)	(81.0)
Net cash provided by (used in) investing activities	378.7	(1,279.4)	(849.5)
Financing activities:			
Proceeds from issuance of common stock relating to employee stock plans	415.5	580.9	361.1
Taxes paid related to net share settlement of equity awards	(56.6)	(24.0)	(11.0)
Repurchase and retirement of common stock	(2,274.0)	(42.5)	(183.7)
Other financing activities	2.0	—	(7.3)
Net cash provided by (used in) financing activities (1)	(1,913.1)	514.4	159.1
Effect of exchange rate changes on cash and cash equivalents	2.1	—	(1.5)
Net increase (decrease) in cash and cash equivalents	(388.4)	322.0	114.3
Cash and cash equivalents, beginning of year	1,036.6	714.6	600.3
Cash and cash equivalents, end of year	$648.2	$1,036.6	$714.6

(1) The Company adopted ASU No. 2016-09, Improvements to Employee Share-based Payment Accounting, during the first quarter of 2017. This ASU eliminates the requirement to reclassify cash flows related to excess tax benefits from operating activities to financing activities on the consolidated statements of cash flows. The Company adopted this provision retrospectively by reclassifying $44.1 million and $34.3 million of excess tax benefits from financing activities to operating activities for the year ended December 31, 2016, and 2015, respectively.

See accompanying Notes to Consolidated Financial Statements.

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INTUITIVE SURGICAL, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. DESCRIPTION OF THE BUSINESS

Intuitive Surgical, Inc. designs, manufactures, and markets da Vinci® Surgical Systems and related instruments and accessories, which taken together, are advanced surgical systems that the Company considers an advanced generation of surgery. This advanced generation of surgery, which the Company calls da Vinci Surgery, combines the benefits of 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 3-D HD vision while simultaneously allowing surgeons to work through the small ports enabled by MIS procedures.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and include the accounts of the Company and its wholly- and majority-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

The Consolidated Financial Statements include the results and the balances of the Company's majority-owned joint venture with Shanghai Fosun Pharmaceutical (Group) Co., Ltd. The Company holds a controlling financial interest in the joint venture and the noncontrolling interest is reflected as a separate component of the consolidated stockholders' equity. Noncontrolling interest in net income was inconsequential to the consolidated results for all periods presented and, therefore, has been included as a component of interest and other income, net in the consolidated statements of income.

Common Stock Split

Shares issued pursuant to the three-for-one stock split (the "Stock Split") of the Company's issued and outstanding common stock, par value $0.001 per share, were distributed on October 5, 2017, to stockholders of record as of September 29, 2017. All share and per share information presented in the Consolidated Financial Statements have been retroactively adjusted to reflect the Stock Split.

Use of Estimates

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

Concentrations of Credit Risk and Other Risks and Uncertainties

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

The Company's accounts receivable are derived from net revenue to customers and distributors located throughout the world. The Company performs credit evaluations of its customers' financial condition and, generally, requires no collateral from its customers. The Company provides reserves for potential credit losses but has not experienced

significant losses to date. As of December 31, 2017, and 2016, 69% and 73%, respectively, of accounts receivable were from domestic customers. No single customer represented more than 10% of total revenue for the years ended December 31, 2017, 2016, and 2015.

During the years ended December 31, 2017, 2016, and 2015, domestic revenue accounted for 73%, 72%, and 71% of total revenue, respectively, while outside of the U.S. revenue accounted for 27%, 28%, and 29%, respectively, of total revenue for each of the years then ended.

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Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity from date of purchase of 90 days or less to be cash equivalents.

Investments

Available-for-sale investments. The Company's investments may consist of U.S. treasury and U.S. government agency securities, taxable and tax exempt municipal notes, corporate notes and bonds, commercial paper, non-U.S. government agency securities, and money market funds. The Company has designated all investments as available-for-sale and, therefore, such investments are reported at fair value, with unrealized gains and losses recorded in accumulated other comprehensive income (loss). For securities sold prior to maturity, the cost of securities sold is based on the specific identification method. Realized gains and losses on the sale of investments are recorded in interest and other income, net in the Consolidated Statements of Income. Investments with original maturities greater than approximately three months and remaining maturities less than one year are classified as short-term investments. Investments with remaining maturities greater than one year are classified as long-term investments.

Other-than-temporary impairment. All of the Company's investments are subject to a periodic impairment review. The Company recognizes an impairment charge when a decline in the fair value of its investments below the cost basis is judged to be other-than-temporary. Factors considered in determining whether a loss is temporary included the extent and length of time the investment's fair value has been lower than its cost basis, the financial condition and near-term prospects of the investee, extent of the loss related to credit of the issuer, the expected cash flows from the security, the Company's intent to sell the security, and whether or not the Company will be required to sell the security prior the expected recovery of the investment's amortized cost basis. No such charges were recorded during the years ended December 31, 2017, 2016, and 2015.

Fair Value Measurements

The Company measures the fair value of money market funds and certain U.S. treasury securities based on quoted prices in active markets for identical assets as Level 1 securities. Marketable securities measured at fair value using Level 2 inputs are primarily comprised of commercial paper, corporate notes and bonds, U.S. and non-U.S. government agencies, and municipal notes. The Company reviews trading activity and pricing for these investments as of the measurement date. When sufficient quoted pricing for identical securities is not available, the Company uses market pricing and other observable market inputs for similar securities obtained from various third party data providers. These inputs either represent quoted prices for similar assets in active markets or have been derived from observable market data. This approach results in the Level 2 classification of these securities within the fair value hierarchy.

Inventory

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

Property, Plant, and Equipment

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

	Useful Lives
Building	Up to 30 years
Building improvements	Up to 15 years
Leasehold improvements	Lesser of useful life or term of lease
Equipment and furniture	5 years
Operating lease assets	Greater of lease term or 1 to 5 years
Computer and office equipment	3 years
Enterprise-wide software	5 years
Purchased software	Lesser of 3 years or life of license

Depreciation expense for the years ended December 31, 2017, 2016, and 2015, was $82.1 million, $70.7 million, and $61.1 million, respectively.

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Capitalized Software Costs for Internal Use

Internally developed software primarily includes enterprise-level business software that the Company customizes to meet its specific operational needs. The Company capitalized costs for internal use software of $22.4 million, $11.8 million, and $14.8 million during the years ended December 31, 2017, 2016, and 2015, respectively. Upon being placed in service, these costs are depreciated over an estimated useful life of up to 5 years.

Goodwill and Intangible Assets

Goodwill and intangible assets with indefinite useful lives are not amortized, but are tested for impairment at least annually during the fourth fiscal quarter, or if circumstances indicate their value may no longer be recoverable. Goodwill represents the excess of the purchase price over the fair value of net tangible and identifiable intangible assets. The Company continues to operate in one segment, which is considered to be the sole reporting unit and, therefore, goodwill was tested for impairment at the enterprise level. As of December 31, 2017, there has been no impairment of goodwill.

Intangible assets are carried at cost, net of accumulated amortization. The Company does not have intangible assets with indefinite useful lives other than goodwill. Amortization is recorded on a straight-line basis over the intangible assets' useful lives, which range from approximately 1 to 9 years.

Impairment of Long-lived Assets

The Company evaluates long-lived assets, which include amortizable intangible and tangible assets, for impairment whenever events or changes in circumstances indicate that the carrying value of long-lived assets may not be recoverable. Recoverability is measured by comparing the net book value to the future undiscounted cash flows attributable to such assets. The Company recognizes an impairment charge equal to the amount by which the net book value exceeds its fair value. No material impairment losses were incurred in the periods presented.

Revenue Recognition

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

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

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

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

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

As part of a trade-in transaction, the customer receives a new generation system in exchange for its pre-owned system. The trade-in credit is negotiated at the time of the trade-in and is applied towards the purchase price of the new

generation unit. Traded-in systems can be reconditioned and resold. The Company accounts for trade-ins consistent with the guidance in AICPA Technical Practice Aid 5100.01, Equipment Sales Net of Trade-Ins (“TPA 5100.01”). The Company applies the accounting guidance by crediting system revenue for the negotiated price of the new generation system, while the difference between (a) the trade-in allowance and (b) the net realizable value of the traded-in system less a normal profit margin is treated as a sales allowance. The value of the traded-in system is determined as the amount, after reconditioning costs are added, that will allow a normal profit

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margin on the sale of the reconditioned unit to be generated. When there is no market for the traded-in units, no value is assigned. Traded-in units are reported as a component of inventory until reconditioned and resold, or otherwise disposed.

In addition, customers may also have the opportunity to upgrade their systems, for example, by adding a fourth arm to a three-arm system, adding a second surgeon console for use with the da Vinci Si, Xi, and X Surgical Systems, or by upgrading a da Vinci X Patient-Side Cart to an Xi Patient-Side Cart. Such upgrades are performed by completing component level upgrades at the customer’s site or by swapping out the component upgraded. Upgrade revenue is recognized when the component level upgrades have been completed and all other revenue recognition criteria have been met.

The Company's system sale arrangements contain multiple elements including a system(s), system accessories, instruments, accessories, and system service. A da Vinci Surgical Systems are comprised of three components; a Patient-Side Cart, Surgeon’s Console, and a Vision Cart. The Company generally delivers all of the elements, other than service, within days of entering into the system sale arrangement. da Vinci X and Xi Patient-Side Carts, Surgeon’s Consoles, and Vision Carts are also sold on a stand-alone basis, as are system accessories, instruments, accessories, and service. Each of these elements is a separate unit of accounting.

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

The Company’s system sales arrangements generally include a one-year period of free service and four additional years of service that are generally billed for separately on an annual basis at a contractually stated price. The revenue allocated to the free service period is deferred and recognized ratably over the free service period. Amounts billed for the additional years of service are recorded into deferred revenue when they are billed and recognized ratably over the service period. Deferred revenue, for the periods presented, was primarily comprised of contract consideration related to services not yet performed.

Because the Company has neither VSOE nor TPE for its systems, the allocation of revenue is based on ESP for the systems sold. The objective of ESP is to determine the price at which the Company would transact a sale, had the product been sold on a stand-alone basis. The Company determines ESP for its systems by considering multiple factors, including, but not limited to, features and functionality of the system, geographies, type of customer, and market conditions. The Company regularly reviews ESP and maintains internal controls over establishing and updating these estimates.

Leases

The Company enters into sales-type lease and operating lease arrangements with certain qualified customers to purchase or rent its systems. Sales-type leases have terms that generally range from 24 to 84 months and are usually collateralized by a security interest in the underlying assets. Revenue related to multiple-element arrangements are allocated to lease and non-lease elements based on their relative selling prices as prescribed by the Company's revenue recognition policy. Lease elements generally include a da Vinci Surgical System or system component, while non-lease elements generally include service, instruments and accessories. In determining whether a transaction should be classified as a sales-type or operating lease, the Company considers the following terms: (1) whether title of the system transfers automatically or for a nominal fee at the end of the term of the lease, (2) whether the present value of the minimum lease payments are equal to or greater than 90% of the fair market value of the leased asset at the inception of the lease, (3) whether the lease term exceeds 75% of the economic life of the leased asset, and (4) whether there is an option to purchase the leased asset at a "bargain price" at the end of the lease term.

The Company generally recognizes revenue from sales-type lease arrangements at the time the system is accepted by the customer, assuming all other revenue recognition criteria have been met. Revenue from sales-type leases is presented as product revenue. Revenue from operating lease arrangements is recognized as earned over the lease term, which is generally on a straight-line basis and is presented as product revenue. Operating lease revenue for the years ended December 31, 2017, 2016, and 2015, was $25.9 million, $16.6 million, and $7.0 million, respectively.

Allowance for Sales Returns and Doubtful Accounts

The allowance for sales returns is based on the Company’s estimates of potential future product returns and other allowances related to current period product revenue. The Company analyzes historical returns, current economic trends, and changes in customer demand and acceptance of the Company's products. The allowance for doubtful accounts is based on the Company’s assessment of the collectability of customer accounts. The Company regularly reviews the allowance by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer’s ability to pay.

Share-Based Compensation

The Company accounts for share-based employee compensation plans using the fair value recognition and measurement provisions under U.S. GAAP. The Company’s share-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as expense on a straight-line basis over the requisite service period.

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

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

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

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

Computation of Net Income per Share

Basic net income per share is computed using the weighted-average number of shares outstanding during the period. Diluted net income per share is computed using the weighted-average number of the Company's shares and dilutive potential shares outstanding during the period. Dilutive potential shares primarily consist of employee stock options, restricted stock units, and shares to be purchased by employees under the Company's employee stock purchase plan. U.S. GAAP requires that employee equity share options, non-vested shares, and similar equity instruments granted by the Company be treated as potential common shares outstanding in computing diluted earnings per share. Diluted shares outstanding include the dilutive effect of equity awards, which is calculated based on the average share price for each fiscal period using the treasury stock method. Under the treasury stock method, the amount the employee must pay for exercising stock options and the amount of compensation cost for future service that the Company has not yet recognized are assumed to be used to repurchase shares.

Research and Development Expenses

Research and development costs are expensed as incurred and include amortization of intangible assets, costs associated with co-development R&D licensing arrangements, costs of prototypes, salaries, benefits and other headcount related costs, contract and other outside service fees, and facilities and overhead costs.

Foreign Currency and Other Hedging Instruments

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

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

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

reclassified immediately into earnings through interest and other income, net. Any subsequent changes in fair value of such derivative instruments also are reflected in current earnings.

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

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Income Taxes

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

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

Segments

The Company operates in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. As of December 31, 2017, and 2016, 88% and 86% of long-lived assets were in the United States. Revenue is attributed to a geographic region based on the location of the end customer.

Legal Contingencies

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

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

Recent Accounting Pronouncements Not Yet Adopted

In May 2014, the Financial Accounting Standards Board (“FASB”) issued ASU No. 2014-09, Revenue from Contracts with Customers, which sets forth a single, comprehensive revenue recognition model for all contracts with customers to improve comparability. Subsequently, the FASB has issued several standards related to ASU 2014-09 (collectively, the “New Revenue Standard”). The New Revenue Standard requires revenue recognition to depict the transfer of goods or services to customers in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. In addition, the New Revenue Standard requires expanded disclosures. This New Revenue Standard permits the use of either the retrospective or cumulative effect transition method when adopted. The New Revenue Standards becomes effective for the Company in the first quarter of fiscal year 2018.

The Company will adopt the New Revenue Standard in the first quarter of fiscal year 2018 using the full retrospective method to restate each prior reporting period presented in its Financial Statements. In preparation of adopting the New Revenue Standard, the Company has implemented additional internal controls and updated key system functionality to enable future preparation of financial information in accordance with the New Revenue Standard. The Company has also substantially completed its evaluation of the impact of the New Revenue Standard on its historical financial statements. Based on that evaluation, the Company has concluded that future billings related to future service included in its multi-year contracts should be part of the consideration allocated to all performance obligations under the New

Revenue Standard. Under the current standard, future service billings are considered to be contingent revenue, and therefore, are not included in the consideration allocated. Accordingly, the amount of consideration allocated to the performance obligations identified in the Company's system arrangements will be different under the New Revenue Standard than the amount allocated under the current standard. In general, this will result in an acceleration of the amount revenue recognized for system sales with multi-year service contracts.

The Company currently expects total revenue to increase by approximately $9 million and $2 million for fiscal 2017 and 2016, respectively. Because future service billings will be included in the contract consideration allocated to all performance

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obligations in system sales arrangements with multi-year service commitments, the Company currently expects that a greater amount of revenue will be allocated to the product related performance obligations under the New Revenue Standard. This is expected to result in a shift or reclassification of $9 million and $6 million from service to product revenue for fiscal year 2017 and 2016, respectively. In addition, contract acquisition costs, such as sales commissions paid in connection with system sales with multi-year service contracts, will be capitalized and amortized over the economic life of the contract under the New Revenue Standard. Under the current guidance, the Company expenses such costs when incurred. As a result, the Company currently expects that operating expenses will decrease by approximately $1 million and $2 million for fiscal years 2017 and 2016, respectively.

The New Revenue Standard is principle based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice, and guidance may evolve as companies and the accounting profession work to implement this new standard. While substantially complete, the Company is still in the process of finalizing its evaluation of the effect of the New Revenue Standard on the Company's historical financial statements and disclosures. The Company will finalize its accounting assessment and quantitative impact of the adoption of the New Revenue Standard during the first quarter of fiscal year 2018. As the Company completes its evaluation of this new standard, new information may arise that could change the Company's current understanding of the impact to revenue and expense recognized. Additionally, the Company will continue to monitor industry activities and any additional guidance provided by regulators, standards setters, or the accounting profession and adjust the Company's assessment and implementation plans accordingly.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which amends the existing accounting standards for leases. The new standard requires lessees to record a right-of-use asset and a corresponding lease liability on the balance sheet (with the exception of short-term leases). The new standard also requires expanded disclosures regarding leasing arrangements. The new standard becomes effective for the Company in the first quarter of fiscal year 2019 and early adoption is permitted. The new standard is required to be adopted using the modified retrospective approach and requires application of the new standard at the beginning of the earliest comparative period presented. The Company generally does not lease equipment or other capital assets, but does lease some of its facilities. The Company's customers finance purchases of systems and ancillary products, including directly with the Company. It is currently unknown whether the new standard will change customer buying patterns or behaviors. The Company is evaluating the effect that this new standard will have on its Financial Statements and related disclosures.

In October 2016, the FASB issued ASU 2016-16, Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other than Inventory, which requires the recognition of the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. Previously, the recognition of current and deferred income taxes associated with an intra-entity asset transfer was prohibited until an asset had been sold to a third party. This ASU will be effective for the Company in first quarter of 2018. This ASU is required to be adopted using the modified retrospective approach, with a cumulative catch-up adjustment to retained earnings in the period of adoption. Upon adoption, the Company will record deferred tax assets with an offset to opening retained earnings for amounts that entity had previously not recognized under existing guidance, but would be required to recognize under the new guidance. The Company currently expects that the adoption will result in an increase in deferred tax assets, with the corresponding cumulative effect adjustment recorded in retained earnings of approximately $390 million associated with an intra-entity transfer of certain intellectual property rights related to the Company's non-U.S. business to its Swiss entity. The estimated adoption date impact may be materially different as a result of recording additional deferred taxes upon finalization of the assessment of global intangible low-taxed income ("GILTI") and other aspects from additional guidance and interpretations by U.S. regulatory and standard-setting bodies related to the Tax Cuts and Jobs Act ("2017 Tax Act").

In January 2017, the FASB issued ASU 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business, which clarifies the definition of a business to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The standard will be effective for the Company in the first quarter of 2018. The Company does not expect a material impact upon the adoption of this ASU. Adoption of this ASU will not impact prior periods but may impact the accounting of future transactions.

Adopted Accounting Pronouncement

Beginning in fiscal year 2017, the Company adopted ASU No. 2016-09, Improvements to Employee Share-based Payment Accounting, which changes among other things, how the tax effects of share-based awards are recognized. ASU No. 2016-09 requires excess tax benefits and tax deficiencies to be recognized in the provision for income taxes as discrete items in the period when the awards vest or are settled, whereas previously such income tax effects were generally recorded as part of additional paid-in capital. The provision for income taxes for the year ended December 31, 2017, included excess tax benefits of $102.8 million that reduced the Company’s effective tax rate by 9.4 percentage points. The recognized excess tax benefits resulted from share-based compensation awards that vested or were settled during the year ended December 31, 2017. This ASU also eliminates the requirement to reclassify cash flows related to excess tax benefits from operating activities to financing activities on the Company's Consolidated Statements of Cash Flows. The Company adopted this provision retrospectively by reclassifying $44.1 million and $34.3 million of excess tax benefits from financing activities to operating activities for the year ended December 31, 2016, and 2015, respectively. The Company also excluded the related tax benefits when applying the treasury stock method for computing diluted shares outstanding on a prospective basis as required by this ASU. In addition, the Company elected to continue its current

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practice of estimating expected forfeitures. The amount of excess tax benefits and deficiencies recognized in the provision for income taxes will fluctuate from period to period based on the price of the Company's stock, the volume of share-based instruments settled or vested, and the value assigned to share-based instruments under U.S. GAAP.

NOTE 3. FINANCIAL INSTRUMENTS

Cash, Cash Equivalents, and Investments

The following tables summarize the Company's cash and available-for-sale marketable securities' amortized cost, gross unrealized gains, gross unrealized losses, and fair value by significant investment category reported as cash and cash equivalents or short-term or long-term investments as of December 31, 2017, and 2016 (in millions):

					Reported as:		
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Cash and Cash Equivalents	Short-term Investments	Long-term Investments
December 31, 2017							
Cash	$ 197.7	$ —	$ —	$ 197.7	$ 197.7	$ —	$ —
Level 1:							
Money market funds	445.0	—	—	445.0	445.0	—	—
U.S. treasuries	1,029.1	—	(4.7)	1,024.4	5.5	396.2	622.7
Subtotal	1,474.1	—	(4.7)	1,469.4	450.5	396.2	622.7
Level 2:							
Commercial paper	38.4	—	—	38.4	—	38.4	—
Corporate securities	946.6	0.2	(4.4)	942.4	—	403.9	538.5
U.S. government agencies	901.3	—	(4.4)	896.9	—	311.7	585.2
Non-U.S. government securities	2.5	—	—	2.5	—	2.5	—
Municipal securities	301.1	—	(1.9)	299.2	—	159.7	139.5
Subtotal	2,189.9	0.2	(10.7)	2,179.4	—	916.2	1,263.2
Total assets measured at fair value	$ 3,861.7	$ 0.2	$ (15.4)	$ 3,846.5	$ 648.2	$ 1,312.4	$ 1,885.9

					Reported as:		
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Cash and Cash Equivalents	Short-term Investments	Long-term Investments
December 31, 2016							
Cash	$ 227.7	$ —	$ —	$ 227.7	$ 227.7	$ —	$ —
Level 1:							
Money market funds	612.4	—	—	612.4	612.4	—	—
U.S. treasuries	625.9	0.1	(2.0)	624.0	157.9	168.4	297.7
Subtotal	1,238.3	0.1	(2.0)	1,236.4	770.3	168.4	297.7
Level 2:							
Commercial paper	139.6	—	—	139.6	31.1	108.5	—
Corporate securities	1,471.8	0.7	(5.0)	1,467.5	2.9	555.4	909.2
U.S. government agencies	938.7	0.5	(2.9)	936.3	—	342.7	593.6
Non-U.S. government securities	18.5	—	—	18.5	—	16.0	2.5
Municipal securities	815.4	—	(3.5)	811.9	4.6	327.0	480.3
Subtotal	3,384.0	1.2	(11.4)	3,373.8	38.6	1,349.6	1,985.6
Total assets measured at fair value	$ 4,850.0	$ 1.3	$ (13.4)	$ 4,837.9	$ 1,036.6	$ 1,518.0	$ 2,283.3

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There were no transfers between Level 1 and Level 2 measurements during the year ended December 31, 2017, and there were no changes in the valuation techniques used.

The following table summarizes the contractual maturities of the Company's cash equivalents and available-for-sale investments (excluding cash and money market funds), at December 31, 2017 (in millions):

	Amortized Cost	Fair Value
Mature in less than one year	$ 1,320.7	$1,317.9
Mature in one to five years	1,898.3	1,885.9
Total	$ 3,219.0	$3,203.8

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

As of December 31, 2017, and 2016, net unrealized losses on investments of $11.3 million and $8.6 million, net of tax, respectively, were included in accumulated other comprehensive loss in the accompanying Consolidated Balance Sheets.

The following tables present the breakdown of the available-for-sale investments with unrealized losses at December 31, 2017, and 2016 (in millions):

	Unrealized losses less than 12 months		Unrealized losses 12 months or greater		Total	
December 31, 2017	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate securities	$ 567.6	$ (2.1)	$277.0	$ (2.3)	$844.6	$ (4.4)
U.S. treasuries	763.5	(2.5)	206.2	(2.2)	969.7	(4.7)
U.S. government agencies	428.9	(1.3)	345.5	(3.1)	774.4	(4.4)
Municipal securities	236.3	(1.3)	51.7	(0.6)	288.0	(1.9)
	$ 1,996.3	$ (7.2)	$880.4	$ (8.2)	$2,876.7	$ (15.4)
December 31, 2016						
Corporate securities	$ 1,056.1	$ (5.0)	$—	$ —	$1,056.1	$ (5.0)
U.S. treasuries	357.1	(2.0)	—	—	357.1	(2.0)
U.S. government agencies	538.2	(2.9)	—	—	538.2	(2.9)
Municipal securities	728.8	(3.5)	—	—	728.8	(3.5)
	$ 2,680.2	$ (13.4)	$—	$ —	$2,680.2	$ (13.4)

The unrealized losses on the available-for-sale investments are related to corporate securities and government securities. The Company determined these unrealized losses to be temporary. Factors considered in determining whether a loss is temporary included the length of time and extent to which the investment's fair value has been less than the cost basis; the financial condition and near-term prospects of the investee; extent of the loss related to credit of the issuer; the expected cash flows from the security; the Company's intent to sell the security; and whether or not the Company will be required to sell the security before the recovery of its amortized cost.

Foreign currency derivatives

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

Cash Flow Hedges. The Company enters into currency forward contracts as cash flow hedges to hedge certain forecasted revenue transactions denominated in currencies other than the USD, primarily the European Euro ("EUR"), the British Pound ("GBP"), the Japanese Yen ("JPY"), and the Korean Won ("KRW"). The Company also enters into currency forward contracts as cash flow hedges to hedge certain forecasted expense transactions denominated in EUR and Swiss Franc ("CHF").

For these derivatives, the Company reports the after-tax gain or loss from the hedge as a component of accumulated other comprehensive loss in stockholders' equity and reclassifies into earnings in the same period in which the hedge

transaction affects earnings. The Company reclassified a net loss of $2.9 million and net gains of $0.9 million and $7.2 million to revenue related to the hedged revenue transactions for the years ended December 31, 2017, 2016, and 2015, respectively. The amounts reclassified to expenses related to the hedged transactions and the ineffective portions of cash flow hedges were not material for the periods presented.

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Other Derivatives Not Designated as Hedging Instruments. Other derivatives not designated as hedging instruments consist primarily of forward contracts that the Company uses to hedge intercompany balances and other monetary assets or liabilities denominated in currencies other than the USD, primarily the EUR, GBP, JPY, KRW, and CHF. These derivative instruments are used to hedge against balance sheet foreign currency exposures. The related gains and losses were as follows (in millions):

	Years Ended December 31,		
	2017	2016	2015
Recognized gains (losses) in interest and other income, net	$(9.2)	$6.4	$7.0
Foreign exchange gains (losses) related to balance sheet re-measurement	$9.7	$(5.6)	$(7.9)

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

	Derivatives Designated as Hedging Instruments		Derivatives Not Designated as Hedging Instruments	
	December 31, 2017	December 31, 2016	December 31, 2017	December 31, 2016
Notional amounts:				
Forward contracts	$128.5	$ 109.7	$168.4	$ 143.7
Gross fair value recorded in:				
Prepaid and other current assets	$0.9	$ 6.2	$1.2	$ 5.6
Other accrued liabilities	$2.9	$ 1.0	$4.6	$ 0.6

NOTE 4. BALANCE SHEET DETAILS AND OTHER FINANCIAL INFORMATION

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

	December 31,	
	2017	2016
Inventory:		
Raw materials	$80.9	$54.8
Work-in-process	19.7	13.4
Finished goods	140.6	114.1
Total inventory	$241.2	$182.3

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

	December 31,	
	2017	2016
Property, plant, and equipment, net:		
Land	$174.8	$131.7
Building and building/leasehold improvements	230.5	199.5
Machinery and equipment	224.8	217.7
Operating lease assets	66.1	34.7
Computer and office equipment	44.8	41.3
Capitalized software	135.6	114.2
Construction-in-process	83.5	41.2
Gross property, plant, and equipment	960.1	780.3
Less: Accumulated depreciation*	(347.0)	(321.9)
Total property, plant, and equipment, net	$613.1	$458.4
*Accumulated depreciation associated with operating lease assets	$(13.8)	$(6.8)

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

	December 31,	
	2017	2016
Other accrued liabilities—short-term:		
Taxes payable	$63.1	$40.4
Tolled product liability claims accrued	12.8	20.5
Other accrued liabilities	93.6	90.1
Total other accrued liabilities—short-term	$169.5	$151.0

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

	December 31,	
	2017	2016
Other long-term liabilities:		
Income taxes—long-term	$286.8	$84.9
Other long-term liabilities	40.3	27.7
Total other long-term liabilities	$327.1	$112.6

Supplemental Cash flow Information

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

	Years Ended December 31,		
	2017	2016	2015
Income taxes paid	$147.5	$138.4	$110.3
Supplemental non-cash investing activities:			
Equipment transfers from inventory to property, plant, and equipment	$65.8	$39.3	$26.7

NOTE 5. LEASES

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

	December 31,	
	2017	2016
Gross lease receivables	$128.0	$104.3
Unearned income	(5.0)	(4.8)
Allowance for credit loss	(0.9)	(0.6)
Net investment in sales-type leases	122.1	98.9
Reported as:		
Prepaids and other current assets	41.9	29.8
Intangible and other assets, net	80.2	69.1
Total, net	$122.1	$98.9

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Contractual maturities of gross lease receivables as of December 31, 2017, are as follows (in millions):

Fiscal Year	Amount
2018	$ 44.4
2019	37.0
2020	26.6
2021	13.1
2022	6.4
2023 and thereafter	0.5
Total	$ 128.0

Operating Leases. The Company's operating lease terms are generally less than five years. Future minimum lease payments related to non-cancellable portion of operating leases as of December 31, 2017, are as follows (in millions):

Fiscal Year	Amount
2018	$ 42.6
2019	41.2
2020	34.0
2021	19.5
2022	8.4
2023 and thereafter	0.7
Total	$ 146.4

Contingent rental revenue relating to operating lease arrangements were not material for the periods presented.

NOTE 6. INTANGIBLE ASSETS

The following table summarizes the components of gross intangible asset, accumulated amortization, and net intangible asset balances as of December 31, 2017, and 2016 (in millions):

	December 31, 2017			December 31, 2016		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents and developed technology	$156.0	$ (140.2)	$ 15.8	$158.7	$ (141.6)	$ 17.1
Distribution rights and others	9.2	(9.2)	—	9.2	(9.1)	0.1
Customer relationships	28.6	(18.4)	10.2	28.6	(14.3)	14.3
Total intangible assets	$193.8	$ (167.8)	$ 26.0	$196.5	$ (165.0)	$ 31.5

Amortization expense related to intangible assets was $12.9 million, $18.2 million, and $24.4 million for the years ended December 31, 2017, 2016, and 2015, respectively.

The estimated future amortization expense related to intangible assets as of December 31, 2017, is as follows (in millions):

Fiscal Year	Amount
2018	$ 9.6
2019	4.6
2020	4.6
2021	3.4
2022	2.1
2023 and thereafter	1.7
Total	$ 26.0

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NOTE 7. COMMITMENTS AND CONTINGENCIES

OPERATING LEASES

The Company leases space for operations in United States, Mexico, Japan, South Korea, and certain other foreign countries. The Company also leases automobiles for certain sales and field service employees. These leases have varying terms up to fifteen years.

Future minimum lease commitments under the Company's operating leases as of December 31, 2017, are as follows (in millions):

Fiscal Year	Amount
2018	$ 8.2
2019	5.8
2020	4.4
2021	3.4
2022	3.0
2023 and thereafter	16.8
Total	$ 41.6

Other commitments include an estimated amount of approximately $478.1 million relating to the Company's open purchase orders and contractual obligations that occur in the ordinary course of business, including commitments with suppliers, for which we have not received the goods or services.

CONTINGENCIES

The Company is involved in a variety of claims, lawsuits, investigations and proceedings relating to securities laws, product liability, intellectual property, insurance, contract disputes, employment, and other matters. Certain of these lawsuits and claims are described in further detail below. It is not possible to predict what the outcome of these matters will be and the Company cannot guarantee that any resolution will be reached on commercially reasonable terms, if at all.

A liability and related charge to earnings are recorded in the Company's Consolidated Financial Statements for legal contingencies when the loss is considered probable and the amount can be reasonably estimated. The assessment is re-evaluated each accounting period and is based on all available information, including impact of negotiations, settlements, rulings, advice of legal counsel, and other information and events pertaining to each case. Nevertheless, it is possible that additional future legal costs (including settlements, judgments, legal fees, and other related defense costs) could have a material adverse effect on the Company's business, financial position, or future results of operations.

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 a number of the Company's current and former officers and directors in the United States District Court for the Northern District of California. A substantially identical complaint, entitled Adel v. Intuitive Surgical, et al., No. 5:13-cv-02365, was filed in the same court against the same defendants on May 24, 2013. The Adel case was voluntarily dismissed without prejudice on August 20, 2013.

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

moved for class certification on September 1, 2015, and following opposition and reply briefing, the court held a hearing on the motion on January 21, 2016. While that motion remained pending, on October 11, 2016, the Company sent plaintiffs' lead counsel, Labaton Sucharow LLP, a letter enclosing a draft motion for sanctions pursuant to Federal Rule of Civil Procedure 11, primarily based on statements to the court that lacked a proper factual basis. In response, on November 1, 2016, plaintiffs' local counsel withdrew from the case entirely and withdrew their signatures from the disputed pleadings. On November 2, 2016, Labaton Sucharow LLP filed a motion for leave to file an amended complaint that did not include the disputed statements. On November 16, 2016, the Company filed an opposition

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to plaintiffs' motion, along with an independent motion to strike the amended complaint and the pleadings from which plaintiffs' local counsel withdrew their signatures. Following additional briefing, the motion for leave to amend and motion to strike were fully submitted to the court on November 23, 2016, and December 7, 2016, respectively. On December 22, 2016, the court entered an order granting plaintiffs' motion for class certification. On January 5, 2017, the Company filed a Petition for Permission to Appeal from the order granting class certification in the U.S. Court of Appeals for the Ninth Circuit. On October 30, 2017, the court of appeals denied the Company's petition. On January 12, 2017, plaintiffs sought leave to file a motion for partial reconsideration of the court's class certification order, which the court granted on March 17, 2017. Plaintiffs filed the motion for reconsideration itself on April 3, 2017, and the Company filed its opposition on April 17, 2017. The court denied the motion on September 29, 2017. On January 25, 2017, the court entered an order granting plaintiffs' motion for leave to amend the complaint and denying the Company's motion to strike. On February 9, 2017, the Company moved to dismiss the amended complaint. Following opposition and reply briefing, the matter was fully submitted to the court on March 2, 2017. The court denied the motion on September 29, 2017. On July 13, 2017, the parties filed a stipulation vacating the case schedule, which the court entered on July 14, 2017. On November 8, 2017, the court entered a new case schedule, with trial set to begin on October 30, 2018. While the Company intends to vigorously defend itself, the actual outcome of this matter is dependent on many variables that are difficult to predict. Based on currently available information, the Company is unable to make a reasonable estimate of loss or range of losses, if any, arising from this matter.

Purported Derivative Actions filed on February 3, 2014, February 21, 2014, March 21, 2014, June 3, 2014, and March 5, 2015

On February 3, 2014, an alleged stockholder, Robert Berg, caused a purported stockholder's derivative lawsuit entitled Berg v. Guthart et al., No. 4:14-CV-00515, to be filed in the United States District Court for the Northern District of California. The lawsuit named the Company as a nominal defendant and named a number of the Company's current and former officers and directors as defendants. The plaintiff sought to recover, on the Company's behalf, unspecified damages purportedly sustained by the Company in connection with allegedly misleading statements and/or omissions made in connection with the Company's financial reporting for the period between 2012 and early 2014. The plaintiff also sought a series of changes to the Company's corporate governance policies and an award of attorneys' fees. On April 3, 2014, the case was related to In re Intuitive Surgical Securities Litigation. On July 30, 2014, the court granted Berg's motion to be appointed lead plaintiff, denied the City of Birmingham's motion seeking such appointment (see below for additional description), and retitled the matter In re Intuitive Surgical, Inc. Shareholder Derivative Litigation, No. 4:14-CV-00515. On August 13, 2014, the plaintiffs filed a consolidated complaint, making allegations substantially similar to the allegations in the original complaint. On September 12, 2014, the Company filed a motion to dismiss the consolidated complaint, which the court denied on November 16, 2015. On January 26, 2016, the Company moved to stay this lawsuit in favor of Public School Teachers' Pension and Retirement Fund of Chicago v. Guthart et al. (see below for additional description). While the motion was pending, the Company and the plaintiff agreed in principle that the plaintiff would file a motion to intervene in the Public School Teachers' Pension and Retirement Fund of Chicago action. Following additional negotiations, the plaintiff filed an unopposed motion to intervene on April 29, 2016. After additional briefing, on May 23, 2016, the court in the Public School Teachers' Pension and Retirement Fund of Chicago action granted the motion. Accordingly, on May 31, 2016, the parties filed a stipulation requesting that the court stay In re Intuitive Surgical, Inc. Shareholder Derivative Litigation, which the court granted on June 2, 2016. Additional discussions between the parties ensued, and on September 15, 2016, they executed a confidential Memorandum of Understanding that contained the essential terms of a settlement to which the parties agreed in principle. That settlement, as later finalized, provided for a dismissal with prejudice and release of all claims brought in both the In re Intuitive Surgical, Inc. Shareholder Derivative Litigation action and the Public School Teachers' Pension and Retirement Fund of Chicago action, as well as City of Plantation Police Officers' Employees' Retirement System v. Guthart et al. (see below for additional description). The settlement, which also included terms that required the Company to reimburse the plaintiffs' lawyers' legal fees, was approved by the court in the Public School Teachers' Pension and Retirement Fund of Chicago action on October 20, 2017, following the notice process described below. Accordingly, on December 26, 2017, the parties in the In re Intuitive Surgical, Inc. Shareholder Derivative Litigation action filed a stipulation requesting that the court dismiss the action with prejudice. The court

entered the stipulation later the same day, and the matter is now resolved.

On February 21, 2014, a second alleged stockholder caused a substantially similar purported stockholder's derivative lawsuit entitled Public School Teachers' Pension and Retirement Fund of Chicago v. Guthart et al., No. CIV 526930, to be filed in the Superior Court of the State of California, County of San Mateo, against the same parties and seeking the same relief. On March 26, 2014, the case was removed to the United States District Court for the Northern District of California, where it was related to In re Intuitive Surgical Securities Litigation and Berg v. Guthart on April 30, 2014. The district court remanded the case back to San Mateo County Superior Court on June 30, 2014. On August 28, 2014, the Company filed a motion seeking to stay the case in favor of the federal action and asking that the plaintiff be required to post a bond on the grounds that the action was duplicative and was not in the Company's best interests. On November 13, 2014, the superior court entered an order denying in part the Company's motion to stay and denying the Company's request for plaintiff's bond. On November 18, 2014, the Company petitioned the First Appellate District of the California, Court of Appeal for a writ of mandate directing the superior court to stay the case in its entirety. At the same time, the Company requested an immediate stay of proceedings pending resolution of the petition. On

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November 19, 2014, the court of appeal granted the Company's request for an immediate stay of the proceedings and set a briefing schedule for the petition. The plaintiff filed its opposition to the petition on December 8, 2014, and the Company filed its reply on December 22, 2014. The petition was denied on January 8, 2015. On January 20, 2015, the Company filed a demurrer (moved to dismiss the complaint). The plaintiff filed its opposition to the demurrer on February 10, 2015, and the Company filed its reply on February 20, 2015. A hearing was held on February 27, 2015, and the court overruled the demurrer on March 27, 2015. The court's order was entered on April 2, 2015. On June 19, 2015, the Company moved for summary judgment, and a hearing on the Company's motion was set for September 4, 2015. On July 6, 2015, the court amended the case schedule, and the Company withdrew its motion for summary judgment. The court later further amended the case schedule, and trial was eventually reset for September 16, 2016. On May 23, 2016, the court granted an unopposed motion to intervene filed by the plaintiffs in In re Intuitive Surgical, Inc. Shareholder Derivative Litigation and City of Birmingham Relief and Retirement System v. Guthart et al. (see above and below for additional description). The Company filed a new motion for summary judgment on June 1, 2016, and the plaintiff filed a motion for summary adjudication regarding certain affirmative defenses on June 2, 2016. Following opposition and reply briefing, the court heard argument on the motions for summary judgment and summary adjudication on August 24, 2016. While the motions were pending, on September 15, 2016, the parties executed the confidential Memorandum of Understanding described above, which contained the essential terms of a settlement to which the parties agreed in principle. The parties notified the court of the Memorandum of Understanding on September 15, 2016, and on September 16, 2016, the court entered an order vacating the trial date and ruling that the motions for summary judgment and summary adjudication (along with other pre-trial motions) were moot. The parties finalized the settlement over the ensuing months, appearing before the court periodically to keep it apprised of their progress. The final settlement provided for a dismissal with prejudice and release of all claims brought in the Public School Teachers' Pension and Retirement Fund of Chicago action, as well as the In re Intuitive Surgical, Inc. Shareholder Derivative Litigation action and the City of Plantation Police Officers' Employees' Retirement System action and the other similar derivative cases (see above and below, respectively, for additional description). The settlement also included terms that required the Company to reimburse the plaintiffs' lawyers' legal fees. On July 7, 2017, the plaintiff filed a motion for preliminary approval of the settlement, and on July 18, 2017, the Company filed a statement of non-opposition. On August 9, 2017, the court entered an order preliminarily approving settlement, providing for notice to the Company's shareholders, and setting a final settlement hearing. On October 20, 2017, the final settlement was approved by the court. During the year ended December 31, 2017, the Company recorded $11.7 million, respectively, of pre-tax charges to reflect the cost of settling this matter. As of December 31, 2017, the final settlement was paid in full.

On March 21, 2014, a third alleged stockholder caused a substantially similar purported stockholder's derivative lawsuit entitled City of Birmingham Relief and Retirement System v. Guthart et al., No. 5-14-CV-01307, to be filed in the United States District Court for the Northern District of California against the same parties and seeking the same relief. On April 8, 2014, the lawsuit was related to In re Intuitive Surgical Securities Litigation and Berg v. Guthart. On July 30, 2014, the court consolidated the case with Berg v. Guthart and, as noted above, granted Berg's motion to be appointed lead plaintiff and denied the City of Birmingham's motion seeking such appointment. Accordingly, the City of Birmingham Relief and Retirement System action was resolved by the settlement of the In re Intuitive Surgical, Inc. Shareholder Derivative Litigation action (see above for additional description), and was subject to the December 26, 2017 stipulated dismissal of that action with prejudice. The matter is now resolved.

On June 3, 2014, a fourth alleged stockholder caused a substantially similar purported stockholder's derivative lawsuit entitled City of Plantation Police Officers' Employees' Retirement System v. Guthart et al., C.A. No. 9726-CB, to be filed in the Court of Chancery of the State of Delaware. The Company filed a motion to stay proceedings in favor of the earlier-filed stockholder derivative lawsuits pending in federal and state courts in California. In light of the Company's motion, the plaintiff agreed to a stay of all proceedings in the case in favor of the earlier-filed actions. While the case was stayed, the parties agreed that the plaintiff would file a motion to intervene in the Public School Teachers' Pension and Retirement Fund of Chicago action (see above for additional description). The plaintiff filed an unopposed motion to intervene on April 29, 2016. After additional briefing, on May 23, 2016, the court in the Public School Teachers' Pension and Retirement Fund of Chicago action granted the plaintiff's motion. However, on June 21,

2016, in response to discovery requests, the plaintiff admitted that it did not continuously hold the Company's stock during all relevant times. Accordingly, on July 21, 2016, the plaintiff filed a request for dismissal as an additional plaintiff in the Public School Teachers' Pension and Retirement Fund of Chicago action, which the court in that action granted with prejudice on July 22, 2016. On September 15, 2016, the parties executed the confidential Memorandum of Understanding described above, which contained the essential terms of a settlement to which the parties had agreed in principle. That settlement, as later finalized, provided for a dismissal with prejudice and release of all claims brought in the City of Plantation Police Officers' Employees' Retirement System action, as well as both the In re Intuitive Surgical, Inc. Shareholder Derivative Litigation action and the Public School Teachers' Pension and Retirement Fund of Chicago action (see above for additional description). The settlement, which also included terms that required the Company to reimburse the plaintiffs' lawyers' legal fees, was approved by the court in the Public School Teachers' Pension and Retirement Fund of Chicago action as described above. Accordingly, on December 26, 2017, the parties in the City of Plantation Police Officers' Employees' Retirement System action filed a stipulation requesting that the court dismiss the action with prejudice. The court entered the stipulation on December 29, 2017, and the matter is now resolved.

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On March 5, 2015, a fifth alleged stockholder caused a substantially similar purported stockholder's derivative lawsuit entitled Back v. Guthart et al., No. 3:15-CV-01037, to be filed in the United States District Court for the Northern District of California. On April 7, 2015, the lawsuit was related to In re Intuitive Surgical Securities Litigation and Berg v. Guthart. The Company filed a motion to dismiss the complaint on July 10, 2015. On August 13, 2015, the parties stipulated to a complete stay of the matter and the court entered an order reflecting the stay on August 17, 2015. On September 11, 2017, the plaintiff filed a motion to lift the stay and reopen the case and for leave to file amended complaint. On September 25, 2017, the individual defendants filed an opposition to plaintiffs' motion, which the Company joined on September 26, 2017. Plaintiff filed his reply October 2, 2017, and the Court set a hearing for January 25, 2018. While the motion was pending however, the settlement described above was approved by the court in the Public School Teachers' Pension and Retirement Fund of Chicago action. Accordingly, on November 22, 2017, the parties in the Back action filed a stipulation requesting that the court dismiss the action with prejudice. The court entered the stipulation later the same day, and the matter is now resolved.

Product Liability Litigation

The Company is currently named as a defendant in approximately 43 individual product liability lawsuits filed in various state and federal courts by plaintiffs who allege that they or a family member underwent surgical procedures that utilized the da Vinci Surgical System and sustained a variety of personal injuries and, in some cases death as a result of such surgery. The Company has also received a large number of product liability claims from plaintiffs' attorneys, many of which are subject to certain tolling agreements further discussed below. The Company has also been named as a defendant in a multi-plaintiff lawsuit filed in Missouri state court. In total, plaintiffs in that case seek damages on behalf of 55 patients from 22 different states who had surgeries in which their surgeons used the da Vinci Surgical System. Several of the filed cases have trial dates in the next 12 months.

The cases raise a variety of allegations including, to varying degrees, that plaintiffs' injuries resulted from purported defects in the da Vinci Surgical System and/or failure on the Company's part to provide adequate training resources to the healthcare professionals who performed plaintiffs' surgeries. The cases further allege that the Company failed to adequately disclose and/or misrepresented the potential risks and/or benefits of the da Vinci Surgical System. Plaintiffs also assert a variety of causes of action, including for example, strict liability based on purported design defects, negligence, fraud, breach of express and implied warranties, unjust enrichment, and loss of consortium. Plaintiffs seek recovery for alleged personal injuries and, in many cases, punitive damages.

Plaintiffs' attorneys have also engaged in well-funded national advertising efforts seeking patients dissatisfied with surgery utilizing the da Vinci Surgical System. The Company has received a significant number of such claims from plaintiffs' attorneys that it believes are a result of these advertising efforts. A substantial number of claims relate to alleged complications from surgeries performed with certain versions of Monopolar Curved Scissor ("MCS") instruments which included an MCS tip cover accessory that was the subject of a market withdrawal in 2012 and MCS instruments that were the subject of a recall in 2013. In an effort to avoid the expense and distraction of defending multiple lawsuits, the Company entered into tolling agreements to pause the applicable statutes of limitations for many of these claims and engaged in confidential mediation efforts.

After an extended confidential mediation process with legal counsel for many of the claimants covered by the tolling agreements, the Company determined during 2014 that, while it denies any and all liability, in light of the costs and risks of litigation, settlement of certain claims was appropriate. During the years ended December 31, 2017, 2016, and 2015, the Company recorded $16.3 million, $8.3 million, and $13.8 million, respectively, of pre-tax charges to reflect the estimated cost of settling a number of the product liability claims covered by the tolling agreements. As of December 31, 2017, and 2016, a total of $12.8 million and $20.5 million, respectively, were included in other accrued liabilities in the accompanying Consolidated Balance Sheets related to the pending product-liability cases and the tolled product liability claims.

The Company's estimate of the anticipated cost of resolving both the pending cases and the tolled claims is based on negotiations with attorneys for claimants who have participated in the mediation process. Nonetheless, it is possible that more claims will be made by additional individuals and that the claimants whose claims were not resolved through the mediation program, as well as those claimants who have not participated in mediations, will choose to pursue greater amounts in a court of law. Consequently, the final outcome of these claims is dependent on many

variables that are difficult to predict and the ultimate cost associated with these product liability claims may be materially different than the amount of the current estimate and accruals and could have a material adverse effect on the Company's business, financial position, and future results of operations. Although there is a reasonable possibility that a loss in excess of the amount recognized exists, the Company is unable to estimate the possible loss or range of loss in excess of the amount recognized at this time.

In February 2011, the Company was named as a defendant in a product liability action that had originally been filed in Washington State Superior Court for Kitsap County against the healthcare providers and hospital involved in a decedent's surgery on such decedent's behalf (Josette Taylor, as Personal Representative of the Estate of Fred E. Taylor, deceased; and on behalf of the Estate of Fred E. Taylor v. Intuitive Surgical, Inc., No. 09-2-03136-5). In Taylor, plaintiff asserted wrongful death and product liability claims against the Company, generally alleging that the decedent died four years after surgery as a result of injuries purportedly suffered during the surgery, which was conducted with the use of the da Vinci Surgical System. The plaintiff in Taylor

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asserted that such injuries were caused, in whole or in part, by the Company's purported failure to properly train, warn, and instruct the surgeon. The lawsuit sought unspecified damages for past medical expenses, pain and suffering, loss of consortium as well as punitive damages. A trial commenced on April 15, 2013. On May 23, 2013, the jury returned a defense verdict, finding that the Company was not negligent. Judgment was entered in the Company's favor on June 7, 2013. Subsequent to the verdict, the plaintiff filed a notice of appeal. That appeal was denied on July 7, 2015. On July 27, 2015, plaintiff filed a motion for reconsideration with the court of appeal; the court of appeal denied the motion for reconsideration on August 10, 2015. On September 9, 2015, plaintiff filed a Petition for Review with the Washington State Supreme Court ("Washington Supreme Court"). On February 10, 2016, the Washington Supreme Court issued an order granting the plaintiff's Petition for Review. Oral argument on the appeal before the Washington Supreme Court was heard on June 7, 2016. On February 9, 2017, the Washington Supreme Court vacated the defense verdict and remanded the case for retrial. In November 2017, the Company reached a confidential settlement with the plaintiff, which did not have a material adverse effect on the Company's business, financial position, or future results of operations.

Patent Litigation

On June 30, 2017, Ethicon LLC, Ethicon Endo-Surgery, Inc., and Ethicon US LLC (collectively, "Ethicon") filed a complaint for patent infringement against the Company in the United States District Court for the District of Delaware. The complaint, which was served on the Company on July 12, 2017, alleges that the Company's EndoWrist Stapler instruments infringe several of Ethicon's patents. Based on currently available information, the Company is unable to make a reasonable estimate of loss or range of losses, if any, arising from this matter.

NOTE 8. STOCKHOLDERS' EQUITY

STOCK REPURCHASE PROGRAM

The Company's Board of Directors (the "Board") has authorized an aggregate of $6.2 billion of funding for the Company's common stock repurchase program (the "Repurchase Program") since originally established in March 2009, of which the most recent authorization occurred in December 2016 when the Board increased the authorized amount available under the Repurchase Program to $3.0 billion. As of December 31, 2017, the remaining amount of share repurchases authorized by the Board under the Repurchase Program was approximately $717.5 million.

On January 24, 2017, the Company entered into an accelerated share repurchase program (the "ASR Program") with Goldman Sachs & Co. LLC ("Goldman") to repurchase $2.0 billion of the Company's common stock. On January 27, 2017, the Company made a payment of $2.0 billion to Goldman and Goldman delivered to the Company an initial delivery of approximately 7.3 million shares of the Company's common stock, which represents 80% of the payment amount divided by the closing price of the Company's common stock on January 23, 2017. Settlement was based on the daily volume-weighted average price per share of the Company's common stock during the repurchase period, less a discount, and resulted in the Company being required either to deliver shares of common stock or to make a cash payment to Goldman. On December 7, 2017, the Company completed the ASR Program by making a final settlement payment of $274.0 million to Goldman.

The following table provides the stock repurchase activities during the years ended December 31, 2017, 2016, and 2015 (in millions, except per share amounts):

	Years Ended December 31,		
	2017	2016	2015
Shares repurchased	7.3	0.2	1.1
Average price per share	$310.32	$201.70	$167.41
Value of shares repurchased	$2,274.0	$42.5	$183.7

The Company uses the par value method of accounting for its stock repurchases. As a result of the share repurchases during the years ended December 31, 2017, 2016, and 2015, the Company reduced common stock and additional paid-in capital by an aggregate of $152.0 million, $4.1 million, and $16.3 million, respectively, and charged $2,122.0 million, $38.4 million, $167.4 million, respectively, to retained earnings.

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ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

The components of accumulated other comprehensive income (loss) net of tax, for the years ended December 31, 2017, and 2016, are as follows (in millions):

	Year Ended December 31, 2017				
	Gains (Losses) on Hedge Instruments	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Translation Gains (Losses)	Employee Benefit Plans	Total
Beginning balance	$5.0	$ (8.6)	$ (1.3)	$ (4.0)	$(8.9)
Other comprehensive income (loss) before reclassifications	(8.6)	(2.7)	3.6	(0.3)	(8.0)
Reclassified from accumulated other comprehensive loss	1.2	—	—	0.2	1.4
Net current-period other comprehensive income (loss)	(7.4)	(2.7)	3.6	(0.1)	(6.6)
Ending balance	$(2.4)	$ (11.3)	$ 2.3	$ (4.1)	$(15.5)

	Year Ended December 31, 2016				
	Gains (Losses) on Hedge Instruments	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Translation Gains (Losses)	Employee Benefit Plans	Total
Beginning balance	$1.5	$ (4.2)	$ (3.3)	$ (3.5)	$(9.5)
Other comprehensive income (loss) before reclassifications	4.1	(4.6)	2.0	(0.7)	0.8
Reclassified from accumulated other comprehensive loss	(0.6)	0.2	—	0.2	(0.2)
Net current-period other comprehensive income (loss)	3.5	(4.4)	2.0	(0.5)	0.6
Ending balance	$5.0	$ (8.6)	$ (1.3)	$ (4.0)	$(8.9)

NOTE 9. SHARE-BASED COMPENSATION

Stock Plans

2010 Incentive Award Plan. In April 2010, the Company's stockholders approved the 2010 Incentive Award Plan ("2010 Plan"). Under this plan, the Company issues nonqualified stock options ("NSOs") and restricted stock units ("RSUs") to employees and certain consultants. The 2010 Plan generally permits NSOs to be granted at no less than the fair market value of the common stock on the date of grant, with terms of 10 years from the date of grant. The 2010 Plan expires in 2020. In April 2017, the Company's stockholders approved an amended and restated 2010 Plan to provide for an increase in the number of shares of common stock reserved for issuance from 21,150,000 to 24,450,000. As of December 31, 2017, approximately 6.2 million shares were reserved for future issuance under the 2010 Plan. A maximum of 2.7 million of these shares can be awarded as RSUs.

2009 Employment Commencement Incentive Plan. In October 2009, the Board adopted the 2009 Employment Commencement Incentive Plan ("New Hire Plan"). The New Hire Plan provides for the shares to be used exclusively for the grant of RSUs and NSOs to new employees ("New Hire Options"), who were not previously employees or non-employee directors of the Company. The Compensation Committee approves all equity awards under the New Hire Plan, which are granted to newly-hired employees once a month on the fifth business day of each month after their hire. Options are granted at an exercise price not less than the fair market value of the stock on the date of grant and have a term not to exceed 10 years.

In April 2015, the Board of Directors amended and restated the New Hire Plan to provide for an increase in the number of shares of common stock authorized for issuance pursuant to awards granted under the New Hire Plan from 3,465,000 to 4,365,000. As of December 31, 2017, approximately 43,000 shares were reserved for future issuance under the New Hire Plan. However, the Company intends to no longer issue grants from the New Hire Plan in the future and plans to instead utilize the 2010 Plan to make grants to new employees.

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2000 Equity Incentive Plan. In March 2000, the Board adopted the 2000 Equity Incentive Plan ("2000 Plan"), which took effect upon the closing of the Company's initial public offering. Under this plan, certain employees, consultants, and non-employee directors could be granted Incentive Stock Options ("ISOs") and Nonstatutory Stock Options ("NSOs") to purchase shares of the Company's common stock. The 2000 Plan permitted ISOs to be granted at an exercise price not less than the fair value on the date of the grant and NSOs at an exercise price not less than 85% of the fair value on the date of grant. Options granted under the 2000 Plan generally expire 10 years from the date of grant and become exercisable upon grant subject to repurchase rights in favor of the Company until vested. The 2000 Plan expired in March 2010. However, options granted prior to the plan's expiration continue to remain outstanding until their original expiration date.

Employee Option Vesting. The Company makes annual option grants on February 15 (or the next business day if the date is not a business day) and on August 15 (or the next business day if the date is not a business day). The February 15 grants vest 6/48 upon completion of 6 months service and 1/48 per month thereafter. The August 15 stock option grants vest 7/48 at the end of one month and 1/48 per month thereafter through a 3.5-year vesting period. New Hire Options generally vest 12/48 upon completion of one year service and 1/48 per month thereafter. Option vesting terms are determined by the Board and, in the future, may vary from past practices.

2000 Non-Employee Directors' Stock Option Plan. In March 2000, the Board of Directors adopted the 2000 Non-Employee Directors' Stock Option Plan (the "Directors' Plan"). In October 2009, the automatic evergreen increase provisions were eliminated so that no further automatic increases will be made to the number of shares reserved for issuance under the Directors' Plan. In addition, the common stock authorized for issuance under the Directors' Plan was reduced to 450,000. Options are granted at an exercise price not less than the fair market value of the stock on the date of grant and have a term not to exceed 10 years. Prior to 2016, initial stock option grants to new non-employee directors vest over a three-year period with 12/36 of the shares vesting after one year from the date of grant and 1/36 of the shares vesting monthly thereafter. Annual stock option grants vest one year from the date of the grant. Since 2016, new non-employee directors receive pro-rated stock option grants that vest on the same term as the annual stock option grants. As of December 31, 2017, approximately 0.1 million shares were reserved for future issuance under the Directors' Plan.

2000 Employee Stock Purchase Plan. In March 2000, the Board adopted the 2000 Employee Stock Purchase Plan (the "ESPP"). Employees are generally eligible to participate in the ESPP if they are customarily employed by the Company for more than 20 hours per week and more than 5 months in a calendar year and are not 5% stockholders of the Company. Under the ESPP, eligible employees may select a rate of payroll deduction up to 15% of their eligible compensation subject to certain maximum purchase limitations. The duration for each offering period is 24 months and is divided into four purchase periods of approximately six months in length. Offerings are concurrent. The purchase price of the shares under the offering is the lesser of 85% of the fair market value of the shares on the offering date or 85% of the fair market value of the shares on the purchase date. A two-year look-back feature in the ESPP causes the offering period to reset if the fair value of the Company's common stock on the first or last day of the purchase period is less than that on the original offering date. ESPP purchases by employees are settled with newly-issued common stock from the ESPP's previously authorized and available pool of shares. In April 2017, the Company's stockholders approved an amended and restated ESPP to provide for an increase in the number of shares of common stock reserved for issuance from 6,090,315 to 7,590,315.

The Company issued 0.2 million, 0.2 million, and 0.3 million shares under the ESPP, representing approximately $38.3 million, $32.5 million, and $31.2 million in employee contributions for the years ended December 31, 2017, 2016, and 2015, respectively. As of December 31, 2017, there were approximately 1.6 million shares reserved for future issuance under the ESPP.

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Restricted Stock Units. Equity awards granted to employees and non-employee directors include a mix of stock options and RSUs. The RSUs to employees vest in one-fourth increments annually over a four-year period. Prior to 2016, initial RSUs granted to new non-employee directors are vested in one-third increments over a three-year period. Annual RSU grants to non-employee directors vest one year from the date of grant. Since 2016, new non-employee directors receive pro-rated RSU grants that vest on the same term as the annual RSU grants. The number of shares issued on the date the RSUs vest is net of the minimum statutory tax withholdings, which are paid in cash to the appropriate taxing authorities on behalf of the Company's employees.

Stock Option Information

Option activity during fiscal 2017 under all the stock plans was as follows (in millions, except per share amounts):

	Stock Options Outstanding	
	Number Outstanding	Weighted Average Exercise Price Per Share
Balance at December 31, 2016	9.3	$ 148.36
Options granted	0.7	$ 287.11
Options exercised	(2.7)	$ 140.70
Options forfeited/expired	(0.1)	$ 204.94
Balance at December 31, 2017	7.2	$ 164.16

The aggregate intrinsic value of stock options exercised under our stock plans determined as of the date of option exercise was $379.9 million, $273.3 million, and $196.5 million during the years ended December 31, 2017, 2016, and 2015, respectively. Cash received from option exercises and employee stock purchase plans for the years ended December 31, 2017, 2016, and 2015, was $415.5 million, $580.9 million, and $361.1 million, respectively. The income tax benefit from stock options exercised was $118.9 million for the year ended December 31, 2017.

The following table summarizes significant ranges of outstanding and exercisable options as of December 31, 2017 (number of shares and aggregate intrinsic value in millions):

	Options Outstanding				Options Exercisable			
Range of Exercise Prices	Number of Shares	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (1)	Number of Shares	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (1)
$31.96 - $113.73	1.6	2.3	$ 92.43		1.6		$ 92.43	
$114.61 - $153.05	1.5	5.9	$ 140.19		1.4		$ 139.87	
$155.57 - $172.44	1.6	5.4	$ 169.56		1.4		$ 169.67	
$172.76 - $213.77	1.4	6.7	$ 184.30		1.0		$ 185.29	
$213.97 - $391.04	1.1	9.1	$ 266.31		0.3		$ 250.46	
Total	7.2	5.6	$ 164.16	$ 1,447.2	5.7	4.9	$ 147.32	$ 1,234.4

(1) The aggregate intrinsic value represents the total pre-tax intrinsic value, based on the Company's closing stock price of $364.94 at December 31, 2017, which would have been received by the option holders had all in-the-money option holders exercised their options as of that date.

As of December 31, 2017, a total of 7.1 million shares of stock options vested and expected to vest had a weighted average remaining contractual life of 5.6 years, an aggregate intrinsic value of $1,429.6 million, and a weighted average exercise price of $162.50.

Restricted Stock Units Information

RSU activity for the year ended December 31, 2017, was as follows (in millions, except per share amounts):

	Shares	Weighted Average Grant Date Fair Value

Unvested balance at December 31, 2016	1.8	$ 174.72
Granted	1.0	$ 249.34
Vested	(0.6)	$ 171.42
Forfeited	(0.1)	$ 204.08
Unvested balance at December 31, 2017	2.1	$ 209.55

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As of December 31, 2017, 1.9 million shares of RSUs were expected to vest with an aggregate intrinsic value of $700.1 million. The aggregate vesting date fair value of RSUs vested was $144.2 million, $65.3 million, and $29.5 million during the years ended December 31, 2017, 2016, and 2015, respectively.

Share-Based Compensation Expense

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

	Years Ended December 31,		
	2017	2016	2015
Cost of sales—products	$28.1	$25.2	$22.8
Cost of sales—services	14.0	12.4	12.9
Total cost of sales	42.1	37.6	35.7
Selling, general and administrative	111.8	97.4	94.7
Research and development	56.0	43.0	37.7
Share-based compensation expense before income taxes	209.9	178.0	168.1
Income tax effect	49.2	56.1	51.8
Share-based compensation expense after income taxes	$160.7	$121.9	$116.3

The Black-Scholes option pricing model is used to estimate the fair value of stock options granted under the Company's share-based compensation plans and rights to acquire stock granted under the Company's employee stock purchase plan. The weighted average estimated fair values of stock options, the rights to acquire stock granted, and RSUs, as well as the weighted average assumptions used in calculating the fair values of stock options and rights to acquire stock under the ESPP that were granted during the years ended December 31, 2017, 2016, and 2015, were as follows:

	Years Ended December 31,					
STOCK OPTION PLANS	2017		2016		2015	
Risk-free interest rate	1.8	%	1.1	%	1.6	%
Expected term (years)	4.1		4.2		4.3	
Volatility	25	%	26	%	28	%
Fair value at grant date	$67.03		$47.06		$43.82	
EMPLOYEE STOCK PURCHASE PLAN						
Risk-free interest rate	1.2	%	0.6	%	0.4	%
Expected term (years)	1.2		1.2		1.2	
Volatility	28	%	30	%	31	%
Fair value at grant date	$79.77		$57.57		$48.91	
RESTRICTED STOCK UNITS						
Fair value at grant date	$249.34		$184.59		$170.64	

As share-based compensation expense recognized in the Consolidated Statements of Income during the years ended December 31, 2017, 2016, and 2015, is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. For share-based compensation accounting, the Company elected to continue estimating expected forfeitures at the time of grant and revise, if necessary, in subsequent periods if actual forfeitures differ from those estimated.

As of December 31, 2017, there were a total of $69.9 million, $278.9 million, and $18.4 million of total unrecognized compensation expense related to unvested stock options, restricted stock units, and employee stock purchases, respectively. The unrecognized compensation expense is expected to be recognized over a weighted average period of 2.3 years for unvested stock options, 2.4 years for unvested restricted stock units, and 1.5 years for rights granted to acquire common stock under the ESPP.

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NOTE 10. INCOME TAXES

Income before provision for income taxes for the years ended December 31, 2017, 2016, and 2015, consisted of the following (in millions):

	Years Ended December 31,		
	2017	2016	2015
U.S.	$765.0	$653.0	$425.1
Foreign	331.5	327.8	333.4
Total income before provision for income taxes	$1,096.5	$980.8	$758.5

The provision for income taxes for the years ended December 31, 2017, 2016, and 2015, consisted of the following (in millions):

	Years Ended December 31,		
	2017	2016	2015
Current			
Federal	$352.1	$207.0	$148.7
State	13.0	13.4	8.4
Foreign	8.7	5.4	7.6
	$373.8	$225.8	$164.7
Deferred			
Federal	$65.5	$18.3	$7.5
State	(0.4)	0.6	0.5
Foreign	(2.4)	0.2	(3.0)
	$62.7	$19.1	$5.0
Total income tax expense	$436.5	$244.9	$169.7

Income tax expense differs from amounts computed by applying the statutory federal income rate of 35% for the years ended December 31, 2017, 2016, and 2015, as a result of the following (in millions):

	Years Ended December 31,		
	2017	2016	2015
Federal tax at statutory rate	$383.8	$343.3	$265.5
Increase (reduction) in tax resulting from:			
State taxes, net of federal benefits	16.0	14.0	8.9
Foreign rate differential	(107.3)	(86.2)	(67.4)
Research and development credit	(15.3)	(7.8)	(6.4)
Share-based compensation not benefited	10.8	3.6	