

INTUITIVE

Annual Report 2018

Intuitive Surgical, Inc.
www.intuitive.com



Dear Owner,

The healthcare industry today stands at an inflection point. Globally, the burden of disease in aging populations is large and growing. Specifically, while surgery and acute interventions have improved significantly in the past decades, there remains a significant need for better outcomes and decreased variability of these outcomes across care teams. The current environment is exerting a large and increasing burden on critical resources, including the professionals who staff care teams; surgeons, anesthesiologists, nurses, and other staff. At the same time, governments are straining to cover the healthcare needs of their populations and are demanding lower total cost to treat disease per patient. In the face of these challenges, scientific, process, and technology advances in biology, computing, imaging, algorithms, and robotics offer the promise of new methods to solve old and difficult problems.

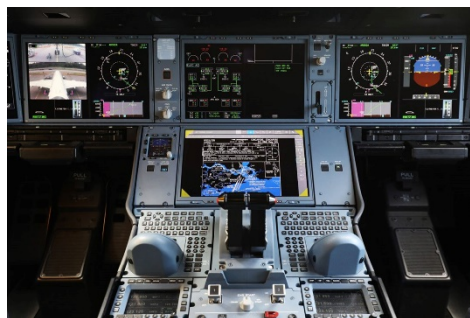
At Intuitive, we address these needs by focusing on what hospitals have termed the *quadruple aim*. First, we focus on products and services that can improve outcomes and decrease variability in the hands of care teams. Second, we seek to improve the patient experience by minimizing disruption to their lives and creating greater predictability for the treatment experience. Third, we seek to improve care team satisfaction by creating products and services that are dependable, smart, and optimized for the care environment in which they are used. Finally, we seek to lower the total cost to treat per patient episode when compared with existing treatment alternatives, providing a return on investment for hospitals and healthcare systems and value for payers.

Much has been said and written in the past couple of years about the promise and perils of technology in healthcare; there is well justified excitement and skepticism about the introduction of computing technologies into the healthcare ecosystem. As shareholders of Intuitive, it is important to recognize that while surgery can benefit from the potential of increased computational capabilities, this is not inherently a consumer industry. An apt analogy for technology in surgery is the use of technology in commercial aviation.

Care team



Control team



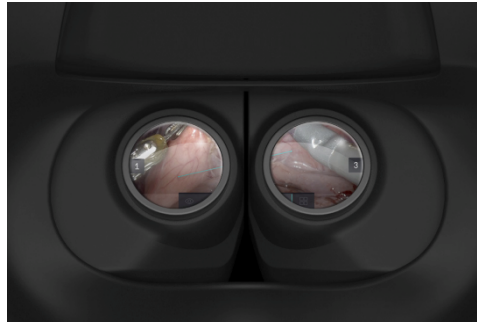
In commercial flight, a highly trained network of professionals (pilots, mechanics, gate agents, air traffic control, flight attendants) uses sophisticated technologies (modern aircraft, mobile technologies, cloud computing, simulation) to provide a safe, repeatable, and economical service to passengers who are not expected to be expert in any of these fields.

Likewise, surgery is performed by a highly trained network of professionals (surgeons, anesthesiologists, nurses, assistants, sterilization departments) using sophisticated technologies (the da Vinci® system, advanced instruments, anesthesia, cloud computing, simulation) to provide a safe, repeatable, and economically sustainable service to patients who are not, and are not expected to be, expert in any of these fields.

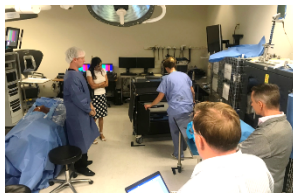
Care team



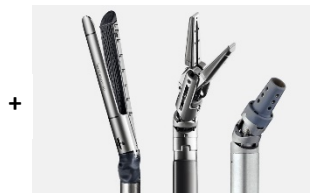
Control team



For Intuitive to provide solutions that create value in the acute care environment, we need to possess: (1) a deep understanding of the human interactions among the care team as well as the patient; (2) outstanding, smart and cloud-enabled robotic systems, imaging systems, and instrumentation; and (3) sensing, computing, and analytics. Alone, each of these elements is not enough – they are necessary but not sufficient. By integrating all three – human understanding, smart systems, imaging and instruments, and validated computational insights – we can build solutions capable of advancing the quadruple aim. To us, this makes surgery more than minimally invasive and more than digital – it makes it intelligent.



Human understanding



Smart systems & instruments



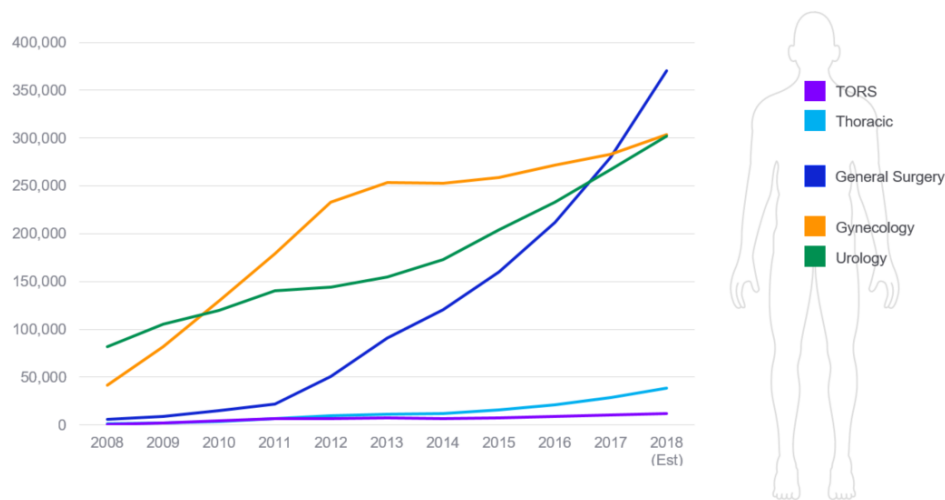
Digital insights

= **Intelligent surgery**

2018 was a strong year for Intuitive in pursuit of our mission. Use of da Vinci systems increased 18 percent from 2017 and our installed base of da Vinci systems in clinical use grew 13 percent in the year. We serve multiple surgical disciplines, including general surgery, urology, gynecology, thoracic, and trans-oral surgery. This year, use of our products grew significantly in general surgery, up 32 percent in the US compared to 2017.

Growth in procedure categories

Global over past 10 years



The opportunity for improvement in acute intervention is global, and we have been building deep capability in our priority countries. For example, a dozen new procedures received reimbursement in Japan in Q2 2018 after several years of clinical assessment and interaction with surgical societies and the Japan Ministry of Health, Labor and Welfare. In the back half of 2018, da Vinci system use in Japan grew more than 40 percent.

In 2018, we strengthened our capabilities in China with our joint venture partner, Fosun Pharma. Regulatory authorities in China granted our da Vinci Xi clearance for sale in Q4 2018, along with releasing a new quota for new system placements. We also integrated the distribution business of our partner, Chindex, into our joint venture in Q1 2019. We began direct operations in India and Taiwan in 2018. We also continued to build our clinical, economics, and commercial capability in Europe in 2018, with the addition of talented staff to better support these markets. As with Japan, we believe these are important investments that will return value over time.

Turning to our innovation pipeline, our teams are making outstanding progress. In pursuit of reducing trauma by decreasing the number and size of incisions, we added a single port option to our fourth-generation product line with the da Vinci SP® system. The FDA granted clearance for the SP system for some urology applications, and we installed the first systems in the back half of the year. In Q3 of 2018,

we submitted to the FDA our 510(k) application for transoral robotic surgery (TORS), our second SP system indication, and we are collecting data for future indications beyond TORS.

To optimize multi-quadrant general surgery procedures using our fourth-generation systems, we released our next generation stapler, the SureForm™ 60mm stapler, as well as our next generation cut-and-seal instrument, Vessel Sealer Extend. Both have received very positive customer feedback. We also released our hernia grasper in 2018. We received FDA clearance for our SureForm 45mm stapler in Q1 2019. Together, we expect these instruments to ease adoption of da Vinci in general surgery specialties like hernia repair, bariatric surgery, and colorectal surgery.

In this first quarter of 2019, the FDA cleared our flexible robotics platform, Ion™, the goal of which is to increase the accuracy and decrease the time to definitive diagnosis of lung cancer, a disease with global needs. We believe the Ion system brings class-leading precision and control to interventional pulmonology, and we anticipate a phased roll-out this year, focused on strengthening our clinical evidence base and enabling outstanding programs.

Lastly, we continue to build our cloud computing and analytics capabilities, through deeper collaboration with InTouch Health, a leading provider of telepresence health. This collaboration enables high reliability, low latency connections to Intuitive systems, which supports remote proctoring and strengthens our remote diagnostics capabilities. Finally, we are advancing our augmented reality capabilities including the integration of 3D pre-operative images naturally displayed in the surgeon's console for use in real-time during surgery, our Iris™ product, with the aim of improved anatomical structure identification and greater efficiency during surgery. Iris imaging received its first 510(k) approval in Q1 2019.



Da Vinci SP



SureForm 60



Ion



Iris

While we have outstanding technologies, our greatest asset is our world-class team of highly talented, mission-driven people from around the globe bringing with them diverse experiences. We now have more than 5,500 employees globally collaborating with our customers, our suppliers, and research institutions. Collectively, we are laser-focused on the total performance of our offerings and seek to invent and deliver effective solutions that advance the quadruple aim.

I believe there is an enormous and durable opportunity to improve acute care through our work at Intuitive. As the pioneer in computer-assisted and robotic surgery, we are investing with an eye toward building the market and the company for the long term. Toward this end, we prioritize our investments as follows: First, we are assertive in developing organic opportunities to improve outcomes and our

capabilities – we believe this delivers the greatest long-term value; Second, we invest in operational capabilities that generate economies of scale, which allow us to lower our costs and share savings with our customers; Third, we look for third parties that can accelerate our capabilities through partnership, collaboration, or acquisition; and Fourth, we seek to return cash to shareholders in tax efficient ways with an eye towards long-term value.

For 2019, we are focused on (1) making significant progress in the continued adoption of our da Vinci systems in general surgery and in other key procedures outside the United States; (2) launching da Vinci SP and Ion platforms; (3) driving intelligent surgery innovation; and (4) supporting clinical and economic validation by global region.

In closing, Intuitive has a substantial opportunity to enhance the capabilities of care teams to fundamentally improve surgery and acute intervention. We appreciate your support on this journey. I assure you that we are focused on working on things that truly make a difference.

Gary Guthart, CEO

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

FORM 10-K

(MARK ONE)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018

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™

Intuitive Surgical, Inc.

(Exact name of Registrant as Specified in its Charter)

DELAWARE

(State or Other Jurisdiction of Incorporation or Organization)

77-0416458

(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:

Common Stock, par value \$0.001 per share

Name of Each Exchange on which Registered

The Nasdaq Global Select Market

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates on June 30, 2018, based upon the closing price of Common Stock on such date as reported on The Nasdaq Global Select Market, was approximately \$53.9 billion. 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 18, 2019, was 114,488,602.

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 25, 2019, to be filed within 120 days of the registrant's fiscal year ended December 31, 2018

INTUITIVE SURGICAL, INC.

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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 words and expressions are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements related to our expected business, new product introductions, procedures and procedure adoption, 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.

PART I

ITEM 1. BUSINESS

In this report, “Intuitive Surgical,” “Intuitive,” the “Company,” “we,” “us,” and “our” refer to Intuitive Surgical, Inc. and its wholly 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[®], da Vinci X[®], SureForm[™], Single-Site[®], and Ion[™] are trademarks or registered trademarks of the Company.

Company Background

Intuitive is committed to advancing patient care in surgery and other acute medical interventions. The Company is focused on innovating to enable physicians and healthcare providers to improve the quality of and access to minimally invasive care. Intuitive has pioneered the introduction of robotic-assisted surgery to clinical practice over the past two decades with our da Vinci Surgical Systems for minimally invasive, robotic-assisted surgery and our 510(k) pending Ion endoluminal system for minimally invasive biopsies in the peripheral lung.

With the aim of entering the body less invasively, seeing anatomy more clearly, interacting with tissue more precisely, and enabling surgical skill, Intuitive launched its first da Vinci Surgical System in 1999. In 2000, it was cleared by the U.S. Food and Drug Administration (“FDA”) for general laparoscopic surgery. The da Vinci Surgical System is designed to enable complex surgery using a minimally invasive approach. It consists of: an ergonomic surgeon console or consoles; a patient-side cart with interactive arm or arms; a high-performance vision system; and proprietary instruments and accessories. Surgeons using the da Vinci system operate while seated comfortably at a console viewing a three dimensional high definition (“3DHD”) 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 approach. Our technology is designed to provide surgeons with a range of motion analogous to the motions of a human wrist, while filtering out the tremors inherent in a surgeon’s hands. 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 3DHD Visualization. Our vision system includes a 3DHD 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 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 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.

Advanced Instruments. We offer a comprehensive suite of stapling, energy and core instrumentation for our surgical systems. Most of our proprietary instruments feature EndoWrist technology, incorporating “wrist” joints. Inspired by the human hand, our wristed instruments enable surgeons to orient the instruments carefully relative to tissue 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 minimally invasive surgery (“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 compensate for the direction reversal by the pivot.

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.

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.

Advanced Training Tools. Training technologies include our Simulation program which provides for independent da Vinci skills development through interactive Virtual Reality (“VR”) exercises, and our telementoring program which provides real-time surgeon-to-surgeon learning and collaboration during robotic-assisted surgery with a da Vinci Surgical System.

Products

da Vinci Surgical Systems

Intuitive’s primary platform for robotic-assisted surgery is our family of da Vinci Surgical Systems. We have commercialized the following four generational platforms of da Vinci Surgical Systems: our fourth generation da Vinci X, da Vinci Xi and da Vinci SP 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 3D 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 da Vinci 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 ways: first, to provide assistance to the primary surgeon during surgery or second, 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 3D 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 surgical 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 the field of vision. A fourth instrument arm extends surgical capabilities by enabling the surgeon to add a third instrument to perform additional tasks. The fourth instrument arm is a standard integrated feature on da Vinci X, Xi, and Si Surgical Systems. Our da Vinci SP Surgical System includes a single arm with three, multi-jointed, wristed instruments and the first da Vinci fully wristed 3DHD camera. The instruments and the camera all emerge through a single cannula and are triangulated around the target anatomy to avoid external instrument collisions that can occur in narrow surgical workspaces.

3DHD Vision System. Our vision system includes our InSite 3D endoscope with two separate vision channels linked to two separate color monitors through high performance video cameras and specialized image processing hardware. The resulting 3DHD image has high resolution, high contrast, low flicker, and low cross fading. A digital zoom feature in the 3DHD 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 3DHD vision is a standard integrated feature on da Vinci X, Xi, SP, Si, and S Surgical Systems.

Da Vinci Skills Simulator. The Skills Simulator is a practice tool that gives a user the opportunity to practice their skills and gain familiarity with the surgeon console controls. The Skills Simulator incorporates 3D, 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 SP 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 managing the patient’s position in real-time while the da Vinci surgical robotic arms remain docked. This gives operating room teams the capability to optimally position the operating table during da Vinci System procedures. Integrated Table Motion enables surgeons to maximize reach, facilitate access, and choose the angle of approach to target anatomy, as well as reposition the table during the procedure to enhance anesthesiologists’ management of the patient.

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 typically used in the categories of urology, gynecology, and general surgery.

Instruments and Accessories

Da Vinci Instruments. We manufacture a variety of instruments, most of which incorporate EndoWrist technology with wristed joints for natural dexterity, and tips customized for various surgical procedures. Da Vinci instruments are offered in a variety of diameters, of which 5mm and 8mm diameter sizes are the most commonly sold. Various da Vinci instrument tips include forceps, scissors, electrocautery tools, scalpels, and other surgical tools that are familiar to the surgeon from open surgery and conventional MIS. A variety of instruments may be selected and used interchangeably during a surgery. Most instruments are sterilizable at the hospital, while others are 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 Stapling. 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 three types of staplers: the EndoWrist Stapler 45 and 30, and the SureForm 60 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. The SureForm 60 is a single-use, fully wristed, stapling instrument intended for resection, transection, and/or creation of anastomoses, with particular utility in bariatric procedures.

Da Vinci Energy. 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 robotic-assisted surgery. This instrument is designed to enhance surgical efficiency and autonomy in a variety of general surgery and gynecologic procedures. The da Vinci Vessel Sealer Extend is our newest instrument in the Vessel Sealing family of products. Da Vinci Vessel Sealer Extend is a single use, fully wristed bipolar electrosurgical instrument compatible with our fourth generation multiport systems. It is intended for grasping and blunt dissection of tissue and for bipolar coagulation and mechanical transection of vessels up to 7mm in diameter and tissue bundles that fit in the jaws of the instrument.

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.

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 3D 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 other acute interventions by enabling physicians and hospitals to improve outcomes for their patients, improve their patient's experience and the care team experience, and lower total cost to treat per patient episode. Through the use of smart, connected systems, robotic technologies, advanced imaging, and informatics, 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. 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 offer surgeons and their operating room staff training on the technical use of our products. 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 robotic-assisted surgery with the da Vinci Surgical System 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 robotic-assisted surgery with the da Vinci Surgical System—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 hysterectomy (“dVH”), da Vinci prostatectomy (“dVP”), da Vinci for hernia repair, da Vinci for colon and rectal procedures, da Vinci for partial nephrectomy, da Vinci for sacrocolpopexy, da Vinci for lobectomy, da Vinci for transoral robotic surgery, and da Vinci for mitral valve repair. 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 Surgical System for use in gynecological procedures in 2005, the majority of hysterectomies performed were open surgeries. We believe that robotic-assisted surgery with the da Vinci Surgical System provides patients 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 robotic-assisted surgery with a da Vinci Surgical System is performed using multi-port techniques. Single-Site instruments enable surgeons to perform surgery through a single port via the patient’s umbilicus, allowing for significantly reduced scarring.

Sacrocolpopexy. The abdominal (open) sacrocolpopexy is one of the operations performed to treat 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 larger 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 robotic-assisted surgery with a da Vinci Surgical System, 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 robotic-assisted surgery with a da Vinci Surgical 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. We believe SureForm 60 may have particular utility in bariatric procedures.

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 robotic-assisted surgery with a da Vinci Surgical 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-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 procedures and (2) procedures for benign conditions. Cancer and other highly complex procedures tend to be reimbursed at higher rates than less complex procedures. Thus, hospitals are more sensitive to the costs associated with treating less complex benign conditions. Our strategy is to provide hospitals with attractive clinical and economic solutions in each of these categories. Our fully featured da Vinci Xi system with advanced instruments including the EndoWrist One Vessel Sealer, EndoWrist Stapler products, and our Integrated Table Motion product cover a wide range of procedures, from complex to those that are less so. Our da Vinci X Surgical System and Single-Site instruments are targeted towards price sensitive markets and procedures.

Clinical Summary

We believe there are numerous additional applications that can be addressed with the da Vinci Surgical System and we work closely with our surgeon customers to refine and explore new techniques in which da Vinci may bring value. As of December 31, 2018, we had an installed base of 4,986 da Vinci Surgical Systems, including 3,196 in the U.S., 872 in Europe, 651 in Asia, and 267 in the rest of the world. We estimate that surgeons using our technology completed approximately 1,037,000 surgical procedures of various types in hospitals throughout the world during the year ended December 31, 2018.

Sales and Customer Support

Sales Model

We provide our products through direct sales organizations in the U.S., Europe, excluding Spain, Portugal, Italy, Greece, and most Eastern European countries, Japan, South Korea, India, and Taiwan. In May and December 2018, we began direct operations in India and Taiwan, respectively. In the remainder of our markets outside of the U.S. (“OUS”), we provide our products through distributors. In January 2019, our joint venture (referred to herein as the “Joint Venture”) with Shanghai Fosun Pharmaceutical (Group) Co., Ltd. (“Fosun Pharma”) acquired certain assets related to the distribution business of Chindex Medical Limited and its affiliates (“Chindex”), a subsidiary of Fosun Pharma, which has been our distribution partner for da Vinci Surgical Systems in China since 2011. In January 2019, our Joint Venture began direct operations for da Vinci products and services in China. See “Item 7. Management Discussion and Analysis” for further details on the Joint Venture. No single customer accounted for more than 10% of revenue during the years ended December 31, 2018, 2017, and 2016. During the years ended December 31, 2018, 2017, and 2016, domestic revenue accounted for 71%, 73%, and 72%, respectively, of total revenue, while revenue from our OUS markets accounted for 29%, 27%, and 28%, respectively. As of December 31, 2018, and 2017, 88% and 88% 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 robotic-assisted surgery with a da Vinci Surgical System, 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 robotic-assisted surgery with a da Vinci Surgical System, potential reductions in complications and length of stay, and the resulting potential for increased patient satisfaction, surgeon recruitment, and procedure volume.

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 current clinical information on robotic surgery practices and new product applications to the hospital teams. Our clinical sales team 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. In the U.S., procedure volumes for procedures associated with benign conditions are typically seasonally higher in the fourth quarter when more patients have met annual deductibles and lower in the first quarter when deductibles are reset. Seasonality outside the U.S. varies and is generally more pronounced around local holidays and vacation periods. 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 system training and ongoing surgical procedural training are provided, the latter led by expert surgeons. Training technologies include our Simulation program which provides for independent da Vinci skills development through interactive VR exercises, and our telementoring program which provides real-time surgeon-to-surgeon learning and collaboration during robotic-assisted surgery.

Research and Development

We focus our research and development efforts on innovation and improvement for products and services that align with our mission: We believe that minimally invasive care is life-enhancing care. Through ingenuity and intelligent technology, we believe we can expand the potential of physicians to heal without constraints. We employ engineering, research and development staff to focus on delivering future innovations and sustaining improvements that advance our mission.

We establish strategic alliances with other medical and technology 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., Bolder Surgical Holdings, Inc. (formerly JustRight Surgical, LLC), Erbe Elektromedizin GmbH, InTouch Technology Inc., Johnson & Johnson, Mimic Technologies, Inc., Novadaq Technologies, Inc., Olympus Corporation, Schoelly Fiberoptic GmbH, and Trumpf Medical (a division of Hill-Rom Holdings, Inc.).

Manufacturing

We manufacture our da Vinci Surgical Systems at our facilities in Sunnyvale, California and Durham, North Carolina. 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 relative to our anticipated demand.

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 robotic-assisted surgery using da Vinci Surgical Systems 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. da Vinci Stapling and da Vinci Vessel Sealer Extend) 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, but not limited to: Auris Health, Inc.; Avatera Medical GmbH; CMR Surgical Limited; Johnson & Johnson and Google Inc. and their joint venture, Verb Surgical Inc.; Medcaroid Inc.; MedRobotics Corp.; Medtronic PLC; meerecompany Inc.; Olympus Corp.; Samsung Corporation; Smart Robot Technology Group Co. Ltd.; Titan Medical Inc.; TransEnterix Inc.; and Wego Holding Co., Ltd. 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, trademark, 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 robust patent portfolio.

As of December 31, 2018, we held ownership or exclusive field-of-use licenses for more than 3,000 U.S. and foreign patents and more than 2,000 U.S. and foreign patent applications. We intend to continue filing new patent applications in the U.S. and foreign jurisdictions to seek protection for our technology.

Patents are granted for finite terms. 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 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 data, typically 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 make 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 FFDCAs 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 investigator 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.

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, and approval for our da Vinci X Surgical Systems in April 2018. National reimbursement status was received in Japan for dVP procedures, effective April 2012 and for da Vinci partial nephrectomy procedures in April 2016. An additional 12 da Vinci procedures were granted reimbursement effective April 1, 2018, including gastrectomy, anterior resection, lobectomy and hysterectomy, for both malignant and benign conditions. These additional 12 reimbursed procedures have varying levels of conventional laparoscopic penetration and will be reimbursed at rates equal to the conventional laparoscopic procedures. Given the reimbursement level and laparoscopic penetration for these procedures, there can be no assurance that adoption will occur or, that the adoption pace for these procedures will be similar to any other da Vinci procedure. If these procedures are not adopted and we are not successful in obtaining adequate procedure reimbursements for additional procedures, then the demand for our products in Japan could be limited. 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).

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 May 2017, the Medical Device Regulation was implemented 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, provincial approvals, and hospitals completing a tender process under the authorization. In October 2018, the China National Health Commission published on its official website the quota for major medical equipment to be imported and sold in China through 2020. The government will allow the sale of 154 new surgical robots into China, which could include da Vinci Surgical Systems as well as surgical systems introduced by others. Da Vinci Surgical systems sales under the quota are uncertain. 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. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals may share in amounts paid by the entity to the government in fines or settlement;
- 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), certain other healthcare professionals, 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 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 laws governing the privacy and security of health information in certain circumstances, including the E.U. General Data Protection Regulation (“GDPR”), 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, ICD-10-PCS codes. For Medicare, CMS generally reimburses hospitals for services provided during an inpatient stay based on a prospective payment system that is determined by a classification system known as Medicare-Severity Diagnostic Related Groupings ("MS-DRGs"). MS-DRGs are assigned using a number of factors including the principal diagnosis, major procedures, discharged status, patient age, and complicating secondary diagnoses among other things. Hospital outpatient services, reported by CPT codes, are assigned to clinically relevant Ambulatory Payment Classifications ("APCs") used to determine the payment amount for services provided.

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. The Consolidated Appropriations Act, 2016 (the "Appropriations Act"), enacted in December 2015, included a two-year moratorium on Medical Device Excise Tax ("MDET") such that medical device sales in 2016 and 2017 were exempt from the MDET. Subsequent 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 2027 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 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 (“2017 Tax 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. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the 2017 Tax Act, the remaining provisions of the ACA are invalid as well. While the current White House Administration and CMS have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the ACA will impact the ACA and our business. 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, 2018, we had 5,527 employees, 771 of whom were engaged directly in research and development, 2,341 in manufacturing and service, and 2,415 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, 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.intuitive.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 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, 2018, 2017, and 2016 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.intuitive.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 robotic-assisted 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 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.

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 ROBOTIC-ASSISTED SURGERY, WHICH WOULD RESULT IN REDUCED REVENUE AND LOSS OF MARKET SHARE.

Robotic-assisted surgery with a da Vinci Surgical System 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 robotic-assisted 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. Companies have introduced products in the field of robotic surgery or have made explicit statements about their efforts to enter the field including, but not limited to: Auris Health, Inc.; Avatera Medical GmbH; CMR Surgical Limited; Johnson & Johnson and Google Inc. and their joint venture, Verb Surgical Inc.; Medcaroid Inc.; MedRobotics Corp.; Medtronic PLC; meerecompany Inc.; Olympus Corp.; Samsung Corporation; Smart Robot Technology Group

Co. Ltd.; Titan Medical Inc.; TransEnterix Inc.; and Wego Holding Co., Ltd. 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 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 or leased;
- changes in the portion of sales involving a trade-in of another system and the amount of trade-in credits given;
- introduction of new products, which may have lower margins than our existing products;
- our ability to maintain or reduce production costs;
- changes to our pricing strategy;
- changes in competition;
- changes in production volume driven by demand for our products;
- changes in material, labor, or other manufacturing-related costs, including the impact of foreign exchange rate fluctuations for foreign-currency denominated costs;
- changes to U.S. and foreign trade policies, such as 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 users with increasing purchasing power and are increasingly evaluating their robotic-assisted surgery programs to optimize the efficiency of surgeries using the da Vinci system. 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, sacrocolpexies, 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 29%, 27%, and 28% of our revenue for the years ended December 31, 2018, 2017, and 2016, 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;
- anti-corruption laws, such as the U.S. Foreign Corrupt Practices Act, and other local laws prohibiting corrupt payments to governmental officials;
- antitrust and anti-competition laws;
- 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 commencement of the official withdrawal process by the UK has created uncertainties affecting business operations in the UK and the EU. Until the terms of the UK’s exit from the EU on March 29, 2019 are determined, including any transition period, it is difficult to predict its impact. It is possible that the withdrawal could, among other things, affect the legal and regulatory environments to which our business is subject, impose greater restrictions on imports and exports between the UK and the EU and other parties, and create economic and political uncertainty in the region.

In addition, the U.S. federal government has made 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. On November 30, 2018, the leaders of the U.S., Mexico and Canada signed a replacement to NAFTA, which remains subject to the ratification by the legislatures of each country. 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. In addition, the U.S. federal government has implemented, or is considering the imposition of, tariffs on certain foreign goods. Such tariffs, and, if enacted, any further legislation or actions taken by the U.S. federal government that restrict trade, such as additional 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. Tariffs could increase the cost of our products and the components and raw materials that go into making them. These increased costs could adversely impact the gross margin that we earn on our products. Tariffs could make our products more expensive for customers, which could make our products less competitive and reduce consumer demand. Countries may also adopt other protectionist measures that could limit our ability to offer our products and services.

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 OFFER ALTERNATIVE CAPITAL ACQUISITION APPROACHES. AS A RESULT, WE ARE EXPOSED TO THE CREDIT RISK OF SOME OF OUR CUSTOMERS AND THE RISK OF LOSSES OF REVENUE, 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.

Certain of our leasing arrangements allow customers to cancel, return, or upgrade the systems leased prior to the end of the lease term without incurring a financial penalty. We also lease our systems to certain qualified customers where the lease payments are based on their usage of the systems. While leases and usage-based arrangements enable our customers to upgrade and get access to new technologies faster, it may also enable competitors to more easily induce customers to switch to a competitor system. If customers do not perform a sufficient number of procedures on systems leased under usage-based arrangements, or return or terminate leases prematurely, it could have a material adverse effect on our business, financial condition, result of operations, or cash flows.

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 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, product liability litigation, and patent 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 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 reports questioning patient safety and efficacy associated with robotic-assisted surgery with the da Vinci Surgical System and its cost 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.

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.

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 the Joint Venture. In January 2019, the Joint Venture acquired certain assets related to the da Vinci distribution business of Chindex, a subsidiary of Fosun Pharma, which has been our distribution partner for da Vinci Surgical Systems in China since 2011, following which the Joint Venture began direct distribution operations for da Vinci products and services in China. There can be no assurance that we and the Joint Venture can successfully complete the development of the robotic-assisted catheter-based medical devices; or that we and the Joint Venture will successfully commercialize such products. There can also be no assurance that the Joint Venture will not require additional contributions to fund its business; that the Joint Venture will become profitable; or that the acquired Chindex assets will be successfully integrated and the expected benefits realized. 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.

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

A change in accounting standards can have a significant effect on our reported results and may retroactively affect previously reported results. 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 that 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.

We are unable to predict what changes to the tax laws of the U.S. and other jurisdictions may be proposed or enacted in the future or what effect such changes would have on our business. Any significant increase in our future effective tax rate could have a material adverse impact 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 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.

OUR BUSINESS IS SUBJECT TO COMPLEX AND EVOLVING LAWS AND REGULATIONS REGARDING PRIVACY, DATA PROTECTION AND OTHER MATTERS RELATING TO INFORMATION COLLECTION.

There are numerous state, federal and foreign laws, regulations, decisions, and directives regarding privacy and the collection, storage, transmission, use, processing, disclosure and protection of personally identifiable information (“PII”) and other personal, customer, or other data, the scope of which is continually evolving and subject to differing interpretations. We may be subject to significant consequences, including penalties and fines, for any failure to comply with such laws, regulations and directives.

For example, as of May 25, 2018, a new privacy framework, the General Data Protection Regulation, or the GDPR, took effect across the European Economic Area, or the EEA. The GDPR imposes several stringent requirements for controllers and processors of personal data and will increase our obligations, including, for example, by imposing higher standards when obtaining consent from individuals to process their personal data, requiring more robust disclosures to individuals, strengthening individual data rights, shortening timelines for data breach notifications, limiting retention periods and secondary use of information, increasing requirements pertaining to health data as well as pseudonymised (i.e., key-coded) data and imposing additional obligations when we contract third-party processors in connection with the processing of personal data. The GDPR provides that EU member states may make their own further laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs could increase, and harm our business and financial condition. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. Compliance with the new data protection rules imposed by GDPR may be onerous and adversely affect our business, financial condition, results of operations and prospects.

In addition, recent legal developments in Switzerland and Europe have created complexity and compliance uncertainty regarding certain transfers of information from Switzerland and the EU to the United States. For example, the EU-US Privacy Shield Framework is regularly reviewed and there is currently litigation challenging the adequacy of EU-specified standard contractual clauses (another data transfer mechanism). It is uncertain whether the Privacy Shield Framework and/or the standard contractual clauses will be invalidated by the European courts or legislature. We rely on a mixture of mechanisms to transfer personal data from our EU business to the United States, and could be impacted by changes in law as a result of a future review of these transfer mechanisms by European regulators under the GDPR, as well as current challenges to these mechanisms in the European courts. If one or more of the legal bases for transferring PII from Europe to the United States is invalidated, or if we are unable to transfer PII between and among countries and regions in which we operate, it could affect the manner in which we provide our services or could adversely affect our financial results.

Furthermore, any failure, or perceived failure, by us to comply with or make effective modifications to our policies, or to comply with any federal, state or international privacy, data-retention or data-protection-related laws, regulations, orders or industry self-regulatory principles could result in proceedings or actions against us by governmental entities or others, a loss of customer confidence, damage to our brand and reputation and a loss of customers, any of which could have an adverse effect on our business. In addition, various federal, state and foreign legislative or regulatory bodies may enact new or additional laws and regulations concerning privacy, data-retention and data-protection issues, including laws or regulations mandating disclosure to domestic or international law enforcement bodies, which could adversely impact our business or our reputation with customers. For example, some countries have adopted laws mandating that some PII regarding customers in their country be maintained solely in their country. Having to maintain local data centers and redesign product, service and business operations to limit PII processing to within individual countries could increase our operating costs significantly.

A PROLONGED GOVERNMENT SHUTDOWN MAY ADVERSELY AFFECT OUR BUSINESS.

Hospital, health systems, and physicians depend on a number of government agencies and services to effectively deliver healthcare to their patients. A prolonged government shutdown could impact inspections, regulatory review and certifications, grants, approvals, or cause other situations that could impede their ability to effectively deliver healthcare, including attempts to reduce payments and other reimbursements to hospitals by federal healthcare programs. These situations could adversely affect our customers’ ability to perform procedures with our devices and/or their decisions to purchase additional products from us. In addition, a prolonged government shutdown may cause significant regulatory delays, and therefore, delay our efforts to seek clearances from the FDA, and adversely affect business travel and import and export of products, all of which could have a material adverse effect 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. Subsequent 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.

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 2027 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 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. 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. The federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, 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 healthcare programs that are false or fraudulent. 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.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

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 fines and penalties, which can be substantial and include monetary damages and penalties, imprisonment, and 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 federal Physicians Payments Sunshine Act imposes reporting and disclosure requirements on device manufacturers for any “transfer of value” made or distributed to physicians (including family members), certain other healthcare providers and teaching hospitals. 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 operations are subject to certain antitrust and competition laws in the jurisdictions in which we conduct our business, in particular the U.S. and the EU. These laws prohibit, among other things, anticompetitive agreements and practices. If any of our commercial agreements or practices are found to violate or infringe such laws, we may be subject to civil and other penalties. We may also be subject to third-party claims for damages. Further, agreements that infringe these antitrust and competition laws may be void and unenforceable, in whole or in part, or require modification in order to be lawful and enforceable. If we are unable to enforce our commercial agreements, whether at all or in material part, our results of operations, financial position, and cash flows could be adversely affected.

We are also subject to claims, suits, and government investigations involving labor and employment. Such claims, suits, and government investigations are inherently uncertain. Regardless of the outcome, any of these types of legal proceedings can have an adverse impact on us because of legal costs, diversion of management resources, and other factors.

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. 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;
- 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 FFDCAs 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 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 May 2017, the Medical Device Regulation was implemented 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, Xi, and X 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. In April 2012 and April 2016, we have received reimbursement approval for prostatectomy and partial nephrectomy, respectively. An additional 12 procedures were granted reimbursement for Japan in April 2018, including gastrectomy, anterior resection, lobectomy and hysterectomy, for both malignant and benign conditions. These additional 12 reimbursed procedures have varying levels of conventional laparoscopic penetration and will be reimbursed at rates equal to the conventional laparoscopic procedures. Given the reimbursement level and laparoscopic penetration for these procedures, there can be no assurance that adoption will occur or, that the adoption pace for these procedures will be similar to any other da Vinci procedure. 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 purchasing tender processes. In October 2018, the China National Health Commission published on its official website the quota for major medical equipment to be imported and sold in China through 2020. The government will allow the sale of 154 new surgical robots into China, which could include da Vinci Surgical Systems. Future system sales and our ability to grow future procedure volumes are dependent on the completion of these purchasing tender authorizations. 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.

We started participating in the Medical Device Single Audit Program ("MDSAP"), which allows an MDSAP-recognized auditing organization to conduct a single regulatory audit of a medical device manufacturer that evaluates the Company's quality system to confirm compliance with the requirements of multiple regulatory jurisdictions including the US, Japan, Brazil, Australia, and Canada. The information will be shared and reviewed amongst all the regulatory authorities in the MDSAP who may or may not determine that additional information or auditing is required.

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

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

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

Our global customers are subject to periodic inspection by regulatory authorities. Our customers are required to comply with applicable local and international regulations, including with respect to the reprocessing of da Vinci instruments and accessories. Hospitals may not follow cleaning and sterilization instructions properly, 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

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, WHICH MAY NOT BE AVAILABLE TO US ON COMMERCIALY REASONABLE TERMS OR AT ALL. 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. There is no assurance that we can obtain licenses on acceptable terms or at all. The license agreements we have entered into with several industry partners 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 failure to obtain or maintain the 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 2016, it reached a high of \$241.61 and a low of \$169.09; during fiscal 2017, it reached a high of \$403.70 and a low of \$209.83; and during fiscal 2018, it reached a high of \$574.74 and a low of \$375.25. 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 or recommendations by analysts;

- changes in accounting policies;
- economic changes and overall market volatility;
- litigation;
- media coverage, whether accurate or inaccurate, fair or misleading;
- political uncertainties;
- short sales on shares of our common stock, or other activities by short sellers; and
- our stock repurchase program.

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, 2018, we own approximately 930,000 square feet of space on 84 acres of land in Sunnyvale, California, where we house our principal headquarters, research and development, service and support functions, and certain of our manufacturing operations.

Outside of Sunnyvale, California, we own facilities in other U.S. locations that are used for sales and training as well as manufacturing. We also lease approximately 435,000 square feet of engineering and warehousing space at various locations in the U.S. Outside of the U.S., we own properties in Mexicali, Mexico, primarily for manufacturing operations, and Aubonne, Switzerland, primarily for our international headquarters. In China, our Joint Venture leases facilities for research and development, manufacturing, and sales operations. In addition, we lease various international facilities for sales and other operations.

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.

PART II

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

COMMON STOCK

Our common stock is being traded on The Nasdaq Global Select Market under the symbol "ISRG."

As of January 18, 2019, there were 178 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, 2018, 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	5,398,420	\$ 203.84	5,670,804
Equity compensation plans not approved by security holders	765,282	\$ 179.28	102,228
Total	<u>6,163,702</u>	<u>\$ 200.79</u>	<u>5,773,032</u>

RECENT SALES OF UNREGISTERED SECURITIES

None.

ISSUER PURCHASES OF EQUITY SECURITIES

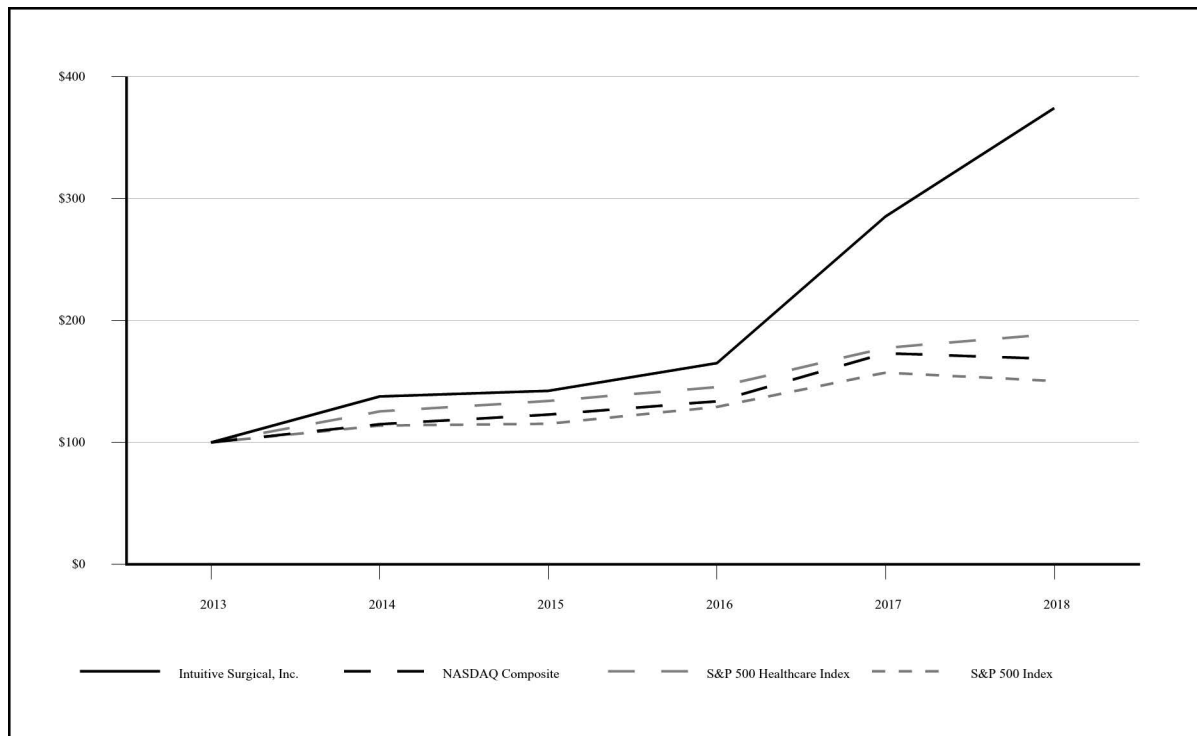
Since March 2009, we have had an active stock repurchase program. As of December 31, 2018, our Board of Directors (the "Board") had authorized an aggregate amount of up to \$6.2 billion for stock repurchases, of which the previous authorization occurred in December 2016 when the Board increased the authorized amount available under our share repurchase program to \$3.0 billion. The remaining amount available to repurchase shares under the authorized repurchase program was \$717.5 million as of December 31, 2018. The authorized stock repurchase program does not have an expiration date. During the year ended December 31, 2018, we did not repurchase any of our stock.

STOCK PERFORMANCE GRAPH

The graph set forth below compares the cumulative total stockholder return on our common stock between December 31, 2013, and December 31, 2018, 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, 2013 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, NASDAQ
COMPOSITE, S&P HEALTH CARE INDEX, AND S&P 500 INDEX**



	December 31,					
	2013	2014	2015	2016	2017	2018
Intuitive Surgical, Inc.	\$ 100.00	\$ 137.72	\$ 142.20	\$ 165.11	\$ 285.05	\$ 374.08
Nasdaq Composite	\$ 100.00	\$ 114.75	\$ 122.74	\$ 133.62	\$ 173.22	\$ 168.30
S&P 500 Healthcare Index	\$ 100.00	\$ 125.34	\$ 133.97	\$ 145.37	\$ 177.47	\$ 188.94
S&P 500 Index	\$ 100.00	\$ 113.69	\$ 115.26	\$ 129.05	\$ 157.22	\$ 150.33

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)				
	2018	2017 (2)	2016	2015	2014
	(In millions, except per share amounts and headcount)				
Revenue	\$ 3,724.2	\$ 3,138.2	\$ 2,706.5	\$ 2,384.4	\$ 2,131.7
Gross profit	\$ 2,604.1	\$ 2,202.0	\$ 1,892.9	\$ 1,577.9	\$ 1,413.8
Net income attributable to Intuitive Surgical, Inc.	\$ 1,127.9	\$ 670.9	\$ 738.3	\$ 588.8	\$ 418.8
Net income per share attributable to Intuitive Surgical, Inc.:					
Basic	\$ 9.92	\$ 6.01	\$ 6.43	\$ 5.29	\$ 3.78
Diluted	\$ 9.49	\$ 5.77	\$ 6.26	\$ 5.18	\$ 3.70
Shares used in computing basic and diluted net income per share:					
Basic	113.7	111.7	114.9	111.3	110.7
Diluted	118.8	116.3	117.9	113.7	113.1
Cash, cash equivalents, and investments	\$ 4,834.4	\$ 3,846.5	\$ 4,837.9	\$ 3,347.8	\$ 2,497.0
Total assets	\$ 7,846.7	\$ 5,776.8	\$ 6,521.4	\$ 4,907.3	\$ 3,959.4
Other long-term liabilities	\$ 338.6	\$ 333.6	\$ 112.1	\$ 95.9	\$ 78.8
Stockholders’ equity	\$ 6,687.5	\$ 4,780.4	\$ 5,820.1	\$ 4,319.5	\$ 3,379.4
Total headcount	5,527	4,444	3,755	3,211	2,978

(1) Fiscal years 2015 and 2014 do not reflect the impact of the adoption of the new revenue accounting standard in fiscal year 2018.

(2) Reflects amounts recorded for the enactment of the 2017 Tax Act.

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 minimally invasive surgery (“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 traditional open surgery or conventional MIS. Surgeons using a da Vinci Surgical System operate while seated comfortably at a console viewing a 3D high definition image of the surgical field. This immersive console 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 open surgical technique. Our technology is designed to provide surgeons with a range of articulation of the surgical instruments used 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 five broad categories: da Vinci Surgical Systems, da Vinci instruments, da Vinci Stapling, da Vinci Energy, and da Vinci Vision, including Firefly Fluorescence imaging systems (“Firefly”), and da Vinci Endoscopes. We also provide a comprehensive suite of services, training, and education programs. Within our integrated ecosystem, our products are designed to decrease variability in surgery by offering dependable, consistent functionality and user experiences for surgeons seeking better outcomes. We take a holistic ‘systems’ approach to offer intelligent technology and systems designed to work together to make MIS intervention more available and applicable.

We have commercialized the following da Vinci Surgical Systems: the da Vinci standard Surgical System in 1999, the da Vinci S Surgical System in 2006, the da Vinci Si Surgical System in 2009, and the fourth generation da Vinci Xi Surgical System, commercialized in 2014. We have extended our fourth generation platform, by adding the da Vinci X Surgical System, commercialized in the second quarter of 2017 and the da Vinci SP Surgical System in the third quarter of 2018. We are early in the launch of our da Vinci SP Surgical System and placed 15 da Vinci SP systems in 2018. Our rollout of the da Vinci SP Surgical System will be measured, putting systems in the hands of experienced da Vinci users first while we optimize training pathways and our supply chain. We received clearances for the da Vinci SP Surgical System for urological surgical procedures in the U.S. and South Korea as well as some other procedure types in South Korea. We plan to seek U.S. FDA clearances for additional indications for da Vinci SP over time. The success of the da Vinci SP product is dependent on positive experiences and improved clinical outcomes for the procedures it has been cleared for and as well as securing additional clinical clearances. All da Vinci 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 to provide surgeons’ flexibility in choosing the types of tools needed to perform a particular surgery. These multi-port instruments are generally robotically controlled and provide end effectors (tips) that are similar to those used 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 da Vinci Vessel Sealer Extend and da Vinci 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 use instruments that are compatible with both X and Xi systems whereas the da Vinci Si Surgical System uses instruments that are not compatible with X or Xi systems. Initially we are offering nine core instruments on our da Vinci SP Surgical System. We plan to expand the SP instrument offering over time.

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 are designed to enable surgeons to perform surgery through a single port via the patient’s umbilicus, resulting in the potential for significantly reduced scarring.

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 placements of da Vinci Surgical Systems in sale or sales-type lease arrangements where revenue is recognized up-front or in operating lease transactions where revenue is recognized over time. We earn recurring revenue from sales of instruments, accessories, and service, as well as the revenue from operating leases. 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 when purchased. 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 earn between approximately \$700 to \$3,500 of instrument and accessory revenue per surgical procedure performed, depending on the type and complexity of the specific procedures performed and the number and type of instruments used. We typically enter into service contracts at the time systems are sold at an annual fee of approximately \$80,000 to \$190,000, 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.

We adopted ASC 606, *Revenue from Contracts with Customers*, effective January 1, 2018, using the full retrospective method. The financial results for 2016 and 2017 have been restated to reflect this adoption. The adoption did not have a material impact on revenue recognized for the periods presented in our Financial Statements. Refer to “Note 2. Summary of Significant Accounting Policies” within Part II, Item 8 of this Form 10-K for further information on the impact of adopting ASC 606.

Recurring Revenue

Recurring revenue consists of instrument and accessory revenue, service revenue, and operating lease revenue. Recurring revenue increased to \$2.6 billion, or 71% of total revenue in 2018, compared with \$2.2 billion, or 71% of total revenue in 2017, and \$1.9 billion, or 71% of total revenue in 2016.

Instrument and accessory revenue has grown at a faster rate than system revenue over time. Instrument and accessory revenue increased to \$2.0 billion in 2018, compared with \$1.6 billion in 2017 and \$1.4 billion in 2016. The growth of instrument and accessory revenue largely reflects continued procedure adoption.

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 4,986 at December 31, 2018; 13% to approximately 4,409 at December 31, 2017; and 9% to approximately 3,919 at December 31, 2016. Service revenue grew 11% to \$635.1 million in 2018; 12% to \$572.9 million in 2017; and 10% to \$510.7 million in 2016.

Operating lease revenue has grown as a larger proportion of systems shipped are under operating lease arrangements. In the years ended December 31, 2018, 2017, and 2016, a total of 229, 108, and 62 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 or based upon system usage. Operating lease revenue for the years ended December 31, 2018, 2017, and 2016, was \$51.4 million, \$25.9 million and \$16.6 million, respectively. As of December 31, 2018, a total of 350 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 robotic-assisted surgery availability while leveraging our balance sheet. These 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 price (“ASP”) computations.

In the years ended December 31, 2018, 2017, and 2016, we shipped 272, 139, and 95 systems under lease arrangements, respectively, of which 229, 108, and 62 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 \$48.8 million, \$39.5 million, and \$38.2 million for the years ended December 31, 2018, 2017, and 2016, 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 alternative structures such as usage-based payment models. Our da Vinci system leasing provides customers with flexibility regarding how they acquire da Vinci Surgical Systems. Generally, lease transactions generate similar gross margins as our sale transactions. 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. Also, usage-based leases generally contain no minimum lease payments; therefore, customers may exit such leases without paying a financial penalty to us.

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 largely aligned with hospital budgeting cycles. We typically place a higher proportion of annual system placements in the fourth quarter and a lower proportion in the first quarter as budgets are reset. System revenue grew 21% to \$1,127.1 million in 2018; 16% to \$928.4 million

in 2017; and 11% to \$800.0 million in 2016. 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 da Vinci Surgical Systems are generally used for soft tissue surgery for areas of the body between the pelvis and the neck, primarily in general surgery, gynecologic surgery, urologic surgery, cardiothoracic surgery, and head and neck surgery. Within these categories, procedures range in complexity from cancer and other highly complex procedures to 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 across the spectrum of procedure complexity. Our fully featured da Vinci Xi Surgical System with advanced instruments, including the EndoWrist Vessel Sealer, EndoWrist Stapler products, and our Integrated Table Motion product target the more complex procedure segment. Our da Vinci X Surgical System and Single-Site instruments are targeted towards price sensitive markets and procedures.

Procedure Seasonality

More than half of da Vinci procedures performed are for benign conditions, most notably benign hysterectomies, hernia repairs, and cholecystectomies. These benign procedures 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., Europe (excluding Spain, Portugal, Italy, Greece, most Eastern European countries), Japan, South Korea, India, and Taiwan. In May and December 2018, we began direct operations in India and Taiwan, respectively. In the remainder of our OUS markets, we provide our products through distributors. Chindex, a subsidiary of Fosun Pharma, has been our distribution partner for da Vinci Surgical Systems in China. In January 2019, the Joint Venture acquired certain assets related to the distribution business of Chindex and began direct operations for da Vinci products and services in China.

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 December 2018, we received clearance for our da Vinci Xi Surgical System in China. The Xi clearance does not include advanced energy, stapling, or wireless table motion products which attach to the Xi system. Separate clearances are required for each of these products by China National Medical Products Administration (“NMPA”).

In May 2018, we obtained U.S. FDA clearance for the da Vinci SP Surgical System for urologic surgical procedures that are appropriate for a single port approach. We also received regulatory clearance for the da Vinci SP Surgical System in South Korea in May 2018. We plan to launch the da Vinci SP Surgical System in a measured fashion and placed 15 da Vinci SP systems with customers in 2018.

In October 2018, the China National Health Commission published on its official website the quota for major medical equipment to be imported and sold in China through 2020. The government will allow the sale of 154 new surgical robots into China, which could include da Vinci Surgical Systems as well as surgical systems introduced by others. Sales of da Vinci Surgical Systems under the quota are uncertain, as they are dependent on hospitals completing a tender process and receiving associated approvals.

In July 2018, we received U.S. FDA clearance to market SureForm 60, our da Vinci EndoWrist 60mm Stapler. In January 2019, we received U.S. FDA clearance to market SureForm 45 (see the description of the SureForm 45 and 60 Staplers in the New Product Introductions section below).

In April 2018, we received U.S. FDA clearance for our Vessel Sealer Extend (see the description of the da Vinci Vessel Sealer Extend in the New Product Introductions section below).

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. 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 and Japan in September 2017 and April 2018, respectively (see the description

of the da Vinci X Surgical System in the New Product Introductions section below). Regulatory clearances for the da Vinci X Surgical System may be received in other markets over time.

The Japanese Ministry of Health, Labor, and Welfare (“MHLW”) considers reimbursement for procedures in April of even numbered years. The process for obtaining reimbursement requires Japanese university hospitals and surgical societies, with our support, to seek reimbursement. There are multiple pathways to obtain reimbursement for procedures including those that require in-country clinical data/economic data. In April 2012 and April 2016, the MHLW granted reimbursement status for da Vinci Prostatectomy (“dVP”) and partial nephrectomy, respectively. An additional 12 da Vinci procedures were granted reimbursement effective April 1, 2018, including gastrectomy, low anterior resection, lobectomy and hysterectomy, for both malignant and benign conditions. These additional 12 reimbursed procedures have varying levels of conventional, laparoscopic penetration and will be reimbursed at rates equal to the conventional laparoscopic procedures. Given the reimbursement level and laparoscopic penetration for these procedures, there can be no assurance that adoption will occur or, that the adoption pace for these procedures will be similar to any other da Vinci procedure. If these procedures are not adopted and we are not successful in obtaining adequate procedure reimbursements for additional procedures, then the demand for our products in Japan could be limited.

In the third quarter of 2018, we filed for U.S. FDA clearance of our Ion endoluminal system for obtaining lung biopsies (see the description of the Ion endoluminal system in the New Product Introductions section below). There can be no assurance that we will receive U.S. FDA clearance for this product.

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.

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 robotic-assisted surgery with the da Vinci Surgical System. Adoption of da Vinci procedures 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 with alternative treatment options for the same disease state or condition.

Worldwide Procedures

Our 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 robotic-assisted surgery using the da Vinci Surgical System has the potential to grow for those procedures that offer greater patient value than non-da Vinci alternatives and competitive total economics for healthcare providers. Our da Vinci Surgical Systems are used primarily in general surgery, gynecologic surgery, urologic surgery, cardiothoracic surgery, and head and neck surgery. We focus our organization and investments on developing, marketing, and training products and services for procedures in which da Vinci can bring patient value relative to alternative treatment options and/or economic benefit to healthcare providers. Target procedures in general surgery include hernia repair (both ventral and inguinal) and colorectal procedures. Target procedures in gynecology include da Vinci hysterectomy (“dVH”), for both cancer and benign conditions, and sacrocolpopexy. Target procedures in urology include prostatectomy (“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. Surgeons and their patients need to consult the product labeling in their specific country and for each product in order to determine the cleared uses, as well as important limitations, restrictions, or contraindications.

In 2018, approximately 1,037,000 surgical procedures were performed with the da Vinci Surgical Systems, compared with approximately 877,000 and 753,000 procedures performed in 2017 and 2016, respectively. The growth in our overall procedure volume in 2018 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 753,000 in 2018, compared with approximately 644,000 in 2017, and approximately 563,000 in 2016. General surgery was our largest and fastest growing U.S. specialty in 2018 with procedure volume that grew to approximately 325,000 in 2018, compared with approximately 246,000 in 2017 and 186,000 in 2016. Gynecology was our second largest U.S. surgical specialty in 2018 with procedure volume of approximately 265,000 in 2018, compared with 252,000 in 2017 and 246,000 in 2016. U.S. urology procedure volume was approximately 128,000 in 2018, compared with approximately 118,000 in 2017 and 109,000 in 2016.

Procedures Outside of the U.S.

Overall OUS procedures grew to approximately 284,000 in 2018, compared with approximately 233,000 in 2017 and approximately 190,000 in 2016. Procedure growth in most OUS markets was driven largely by urology procedure volume, which grew to approximately 175,000 in 2018, compared with approximately 149,000 in 2017 and approximately 124,000 in 2016. 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, 2018, total da Vinci procedures grew approximately 18% compared with 16% for the year ended December 31, 2017. U.S. procedure growth during the year ended December 31, 2018, was approximately 17% compared with approximately 14% for the year ended December 31, 2017. The higher 2018 U.S. procedure growth was largely attributable to growth in general surgery procedures (most notably hernia repair, colorectal, cholecystectomy, and bariatric procedures) and thoracic procedures, as well as moderate growth in more mature gynecologic and urologic procedure categories.

Procedure volume OUS for the year ended December 31, 2018, grew approximately 22% compared with approximately 23% growth for the year ended December 31, 2017, driven by continued growth in dVP procedures and earlier stage growth in general surgery, gynecology, and kidney cancer procedures. 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. The growth rate for 2018 was lower than the growth rate in the previous year primarily due to lower procedure growth in China. Procedure growth in China moderated as da Vinci system capacity expansion was constrained by system quota requirements, as the previous quota expired at the end of 2015 and the most recent quota was not issued until the fourth quarter of 2018 (see discussion of the China quota below under “OUS Procedures”).

U.S. General Surgery. In 2018, general surgery was our largest and fastest growing specialty in the U.S. with procedure volume that grew to approximately 325,000 in 2018, compared with approximately 246,000 in 2017, and 186,000 in 2016. Ventral and inguinal hernia, combined, contributed to the most incremental growth in U.S. general surgery procedures in 2018 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 encompasses 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. This adoption is supported by our recently launched technologies such as the da Vinci Xi Surgical System, EndoWrist Stapler products, EndoWrist Vessel Sealer, and Integrated Table Motion.

During 2018, we have seen increasing contributions to growth from other U.S. general surgery procedures, including cholecystectomy and bariatric procedures. Our third quarter 2018 introduction of the SureForm 60mm stapler product optimizes our robotic tool set for bariatric procedures. We introduced the SureForm 60mm stapler at a measured pace during the second half of 2018 and we intend to broaden availability in 2019.

U.S. Gynecology. In 2018, U.S. gynecology grew mid-single digits compared to 2017. Procedure volume was approximately 265,000 in 2018, compared with 252,000 in 2017 and 246,000 in 2016. Combining robotic, laparoscopic, and vaginal approaches, MIS represents approximately 80% of the U.S. hysterectomy market for benign conditions. We believe that our growth in gynecologic procedures over the past several years has primarily been driven by consolidation of gynecologic procedures into higher volume surgeons that focus on cancer and complex surgeries.

Global Urology. Along with U.S. general surgery, global urology procedures drove our recent procedure growth. In the U.S., dVP is the largest urology procedure. 2018 growth in U.S. dVP procedures moderated slightly compared with 2017. We believe our growth in U.S. dVP procedures is largely aligned with overall prostate cancer surgical volumes as dVP is a highly penetrated procedure. DVP is the largest overall OUS procedure. 2018 growth in OUS dVP was consistent with growth in 2017. Adoption of dVP is at varying stages in our OUS markets.

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 typically conforms to surgical society guideline recommendations.

OUS Procedures. The 2018 OUS procedure growth rate reflects continued da Vinci adoption in European and Asian markets. In China, we have experienced strong procedure utilization on systems sold under the previous public hospital quota. In 2018, procedure growth in China moderated as the previous quota expired at the end of 2015 and the 38 systems shipped under that quota reached high levels of utilization. In October 2018, the China National Health Commission announced a new quota to allow the sale of 154 new surgical robots into China through 2020, which could include da Vinci Surgical Systems. This quota applies to the da Vinci Si and recently approved Xi Surgical Systems (refer to the previous discussion in the “Clearances and Approvals” section), as well as competitors’ products when and if cleared by NMPA. Sales of da Vinci Surgical Systems under the quota are uncertain, as they are dependent on hospitals completing a tender process and receiving associated approvals. In Japan, we have experienced strong procedure growth since receiving national reimbursements for dVP and partial nephrectomy. However, as adoption for these procedures has progressed towards higher levels of penetration, growth in these two urologic procedures has moderated. Reimbursement for dVP and partial nephrectomy were set at a premium to reimbursements for open procedures, which was the dominant treatment modality. A total of 12 additional da Vinci procedures were granted national reimbursements status effective April 1, 2018, including gastrectomy, low anterior resection, lobectomy and hysterectomy, for both malignant and benign conditions. Procedure growth has accelerated in Japan since the new reimbursements became effective. However, these additional 12 procedures have reimbursement rates equal to conventional laparoscopic procedures, which are the dominant surgical approaches. Given the reimbursement level and laparoscopic penetration for these procedures, there can be no assurance that adoption will occur or that the adoption pace for these procedures will be similar to other da Vinci procedures. If these procedures are not adopted and we are not successful in obtaining adequate procedure reimbursement for additional procedures, then the demand for our products in Japan could be limited.

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 da Vinci Xi Surgical System, da Vinci X Surgical System, and da Vinci SP Surgical System, and related instruments, market response as well as other economic and geopolitical factors. Market acceptance of our recently launched da Vinci SP Surgical System and the nature and timing of additional da Vinci SP regulatory indications may also impact future system placements. Demand may also be impacted by robotic surgery competition, including from companies that have introduced products in the field of robotic surgery or have made explicit statements about their efforts to enter the field including, but not limited to: Auris Health, Inc.; Avatera Medical GmbH; CMR Surgical Limited; Johnson & Johnson and Google Inc. and their joint venture, Verb Surgical Inc.; Medcaroid Inc.; MedRobotics Corp.; Medtronic PLC.; meerecompany Inc.; Olympus Corp.; Samsung Corporation; Smart Robot Technology Group Co. Ltd.; Titan Medical, Inc.; TransEnterix, Inc.; and Wego Holding Co., Ltd.

New Product Introductions

Ion endoluminal system. In the third quarter of 2018, we filed for U.S. FDA clearance of our Ion endoluminal system for obtaining lung biopsies. Ion is our new flexible robotic-assisted catheter-based platform, designed to navigate through very small airways to reach peripheral nodes for biopsies. There can be no assurance that we will receive the clearance we are seeking.

Da Vinci SP Surgical System. In May 2018, we obtained U.S. FDA clearance for the da Vinci SP Surgical System for urologic surgical procedures that are appropriate for a single port approach. The da Vinci SP system includes three, multi-jointed, wristed instruments and the first da Vinci fully wristed 3DHD camera. The instruments and the camera all emerge through a single cannula and are triangulated around the target anatomy to avoid external instrument collisions that can occur in narrow surgical workspaces. The system enables flexible port placement and broad internal and external range of motion (e.g. 360-degrees of anatomical access) through the single SP arm. Surgeons control the fully articulating instruments and the camera on the da Vinci SP system, which uses the same fourth generation surgeon console as the da Vinci X and Xi systems. The da Vinci SP system provides surgeons with robotic-assisted technology designed for deep and narrow access to tissue in the body. We anticipate pursuing further regulatory clearances for the da Vinci SP, including transoral and colorectal applications, broadening the applicability of the SP platform over time. We plan to launch the da Vinci SP Surgical System in a measured fashion, having shipped 15 SP Surgical Systems to customers during 2018.

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 fourth generation da Vinci 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. For new customers, the da Vinci X System provides a cost effective capital entry point while providing a pathway for upgrading to other fourth generation systems. Existing customers may negotiate to trade in their older da Vinci systems in order to standardize their robotics programs onto the fourth generation platform, and choosing which system model by considering clinical and economic factors.

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 3D 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.

SureForm 60 and SureForm 45 Staplers. In July 2018, we received U.S. FDA clearance in the U.S. for SureForm 60 instrument with White, Blue, Green, and Black 60mm reloads. In January 2019, we received U.S. FDA clearance in the U.S. for SureForm 45 instrument with White, Blue, Green, and Black 45mm reloads. The SureForm 60 and SureForm 45 are single-use, fully wristed, stapling instruments intended for resection, transection, and/or creation of anastomoses. The SureForm 60 has particular utility in bariatric procedures, while the SureForm 45 has particular utility in colorectal procedures. SureForm 60 and SureForm 45 broaden our existing stapler product line, which also includes EndoWrist Stapler 45 with White, Blue, and Green, 45mm reloads and EndoWrist 30 with White, Blue, Green, and Gray 30mm reloads. Not all reloads or staplers are available for use on all systems or in all countries.

Da Vinci Vessel Sealer Extend. In April 2018, we received U.S. FDA clearance for da Vinci Vessel Sealer Extend, our newest instrument in the Vessel Sealing family of products. Da Vinci Vessel Sealer Extend is a single-use, fully wristed bipolar electro-surgical instrument compatible with our fourth generation multiport systems. It is intended for grasping and blunt dissection of tissue and for bipolar coagulation and mechanical transection of vessels up to 7mm in diameter and tissue bundles that fit in the jaws of the instrument.

Intuitive Surgical-Fosun Joint Venture

In September 2016, we agreed to establish the Joint Venture to research, develop, manufacture, and sell robotic-assisted catheter-based medical devices. The catheter-based technology will initially target 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. Distribution of catheter-based medical devices in China will be conducted by the Joint Venture, while distribution outside of China will be conducted by us. The Joint Venture is located in China. In January 2019, the Joint Venture acquired these distribution rights along with certain other assets related to the distribution business of Chindex, a wholly-owned subsidiary of Fosun Pharma, and began direct operations for da Vinci products and services in China. The Joint Venture is owned 60% by us and 40% by Fosun Pharma. As of December 31, 2018, the companies have contributed \$30 million of up to \$100 million stipulated by the joint venture agreement. In 2018, the net loss attributable to the noncontrolling interest in the joint venture was \$2.9 million.

We do not expect the Joint Venture to generate revenue in 2019 related to the sale of robotic-assisted catheter-based medical devices. There can be no assurance that we and the Joint Venture can successfully complete the development of the robotic-assisted catheter-based medical devices; or that we and the Joint Venture will successfully commercialize such products. There can also be no assurance that the Joint Venture will not require additional contributions to fund its business; that the Joint Venture will become profitable; or that the acquired Chindex assets will be successfully integrated and the expected benefits realized.

2018 Operational and Financial Highlights

- Total revenue increased by 19% to \$3.7 billion for the year ended December 31, 2018, compared with \$3.1 billion for the year ended December 31, 2017.
- Approximately 1,037,000 da Vinci procedures were performed during the year ended December 31, 2018, an increase of approximately 18% compared with approximately 877,000 for the year ended December 31, 2017.
- Instrument and accessory revenue increased by 20% to \$2.0 billion for the year ended December 31, 2018, compared with \$1.6 billion for the year ended December 31, 2017.
- Systems revenue increased by 21% to \$1,127.1 million for the year ended December 31, 2018, compared with \$928.4 million for the year ended December 31, 2017. A total of 926 da Vinci Surgical Systems were shipped for the year ended December 31, 2018, compared with 684 for the year ended December 31, 2017.
- As of December 31, 2018, we had a da Vinci Surgical System installed base of approximately 4,986 systems, an increase of approximately 13% compared with the installed base as of December 31, 2017.
- Gross profit as a percentage of revenue decreased to 69.9% for the year ended December 31, 2018, compared with 70.2% for the year ended December 31, 2017. Lower gross profit in 2018 is primarily attributable to lower service margins.
- Operating income increased by 13% to \$1,199.4 million for the year ended December 31, 2018, compared with \$1,062.9 million for the year ended December 31, 2017. Operating income included \$262.6 million and \$209.9 million of share-based compensation expense related to employee stock plans for the years ended December 31, 2018, and 2017, respectively. Operating income for the years ended December 31, 2018, and 2017, also included pre-tax net litigation charges of \$45.2 million and \$25.3 million, respectively. Operating income for the year ended December 31, 2018, included \$25.2 million of expense related to a contribution made to the Intuitive Foundation.

- As of December 31, 2018, we had \$4.8 billion in cash, cash equivalents, and investments. Cash, cash equivalents, and investments increased by \$987.9 million compared with December 31, 2017, primarily as a result of cash generated from operating activities.
- In August 2018, we filed for U.S. FDA clearance of the Ion endoluminal system, our new flexible robotic-assisted catheter-based platform, designed to navigate through very small lung airways to reach peripheral nodules for biopsies.

Results of Operations

We adopted ASC 606, *Revenue from Contracts with Customers*, effective January 1, 2018, using the full retrospective method. The 2017 and 2016 financial results presented below have been restated to reflect this adoption. Refer to “Note 2. Summary of Significant Accounting Policies” within Part II, Item 8 of this Form 10-K for further information on the impact of adopting ASC 606.

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

	Years Ended December 31,					
	2018	% of total revenue	2017	% of total revenue	2016	% of total revenue
Revenue:						
Product	\$ 3,089.1	83 %	\$ 2,565.3	82%	\$ 2,195.8	81%
Service	635.1	17 %	572.9	18%	510.7	19%
Total revenue	3,724.2	100 %	3,138.2	100%	2,706.5	100%
Cost of revenue:						
Product	906.2	24 %	756.3	24%	662.6	24%
Service	213.9	6 %	179.9	6%	151.0	6%
Total cost of revenue	1,120.1	30 %	936.2	30%	813.6	30%
Product gross profit	2,182.9	59 %	1,809.0	58%	1,533.2	57%
Service gross profit	421.2	11 %	393.0	12%	359.7	13%
Gross profit	2,604.1	70 %	2,202.0	70%	1,892.9	70%
Operating expenses:						
Selling, general and administrative	986.6	27 %	810.5	26%	703.6	26%
Research and development	418.1	11 %	328.6	10%	239.6	9%
Total operating expenses	1,404.7	38 %	1,139.1	36%	943.2	35%
Income from operations	1,199.4	32 %	1,062.9	34%	949.7	35%
Interest and other income, net	80.1	2 %	41.9	1%	35.6	1%
Income before taxes	1,279.5	34 %	1,104.8	35%	985.3	36%
Income tax expense	154.5	4 %	433.9	14%	247.0	9%
Net income	1,125.0	30 %	670.9	21%	738.3	27%
Less: net loss attributable to noncontrolling interest in joint venture	(2.9)	— %	—	—%	—	—%
Net income attributable to Intuitive Surgical, Inc.	\$ 1,127.9	30 %	\$ 670.9	21%	\$ 738.3	27%

Total Revenue

Total revenue increased by 19% to \$3.7 billion for the year ended December 31, 2018, compared with \$3.1 billion for the year ended December 31, 2017. Total revenue for the year ended December 31, 2017, increased by 16% compared with \$2.7 billion for the year ended December 31, 2016. The increase in total revenue for the year ended December 31, 2018, reflects 20% higher instrument and accessory revenue driven by approximately 18% higher procedure volume, 21% higher systems revenue, and 11% higher service revenue. 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, 16% higher systems revenue, and 12% higher service revenue.

Revenue denominated in foreign currencies was approximately 20%, 17%, and 19% of total revenue for the years ended December 31, 2018, 2017, and 2016, respectively. We sell our products and services in local currencies where we have direct distribution channels. Foreign currency rate fluctuations did not have a material impact on total revenue for the year ended December 31, 2018, as compared with 2017, or for the year ended December 31, 2017, as compared with 2016.

Revenue generated in the U.S. accounted for 71%, 73%, and 72% of total revenue during the years ended December 31, 2018, 2017, and 2016, 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 our 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.

The following table summarizes our revenue and da Vinci Surgical System unit shipments for the years ended December 31, 2018, 2017, and 2016, respectively (in millions, except percentages and unit shipments):

	Years Ended December 31,		
	2018	2017	2016
<u>Revenue</u>			
Instruments and accessories	\$ 1,962.0	\$ 1,636.9	\$ 1,395.8
Systems	1,127.1	928.4	800.0
Total product revenue	<u>3,089.1</u>	<u>2,565.3</u>	<u>2,195.8</u>
Services	635.1	572.9	510.7
Total revenue	<u>\$ 3,724.2</u>	<u>\$ 3,138.2</u>	<u>\$ 2,706.5</u>
United States	<u>\$ 2,633.5</u>	<u>\$ 2,285.8</u>	<u>\$ 1,956.4</u>
OUS	1,090.7	852.4	750.1
Total revenue	<u>\$ 3,724.2</u>	<u>\$ 3,138.2</u>	<u>\$ 2,706.5</u>
% of Revenue - U.S.	71%	73%	72%
% of Revenue - OUS	29%	27%	28%

Instruments and accessories	\$ 1,962.0	\$ 1,636.9	\$ 1,395.8
Services	635.1	572.9	510.7
Operating lease	51.4	25.9	16.6
Total recurring revenue	<u>\$ 2,648.5</u>	<u>\$ 2,235.7</u>	<u>\$ 1,923.1</u>
% of Total revenue	71%	71%	71%

Unit Shipments by Region:

U.S. unit shipments	581	417	338
OUS unit shipments	345	267	199
Total unit shipments*	<u>926</u>	<u>684</u>	<u>537</u>
*Systems shipped under operating leases (included in total unit shipments)	229	108	62

Unit Shipments involving System Trade-ins:

Unit shipments involving trade-ins	277	163	156
Unit shipments not involving trade-ins	649	521	381

Product Revenue

2017-2018

Product revenue increased by 20% to \$3.1 billion for the year ended December 31, 2018, compared with \$2.6 billion for the year ended December 31, 2017.

Instrument and accessory revenue increased by 20% to \$2.0 billion for the year ended December 31, 2018, compared with \$1.6 billion for the year ended December 31, 2017. The increase in instrument and accessory revenue was driven by procedure growth of approximately 18% and higher sales of our advanced instruments, partially offset by procedure mix. U.S. procedure growth in 2018 was approximately 17% compared with 14% in 2017 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 in 2018 was approximately 22% compared with 23% in 2017. Key drivers for OUS procedure growth in both years reflected growth in dVP procedures and earlier stage growth in kidney cancer procedures, general surgery, and gynecology. Geographically, OUS procedure growth has been driven by procedure expansion in Japan, China, and South Korea. Procedure growth varied by country in our European market.

Systems revenue increased by 21% to \$1,127.1 million for the year ended December 31, 2018, compared with \$928.4 million for the year ended December 31, 2017. Higher systems revenue was primarily driven by higher system shipments, partly offset by a higher number of system placements under operating lease arrangements.

During 2018, a total of 926 systems were shipped compared with 684 systems in 2017. By geography, 581 systems were shipped into the U.S., 169 into Europe, 116 into Asia, and 60 into other markets, compared with 417 systems shipped into the U.S., 122 into Europe, 108 into Asia, and 37 into other markets in 2017. During 2018, 229 of the 926 systems were shipped under operating lease arrangements compared with 108 of 684 systems shipped during 2017. The increase in system shipments was primarily driven by procedure growth and the need for hospitals to expand or establish capacity. Higher 2018 capital replacement shipments also contributed to overall 2018 system growth as 277 of 926 systems placed in 2018 involved trade-ins of older models, compared to 163 of 684 systems in 2017.

Operating lease revenue was \$51.4 million for the year ended December 31, 2018, compared with \$25.9 million for the year ended December 31, 2017. Revenue from Lease Buyouts was \$48.8 million for year ended December 31, 2018, compared with \$39.5 million for the year ended December 31, 2017.

The ASP for da Vinci Surgical Systems sold, which excludes operating lease and lease buyout revenue, was approximately \$1.45 million and \$1.47 million for 2018 and 2017, respectively. ASPs fluctuate period to period based on geographic and product mix, product pricing, systems shipped involving trade-ins, and changes in foreign exchange rates.

2016-2017

Product revenue increased by 17% to \$2.6 billion during the year ended December 31, 2017, from \$2.2 billion during 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 16% to \$928.4 million during the year ended December 31, 2017, compared with \$800.0 million during the year ended December 31, 2016. Higher systems revenue was primarily driven by higher system shipments and partly offset by a higher number of system placements under operating lease arrangements and lower da Vinci Surgical System 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 to 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 system shipments was primarily driven by procedure growth and the need for hospitals to establish or expand capacity.

The ASP for da Vinci Surgical Systems sold, which excludes operating lease and lease buyout revenue, 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.

Service Revenue

Service revenue increased by 11% to \$635.1 million for the year ended December 31, 2018, compared with \$572.9 million for the year ended December 31, 2017. Service revenue increased by 12% to \$572.9 million for the year ended December 31, 2017, compared with \$510.7 million for the year ended December 31, 2016. Higher service revenue in 2018 and 2017 was primarily driven by a larger installed base of da Vinci Surgical Systems producing service revenue.

Gross Profit

Product gross profit increased by 21% for the year ended December 31, 2018, to \$2.2 billion, representing 70.7% of product revenue, compared with \$1.8 billion, representing 70.5% of product revenue, for the year ended December 31, 2017. The higher 2018 product gross profit was primarily driven by higher product revenue.

Product gross profit margin for the year ended December 31, 2018, was consistent with the year ended December 31, 2017, as higher costs associated with new product introductions were largely offset by manufacturing efficiencies and product cost reductions.

Product gross profit for the year ended December 31, 2017, increased by 18% to \$1.8 billion, or 70.5% of product revenue, compared with \$1.5 billion, or 69.8% of product revenue, for the year ended December 31, 2016. The slightly higher 2017 product gross profit 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 in until January 1, 2020.

Product gross profit for the year ended December 31, 2018, 2017, and 2016, included share-based compensation expense of \$36.4 million, \$28.1 million, and \$25.2 million, respectively, and amortization expense of intangible assets of \$6.1 million, \$5.4 million, and \$7.8 million, respectively.

Service gross profit for the year ended December 31, 2018, increased to \$421.2 million, or 66.3% of service revenue, compared with \$393.0 million, or 68.6% of service revenue, for the year ended December 31, 2017. The higher 2018 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, 2018 was driven by higher costs associated with the repair and replacement of da Vinci Xi/X endoscope products.

Service gross profit for the year ended December 31, 2017, increased to \$393.0 million, or 68.6% of service revenue, compared with \$359.7 million, or 70.4% of service revenue, for the year ended December 31, 2016. The higher 2017 service gross profit was driven by higher service revenue, reflecting a large 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 years ended December 31, 2018, 2017, and 2016, included share-based compensation expense of \$16.8 million, \$14.0 million, and \$12.4 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, 2018, increased by 22% to \$986.6 million, compared with \$810.5 million for the year ended December 31, 2017. The higher selling, general and administrative expenses in 2018 were primarily associated with expansion of our Asian and European teams, infrastructure to support our growing operations, litigation charges, increased headcount in our U.S. commercial teams to support our growth, and the establishment of the Intuitive Foundation. In 2018, we made a charitable contribution of \$25.2 million to establish the Intuitive Foundation, a section 501(c)(3) qualifying not-for-profit entity whose mission is to reduce the global burden of disease and suffering through research, education, and philanthropy aimed at better outcomes for patients around the globe.

Selling, general and administrative expenses included pre-tax litigation charges of \$45.2 million and \$17.5 million for the year ended December 31, 2018, and 2017, respectively. The litigation charge for the year ended December 31, 2018, was primarily related to the settlement of the Abrams class action lawsuit further described in Note 7 to the Consolidated Financial Statements included in Part II, Item 8.

Selling, general and administrative expenses for the year ended December 31, 2017, increased by 15% to \$810.5 million compared with \$703.6 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 years ended December 31, 2017, and 2016 respectively.

Share-based compensation expense charged to selling, general and administrative expenses during the years ended December 31, 2018, 2017, and 2016, was \$133.2 million, \$111.8 million, and \$97.4 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, 2018, increased by 27% to \$418.1 million, compared with \$328.6 million for the year ended December 31, 2017. The increase was primarily due to higher personnel and other project costs to support a broader set of product development initiatives, including our robotic-assisted catheter-based medical devices; advanced imaging and analytics; advanced instrumentation; future generations of robotics; and expenses related to licensed intellectual property.

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 da Vinci platform products; da Vinci Single Port Surgical System; our robotic-assisted catheter-based medical devices; advanced imaging and analytics; advanced instrumentation; future generation of robotics; and expense related to licensed intellectual property.

Share-based compensation expense charged to research and development expense during the years ended December 31, 2018, 2017, and 2016, was \$76.2 million, \$56.0 million, and \$43.0 million, respectively. Amortization expense related to intangible assets for the years ended December 31, 2018, 2017, and 2016, was \$5.8 million, \$7.5 million, and \$10.4 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.

Interest and Other Income, Net

Interest and other income, net, was \$80.1 million for the year ended December 31, 2018, compared with \$41.9 million for 2017 and \$35.6 million for 2016. The increase in interest and other income, net, for the year ended December 31, 2018, was primarily driven by higher interest rates and higher cash and investment balances. 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.

Income Tax Expense

Our income tax expense was \$154.5 million, \$433.9 million, and \$247.0 million for the years ended December 31, 2018, 2017, and 2016, respectively. The effective tax rate for 2018 was approximately 12.1% compared with 39.3% for 2017, and 25.1% for 2016. Our effective tax rate for 2018 differs from the U.S. federal statutory rate of 21% primarily due to the excess tax benefits recognized for employee share-based compensation, the effect of income earned by certain overseas entities being taxed at rates lower than the federal statutory rate, federal research and development credit benefit, and the release of unrecognized tax benefits from expiration of statutes of limitations, partially offset by state income taxes (net of federal benefit) and U.S. tax on foreign earnings.

Our tax rate for 2017 reflected the effect of the below mentioned one-time discrete items associated with the enactment of the 2017 Tax Act. Besides the impact of the 2017 Tax Act, our tax rates for 2017 and 2016 differ from the U.S. federal statutory rate of 35% also due to the effect of income earned by certain 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). Our 2018, 2017, and 2016 tax provision reflected tax benefits of \$5.2 million, \$62.4 million, and \$15.8 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.

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 estimated an income tax expense of \$317.8 million related to the 2017 Tax Act, \$270.2 million of which related to the one-time deemed repatriation toll charge (“Toll Tax”), and \$47.6 million related to the re-measurement of our net deferred tax assets at the reduced U.S. federal statutory rate of 21%.

In December 2018, we completed our accounting for the effect of the 2017 Tax Act within the measurement period under the SEC guidance, and reflected a \$0.5 million net increase in the 2018 income tax expense. We have adopted the approach of recording the consequences of the Global Intangible Low-Taxed Income provision of the 2017 Tax Act as period costs when incurred. In addition, we repatriated \$1.6 billion of our cumulative undistributed foreign earnings back to the U.S. in June 2018 without any significant U.S. income tax consequences. We intend to repatriate earnings from our Swiss subsidiary as needed since the U.S.

and foreign tax implications of such repatriations are not expected to be significant. We will continue to indefinitely reinvest earnings from the rest of our foreign subsidiaries, which are not significant.

ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*, changes how the tax effects of share-based awards are recognized and 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 2018 and 2017 provisions for income taxes included excess tax benefits associated with employee equity plans of \$116.2 million and \$102.8 million, respectively, which reduced our effective tax rate by 9.1 and 9.3 percentage points, respectively, for the years ended December 31, 2018 and 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, and will result in increased income tax expense volatility.

Our 2007 Swiss tax holiday ended on December 31, 2017 and we received a new Swiss tax ruling for new business operations in Switzerland. 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 allows 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. We currently do not expect that the change to the new ruling will materially impact our future annual Swiss income tax expense.

We file federal, state, and foreign income tax returns in many jurisdictions in the U.S. and abroad. Years prior to 2015 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.

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 increased by \$1.0 billion to \$4.8 billion as of December 31, 2018, from \$3.8 billion as of December 31, 2017, primarily as a result of cash provided by our operations and employee stock option exercises. 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 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, 2018, \$225.8 million of our cash, cash equivalents, and investments were held by foreign subsidiaries, which decreased from \$1.5 billion as of December 31, 2017, primarily due to the repatriation of \$1.4 billion of foreign subsidiaries' cash, cash equivalents, and investments in the second quarter of 2018. We intend to repatriate earnings from our Swiss subsidiary as needed since the U.S. and foreign tax implications of such repatriations are not expected to be significant. We will continue to indefinitely reinvest earnings from the rest of our foreign subsidiaries, which are not significant. We believe the cash 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,		
	2018	2017	2016
<i>(in millions)</i>			
Net cash provided by (used in)			
Operating activities	\$ 1,169.6	\$ 1,143.9	\$ 1,087.0
Investing activities	(1,049.6)	378.7	(1,279.4)
Financing activities	126.3	(1,913.1)	514.4
Effect of exchange rates on cash, cash equivalents, and restricted cash	(0.1)	2.1	—
Net increase (decrease) in cash, cash equivalents, and restricted cash	\$ 246.2	\$ (388.4)	\$ 322.0

Operating Activities

For the year ended December 31, 2018, cash provided by our operating activities of \$1,169.6 million exceeded our net income of \$1,125.0 million due to non-cash charges and changes in operating assets and liabilities as outlined below:

1. Our net income included non-cash charges: share-based compensation of \$261.2 million; depreciation and loss on disposal of property, plant, and equipment of \$108.6 million; deferred income taxes of \$31.9 million; amortization of intangible assets of \$14.2 million; amortization of contract acquisition asset of \$10.6 million; and investment related non-cash charges of \$1.8 million.
2. Changes in operating assets and liabilities resulted in \$383.7 million of cash used in operating activities during the year ended December 31, 2018. Operating assets and liabilities are primarily comprised of accounts receivable, inventory, prepaid expenses and other assets, accrued compensation and employee benefits, deferred revenue, and other accrued liabilities. Inventory, including the transfer of equipment from inventory to property, plant, and equipment, increased by \$279.0 million primarily due to more systems under operating lease arrangements and an increase in inventory to meet higher sales volumes and add safety stock to mitigate possible trade and supplier matters. Accounts receivable increased by \$161.3 million primarily due to higher customer billings and timing of billings and collections. Prepaid expenses and other assets increased by \$77.7 million. The unfavorable impact of these items on cash used by operating activities was partly offset by a \$54.3 million increase in deferred revenue, a \$37.1 million increase in other accrued liabilities, and a \$26.2 million increase in accrued compensation and employee benefits.

For the year ended December 31, 2017, cash provided by our operating activities of \$1,143.9 million exceeded our net income of \$670.9 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 \$60.2 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 \$73.5 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 \$219.4 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 \$43.7 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 \$81.4 million in accounts receivable; and an increase of \$38.9 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 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 \$20.9 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 \$17.7 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 \$34.2 million primarily driven by higher revenue and timing of collections. Prepaids and other assets increased \$39.2 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 \$53.7 million increase in other liabilities, primarily due to higher income tax payable, a \$14.1 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.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2018, consisted of purchases of investments (net of the proceeds from the sales and maturities of investments) of \$774.3 million, the purchases of property, plant, and equipment of \$187.4 million, and acquisition of businesses for \$87.9 million.

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.

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 provided by financing activities during 2018 primarily consisted of proceeds from stock option exercises and employee stock purchases of \$236.6 million, partly offset by taxes paid on behalf of employees related to net share settlement of vested employee equity awards of \$120.0 million.

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 and taxes paid on behalf of employees related to net share settlement of vested employee equity awards of \$56.6 million. These uses were 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.

Our business has not been capital intensive. However, with the growth of our business and our investments in property and facilities and in manufacturing automation, capital investments have increased. We expect capital investments to exceed \$250 million in each of the next two years. We intend to fund these needs with cash generated from operations.

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, 2018 (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	\$ 95.4	\$ 15.1	\$ 27.2	\$ 22.2	\$ 30.9
Purchase commitments and obligations	711.2	704.7	4.6	1.0	0.9
Other	246.7	21.4	42.9	61.7	120.7
Total	\$ 1,053.3	\$ 741.2	\$ 74.7	\$ 84.9	\$ 152.5

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. As of December 31, 2018, our obligation associated with the deemed repatriation toll charge is \$246.7 million, which is expected to be paid in installments.

Off-Balance Sheet Arrangements

As of December 31, 2018, we did not have any significant off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K promulgated under the Exchange Act.

Critical Accounting Estimates

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

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

- the standalone selling prices used to allocate the contract consideration to the individual performance obligations, which impacts revenue recognition;
- the allowance for sales returns and doubtful accounts, which impacts revenue;
- the estimation of transactions to hedge, which impacts revenue and expense;
- the valuation of inventory, which impacts gross profit margins;
- the valuation of and 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 legal contingencies, 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-sale instruments, gains or losses on these securities are recorded to other comprehensive income (“OCI”), 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 significant impairment charges were recorded during the years ended December 31, 2018, 2017, and 2016. As of December 31, 2018, and 2017, net unrealized losses on investments of \$9.8 million and \$11.3 million, net of tax, respectively, were included in accumulated other comprehensive loss.

Revenue recognition. Our system sale arrangements contain multiple products and services, including system(s), system components, system accessories, instruments, accessories, and service. Other than service, we generally deliver all of the products upfront. Each of these products and services is a distinct performance obligation. System accessories, instruments, accessories, and service are also sold on a standalone basis.

For multiple-element arrangements, revenue is allocated to each performance obligation based on its relative standalone selling price. Standalone selling prices are based on observable prices at which we separately sell the products or services. If a standalone selling price is not directly observable, then we estimate the standalone selling prices considering market conditions and entity-specific factors including, but not limited to, features and functionality of the products and services, geographies, type of customer, and market conditions. We regularly review standalone selling prices and maintain internal controls over establishing and updating these estimates.

Our system sales arrangements generally include a five-year period of service. The first year of service is generally free and included in the system sale arrangement and the remaining four years are at a stated service price. Revenue that is allocated to service obligation is deferred and recognized ratably over the service period.

Allowance for sales returns and doubtful accounts. We record estimated reductions in revenue for potential returns of certain 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.

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 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, licenses, and non-competition arrangements. 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 such impairments.

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, 2018, 2017, and 2016. 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.

Business combinations. We allocate the fair value of the purchase consideration to the assets acquired and liabilities assumed based on their estimated fair values at the acquisition date. The excess of the fair value of the purchase consideration over the fair value of assets acquired and liabilities assumed is recorded as goodwill. When determining the fair value of assets acquired and liabilities assumed, management is required to make certain estimates and assumptions, especially with respect to intangible assets. The estimates and assumptions used in valuing intangible assets include, but are not limited to, the amount and timing of projected future cash flows, the discount rate used to determine the present value of these cash flows, and the determination of the assets' life cycle. These estimates are inherently uncertain and, therefore, actual results may differ from the estimates made.

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

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

- the sufficiency of the trading volume of freely traded options;

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

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

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. In the event that all or part of our deferred tax assets are not recoverable in the future, 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. In order for our deferred tax assets to be recoverable, we must be able to generate sufficient taxable income in those jurisdictions where the deferred tax assets are located. We consider forecasted income, including income that may be generated as a result of certain tax planning strategies, together with future reversals of existing taxable temporary differences, in determining the need for a valuation allowance. As of December 31, 2018, 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 re-evaluated each accounting period and is based on all available information, including discussion with any outside legal counsel that represents us. If a reasonable estimate of a known or probable loss cannot be made, but a range of probable losses can be estimated, the low-end of the range of losses is recognized if no amount within the range is a better estimate than any other. If a loss is reasonably possible, but not probable and can be reasonably estimated, the estimated loss or range of loss is disclosed in the Notes to the Consolidated Financial Statements.

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

judgments and estimates could have a material adverse effect on our business, financial condition, and results of operations or cash flows.

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, 2018, was approximately 0.7 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 \$8.5 million as of December 31, 2018. 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 generally sell our products and services in local currencies where we have direct distribution channels. We operate in a number of markets on a direct sales basis and incur operating expenses in local currencies. 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, 2018, sales denominated in foreign currencies were approximately 20% 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, 2018, our revenue would have decreased by approximately \$42.0 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, 2018, would have resulted in approximately \$0.2 million increase 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.

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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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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 (the “Company”) as of December 31, 2018 and 2017, 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, 2018, including the related notes and schedule of valuation and qualifying accounts for each of the three years in the period ended December 31, 2018 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, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 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, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Change in Accounting Principles

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for recognition of the income tax consequences of an intra-entity transfer of an asset, other than inventory, in 2018 and 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 4, 2019

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

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

	December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 857.9	\$ 648.2
Short-term investments	2,205.2	1,312.4
Accounts receivable, net of allowances of \$8.2 and \$4.6 as of December 31, 2018, and 2017, respectively	682.3	507.9
Inventory	409.0	241.2
Prepays and other current assets	178.8	99.2
Total current assets	4,333.2	2,808.9
Property, plant, and equipment, net	812.0	613.1
Long-term investments	1,771.3	1,885.9
Deferred tax assets	428.6	72.0
Intangible and other assets, net	261.0	195.8
Goodwill	240.6	201.1
Total assets	\$ 7,846.7	\$ 5,776.8
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 100.7	\$ 82.5
Accrued compensation and employee benefits	193.8	167.6
Deferred revenue	294.3	243.8
Other accrued liabilities	231.8	168.9
Total current liabilities	820.6	662.8
Other long-term liabilities	338.6	333.6
Total liabilities	1,159.2	996.4
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, 2.5 shares authorized, \$0.001 par value, issuable in series; no shares issued and outstanding as of December 31, 2018, and 2017	—	—
Common stock, 300.0 shares authorized, \$0.001 par value, 114.5 shares and 112.3 shares issued and outstanding as of December 31, 2018, and 2017, respectively	0.1	0.1
Additional paid-in capital	5,170.3	4,679.2
Retained earnings	1,521.7	115.0
Accumulated other comprehensive loss	(13.3)	(15.5)
Total Intuitive Surgical, Inc. stockholders' equity	6,678.8	4,778.8
Noncontrolling interest in joint venture	8.7	1.6
Total stockholders' equity	6,687.5	4,780.4
Total liabilities and stockholders' equity	\$ 7,846.7	\$ 5,776.8

The accompanying notes are an integral part of these Consolidated Financial Statements.

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

	Years Ended December 31,		
	2018	2017	2016
Revenue:			
Product	\$ 3,089.1	\$ 2,565.3	\$ 2,195.8
Service	635.1	572.9	510.7
Total revenue	<u>3,724.2</u>	<u>3,138.2</u>	<u>2,706.5</u>
Cost of revenue:			
Product	906.2	756.3	662.6
Service	213.9	179.9	151.0
Total cost of revenue	<u>1,120.1</u>	<u>936.2</u>	<u>813.6</u>
Gross profit	<u>2,604.1</u>	<u>2,202.0</u>	<u>1,892.9</u>
Operating expenses:			
Selling, general and administrative	986.6	810.5	703.6
Research and development	418.1	328.6	239.6
Total operating expenses	<u>1,404.7</u>	<u>1,139.1</u>	<u>943.2</u>
Income from operations	1,199.4	1,062.9	949.7
Interest and other income, net	80.1	41.9	35.6
Income before taxes	1,279.5	1,104.8	985.3
Income tax expense	154.5	433.9	247.0
Net income	1,125.0	\$ 670.9	\$ 738.3
Less: net loss attributable to noncontrolling interest in joint venture	(2.9)	—	—
Net income attributable to Intuitive Surgical, Inc.	<u>\$ 1,127.9</u>	<u>\$ 670.9</u>	<u>\$ 738.3</u>
Net income per share attributable to Intuitive Surgical, Inc.:			
Basic	\$ 9.92	\$ 6.01	\$ 6.43
Diluted	<u>\$ 9.49</u>	<u>\$ 5.77</u>	<u>\$ 6.26</u>
Shares used in computing net income per share attributable to Intuitive Surgical, Inc.:			
Basic	113.7	111.7	114.9
Diluted	<u>118.8</u>	<u>116.3</u>	<u>117.9</u>
Total comprehensive income attributable to Intuitive Surgical, Inc.	<u>\$ 1,130.1</u>	<u>\$ 664.3</u>	<u>\$ 738.9</u>

The accompanying notes are an integral part of these Consolidated Financial Statements.

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

	Years Ended December 31,		
	2018	2017	2016
Net income attributable to Intuitive Surgical, Inc.	\$ 1,127.9	\$ 670.9	\$ 738.3
Other comprehensive income (loss):			
Change in foreign currency translation gains (losses)	(2.6)	3.6	2.0
Available-for-sale investments (net of tax):			
Change in unrealized gains (losses)	0.3	(2.7)	(4.6)
Less: Reclassification adjustment for net losses on investments	1.2	—	0.2
Net change	1.5	(2.7)	(4.4)
Derivative instruments (net of tax):			
Change in unrealized gains (losses)	3.6	(8.6)	4.1
Less: Reclassification adjustment for (gains) losses on derivative instruments	(1.0)	1.2	(0.6)
Net change	2.6	(7.4)	3.5
Employee benefit plans (net of tax):			
Change in unrealized gains (losses)	0.4	(0.3)	(0.7)
Less: Reclassification adjustment for losses on employee benefit plans	0.3	0.2	0.2
Net change	0.7	(0.1)	(0.5)
Other comprehensive gains (losses)	2.2	(6.6)	0.6
Total comprehensive income attributable to Intuitive Surgical, Inc.	\$ 1,130.1	\$ 664.3	\$ 738.9

The accompanying notes are an integral part of these Consolidated Financial Statements.

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	Noncontrolling Interest in Joint Venture	Total Stockholders' Equity
	Shares	Amount						
Balances at December 31, 2015	37.4	\$ —	\$3,429.8	\$ 899.2	\$ (9.5)	\$ 4,319.5	\$ —	\$ 4,319.5
Adoption of new accounting standard (1)				40.3		40.3		40.3
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				738.3		738.3		738.3
Other comprehensive income					0.6	0.6		0.6
Balances at December 31, 2016	38.8	\$ —	\$4,211.8	\$1,617.6	\$ (8.9)	\$ 5,820.5	\$ —	\$ 5,820.5
Three-for-one stock split	77.6	0.1	(0.1)			—		—
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 awards	(0.2)		(5.1)	(51.5)		(56.6)		(56.6)
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				670.9		670.9		670.9
Other comprehensive loss					(6.6)	(6.6)		(6.6)
Capital contribution from noncontrolling interest						—	2.0	2.0
Loss in noncontrolling interest						—	(0.4)	(0.4)
Balances at December 31, 2017	112.3	\$ 0.1	\$4,679.2	\$ 115.0	\$ (15.5)	\$ 4,778.8	\$ 1.6	\$ 4,780.4
Adoption of new accounting standards (1)				392.1	(1.3)	390.8		390.8
Issuance of common stock through employee stock plans	2.5		236.6			236.6		236.6
Shares withheld related to net share settlement of equity awards	(0.3)		(6.7)	(113.3)		(120.0)		(120.0)
Share-based compensation expense related to employee stock plans			261.2			261.2		261.2
Net income				1,127.9		1,127.9		1,127.9
Other comprehensive income					3.5	3.5		3.5
Capital contribution from noncontrolling interest						—	10.0	10.0
Loss in noncontrolling interest						—	(2.9)	(2.9)
Balances at December 31, 2018	114.5	\$ 0.1	\$5,170.3	\$1,521.7	\$ (13.3)	\$ 6,678.8	\$ 8.7	\$ 6,687.5

(1) Represents the adjustments related to the adoption of new accounting standards. See Note 2 for details.

The accompanying notes are an integral part of these Consolidated Financial Statements.

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

	Years Ended December 31,		
	2018	2017	2016
Operating activities:			
Net income	\$ 1,125.0	\$ 670.9	\$ 738.3
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and loss on disposal of property, plant, and equipment, net	108.6	86.2	73.9
Amortization of intangible assets	14.2	12.9	18.2
Loss on investment, accretion of discounts, and amortization of premiums on investments, net	1.8	21.2	35.9
Deferred income taxes	31.9	60.2	20.9
Income tax benefits from employee stock plans	—	—	29.8
Share-based compensation expense	261.2	209.1	177.6
Amortization of contract acquisition asset	10.6	10.9	10.1
Changes in operating assets and liabilities, net of effects of acquisitions:			
Accounts receivable	(161.3)	(81.4)	(34.2)
Inventory	(279.0)	(115.5)	(46.7)
Prepays and other assets	(77.7)	(38.9)	(39.2)
Accounts payable	16.7	14.0	15.9
Accrued compensation and employee benefits	26.2	31.2	18.7
Deferred revenue	54.3	43.7	14.1
Other liabilities	37.1	219.4	53.7
Net cash provided by operating activities	<u>1,169.6</u>	<u>1,143.9</u>	<u>1,087.0</u>
Investing activities:			
Purchase of investments	(2,581.9)	(1,995.0)	(2,585.5)
Proceeds from sales of investments	274.0	1,861.3	389.9
Proceeds from maturities of investments	1,533.6	703.1	970.1
Purchase of property, plant and equipment, and intellectual property	(187.4)	(190.7)	(53.9)
Acquisition of businesses, net of cash	(87.9)	—	—
Net cash provided by (used in) investing activities	<u>(1,049.6)</u>	<u>378.7</u>	<u>(1,279.4)</u>
Financing activities:			
Proceeds from issuance of common stock relating to employee stock plans	236.6	415.5	580.9
Taxes paid related to net share settlement of equity awards	(120.0)	(56.6)	(24.0)
Repurchase common stock	—	(2,274.0)	(42.5)
Other financing activities	9.7	2.0	—
Net cash provided by (used in) financing activities	<u>126.3</u>	<u>(1,913.1)</u>	<u>514.4</u>
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(0.1)	2.1	—
Net increase (decrease) in cash, cash equivalents, and restricted cash	246.2	(388.4)	322.0
Cash, cash equivalents, and restricted cash, beginning of year	663.2	1,051.6	729.6
Cash, cash equivalents, and restricted cash, end of year	<u>\$ 909.4</u>	<u>\$ 663.2</u>	<u>\$ 1,051.6</u>

The accompanying notes are an integral part of these Consolidated Financial Statements.

INTUITIVE SURGICAL, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. DESCRIPTION OF THE BUSINESS

Intuitive Surgical, Inc. (“Intuitive” or the “Company”) develops, manufactures, and markets the da Vinci[®] Surgical System. The Company’s products and related services enable physicians and healthcare providers to improve the quality of and access to minimally invasive care. The da Vinci Surgical System consists of a surgeon console or consoles, a patient-side cart, a high-performance vision system, and proprietary instruments and accessories.

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 (“Joint Venture”) with Shanghai Fosun Pharmaceutical (Group) Co., Ltd. (“Fosun Pharma”). Chindex Medical Limited (“Chindex”), a subsidiary of Fosun Pharma, has been its distribution partner for da Vinci Surgical Systems in China. 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. The noncontrolling interest’s share of the earnings in the Joint Venture is presented separately in the Consolidated Statements of Income for the year ended December 31, 2018, while the amount was inconsequential for the year ended December 31, 2017, and was included as a component of interest and other income, net in the Consolidated Statements of Income.

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 revenue and allowance for sales returns and doubtful accounts, the estimation of hedging transactions, the valuation of inventory, the valuation of and 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, along with the assessment of recoverability, 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, 2018, and 2017, 71% and 69%, respectively, of accounts receivable were from domestic customers. No single customer represented more than 10% of total revenue for the years ended December 31, 2018, 2017, and 2016.

During the years ended December 31, 2018, 2017, and 2016, domestic revenue accounted for 71%, 73%, and 72% of total revenue, respectively, while outside of the U.S. revenue accounted for 29%, 27%, and 28%, respectively, of total revenue for each of the years then ended.

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 remaining maturities at date of purchase greater than approximately three months and remaining maturities as of the reporting period 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 to the expected recovery of the investment's amortized cost basis. No significant charges were recorded during the years ended December 31, 2018, 2017, and 2016.

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, 2018, 2017, and 2016, was \$105.9 million, \$82.1 million, and \$70.7 million, respectively.

Capitalized Software Costs for Internal Use

Internally developed software primarily includes enterprise-level business software that the Company customizes to meet its specific operational needs. The Company capitalized costs for internal use software of \$17.4 million, \$22.4 million, and \$11.8 million during the years ended December 31, 2018, 2017, and 2016, respectively. Upon being placed in service, these costs are depreciated over an estimated useful life of up to 5 years.

Business Combinations

The Company includes the results of operations of the businesses that are acquired as of the acquisition date. The Company allocates the purchase price of acquisitions to the assets acquired and liabilities assumed based on the estimated fair values. The

excess of the purchase price over the fair values of the identifiable assets and liabilities is recorded as goodwill. Acquisition related costs are recognized separately from the business combination and are expensed as incurred.

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 identifiable assets and liabilities. 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, 2018, 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 adopted ASC Topic 606, *Revenue from Contracts with Customers*, on January 1, 2018. The Company's revenue consists of product revenue resulting from the sale of systems, system components, instruments and accessories, and service revenue. The Company accounts for a contract with a customer when there is a legally enforceable contract between the Company and its customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. The Company's revenues are measured based on the consideration specified in the contract with each customer, net of any sales incentives and taxes collected from customers that are remitted to government authorities.

The Company's system sale arrangements generally contain multiple products and services. For these bundled sale arrangements, the Company accounts for individual products and services as separate performance obligations if they are a distinct product or service that is separately identifiable from other items in bundled packages; and if a customer can benefit from the product or service on its own or with other resources that are readily available to the customer. The Company's system sale arrangements include a combination of the following performance obligations: system(s); system components; system accessories; instruments; accessories; and system service. The Company's system sale arrangements generally include a five-year period of service. The first year of service is generally free and included in the system sale arrangement and the remaining four years are generally included at a stated service price. The Company considers the service terms in the arrangements that are legally enforceable to be performance obligations. Other than service, the Company generally satisfies all of the performance obligations up-front. System components, system accessories, instruments, accessories, and service are also sold on a stand-alone basis.

The Company recognizes revenue as the performance obligations are satisfied by transferring control of the product or service to a customer. The Company generally recognizes revenue for the performance obligations at the following points in time:

System sales. For systems (including system components and system accessories) sold directly to end customers, revenue is recognized when the Company transfers control to the customer, which is generally at the point when acceptance occurs that indicates customer acknowledgment of delivery or installation, depending on the terms of the arrangement. For systems sold through distributors, revenue is recognized generally at the time of shipment. The Company's system arrangements generally do not provide a right of return. The systems are generally covered by a one-year warranty. Warranty costs were not material for the periods presented.

Instruments and accessories. Revenue from sales of instruments and accessories is recognized when control is transferred to the customers, which generally occurs at the time of shipment, but also occurs at the time of delivery depending on the customer arrangement. 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 for estimated returns.

Service. Service revenue is recognized over the term of the service period as the customer benefits from the services throughout the service period. Revenue related to services performed on a time-and-materials basis is recognized when performed.

The Company offers its customers the opportunity to trade in their older systems for a 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 performance obligations 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 unit. Traded-in systems generally can be reconditioned and resold. The Company accounts for the fair value of the traded-in system in the total consideration in the arrangement by including the net realizable value of the traded-in system less a normal profit margin. The value of the traded-in system is determined as the amount, after reconditioning costs are added, that will allow a normal profit margin on the sale of the reconditioned unit to be generated. When there is no market for the traded-in units, no value is assigned. Traded-in units are reported as a component of inventory until resold, or otherwise disposed.

In addition, customers may also have the opportunity to upgrade their systems at a price determined at the time of the upgrade, for example, by adding a second surgeon console for use with the da Vinci Surgical System. Such upgrades are performed by completing component level upgrades at the customer's site. Upgrade revenue is recognized when the component level upgrades are complete and all revenue recognition criteria are met.

For multiple-element arrangements, revenue is allocated to each performance obligation based on its relative standalone selling price. Standalone selling prices are based on observable prices at which the Company separately sells the products or services. If a standalone selling price is not directly observable, then the Company estimates the standalone selling price considering market conditions and entity-specific factors including, but not limited to, features and functionality of the products and services, geographies, and type of customer. The Company regularly reviews standalone selling prices and updates these estimates as necessary.

The following table presents revenue disaggregated by types and geography (in millions):

	Years Ended December 31,		
	2018	2017	2016
U.S.			
Instruments and accessories	\$ 1,485.2	\$ 1,263.1	\$ 1,077.3
Systems	692.2	603.5	501.3
Services	456.1	419.2	377.8
Total U.S. revenue	<u>\$ 2,633.5</u>	<u>\$ 2,285.8</u>	<u>\$ 1,956.4</u>
Outside of U.S. ("OUS")			
Instruments and accessories	\$ 476.8	\$ 373.8	\$ 318.5
Systems	434.9	324.9	298.7
Services	179.0	153.7	132.9
Total OUS revenue	<u>\$ 1,090.7</u>	<u>\$ 852.4</u>	<u>\$ 750.1</u>
Total			
Instruments and accessories	\$ 1,962.0	\$ 1,636.9	\$ 1,395.8
Systems	1,127.1	928.4	800.0
Services	635.1	572.9	510.7
Total revenue	<u>\$ 3,724.2</u>	<u>\$ 3,138.2</u>	<u>\$ 2,706.5</u>

The transaction price allocated to remaining performance obligations relates to amounts allocated to products and services for which revenue has not yet been recognized. A significant portion of this amount relates to performance obligations in the Company's service contracts that will be satisfied and recognized as revenue in future periods. Transaction price allocated to remaining performance obligations was approximately \$1,448.7 million as of December 31, 2018.

The following information summarizes the Company's contract assets and liabilities (in millions):

	As of	
	December 31, 2018	December 31, 2017
Contract assets	\$ 12.4	\$ 8.3
Deferred revenue	\$ 327.3	\$ 268.6

The Company invoices its customers based on the billing schedules in its sales arrangements. Payments are generally due 30 days from date of invoice. Contract assets for the periods presented primarily represent the difference between the revenue that was recognized based on the relative standalone selling price of the related performance obligations satisfied and the contractual billing terms in the arrangements. Deferred revenue for the periods presented primarily relates to service contracts where the service fees are billed up-front, generally quarterly or annually, prior to those services having been performed. The associated deferred revenue is generally recognized over the term of the service period. The Company did not have any significant impairment losses on its contract assets for the periods presented.

During the year ended December 31, 2018, the Company recognized \$268.9 million of revenue that was included in the deferred revenue balance as of December 31, 2017. During the year ended December 31, 2017, the Company recognized \$225.5 million of revenue that was included in the deferred revenue balance as of December 31, 2016.

Assets Recognized from the Costs to Obtain a Contract with a Customer

The Company has determined that certain sales incentives provided to the Company's sales team are required to be capitalized when the Company expects to generate future economic benefits from the related revenue-generating contracts subsequent to the initial capital sales transaction. When determining the economic life of the contract acquisition assets recognized, the Company considers historical service renewal rates, expectations of future customer renewals of service contracts, and other factors that could impact the economic benefits that the Company expects to generate from the relationship with its customers. The costs capitalized as contract acquisition costs included in intangible and other assets, net in the Consolidated Balance Sheets were \$34.2 million and \$31.4 million as of December 31, 2018, and 2017, respectively. The Company did not incur any impairment losses during the periods presented.

Leases

The Company enters into sales-type lease and operating lease arrangements with certain qualified customers. 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 standalone 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, 2018, 2017, and 2016, was \$51.4 million, \$25.9 million, and \$16.6 million, respectively.

Allowance for Sales Returns and Doubtful Accounts

The allowance for sales returns is based on the Company's estimates of potential future returns of certain products 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. The Company estimates expected forfeitures at the time of grant and revises, if necessary, in subsequent periods if actual forfeitures differ from those estimated.

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 attributable to Intuitive Surgical, Inc. is computed using the weighted average number of shares outstanding during the period. Diluted net income per share attributable to Intuitive Surgical, Inc. 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 research and development 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.

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 has elected to account for Global Intangible Low-Taxed Income (“GILTI”) under the Tax Cuts and Jobs Act (“2017 Tax Act”) as period costs when incurred.

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, 2018, and 2017, 88% and 88% of long-lived assets were in the United States, respectively. 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.

Adopted Accounting Pronouncements

Revenue from Contracts with Customers

The Company adopted FASB Accounting Standards Codification Topic 606 (“ASC 606”), *Revenue from Contracts with Customers* in the first quarter of the Company’s fiscal year that began on January 1, 2018, using the full retrospective method, which required the Company to restate each prior reporting period presented. This new standard replaced the previous revenue recognition guidance in U.S. GAAP. Please see the Company’s “Revenue Recognition” policy in the “Significant Accounting Policies” section above.

The areas impacted include future contractual billings related to services included in the Company’s multi-year contracts, which are considered performance obligations that should be part of the contract consideration allocated to all performance obligations rather than being excluded due to its contingent nature as required under the previous revenue standard. Accordingly, the amount of contract consideration allocated to the performance obligations identified in the Company’s system arrangements is different from the amounts allocated under the previous revenue standard. In general, revenue is recognized earlier as a greater amount of the contract consideration is allocated to the product-related performance obligations that generally are delivered upfront, and therefore, less consideration is allocated to the service performance obligation that is generally recognized over the service period.

In addition, the Company recognized an asset associated with the incremental costs of obtaining revenue generating customer contracts that it expects to benefit from over a period longer than one year. The Company capitalized sales commissions paid in connection with system sale arrangements that include multi-year service obligations and is amortizing such asset over the economic life of those contracts. Previously, sales commissions were expensed as incurred. The impact of this change on operating expenses in any given period will depend, in part, on the amount of such commissions incurred and capitalized in relation to the amount of ongoing amortization expense.

Adoption of the standard using the full retrospective method also require the Company to restate certain previously reported results, including the impact to provision for income taxes. The adjustments to the Consolidated Statements of Comprehensive Income are as follows (in millions, except per share amounts):

	Fiscal 2017			Fiscal 2016		
	As Previously Reported	Adjustments	As Restated	As Previously Reported	Adjustments	As Restated
Revenue:						
Product	\$ 2,547.1	\$ 18.2	\$ 2,565.3	\$ 2,187.4	\$ 8.4	\$ 2,195.8
Service	581.8	(8.9)	572.9	517.0	(6.3)	510.7
Total revenue	3,128.9	9.3	3,138.2	2,704.4	2.1	2,706.5
Cost of revenue:						
Product	754.9	1.4	756.3	663.3	(0.7)	662.6
Service	179.9	—	179.9	151.0	—	151.0
Total cost of revenue	934.8	1.4	936.2	814.3	(0.7)	813.6
Gross profit	2,194.1	7.9	2,202.0	1,890.1	2.8	1,892.9
Operating expenses:						
Selling, general and administrative	810.9	(0.4)	810.5	705.3	(1.7)	703.6
Research and development	328.6	—	328.6	239.6	—	239.6
Total operating expenses	1,139.5	(0.4)	1,139.1	944.9	(1.7)	943.2
Income from operations	1,054.6	8.3	1,062.9	945.2	4.5	949.7
Interest and other income, net	41.9	—	41.9	35.6	—	35.6
Income before taxes	1,096.5	8.3	1,104.8	980.8	4.5	985.3
Income tax expense	436.5	(2.6)	433.9	244.9	2.1	247.0
Net income attributable to Intuitive Surgical, Inc.	\$ 660.0	\$ 10.9	\$ 670.9	\$ 735.9	\$ 2.4	\$ 738.3
Net income per share attributable to Intuitive Surgical, Inc.:						
Basic	\$ 5.91	\$ 0.10	\$ 6.01	\$ 6.40	\$ 0.03	\$ 6.43
Diluted	\$ 5.67	\$ 0.10	\$ 5.77	\$ 6.24	\$ 0.02	\$ 6.26
Total comprehensive income attributable to Intuitive Surgical, Inc.	\$ 653.4	\$ 10.9	\$ 664.3	\$ 736.5	\$ 2.4	\$ 738.9

The adjustments to the Consolidated Statement of Financial Position are as follows (in millions):

	December 31, 2017		
	As Previously Reported	Adjustments	As Restated
ASSETS			
Accounts receivable, net	\$ 511.9	\$ (4.0)	\$ 507.9
Prepays and other current assets	\$ 97.2	\$ 2.0	\$ 99.2
Deferred tax assets	\$ 87.3	\$ (15.3)	\$ 72.0
Intangible and other assets, net	\$ 159.7	\$ 36.1	\$ 195.8
LIABILITIES AND STOCKHOLDERS' EQUITY			
Deferred revenue	\$ 284.5	\$ (40.7)	\$ 243.8
Other accrued liabilities	\$ 169.5	\$ (0.6)	\$ 168.9
Other long-term liabilities	\$ 327.1	\$ 6.5	\$ 333.6
Retained earnings	\$ 61.4	\$ 53.6	\$ 115.0

In addition, the cumulative effect of ASC 606 to the Company's retained earnings at January 1, 2016, was \$40.3 million. Adoption of the standard had no impact to total net cash from or used in operating, investing, or financing activities within the consolidated statements of cash flows.

As part of the Company's adoption of ASC 606, the Company elected to use the following practical expedients: (i) to exclude disclosures of transaction prices allocated to remaining performance obligations when the Company expects to recognize such

revenue for all periods prior to the date of initial application of ASC 606; (ii) not to adjust the promised amount of consideration for the effects of a significant financing component when the Company expects, at contract inception, that the period between the Company's transfer of a promised product or service to a customer and when the customer pays for that product or service will be one year or less; (iii) to expense costs as incurred for costs to obtain a contract when the amortization period would have been one year or less; (iv) not to recast revenue for contracts that begin and end in the same fiscal year; and (v) not to assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer.

Intra-Entity Transfer of Assets Other than Inventory

Beginning fiscal 2018, the Company adopted 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. The Company adopted this standard using the modified retrospective approach, and as a result, recorded a deferred tax asset with a corresponding cumulative adjustment to retained earnings of \$390.8 million as of January 1, 2018, associated with an intra-entity transfer of certain intellectual property rights related to the Company's non-U.S. business to its Swiss entity.

Business Combinations: Clarifying the Definition of a Business

Beginning fiscal 2018, the Company adopted 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, and applied the new guidance prospectively. Refer to "Note 6. Goodwill and Intangible Assets" for further information on acquisitions accounted for as business combinations during fiscal 2018.

Statement of Cash Flows: Restricted Cash

Beginning fiscal 2018, the Company adopted ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which requires the statement of cash flows to explain the change during the period relating to total cash, cash equivalents, and restricted cash. The Company adopted this standard using the retrospective transition method by restating its Consolidated Statements of Cash Flows to include restricted cash of \$15.0 million in the beginning and ending cash, cash equivalents, and restricted cash balances for 2017 and 2016. Net cash flows for 2017 and 2016 did not change as a result of including restricted cash with cash and cash equivalents when reconciling the beginning-of-period and end-of-period amounts presented on the statements of cash flows. As of December 31, 2018, the cash, cash equivalents, and restricted cash balance includes restricted cash of \$51.5 million. Restricted cash was included in prepaids and other current assets and intangible and other assets, net on the Consolidated Balance Sheets.

Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income

In 2018, the Company elected to early adopt ASU 2018-02, *Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, which allows a reclassification from accumulated other comprehensive income (loss) to retained earnings for stranded tax effects resulting from the 2017 Tax Act. The Company elected to reclassify such tax effects in the period of adoption and resulted in the reclassification of \$1.3 million from accumulated other comprehensive loss to retained earnings.

Disclosure Framework for Fair Value Measurement

In 2018, the Company elected to early adopt ASU No. 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which amends ASC 820, Fair Value Measurement. ASU 2018-13 modified the disclosure requirements for fair value measurements by removing, modifying, and adding certain disclosures. The adoption did not have a material impact on the Consolidated Financial Statements.

Improvements to Employee Share-based Payment Accounting

In 2017, the Company adopted ASU No. 2016-09, *Improvements to Employee Share-based Payment Accounting* ("ASU 2016-09"), which changes among other things, how the tax effects of share-based awards are recognized. ASU 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 years ended December 31, 2018, and 2017, included excess tax benefits associated with employee equity plans of \$116.2 million and \$102.8 million, respectively, which reduced the Company's effective tax rate by 9.1 and 9.3 percentage points, respectively, for the years ended December 31, 2018, and 2017. This ASU also 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. In 2017, the Company adopted this provision retrospectively by reclassifying \$44.1 million of excess tax benefits from financing activities to operating activities for the year ended December 31, 2016.

Recent Accounting Pronouncements Not Yet Adopted

Leases (Topic 842)

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, *Leases (Topic 842)* (“ASU 842”), which amends the existing accounting standards for leases. The new standard requires lessees to record a right-of-use (“ROU”) asset and a corresponding lease liability on the balance sheet (with the exception of short-term leases), whereas under current accounting standards, the Company’s lease portfolio consists of operating leases and is not recognized on its consolidated balance sheets. The new standard also requires expanded disclosures regarding leasing arrangements. The new standard is effective for the Company beginning January 1, 2019. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides an alternative modified transition method. Under this method, the cumulative-effect adjustment to the opening balance of retained earnings is recognized on the date of adoption with prior periods not restated.

The new standard provides a number of optional practical expedients in transition. The Company expects to elect: (1) the ‘package of practical expedients’, which permits it not to reassess under the new standard its prior conclusions about lease identification, lease classification, and initial direct costs; (2) the use-of-hindsight; and (3) the practical expedient pertaining to land easements. In addition, the new standard provides practical expedients for an entity’s ongoing accounting that the Company anticipates making, such as the (1) the election for certain classes of underlying asset to not separate non-lease components from lease components and (2) the election for short-term lease recognition exemption for all leases that qualify.

The Company will adopt ASU 842 as of January 1, 2019, using the alternative modified transition method. In preparation of adopting ASC 842, the Company is implementing additional internal controls to enable future preparation of financial information in accordance with ASC 842. The Company has also substantially completed its evaluation of the impact on the Company’s lease portfolio. The Company believes the largest impact will be on the consolidated balance sheets for the accounting of facilities-related leases, which represents a majority of its operating leases it has entered into as a lessee. These leases will be recognized under the new standard as ROU assets and operating lease liabilities. The Company will also be required to provide expanded disclosures for its leasing arrangements. As of December 31, 2018, the Company had \$95.4 million of undiscounted future minimum operating lease commitments that are not recognized on its consolidated balance sheets as determined under the current standard. For a lessee, the results of operations are not expected to significantly change after adoption of the new standard.

In addition, the Company’s customers finance purchases of da Vinci systems and ancillary products, including directly with the Company as the lessor. For a lessor, the new standard applied is largely unchanged from the previous standard and the Company does not anticipate a material impact on its Consolidated Financial Statements.

While substantially complete, the Company is still in the process of finalizing its evaluation of the effect of ASU 842 on the Company’s financial statements and disclosures. The Company will finalize its accounting assessment and quantitative impact of the adoption during the first quarter of fiscal year 2019. 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 leases. 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.

Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles (Topic 350): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. This new standard also requires customers to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. This new standard becomes effective for the Company in the first quarter of fiscal year 2020, with early adoption permitted. This new standard can be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is currently evaluating the impact and timing of adopting this new standard on its Consolidated Financial Statements.

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, 2018, and 2017 (in millions):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Reported as:		
					Cash and Cash Equivalents	Short-term Investments	Long-term Investments
December 31, 2018							
Cash	\$ 269.4	\$ —	\$ —	\$ 269.4	\$ 269.4	\$ —	\$ —
Level 1:							
Money market funds	569.1	—	—	569.1	569.1	—	—
U.S. treasuries	1,477.8	1.7	(5.3)	1,474.2	10.0	897.8	566.4
Subtotal	2,046.9	1.7	(5.3)	2,043.3	579.1	897.8	566.4
Level 2:							
Commercial paper	110.7	—	—	110.7	1.4	109.3	—
Corporate securities	1,607.8	1.3	(4.8)	1,604.3	8.0	724.5	871.8
U.S. government agencies	791.8	0.3	(3.8)	788.3	—	468.9	319.4
Municipal securities	18.4	—	—	18.4	—	4.7	13.7
Subtotal	2,528.7	1.6	(8.6)	2,521.7	9.4	1,307.4	1,204.9
Total assets measured at fair value	\$ 4,845.0	\$ 3.3	\$ (13.9)	\$ 4,834.4	\$ 857.9	\$ 2,205.2	\$ 1,771.3

As of December 31, 2018, the Company also recorded \$36.5 million of restricted cash equivalents (comprised of money market funds and U.S. treasuries which would be considered highly liquid investments with original maturity dates that are 90 days or less) in prepaids and other current assets in the accompanying Consolidated Balance Sheets.

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Reported as:		
					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

During the year ended December 31, 2018, 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, 2018 (in millions):

	Amortized Cost	Fair Value
Mature in less than one year	\$ 2,230.2	\$ 2,224.6
Mature in one to five years	1,776.3	1,771.3
Total	\$ 4,006.5	\$ 3,995.9

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

As of December 31, 2018, and 2017, net unrealized losses on investments of \$9.8 million and \$11.3 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, 2018, and 2017 (in millions):

	Unrealized losses less than 12 months		Unrealized losses 12 months or greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
December 31, 2018						
Corporate securities	\$ 727.4	\$ (1.7)	\$ 409.6	\$ (3.1)	\$ 1,137.0	\$ (4.8)
U.S. treasuries	478.7	(0.9)	592.8	(4.4)	1,071.5	(5.3)
U.S. government agencies	228.0	(0.2)	425.2	(3.6)	653.2	(3.8)
	<u>\$ 1,434.1</u>	<u>\$ (2.8)</u>	<u>\$ 1,427.6</u>	<u>\$ (11.1)</u>	<u>\$ 2,861.7</u>	<u>\$ (13.9)</u>
December 31, 2017						
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)
	<u>\$ 1,996.3</u>	<u>\$ (7.2)</u>	<u>\$ 880.4</u>	<u>\$ (8.2)</u>	<u>\$ 2,876.7</u>	<u>\$ (15.4)</u>

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 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 amounts reclassified to revenue and expenses related to the hedged transactions and the ineffective portions of cash flow hedges were not material for the periods presented.

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, CHF, and Indian Rupee (“INR”).

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,		
	2018	2017	2016
Recognized gains (losses) in interest and other income, net	\$ 8.7	\$ (9.2)	\$ 6.4
Foreign exchange gains (losses) related to balance sheet re-measurement	\$ (2.6)	\$ 9.7	\$ (5.6)

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, 2018	December 31, 2017	December 31, 2018	December 31, 2017
Notional amounts:				
Forward contracts	\$ 183.0	\$ 128.5	\$ 182.7	\$ 168.4
Gross fair value recorded in:				
Prepaid and other current assets	\$ 3.1	\$ 0.9	\$ 4.1	\$ 1.2
Other accrued liabilities	\$ 0.9	\$ 2.9	\$ 1.1	\$ 4.6

NOTE 4. CONSOLIDATED FINANCIAL STATEMENT DETAILS

The following tables provide details of selected consolidated financial statement items (in millions):

	December 31,	
	2018	2017
<u>Inventory:</u>		
Raw materials	\$ 164.1	\$ 80.9
Work-in-process	40.0	19.7
Finished goods	204.9	140.6
Total inventory	<u>\$ 409.0</u>	<u>\$ 241.2</u>

	December 31,	
	2018	2017
<u>Property, plant, and equipment, net:</u>		
Land	\$ 184.6	\$ 174.8
Building and building/leasehold improvements	266.2	230.5
Machinery and equipment	280.1	224.8
Operating lease assets	150.2	66.1
Computer and office equipment	52.6	44.8
Capitalized software	157.8	135.6
Construction-in-process	156.7	83.5
Gross property, plant, and equipment	1,248.2	960.1
Less: Accumulated depreciation*	(436.2)	(347.0)
Total property, plant, and equipment, net	<u>\$ 812.0</u>	<u>\$ 613.1</u>

*Accumulated depreciation associated with operating lease assets

	\$ (32.1)	\$ (13.8)
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	December 31,	
	2018	2017
Other accrued liabilities—short-term:		
Taxes payable	\$ 39.1	\$ 63.1
Litigation related accruals	55.0	13.8
Other accrued liabilities	137.7	92.0
Total other accrued liabilities—short-term	<u>\$ 231.8</u>	<u>\$ 168.9</u>

	December 31,	
	2018	2017
Other long-term liabilities:		
Income taxes—long-term	\$ 270.2	\$ 286.8
Deferred revenue—long-term	33.0	24.8
Other long-term liabilities	35.4	22.0
Total other long-term liabilities	<u>\$ 338.6</u>	<u>\$ 333.6</u>

Supplemental Cash flow Information

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

	Years Ended December 31,		
	2018	2017	2016
Income taxes paid	\$ 179.2	\$ 147.5	\$ 138.4
Supplemental non-cash investing activities:			
Equipment transfers from inventory to property, plant, and equipment	\$ 125.7	\$ 65.8	\$ 39.3
Deferred payments related to business combinations	\$ 16.7	\$ —	\$ —

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,	
	2018	2017
Gross lease receivables	\$ 150.4	\$ 128.0
Unearned income	(6.3)	(5.0)
Allowance for credit loss	(1.0)	(0.9)
Net investment in sales-type leases	<u>\$ 143.1</u>	<u>\$ 122.1</u>
Reported as:		
Prepays and other current assets	\$ 51.2	\$ 41.9
Intangible and other assets, net	91.9	80.2
Total, net	<u>\$ 143.1</u>	<u>\$ 122.1</u>

Contractual maturities of gross lease receivables as of December 31, 2018, are as follows (in millions):

<u>Fiscal Year</u>	<u>Amount</u>
2019	\$ 50.8
2020	46.5
2021	29.7
2022	14.9
2023	7.5
2024 and thereafter	1.0
Total	<u>\$ 150.4</u>

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, 2018, are as follows (in millions):

<u>Fiscal Year</u>	<u>Amount</u>
2019	\$ 88.0
2020	85.8
2021	68.8
2022	51.3
2023	25.4
2024 and thereafter	1.9
Total	<u>\$ 321.2</u>

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

NOTE 6. GOODWILL AND INTANGIBLE ASSETS

The increases in goodwill and intangible assets from December 31, 2017, to December 31, 2018, primarily relate to three transactions accounted for as business combinations.

During the second quarter of fiscal 2018, the Company terminated its India distribution relationship with Vattikuti Technologies Pvt. Ltd. and acquired certain assets related to that distribution business on May 25, 2018, which collectively met the definition of a business. The transaction enhances the Company's ability to serve patients, surgeons, and hospitals in India. The purchase consideration consisted of \$38.1 million in cash. The Company preliminarily recorded \$4.1 million of net tangible assets, \$24.2 million of intangible assets, and \$9.8 million of residual goodwill. Intangible assets included reacquired distribution rights, customer relationships, and a non-compete agreement, which are being amortized over a weighted average period of 4.3 years.

During the third quarter of fiscal 2018, the Company acquired intellectual property, exclusive field of use rights, and certain key employees from InTouch Technologies, Inc. on August 17, 2018, which collectively met the definition of a business. The transaction enhances the Company's network capabilities in using real-time data to support surgeons. The total purchase consideration of \$38.7 million, as of the acquisition date, consisted of an initial cash payment of \$22.0 million and subsequent cash payments totaling approximately \$16.7 million. The Company recorded \$13.3 million of intangible assets and \$25.4 million of residual goodwill. Intangible assets included developed technology and a non-compete agreement, which are being amortized over a weighted average period of 5.7 years. The goodwill will be amortized for income tax purposes.

During the fourth quarter of fiscal 2018, the Company acquired its Taiwan distributor, Unison Surgicals Company, on December 11, 2018, which met the definition of a business. The transaction enhances the Company's ability to serve patients, surgeons, and hospitals in Taiwan. The purchase consideration consisted of \$35.4 million in cash. The Company preliminarily recorded \$13.1 million of net tangible assets, which included \$7.6 million of cash, \$17.3 million of intangible assets, and \$5.0 million of residual goodwill. Intangible assets included customer relationships and non-compete agreements, which are being amortized over a weighted average period of 6.6 years.

The Company has included the results of the businesses, since their acquisition dates, in its Consolidated Financial Statements, which have not been material to date. Pro forma results of operations related to the acquisitions have not been presented since the operating results of the acquired businesses are not material to the Consolidated Financial Statements.

The following table summarizes the components of gross intangible asset, accumulated amortization, and net intangible asset balances as of December 31, 2018, and 2017 (in millions):

	December 31, 2018			December 31, 2017		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents and developed technology	\$ 158.7	\$ (144.7)	\$ 14.0	\$ 156.0	\$ (140.2)	\$ 15.8
Distribution rights and others	40.2	(12.9)	27.3	9.2	(9.2)	—
Customer relationships	48.5	(23.1)	25.4	28.6	(18.4)	10.2
Total intangible assets	<u>\$ 247.4</u>	<u>\$ (180.7)</u>	<u>\$ 66.7</u>	<u>\$ 193.8</u>	<u>\$ (167.8)</u>	<u>\$ 26.0</u>

Amortization expense related to intangible assets was \$14.2 million, \$12.9 million, and \$18.2 million for the years ended December 31, 2018, 2017, and 2016, respectively.

The estimated future amortization expense related to intangible assets as of December 31, 2018, is as follows (in millions):

<u>Fiscal Year</u>	<u>Amount</u>
2019	\$ 15.9
2020	15.8
2021	12.5
2022	10.1
2023	6.2
2024 and thereafter	6.2
Total	<u>\$ 66.7</u>

NOTE 7. COMMITMENTS AND CONTINGENCIES

OPERATING LEASES

The Company leases space for operations in United States, Mexico, Japan, South Korea, China, 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, 2018, are as follows (in millions):

<u>Fiscal Year</u>	<u>Amount</u>
2019	\$ 15.1
2020	14.5
2021	12.7
2022	11.2
2023	11.0
2024 and thereafter	30.9
Total	<u>\$ 95.4</u>

OTHER COMMITMENTS

Other commitments include an estimated amount of approximately \$711.2 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 the Company has not received the goods or services. Although open purchase orders are considered enforceable and legally binding, the terms generally allow the Company the option to cancel, reschedule, and adjust its requirements based on its business needs prior to the delivery of goods or performance of services. In addition to the above, the Company has committed to make certain future milestone payments to third parties as part of licensing, collaboration, and development arrangements. Payments under these arrangements generally become due and payable only upon the achievement of certain specified developmental, regulatory, and/or commercial milestones. Because the achievement of these milestones is neither probable nor reasonably estimable, such contingencies are not included in the estimated amount.

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 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. During the years ended December 31, 2018, 2017, and 2016, the Company recorded pre-tax charges of \$45.2 million, \$16.3 million, and \$8.3 million, respectively, related to the securities class action lawsuits and the tolled product liability claims described below. A total of \$53.0 million and \$12.8 million associated with these matters were included in other accrued liabilities in the accompanying Consolidated Balance Sheets as of December 31, 2018, and 2017, respectively.

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 U.S. District Court for the Northern District of California.

The case has since been retitled *In re Intuitive Surgical Securities Litigation*, No. 5:13-cv-1920. The plaintiffs sought 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 alleged 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 June 11, 2018, the Company reached an agreement in principle to enter into a settlement agreement which stipulates a payment of \$42.5 million by the Company. The court granted preliminary approval on October 4, 2018, and on December 20,

2018, the court granted final approval. During the year ended December 31, 2018, the Company recorded a pre-tax charge of \$42.5 million for this matter. In connection with the settlement, the Company deposited \$42.5 million into an escrow account established for disbursements, which was recorded in prepaids and other current assets in the accompanying Consolidated Balance Sheets as of December 31, 2018. The appeals period expired on January 21, 2019 and the matter has been concluded.

Product Liability Litigation

The Company is currently named as a defendant in a number of individual product liability lawsuits filed in various state and federal courts. The plaintiffs generally 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. 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.

In addition to the filed cases, the Company previously received a substantial number of claims relating 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. As of December 31, 2018, all such "tolling agreements" have expired and the majority of the "tolled claims" have either been resolved or the matters have been filed.

During the years ended December 31, 2018, 2017, and 2016, the Company recorded \$2.7 million, \$16.3 million, and \$8.3 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, 2018, and 2017, a total of \$10.5 million and \$12.8 million, respectively, were included in other accrued liabilities in the accompanying Consolidated Balance Sheets related to the tolled product liability claims.

The Company's estimate of the anticipated cost of resolving the pending lawsuits and claims is based on negotiations with attorneys for the plaintiffs/claimants. The final outcome of the pending lawsuits and claims, and others that might arise, is dependent on many variables that are difficult to predict and the ultimate cost associated with these product liability lawsuits and 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.

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 U.S. 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. Ethicon asserts infringement of the U.S. Patent Nos. 9,585,658, 8,479,969, 9,113,874, 8,998,058, 8,991,677, 9,084,601, and 8,616,431. The parties are currently engaged in fact discovery regarding Ethicon's allegations. A claim construction hearing occurred on October 1, 2018, and the court issued an order on December 28, 2018. Trial is currently scheduled for October 15, 2019. 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.

On August 27, 2018, Ethicon LLC, Ethicon Endo-Surgery, Inc., and Ethicon US LLC (collectively, "Ethicon") filed a second complaint for patent infringement against the Company in the U.S. District Court for the District of Delaware. The complaint alleges that the Company's SureForm 60 Staplers infringe five of Ethicon's patents. Ethicon asserts infringement of the U.S. Patent Nos. 9,884,369, 7,490,749, 8,602,288, 8,602,287, and 9,326,770. The Company filed an answer denying all claims. Ethicon has indicated it may seek preliminary injunctive relief, but it has yet to confirm, or to file such a motion. The case is set for a claim construction hearing on September 23, 2019, and trial is set for October 13, 2020. 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

Through December 31, 2018, the Company's Board of Directors (the "Board") had 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 previous authorization occurred in December 2016 when the Board increased the authorized amount available under the Repurchase Program to \$3.0 billion. During the first quarter of 2017, the Company entered into an accelerated share repurchase program (the "ASR Program") with Goldman Sachs & Co. LLC ("Goldman") and Goldman delivered to the Company approximately 7.3 million shares of the Company's common stock, for which the Company made a payment of \$2.0 billion to Goldman. During the fourth quarter of 2017, the Company completed the ASR Program by making a final settlement payment of \$274.0 million to Goldman. As of December 31, 2018, the remaining amount of share repurchases authorized by the Board under the Repurchase Program was approximately \$717.5 million.

The following table provides the stock repurchase activities during the years ended December 31, 2018, 2017, and 2016 (in millions, except per share amounts):

	Years Ended December 31,		
	2018	2017	2016
Shares repurchased	—	7.3	0.2
Average price per share	\$ —	\$ 310.32	\$ 201.70
Value of shares repurchased	\$ —	\$ 2,274.0	\$ 42.5

The Company uses the par value method of accounting for its stock repurchases. As a result of share repurchase activities during the years ended December 31, 2018, 2017, and 2016, the Company reduced common stock and additional paid-in capital by an aggregate of zero, \$152.0 million, and \$4.1 million, respectively, and charged zero, \$2,122.0 million, \$38.4 million, respectively, to retained earnings.

ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

The components of accumulated other comprehensive income (loss) net of tax, for the years ended December 31, 2018, and 2017, are as follows (in millions):

	Year Ended December 31, 2018				
	Gains (Losses) on Hedge Instruments	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Translation Gains (Losses)	Employee Benefit Plans	Total
Beginning balance	\$ (2.4)	\$ (11.3)	\$ 2.3	\$ (4.1)	\$ (15.5)
Other comprehensive income (loss) before reclassifications	3.6	0.3	(2.6)	0.4	1.7
Reclassified from accumulated other comprehensive income (loss)	(1.0)	1.2	—	0.3	0.5
Net current-period other comprehensive income (loss)	2.6	1.5	(2.6)	0.7	2.2
Ending balance	\$ 0.2	\$ (9.8)	\$ (0.3)	\$ (3.4)	\$ (13.3)

	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 income	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)

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, 2018, approximately 4.1 million shares were reserved for future issuance under the 2010 Plan. A maximum of 1.8 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, 2018, approximately 102,000 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.

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, 2018, 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 0.2 million shares under the ESPP, representing approximately \$46.8 million, \$38.3 million, and \$32.5 million in employee contributions for the years ended December 31, 2018, 2017, and 2016, respectively. As of December 31, 2018, there were approximately 1.4 million shares reserved for future issuance under the ESPP.

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 2018 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, 2017	7.2	\$ 164.16
Options granted	0.6	\$ 475.38
Options exercised	(1.5)	\$ 126.52
Options forfeited/expired	(0.1)	\$ 237.05
Balance at December 31, 2018	6.2	\$ 200.79

The aggregate intrinsic value of stock options exercised under the Company's stock plans determined as of the date of option exercise was \$526.6 million, \$379.9 million, and \$273.3 million during the years ended December 31, 2018, 2017, and 2016, respectively. Cash received from option exercises and employee stock purchase plans for the years ended December 31, 2018, 2017, and 2016, was \$236.6 million, \$415.5 million, and \$580.9 million, respectively. The income tax benefit from stock options exercised was \$87.0 million for the year ended December 31, 2018.

The following table summarizes significant ranges of outstanding and exercisable options as of December 31, 2018 (number of shares and aggregate intrinsic value in millions):

Range of Exercise Prices	Options Outstanding				Options Exercisable			
	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 - \$127.91	1.4	2.7	\$ 115.05		1.4		\$ 115.05	
\$128.30 - \$168.41	1.3	4.6	\$ 156.67		1.3		\$ 156.62	
\$169.42 - \$178.39	1.4	5.6	\$ 174.50		1.2		\$ 174.17	
\$178.75 - \$283.51	1.2	6.2	\$ 214.60		0.9		\$ 207.77	
\$310.67 - \$548.71	0.9	9.1	\$ 423.33		0.2		\$ 388.12	
Total	<u>6.2</u>	5.4	\$ 200.79	<u>\$1,727.7</u>	<u>5.0</u>	4.7	\$ 168.62	<u>\$1,554.5</u>

(1) The aggregate intrinsic value represents the total pre-tax intrinsic value, based on the Company's closing stock price of \$478.92 at December 31, 2018, 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, 2018, a total of 6.1 million shares of stock options vested and expected to vest had a weighted average remaining contractual life of 5.3 years, an aggregate intrinsic value of \$1,715.2 million, and a weighted average exercise price of \$197.45.

Restricted Stock Units Information

RSU activity for the year ended December 31, 2018, was as follows (in millions, except per share amounts):

	Shares	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2017	2.1	\$ 209.55
Granted	0.8	\$ 431.11
Vested	(0.8)	\$ 195.67
Forfeited	(0.1)	\$ 277.10
Unvested balance at December 31, 2018	<u>2.0</u>	\$ 295.70

As of December 31, 2018, 1.8 million shares of RSUs were expected to vest with an aggregate intrinsic value of \$879.4 million. The aggregate vesting date fair value of RSUs vested was \$334.3 million, \$144.2 million, and \$65.3 million during the years ended December 31, 2018, 2017, and 2016, respectively.

Share-Based Compensation Expense

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

	Years Ended December 31,		
	2018	2017	2016
Cost of sales—products	\$ 36.4	\$ 28.1	\$ 25.2
Cost of sales—services	16.8	14.0	12.4
Total cost of sales	53.2	42.1	37.6
Selling, general and administrative	133.2	111.8	97.4
Research and development	76.2	56.0	43.0
Share-based compensation expense before income taxes	262.6	209.9	178.0
Income tax effect	54.3	49.2	56.1
Share-based compensation expense after income taxes	<u>\$ 208.3</u>	<u>\$ 160.7</u>	<u>\$ 121.9</u>

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, 2018, 2017, and 2016, were as follows:

	Years Ended December 31,		
	2018	2017	2016
STOCK OPTION PLANS			
Risk-free interest rate	2.7%	1.8%	1.1%
Expected term (years)	4.3	4.1	4.2
Volatility	33%	25%	26%
Fair value at grant date	\$ 146.30	\$ 67.03	\$ 47.06
EMPLOYEE STOCK PURCHASE PLAN			
Risk-free interest rate	2.1%	1.2%	0.6%
Expected term (years)	1.3	1.2	1.2
Volatility	32%	28%	30%
Fair value at grant date	\$ 135.84	\$ 79.77	\$ 57.57
RESTRICTED STOCK UNITS			
Fair value at grant date	\$ 431.11	\$ 249.34	\$ 184.59

As share-based compensation expense recognized in the Consolidated Statements of Income during the years ended December 31, 2018, 2017, and 2016, is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures.

As of December 31, 2018, there were a total of \$91.6 million, \$373.5 million, and \$11.6 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, 2.2 years for unvested restricted stock units, and 0.9 years for rights granted to acquire common stock under the ESPP.

NOTE 10. INCOME TAXES

Income before provision for income taxes for the years ended December 31, 2018, 2017, and 2016, consisted of the following (in millions):

	Years Ended December 31,		
	2018	2017	2016
U.S.	\$ 852.7	\$ 774.7	\$ 657.0
Foreign	426.8	330.1	328.3
Total income before provision for income taxes	\$ 1,279.5	\$ 1,104.8	\$ 985.3

The provision for income taxes for the years ended December 31, 2018, 2017, and 2016, consisted of the following (in millions):

	Years Ended December 31,		
	2018	2017	2016
Current			
Federal	\$ 89.5	\$ 352.1	\$ 207.0
State	21.1	13.0	13.4
Foreign	9.9	8.7	5.4
	\$ 120.5	\$ 373.8	\$ 225.8
Deferred			
Federal	\$ (4.1)	\$ 62.8	\$ 20.5
State	(0.3)	(0.3)	0.6
Foreign	38.4	(2.4)	0.1
	\$ 34.0	\$ 60.1	\$ 21.2
Total income tax expense	\$ 154.5	\$ 433.9	\$ 247.0

Income tax expense differs from amounts computed by applying the statutory federal income rate of 21% for the year ended December 31, 2018 and 35% for the years ended December 31, 2017, and 2016, as a result of the following (in millions):

	Years Ended December 31,		
	2018	2017	2016
Federal tax at statutory rate	\$ 268.7	\$ 386.7	\$ 344.9
Increase (reduction) in tax resulting from:			
State taxes, net of federal benefits	20.8	16.0	14.0
Foreign rate differential	(44.7)	(115.7)	(91.2)
U.S. tax on foreign earnings	43.7	8.4	5.0
Research and development credit	(25.2)	(15.3)	(7.8)
Share-based compensation not benefited	9.9	10.8	3.6
Domestic production activities deduction	—	(7.9)	(8.0)
Reversal of unrecognized tax benefits	(5.2)	(62.4)	(15.8)
Tax Cuts and Jobs Act impact	0.5	317.8	—
Excess tax benefits related to share-based compensation arrangements	(116.2)	(102.8)	—
Other	2.2	(1.7)	2.3
Total income tax expense	<u>\$ 154.5</u>	<u>\$ 433.9</u>	<u>\$ 247.0</u>

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

	December 31,	
	2018	2017
Deferred tax assets:		
Share-based compensation expense	\$ 87.2	\$ 79.1
Expenses deducted in later years for tax purposes	29.1	29.7
Intangible assets	351.9	—
Research and other credits	40.1	27.5
Other	9.0	10.5
Gross deferred tax assets	<u>\$ 517.3</u>	<u>\$ 146.8</u>
Valuation allowance	(42.3)	(29.4)
Deferred tax assets	<u>\$ 475.0</u>	<u>\$ 117.4</u>
Deferred tax liabilities:		
Fixed assets	\$ (42.2)	\$ (26.3)
Intangible assets	(7.5)	(3.6)
Other	(0.1)	(15.5)
Deferred tax liabilities	<u>\$ (49.8)</u>	<u>\$ (45.4)</u>
Net deferred tax assets	<u>\$ 425.2</u>	<u>\$ 72.0</u>

In December 2017, the 2017 Tax Act was enacted, which 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. The Securities Exchange Commission (“SEC”) issued guidance for a measurement period of one year from the enactment date to finalize the accounting for effects of the 2017 Tax Act. The Company recorded an income tax expense of \$317.8 million in its 2017 income tax provision related to the 2017 Tax Act which included a provisional estimate of \$270.2 million related to the one-time deemed repatriation toll charge (“Toll Tax”), and a provisional estimate of \$47.6 million income tax expense in 2017 due to the re-measurement of its net deferred tax assets at a reduced U.S. federal statutory rate of 21%.

The Company repatriated \$1.6 billion of its cumulative undistributed foreign earnings back to the U.S. in June 2018 without any significant U.S. income tax consequences. The Company intends to repatriate earnings from its Swiss subsidiary as needed since the U.S. and foreign tax implications of such repatriations are not expected to be significant. The Company will continue to indefinitely reinvest earnings from the rest of our foreign subsidiaries, which are not significant.

In December 2018, the Company completed its accounting for the effect of the 2017 Tax Act within the measurement period under the SEC guidance, and reflected a net \$0.5 million increase in the 2018 income tax expense. The Company has adopted the approach of recording the consequences of the GILTI provision of the 2017 Tax Act as period costs when incurred.

The Company’s tax holiday obtained in 2007 for business operations in Switzerland ended on December 31, 2017. The Company received a new tax ruling in Switzerland for new business operations. The new 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 allows for a reduced cantonal tax rate based on various thresholds of investment, including the ownership, development, and use of the non-U.S. intellectual property rights and employment in such jurisdiction. The tax benefits from Swiss tax holidays for the year ended December 31, 2018 were insignificant, while for the years ended December 31, 2017 and 2016 were approximately \$10.9 million, or \$0.09 per diluted share, and \$10.0 million, or \$0.08 per diluted share, respectively.

As of December 31, 2018, and 2017, the Company had valuation allowances of \$42.3 million and \$29.4 million, respectively, primarily related to California deferred tax assets generated by California R&D credit forwards which have no expiration period. The Company recorded a valuation allowance against its California deferred tax assets as it is more likely than not these deferred tax assets will not be realized as a result of the computation of California taxes under the single sales factor.

The Company recorded a net increase of its gross unrecognized tax benefits of approximately \$13.4 million during the year ended December 31, 2018. The net increase was primarily due to increases related to 2018 uncertain tax positions, partially offset by the reversal of gross unrecognized tax benefits in connection with the expiration of certain statutes of limitation in various jurisdictions. The Company had gross unrecognized tax benefits of approximately \$78.8 million, \$65.4 million, and \$106.0 million as of December 31, 2018, 2017, and 2016, respectively, which if recognized, would result in a reduction of the Company’s effective tax rate. The Company included interest expense accrued on unrecognized tax benefits as a component of its income tax expense. As of December 31, 2018, 2017, and 2016, gross interest related to unrecognized tax benefits accrued was approximately \$2.6 million, \$1.8 million, and \$3.7 million, respectively. A majority of the Company’s net unrecognized tax benefits and related interest is presented in other accrued liabilities on the Consolidated Balance Sheets.

A reconciliation of the beginning and ending amounts of gross unrecognized income tax benefits for the years ended December 31, 2018, 2017, and 2016, are as follows (in millions):

	Years Ended December 31,		
	2018	2017	2016
Beginning balance	\$ 65.4	\$ 106.0	\$ 92.4
Increases related to tax positions taken during the current year	22.5	21.1	29.9
Decreases related to tax positions taken during a prior year	(0.9)	(46.5)	(0.5)
Decreases related to settlements with tax authorities	—	(0.5)	—
Decreases related to expiration of statute of limitations	(8.2)	(14.7)	(15.8)
Ending balance	<u>\$ 78.8</u>	<u>\$ 65.4</u>	<u>\$ 106.0</u>

The Company files federal, state and foreign income tax returns in many U.S. and OUS jurisdictions. Years before 2015 are closed for the significant jurisdictions. Certain of the Company’s unrecognized tax benefits could change due to activities of various tax authorities, including potential assessment of additional tax, possible settlement of audits, or through normal expiration of various statutes of limitations, which could affect the Company’s effective tax rate in the period in which they change. Due to the uncertainty related to the timing and potential outcome of audits, the Company cannot estimate the range of reasonably possible change in unrecognized tax benefits that may occur in the next 12 months.

The Company is subject to the examination of its income tax returns by the Internal Revenue Service and other tax authorities. The outcome of these audits cannot be predicted with certainty. The Company’s management regularly assesses the likelihood of

adverse outcomes resulting from these examinations to determine the adequacy of the Company's provision for income taxes. If any issues addressed in the Company's tax audits are resolved in a manner not consistent with management's expectations, the Company could be required to adjust its provision for income taxes in the period such resolution occurs.

NOTE 11. NET INCOME PER SHARE

The following table presents the computation of basic and diluted net income per share attributable to Intuitive Surgical, Inc. (in millions, except per share amounts):

	Years Ended December 31,		
	2018	2017	2016
Numerator:			
Net income attributable to Intuitive Surgical, Inc.	\$ 1,127.9	\$ 670.9	\$ 738.3
Denominator:			
Weighted average shares outstanding used in basic calculation	113.7	111.7	114.9
Add: dilutive effect of potential common shares	5.1	4.6	3.0
Weighted average shares outstanding used in diluted calculation	118.8	116.3	117.9
Net income per share attributable to Intuitive Surgical, Inc.:			
Basic	\$ 9.92	\$ 6.01	\$ 6.43
Diluted	\$ 9.49	\$ 5.77	\$ 6.26

Share-based compensation awards of approximately 0.4 million, 0.2 million, and 0.6 million shares for the years ended December 31, 2018, 2017, and 2016, respectively, were outstanding, but were not included in the computation of diluted net income per share attributable to Intuitive Surgical, Inc. common stockholders because the effect of including such shares would have been anti-dilutive in the periods presented.

NOTE 12. EMPLOYEE BENEFIT PLANS

The Company sponsors various retirement plans for its eligible U.S. and non-U.S. employees. For employees in the U.S., the Company maintains the Intuitive Surgical, Inc. 401(k) Plan (the "Plan"). As allowed under Section 401(k) of the Internal Revenue Code, the Plan provides tax-deferred salary contributions for eligible U.S. employees. The Plan allows employees to contribute up to 100% of their annual compensation to the Plan on a pre-tax and after-tax basis. Employee contributions are limited to a maximum annual amount as set periodically by the Internal Revenue Code. The Company matches 200% of employee contributions up to \$1,500 per calendar year per person. All matching employer contributions vest immediately.

NOTE 13. SUBSEQUENT EVENTS

Acquisition of Certain Assets from Chindex

In January 2019, the Joint Venture acquired certain assets from Chindex and its affiliates, a subsidiary of Fosun Pharma, including distribution rights, customer relationships, and certain personnel for estimated cash payments of approximately \$80 to \$90 million that are contingent on achieving certain commercial milestones in 2019 and 2020. Chindex was the Company's distributor of da Vinci products and services in China. Subsequent to the acquisition of the above mentioned assets, the Company's Joint Venture began direct operations for da Vinci products and services in China. The Company is currently completing its accounting assessment of this transaction.

Increase Authorization of Common Stock Repurchase Program

On January 31, 2019, the Board increased the authorized amount available under the Repurchase Program to an aggregate of \$2.0 billion, including amounts remaining under previous authorization. The Repurchase Program does not have an expiration date.

SELECTED QUARTERLY DATA
(UNAUDITED, IN MILLIONS, EXCEPT PER SHARE AMOUNTS)

	Three Months Ended			
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
Revenue	\$ 1,046.5	\$ 920.9	\$ 909.3	\$ 847.5
Gross profit	\$ 735.7	\$ 642.3	\$ 632.3	\$ 593.8
Net income attributable to Intuitive Surgical, Inc. ⁽¹⁾⁽²⁾⁽³⁾	\$ 292.5	\$ 292.5	\$ 255.3	\$ 287.6
Net income attributable to Intuitive Surgical, Inc. per share:				
Basic	\$ 2.56	\$ 2.57	\$ 2.25	\$ 2.55
Diluted	\$ 2.45	\$ 2.45	\$ 2.15	\$ 2.44

(1) Includes discrete tax benefits as follows:

Excess tax benefits related to share-based compensation arrangements	\$ 15.8	\$ 24.1	\$ 21.6	\$ 54.7
Certain one-time tax benefits	\$ 2.5	\$ 4.6	\$ —	\$ —
(2) Includes pre-tax litigation benefits (charges)	\$ —	\$ 1.8	\$ (42.5)	\$ (4.5)
(3) Includes charitable foundation contribution expense	\$ (25.2)	\$ —	\$ —	\$ —

	Three Months Ended			
	December 31, 2017	September 30, 2017	June 30, 2017	March 31, 2017
Revenue	\$ 892.0	\$ 807.8	\$ 758.8	\$ 679.6
Gross profit	\$ 634.0	\$ 568.1	\$ 530.1	\$ 469.8
Net income (loss) attributable to Intuitive Surgical, Inc. ⁽¹⁾⁽²⁾	\$ (31.5)	\$ 298.6	\$ 223.0	\$ 180.8
Net income (loss) attributable to Intuitive Surgical, Inc. per share:				
Basic	\$ (0.28)	\$ 2.67	\$ 2.01	\$ 1.62
Diluted	\$ (0.28)	\$ 2.56	\$ 1.94	\$ 1.57

(1) Includes discrete tax benefits (expense) as follows:

Income expense related to the 2017 Tax Act	\$ (317.8)	\$ —	\$ —	\$ —
Excess tax benefits related to share-based compensation arrangements	\$ 19.9	\$ 19.7	\$ 30.6	\$ 32.6
Certain one-time tax benefits	\$ —	\$ 68.4	\$ —	\$ —
(2) Includes pre-tax litigation benefits (charges)	\$ 1.2	\$ (9.7)	\$ 4.5	\$ (21.3)

VALUATION AND QUALIFYING ACCOUNTS
(IN MILLIONS)

	Balance at Beginning of Year		Additions		Deductions ⁽¹⁾		Balance at End of Year
Allowance for doubtful accounts, loan credit losses, and sales returns							
Year ended December 31, 2018	\$ 14.6	\$	46.0	\$	(40.2)	\$	20.4
Year ended December 31, 2017	\$ 10.8	\$	36.1	\$	(32.3)	\$	14.6
Year ended December 31, 2016	\$ 9.4	\$	24.6	\$	(23.2)	\$	10.8

(1) Primarily represents products returned.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

None.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Inherent Limitations Over Internal Controls

Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our 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 our assets;
- (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Management, including our principal executive officer and principal financial officer, does not expect that our internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in the Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an assessment of the effectiveness of our internal control over financial reporting based on the framework in Internal Control Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of our assessment under the framework in the Internal Control—Integrated Framework (2013), our management concluded that our internal control over financial reporting was effective as of December 31, 2018.

The effectiveness of our internal control over financial reporting as of December 31, 2018, has been audited by an independent registered public accounting firm, as stated in their attestation report, which is included in their annual report under "Item 8. Financial Statements and Supplementary Data" of this Annual Report.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2018, that have materially affected, or are reasonably likely to materially affect, our internal control over financial statements.

ITEM 9B. OTHER INFORMATION

None.

PART III

Certain information required by Part III is omitted from this report on Form 10-K and is incorporated herein by reference to our definitive Proxy Statement for our next Annual Meeting of Stockholders (the “Proxy Statement”), which we intend to file pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, within 120 days after December 31, 2018.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item concerning our directors and corporate governance is incorporated by reference to the information set forth in the section titled “Directors and Corporate Governance” in our Proxy Statement. Information required by this item concerning our executive officers is incorporated by reference to the information set forth in the section entitled “Executive Officers of the Company” in our Proxy Statement. Information regarding our Section 16 reporting compliance and code of business conduct and ethics is incorporated by reference to the information set forth in the section entitled “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” in our Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item regarding executive compensation is incorporated by reference to the information set forth in the sections titled “Executive Compensation” and “Compensation for Directors” in our Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth in the section titled “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” in our Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item regarding certain relationships and related transactions and director independence is incorporated by reference to the information set forth in the sections titled “Certain Relationships and Related Transactions” and “Directors and Corporate Governance” in our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item regarding principal accountant fees and services is incorporated by reference to the information set forth in the section titled “Principal Accountant Fees and Services” in our Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULE

- (a) The following documents are filed as part of this Annual Report on Form 10-K
- 1) Financial Statements—See Index to Consolidated Financial Statements at Item 8 of this report on Form 10-K.
 - 2) The following financial statement schedule of Intuitive Surgical, Inc. is filed as part of this report and should be read in conjunction with the financial statements of Intuitive Surgical, Inc.:

Schedule II: Valuation and Qualifying Accounts.

All other schedules have been omitted because they are not applicable, not required under the instructions, or the information requested is set forth in the consolidated financial statements or related notes thereto.

- 3) Exhibits

The exhibits filed as part of this report are listed under “Exhibits” at subsection (b) of this Item 15.

- (b) Exhibits

EXHIBIT INDEX

- 3.1(1) Amended and Restated Certificate of Incorporation of the Company, as amended.
- 3.2(2) Amended and Restated Bylaws of the Company.
- 4.1(3) Specimen Stock Certificate.
- 10.1(4) 2000 Equity Incentive Plan. *
- 10.2(4) 2000 Non-Employee Directors' Stock Option Plan. *
- 10.3(5) Form of Indemnity Agreement. *
- 10.4(6) 2009 Employment Commencement Incentive Plan, as amended and restated. *
- 10.5(7) 2000 Employee Stock Purchase Plan. *
- 10.6(8) 2010 Incentive Award Plan, as amended and restated. *
- 10.7(9) Severance Plan. *
- 10.8(10) Form of Intuitive Surgical, Inc. 2000 Equity Incentive Plan Stock Option Agreement (Incentive and Nonstatutory Stock Options). *
- 10.9(11) Form of Intuitive Surgical, Inc. 2009 Employment Commencement Incentive Plan Stock Option Grant Notice. *
- 10.10(12) Form of Intuitive Surgical, Inc. 2009 Employment Commencement Incentive Plan Restricted Stock Unit Grant Notice. *
- 10.11(13) Form of Intuitive Surgical, Inc. 2010 Incentive Award Plan Stock Option Grant Notice. *
- 10.12(14) Form of Intuitive Surgical, Inc. 2010 Incentive Award Plan Restricted Stock Unit Grant Notice. *
- 10.13(15) Master Confirmation and Supplemental Confirmation between Intuitive Surgical, Inc. and Goldman Sachs & Co. LLC dated January 24, 2017.
- 21.1 Intuitive Surgical, Inc. Subsidiaries.
- 23.1 Consent of Independent Registered Public Accounting Firm.
- 31.1 Certification of Principal Executive Officer.
- 31.2 Certification of Principal Financial Officer.
- 32.1 Certification of Chief Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101 The following materials from Intuitive Surgical, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Income, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to Consolidated Financial Statements, tagged at Level I through IV.

-
- (1) Incorporated by reference to Exhibit 3.1 filed with the Company's Quarterly Report on Form 10-Q filed on October 20, 2017 (File No. 000-30713).
 - (2) Incorporated by reference to Exhibit 3.1 filed with the Company's Current Report on Form 8-K filed on December 13, 2016 (File No. 000-30713).
 - (3) Incorporated by reference to Exhibit 4.2 filed with the Company's Registration Statement Amendment on Form S-1/A filed on May 2, 2000 (File No. 333-33016).
 - (4) Incorporated by reference to exhibits filed with the Company's Registration Statement on Form S-1 filed on March 22, 2000 (File No. 333-33016).
 - (5) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on August 3, 2015 (File No. 000-30713).
 - (6) Incorporated by reference to Exhibit 4.2 filed with the Company's Registration Statement on Form S-8 filed on May 1, 2015 (File No. 333-203793).
 - (7) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on April 26, 2017 (File No. 000-30713).
 - (8) Incorporated by reference to Exhibit 10.2 filed with the Company's Current Report on Form 8-K filed on April 26, 2017 (File No. 000-30713).
 - (9) Incorporated by reference to Exhibit 10.1 filed with the Company's Current Report on Form 8-K filed on December 2, 2008 (File No. 000-30713).
 - (10) Incorporated by reference to Exhibit 10.2 filed with the Company's Quarterly Report on Form 10-Q filed on July 23, 2009 (File No. 000-30713).
 - (11) Incorporated by reference to Exhibit 10.9 filed with the Company's 2015 Annual Report on Form 10-K filed on February 2, 2016 (File No. 000-30713).
 - (12) Incorporated by reference to Exhibit 10.10 filed with the Company's 2015 Annual Report on Form 10-K filed on February 2, 2016 (File No. 000-30713).
 - (13) Incorporated by reference to Exhibit 10.11 filed with the Company's 2015 Annual Report on Form 10-K filed on February 2, 2016 (File No. 000-30713).
 - (14) Incorporated by reference to Exhibit 10.12 filed with the Company's 2015 Annual Report on Form 10-K filed on February 2, 2016 (File No. 000-30713).
 - (15) Incorporated by reference to Exhibit 10.13 filed with the Company's 2016 Annual Report on Form 10-K filed on February 6, 2017 (File No. 000-30713).

* Management contract or compensatory plan or arrangement.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

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

INTUITIVE SURGICAL, INC.

By: /s/ GARY S. GUTHART
Gary S. Guthart, Ph.D.
 President and Chief Executive Officer

Date: February 4, 2019

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ GARY S. GUTHART Gary S. Guthart, Ph.D.	President, Chief Executive Officer, and Director (Principal Executive Officer)	February 4, 2019
/s/ MARSHALL L. MOHR Marshall L. Mohr	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	February 4, 2019
/s/ JAMIE E. SAMATH Jamie E. Samath	Vice President, Corporate Controller (Principal Accounting Officer)	February 4, 2019
/s/ LONNIE M. SMITH Lonnie M. Smith	Chairman of the Board of Directors	February 4, 2019
/s/ CRAIG H. BARRATT Craig H. Barratt, Ph.D.	Director	February 4, 2019
/s/ MICHAEL A. FRIEDMAN Michael A. Friedman, M.D.	Director	February 4, 2019
/s/ AMAL M. JOHNSON Amal M. Johnson	Director	February 4, 2019
/s/ DON R. KANIA Don R. Kania, Ph.D.	Director	February 4, 2019
/s/ KEITH R. LEONARD JR. Keith R. Leonard Jr.	Director	February 4, 2019
/s/ ALAN J. LEVY Alan J. Levy, Ph.D.	Director	February 4, 2019
/s/ JAMI DOVER NACHTSHEIM Jami Dover Nachtsheim	Director	February 4, 2019
/s/ MARK J. RUBASH Mark J. Rubash	Director	February 4, 2019

INTUITIVE SURGICAL, INC.**SUBSIDIARIES (All 100% Owned other than Intuitive Surgical-Fosun (HongKong) Co., Ltd. and Intuitive Surgical-Fosun Medical Technology (Shanghai) Co., Ltd.)**

<u>Subsidiaries of the Registrant</u>	<u>State or Other Jurisdiction of Incorporation</u>
I.S. Holdings C.V.	Netherlands
I.S. Netherlands C.V.	Netherlands
Intuitive Surgical AB	Sweden
Intuitive Surgical ApS	Denmark
Intuitive Surgical Australia Proprietary Limited	Australia
Intuitive Surgical Brasil Importacao E Comercio De Equipamentos Cirurgicos Ltda.	Brazil
Intuitive Surgical BV	Netherlands
Intuitive Surgical Deutschland GmbH	Germany
Intuitive Surgical GK	Japan
Intuitive Surgical HK Limited	Hong Kong
Intuitive Surgical Holdings, LLC	Delaware, U.S.
Intuitive Surgical India Private Limited	India
Intuitive Surgical International Ltd.	Cayman
Intuitive Surgical Ireland Limited	Ireland
Intuitive Surgical Korea Limited	South Korea
Intuitive Surgical Limited	United Kingdom
Intuitive Surgical Medical Device and Technology (Shanghai) Co., Ltd.	China
Intuitive Surgical Medical Device Taiwan Ltd.	Taiwan
Intuitive Surgical Operations, Inc.	Delaware, U.S.
Intuitive Surgical Pte. Ltd.	Singapore
Intuitive Surgical S. de R. L. de C.V.	Mexico
Intuitive Surgical S.A.S.	France
Intuitive Surgical s.r.o.	Czech Republic
Intuitive Surgical Sarl	Switzerland
Intuitive Surgical Spain SL	Spain
Intuitive Surgical SPRL	Belgium
Intuitive Surgical Turkey Medikal Cihaz Ticaret Limited Serketi	Turkey
Intuitive Surgical-Fosun (HongKong) Co., Ltd.	Hong Kong
Intuitive Surgical-Fosun Medical Technology (Shanghai) Co., Ltd.	China
Unison Surgicals Company	Taiwan

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-221043, 333-211064, 333-203793, 333-189399, 333-184488, 333-180863, 333-175904, 333-173803, 333-166833, 333-164586, 333-159228, 333-152558, 333-143433, 333-135004, 333-127162, 333-116499, 333-99893, 333-65342, and 333-43558) of Intuitive Surgical, Inc. of our report dated February 4, 2019 relating to the financial statements, financial statement schedule and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

San Jose, California

February 4, 2019

**Certification of Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Marshall L. Mohr, certify that:

1. I have reviewed this annual report on Form 10-K of Intuitive Surgical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 4, 2019

By: /s/ MARSHALL L. MOHR
Marshall L. Mohr
Executive Vice President and Chief Financial Officer

**Certification of Chief Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Intuitive Surgical, Inc. (the “Company”) hereby certifies, to such officer’s knowledge, that:

- (i) the accompanying Annual Report on Form 10-K of the Company for the period ended December 31, 2018 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ GARY S. GUTHART

Gary S. Guthart, Ph.D.
President and Chief Executive Officer

Date: February 4, 2019

**Certification of Principal Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Intuitive Surgical, Inc. (the “Company”) hereby certifies, to such officer’s knowledge, that:

- (i) the accompanying Annual Report on Form 10-K of the Company for the period ended December 31, 2018 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ MARSHALL L. MOHR

Marshall L. Mohr
Executive Vice President and Chief Financial Officer

Date: February 4, 2019

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INTUITIVE