INTUITIVE

Annual Report 2019

Intuitive Surgical, Inc.
www.intuitive.com

Dear Owner,

As we enter our 25th year, the field of robotic-assisted surgery (RAS) we helped pioneer is poised to enter a new phase. Our early history established baseline capabilities in robotics, instruments, real-time computing and imaging while designing core products that surgeons and hospitals found value in using. Throughout our history, the north star for our innovation has been the desire to deliver real clinical benefit and economic value for health systems. This ambition can be seen both in the way we continue to develop our systems and technologies, and in how we build our ecosystem of programs and solutions to train, service, and support our customers.

We measure our progress in terms of our customers' goals – the quadruple aim – better outcomes, better patient experience, better care team experience, and lower total cost to treat per patient episode. This aligns with an important shift we have seen among our customers in how they assess value and how they view data.

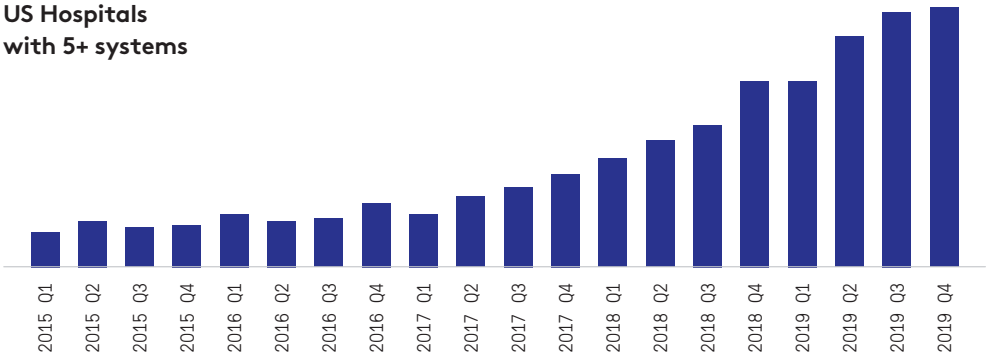
Enabling Actionable Insights

Medical institutions over the past two decades have evaluated the clinical and economic benefits of our products – there are now over 21,000 peer reviewed published articles that, taken together, support the safety, efficacy, and benefits of da Vinci surgical systems.[1]

Clinical research and publication surrounding RAS has been in place for decades – what has changed in the past few years has been the introduction of electronic health records into many health systems. We have been working with hospitals to combine our robotic surgery data with their electronic health records to enable their leadership to assess, for themselves, the relative clinical outcomes, efficiency metrics, direct and indirect costs of their surgery departments – comparing open surgery, laparoscopic surgery and da Vinci robotic-assisted surgery in their own settings, with their patient populations, care teams, and reimbursements.

This 'local data, local truth' analysis is changing perceptions of the value of robotics programs. Over the past three years, the number of hospitals that are operating five or more da Vinci systems at a single campus has grown more than 400%.

US Hospitals with 5+ systems



[1] While Intuitive funds and participates in scientific and clinical research of our products, the vast majority of these thousands of articles are conducted independently without our input or financial support.

We believe there are three primary drivers for this trend. First, our ecosystem of products and services provides the support necessary to enable an effective robotic surgery program at scale. Second, surgeons find value in using our products and personally advocate to use them. And third, local, hospital-specific data analysis is showing that outcomes, efficiency and hospital profitability enabled by da Vinci surgical systems supports the use and expansion of their programs.

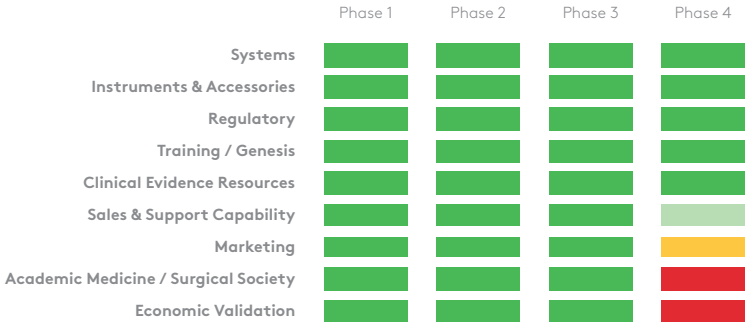
More than a Robot: An Ecosystem

We know that achieving meaningful improvements in the quadruple aim requires a sophisticated ecosystem to support the safety, efficacy, and success of a robotic surgery program; a robot and a few instruments are insufficient. Over the past several years, we have invested heavily in enabling our ecosystem in those countries leading the charge in robotic-assisted surgery.

Building a robot is just the beginning.

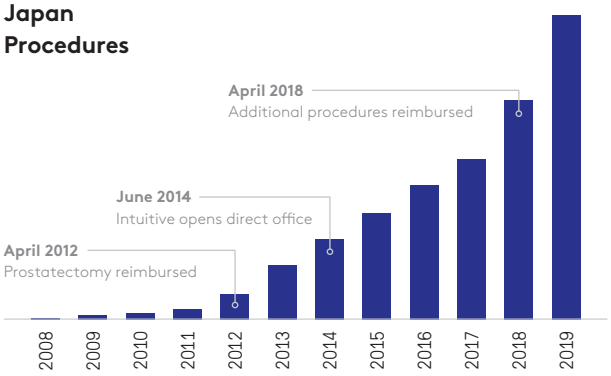
A robust ecosystem is a must-have to enable an effective program.

Building the ecosystem takes expertise, time, and resources

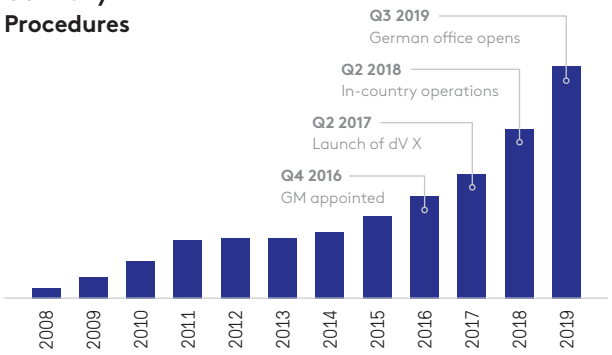


When the elements of the ecosystem are executed at a high-quality level, surgical markets respond. Over the past several years, we have communicated our investments in Japan and Germany. Below is the procedure utilization of our products in these countries over time.

Intuitive Japan Procedures



Intuitive Germany Procedures



We evaluate our progress and direct our investment with these concepts in mind – progress towards the quadruple aim measured in the setting in which it is practiced.

Turning to our performance in 2019, our team delivered a strong performance in support of our customers. Globally procedures grew approximately 18%. Our installed base of da Vinci systems grew 12%. As a result of customer adoption, our revenue grew 20% compared to 2018. Looking beyond financial measures, self-reported customer satisfaction is important to us. In 2019 the company's net promotor score was strong.[2] That said, we practice continuous improvement and actively pursue opportunities to do better.

While we have made great progress to date, there is enormous opportunity for improvement in surgery and other acute medical interventions, and real innovation is required. We have been accelerating our investments in four pillars of our business. First, we are investing in increased quality and lower costs of our high-volume products to realize benefits of scale for our customers and our company, often through use of automation in our production processes. Second, we are investing in market access capabilities outside the United States in countries that are poised to adopt computer-assisted interventions. Third, we are inventing and designing the next generation of systems, instruments, imaging and accessories to advance outcomes and improve care team experiences for existing procedures and new categories altogether. Lastly, our smallest but fastest growing segment of investment is informatics: (a) big data capability; (b) Intuitive Cloud computing and telemedicine; (c) machine learning; and (d) training technologies.

Focus on Clinically Meaningful Innovation

Our innovation teams performed well in 2019. Our instruments and accessories teams introduced important new products like our SureForm™ 60 mm stapler (used primarily in general surgery), our Synchroseal™ instrument for fast sealing with transection, and our first advanced energy generator, the E-100. They did this while increasing manufacturing capacity and improving the quality and costs of our existing products. In endoscopy, we introduced our fifth-generation stereo endoscope, Endoscope Plus, which both improves imaging performance and is more robust than our market leading fourth-generation stereo endoscope. In the year, we welcomed the 3D team from our endoscopy partner, Schölly Fiberoptics, as Intuitive employees. Integrating this team will allow us to accelerate time-to-market for new imaging innovations, to increase our manufacturing capacity more quickly, and to lower costs for us and our customers over time.

[2] We contracted with JD Power to run a blinded study of Intuitive's Net Promotor Score (NPS) with our customers. Our score was the highest in the cohort of like companies that were tested in this study.

Key clearances and first cases completed in 2019

Ion Endoluminal System
Biopsy in the periphery of the lung

SureForm Stapler
Intelligent stapling
SureForm 45: OUS, Japan, Korea.
SureForm 60: Taiwan

Endoscope Plus
Higher performance, better resolution

SP
TORS
US Launch
Pre-submission
for Colorectal

SynchroSeal & E-100 Generator
Integrated Energy
for fast transection

Iris Augmented Reality
Pre-and intra-operative guidance by delivering 3D image of patient anatomy

Da Vinci hand-held camera
Enhanced visualization

Turning to new platforms, our team obtained 510(k) clearance and started both our multi-center clinical trial and our commercial efforts for Ion™, our flexible robotic lung biopsy program. With hundreds of procedures completed by our customers to date, early feedback is highly supportive. We are looking forward to the review and publication of clinical data on Ion's efficacy in the coming year compared with alternative approaches to lung biopsy. Launch of new platforms is complex, and we were disciplined in our launch in 2019 as we learn from our first installs and customer interactions.

Our single port da Vinci platform, da Vinci SP®, is now in use in more than 40 centers. Customer feedback has been supportive, with surgeons refining their technique and starting to publish their results. I look forward to assessing the impact of SP in the coming quarters. Overall, progress in SP has been slower than I'd like, a combination of changing data requirements by global regulators and some difficulties in robustness of our SP endoscope. Nevertheless, over the mid-to-long-term, I believe SP will improve outcomes and patient satisfaction in some procedures being performed with RAS today and is likely to open new procedure types to RAS in the future.

In the first quarter this year, we welcomed the team from Orpheus Medical to join our growing informatics efforts. Orpheus brings customer-friendly information and video routing capabilities to hospitals and complements our cloud connectivity and machine learning initiatives. We have been cloud connected to our customers for the past decade and our big data, cloud and telemedicine, machine learning and training technologies teams have had a strong year. We initiated our first phase launch for our Iris™ augmented reality imaging system in Q4 of 2019. This program uses cloud and machine learning technologies to create clinically meaningful models of pre-operative CT scans that surgeons can access before a case and real-time during surgery. Our Intuitive Telepresence team has established low latency connections to customers to allow real-time video and voice sharing during surgery, enabling easier access to surgeon-to-surgeon mentoring.

2020 Focus
As we enter 2020, we are focused on the following business objectives for the year. First, growth in general surgery, particularly in the United States. Second, deepening our skills and performance in key markets in Europe and Asia, in particular by building strength beyond urology. Third, advancing our product innovation in SP, Ion, advanced instruments, endoscopy, and informatics. Finally, continuing to expand clinical, economic and hospital-by-hospital validation in key procedures and countries.

Our business requires the contributions of a diverse and increasingly global workforce. From our founding, we have been the beneficiaries of the work of an outstanding team of highly capable people. At the end of 2019, we employed roughly 7,300 people residing in 27 countries. We are committed to serving our customers, enabling and cultivating our employees, and investing in the communities in which we live and work. This January, we published our first Corporate Sustainability Report, which can be found at https://isrg.gcs-web.com/investors.

Many of you have been investors in our company for years, and some of you are recipients of da Vinci surgery. Thank you for your continued support in this journey to improve surgery and acute intervention. I assure you that we are focused on delivering products and services that truly make a difference.

Gary Guthart, Ph.D.
Chief Executive Officer

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, 2019

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	**77-0416458**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

1020 Kifer Road
Sunnyvale, California 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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	ISRG	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 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	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates on June 30, 2019, based upon the closing price of Common Stock on such date as reported on The Nasdaq Global Select Market, was approximately $59.9 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 17, 2020, was 115,984,044.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference to the definitive proxy statement for the Company's Annual Meeting of Stockholders to be held on or about April 23, 2020, to be filed within 120 days of the registrant's fiscal year ended December 31, 2019.

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; our ability to integrate acquisitions; the results of any collaborations, in-licensing arrangements, joint ventures, strategic alliances, or partnerships, including the joint venture with Shanghai Fosun Pharmaceutical (Group) Co., Ltd.; our completion of and ability to successfully integrate the acquisition of Schölly Fiberoptic's robotic endoscope business; 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™, Ion™, IRIS®, and SynchroSeal™ 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. We believe that minimally invasive care is life-enhancing care. Intuitive brings more than two decades of leadership in robotic-assisted surgical technology and solutions to its offerings. 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 healthcare 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 per patient to treat disease. In the face of these challenges, we believe scientific, process, and technological advances in biology, computing, imaging, algorithms, and robotics offer the promise of new methods to solve old and difficult problems.

We address these needs by focusing on 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 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.

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. In 2019, our Ion endoluminal system was cleared by the FDA and enables minimally invasive biopsies in the lung. Our Ion system is a flexible, robotic-assisted, catheter-based platform that utilizes instruments and accessories, which extends our commercial offering beyond surgery into diagnostic procedures with this first application.

Our da Vinci Surgical 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 the 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 the 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 of 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 of 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 current systems (da Vinci X, da Vinci Xi, and da Vinci Si), a second surgeon's console may be used in two ways: to provide assistance to the primary surgeon during surgery or to act as an active aid during surgeon-proctor training sessions. With the da Vinci 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 the 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 system is a standard, integrated feature on the 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 Surgical 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 Systems and is 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 8mm and 12mm 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 four staplers available with the da Vinci X and Xi Surgical Systems: the EndoWrist Stapler 30 and 45 and the SureForm 45 and 60, where the numeric designation indicates the length of the staple line. The EndoWrist Stapler 45 is used in general, gynecologic, thoracic, and urologic surgery. The EndoWrist Stapler 30 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. The SureForm 45 is intended to deliver particular utility in thoracic procedures. We market five stapler reloads: gray (2.0 mm), white (2.5 mm), blue (3.5 mm), green (4.3 mm), and black (4.6 mm). Not all reloads are available for use on all staplers. Not all staplers or reloads are available in all countries.

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. The 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.

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.

Ion endoluminal system

Our Ion endoluminal system extends our commercial offerings beyond surgery into diagnostic procedures with its first application. The Ion system is our flexible, robotic-assisted, catheter-based platform designed to navigate through very small lung airways to reach peripheral nodules for biopsies. The Ion system uses an ultra-thin articulating robotic catheter that can move 180 degrees in all directions. The outer diameter of the catheter is 3.5mm, which allows physicians to navigate through small and tortuous airways to reach nodules in most airway segments within the lung. The Ion system's flexible biopsy needle can also pass through very tight bends via Ion's catheter to collect tissue in the peripheral lung. The catheter's 2mm working channel can also accommodate other biopsy tools, such as biopsy forceps or cytology brushes, if necessary.

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 and the care team's experience, and lower the 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 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 that da Vinci Surgery, which could potentially result in a local market share shift. Adoption of da Vinci procedures occurs procedure by procedure and market by market and is driven by the relative patient value and the total treatment costs of da Vinci procedures as compared to alternative treatment options for the same disease state or condition. We believe that 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 lengths 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 and minimally invasive biopsies with the Ion endoluminal 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 that 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, and da Vinci for transoral robotic surgery. We also focus on minimally invasive biopsies in the lung. 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 the 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.

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 it 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 that 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-assisted 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. Firefly technology can be used to visualize biliary anatomy in three dimensions beneath the tissue surfaces during 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 due to 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. Also, 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. Also, 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.

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.

Da Vinci Procedure Mix

Our da Vinci 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 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 and EndoWrist and SureForm Stapler products, and our Integrated Table Motion product, targets the more complex procedure segment. Our da Vinci X Surgical System is targeted towards price sensitive markets and procedures. Our da Vinci SP Surgical System complements the da Vinci Xi and X Surgical Systems by enabling surgeons to access narrow workspaces.

Clinical Summary

We believe that 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 a da Vinci Surgical System may bring value. As of December 31, 2019, we had an installed base of 5,582 da Vinci Surgical Systems, including 3,531 in the U.S., 977 in Europe, 780 in Asia, and 294 in the rest of the world. We estimate that surgeons using our technology completed approximately 1,229,000 surgical procedures of various types in hospitals throughout the world during the year ended December 31, 2019.

Additionally, we believe that there are numerous additional applications that can be addressed with the Ion endoluminal system. As of December 31, 2019, we had an installed base of 10 Ion endoluminal systems, all of which are located in the U.S.

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), China, Japan, South Korea, India, and Taiwan. In January 2019, our Intuitive-Fosun 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, and 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. In the remainder of our markets outside of the U.S. ("OUS"), we provide our products through distributors. No single customer accounted for more than 10% of revenue during the years ended December 31, 2019, 2018, and 2017. During the years ended December 31, 2019, 2018, and 2017, domestic revenue accounted for 70%, 71%, and 73%, respectively, of total revenue, while revenue from our OUS markets accounted for 30%, 29%, and 27%, respectively, of total revenue. As of December 31, 2019, and 2018, 85% 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 systems, and a clinical sales team, responsible for supporting system use in procedures performed at our hospital accounts. Our hospital accounts include both individual hospitals and healthcare facilities as well as hospitals and healthcare facilities that are part of an integrated delivery network ("IDN groups"). The initial system sale into an account is a major capital equipment purchase by our customers and typically has a lengthy sales cycle that can be affected by macroeconomic factors, capital spending prioritization, timing of budgeting cycles, and competitive bidding processes. Capital sales activities include educating surgeons or physicians and hospital staff across multiple specialties on the benefits of robotic-assisted surgery with a da Vinci Surgical System or robotic-assisted bronchoscopy with an Ion endoluminal 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 the clinical benefits of robotic-assisted surgery with a da Vinci Surgical System or robotic-assisted bronchoscopy with an Ion endoluminal system, potential reductions in complications and length of stay, and the resulting potential for increased patient satisfaction, surgeon or physician recruitment, and procedure volume.

Our clinical sales team works on site at hospitals, interacting with surgeons or physicians, operating room staff, and hospital administrators to develop and sustain successful robotic surgery or bronchoscopy programs. They assist the hospital in identifying surgeons or physicians who have an interest in robotic-assisted surgery or bronchosocpy and the potential benefits provided by the da Vinci Surgical System and the Ion endoluminal system. Our clinical sales team provides current clinical information on robotic-assisted surgery or bronchoscopy 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, the new installed base of Ion endoluminal 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 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 heavier in the fourth quarter and lighter in the first quarter, as hospital budgets are reset. In addition, we have historically experienced lower procedure volume in the first and third quarters and higher procedure volume in the second and fourth quarters. In the U.S., 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 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 systems 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 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 that we can expand the potential of physicians to heal without constraints. We employ engineering and research and development staff to focus on delivering future innovations and sustaining improvements that advance our mission. In certain instances, we complement our research and development effort through collaborations with other companies, such as Trumpf Medical (a division of Hill-Rom Holdings, Inc.).

Manufacturing

We manufacture our systems at our facilities in Sunnyvale, California and Durham, North Carolina. We manufacture our instruments at our Sunnyvale and Mexicali, Mexico facilities. In 2019, we acquired certain assets and operations from Schölly Fiberoptic GmbH, and we are integrating endoscope manufacturing operations across multiple sites in Germany and the U.S., which is expected to be completed around the end of 2020.

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 capabilities 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-assisted surgery or have made explicit statements about their efforts to enter the field, including, but not limited to, the following companies: Avatera Medical GmbH; CMR Surgical Limited; Johnson & Johnson (including their wholly-owned subsidiaries Auris Health, Inc. and Verb Surgical Inc.); Medicaroid 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, 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, 2019, we held ownership or exclusive field-of-use licenses for more than 3,500 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 that 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 Regulation

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 a 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, although 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.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FFDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. In May 2019, the FDA solicited public feedback on these proposals. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation.

More recently, in September 2019, the FDA finalized guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA intends to develop and maintain a list of device types appropriate for the "safety and performance based" pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible.

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

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

Our manufacturing processes are required to comply with the FDA's Good Manufacturing Practice ("GMP") requirements contained in its Quality System Regulation ("QSR") and associated regulations and guidance. The QSR covers, among other things, the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all medical devices intended for human use. The QSR also requires maintenance of extensive records, which demonstrate compliance with the 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 Form 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 of 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, secure reimbursement, or demonstrate other requirements. We cannot provide assurance that access to clinical investigators, sites, subjects, documentation, and data will be available on the terms and in the 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 with 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 the suspension of routine periodic inspections, there can be no assurance that the State of California will not resume such inspections or conduct such inspections under specific circumstances that 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 that are substantially longer than U.S. processes. Failure to obtain regulatory approval in a timely manner and meet all of the 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.

For example, most medical devices must undergo thorough safety examinations and demonstrate medical efficacy before they receive regulatory approval to be sold in Japan. We obtained approval from the Japanese Ministry of Health, Labor, and Welfare ("MHLW") for our da Vinci Si Surgical Systems in October 2012, for our da Vinci Xi Surgical Systems in March 2015, and for our da Vinci X Surgical Systems in April 2018. National reimbursement status in Japan was received for dVP procedures in 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, 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 12 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 procedures. 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 that 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 Systems 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 and provincial approvals, as well as 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. 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 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 that 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 that 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 (as described below), and teaching hospitals, and (ii) applicable manufacturers and group purchasing organizations to report annually to CMS ownership any investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners. Additionally, on October 25, 2018, President Trump signed into law the "Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act," which, in part (under a provision entitled "Fighting the Opioid Epidemic with Sunshine"), extends the reporting and transparency requirements for physicians in the Physician Payments Sunshine Act to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives (with reporting requirements going into effect in 2022 for payments made in 2021). 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 value 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 Systems have 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. Governmental and third-party payors may also consider additional factors when determining coverage and reimbursement, including the designation of the surgical procedure as a covered benefit, the appropriateness of the procedure for the specific patient, support by guidelines established by the relevant professional college or medical society, and a payor determination that the procedure is neither experimental nor investigational. 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. The U.S. Medical Device Excise Tax ("MDET") initially became effective on January 1, 2013. 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. In December 2015, the Consolidated Appropriations Act, 2016 (the "Appropriations Act") was signed into law. The Appropriations Act included a two-year moratorium on the MDET such that medical device sales in 2016 and 2017 were exempt from the excise tax. This moratorium was extended through December 31, 2019, by the Extension of Continuing Appropriations Act of 2018, signed into law on January 22, 2018. The MDET was repealed in December 2019.

The PPACA also appropriated funding to research the comparative effectiveness of healthcare 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 healthcare 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. Legislation to appropriate funds for CSR payments has been introduced in Congress, but the future of such legislation is uncertain. In addition, CMS has finalized regulations that are effective beginning with the 2020 plan year 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. As a result 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 was 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 pending appeals, 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 may 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, 2019, we had 7,326 employees, 999 of whom were engaged directly in research and development, 3,243 in manufacturing and service, and 3,084 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, 2019, 2018, and 2017 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 healthcare reform initiatives and the evolving U.S. healthcare 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 HAVE A MATERIAL ADVERSE EFFECT ON 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, has caused and may continue to cause disruptions in the financial credit markets, volatile currency exchange rates, concerns about inflation, slower economic activity, decreased consumer confidence, reduced corporate profits and capital spending, 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 manufacturing 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 replacement of the North American Free Trade Agreement ("NAFTA") contemplated by the pending United States-Mexico-Canada Agreement ("USMCA"), that 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 or 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-assisted, 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, the following companies: Avatera Medical GmbH; CMR Surgical Limited; Johnson & Johnson (including their wholly-owned subsidiaries

Auris Health, Inc. and Verb Surgical Inc.); Medicaroid 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-assisted 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 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. In the past, we have 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 the 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 the 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 da Vinci Surgical Systems. 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 heavier in the fourth quarter and lighter in the first quarter, as hospital budgets are reset.

We have experienced procedure growth for a number of benign conditions, including hysterectomies, sacrocolpopexies, hernia repairs, cholecystectomies, and certain other surgeries. Many of these types of surgeries may be postponed in the short term by patients to avoid vacation periods and for other personal scheduling reasons. Patients may also accelerate procedures to take advantage of insurance funding cut-off dates. Historically, we have experienced lower procedure volume in the first and third quarters of the year and higher procedure volume in the second and fourth quarters of the year. The 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 30%, 29%, and 27% of our revenue for the years ended December 31, 2019, 2018, and 2017, 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, including differing labor relations;
- the expense of establishing facilities and operations in new foreign markets;
- building and maintaining an organization capable of supporting geographically dispersed operations, including appropriate business procedures and controls;
- 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. On January 24, 2020, the UK and EU entered into a withdrawal agreement pursuant to which the UK will leave the EU on January 31, 2020, but will, for a transition period ending on December 31, 2020, maintain access to the EU single market and to the global trade deals negotiated by the EU on behalf of its members and remain subject to EU law. The ongoing uncertainty within the UK's government and Parliament on the status of Brexit has negatively impacted the UK's economy and will likely continue to have a negative impact until the UK and EU reach a definitive resolution on the outstanding trade and legal matters. Until the terms of the UK's exit from the EU are determined, including any transition period, it is difficult to predict its impact. Even if the UK maintains access to the EU single market and trade deals following the transition period, Brexit could result in further economic downturn globally. If the UK ultimately loses access to the EU single market and trade deals, significant market and economic disruption would likely occur, our business would likely be negatively impacted, and the demand for our products could be depressed. In addition, 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. We may face new regulations in the UK. Compliance with such regulations could be costly, negatively impacting our business, results of operations, and financial condition. Brexit could also adversely affect European and worldwide economic and market conditions and could contribute to instability in global financial and foreign exchange markets, including volatility in the value of the euro, British pound, and other currencies that Intuitive conducts business in.

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, renegotiating the terms of NAFTA, as contemplated by the USMCA, and imposing border taxes on imports into the U.S. On November 30, 2018, the leaders of the U.S., Mexico, and Canada signed the USMCA, a replacement to NAFTA, which remains subject to the ratification by the legislatures of each country. We manufacture a majority of the instruments that 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 cases.

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 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 8 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, 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. In addition, to the extent that there is a shift from an inpatient setting to outpatient settings, we may experience pricing pressure and a reduction in the number of procedures performed. Our success in OUS markets also depends upon the eligibility of our products for coverage and reimbursement through government-sponsored healthcare 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, healthcare 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 has experienced both severe earthquakes and other natural disasters in the past. 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 epidemic, pandemic, or contagious diseases, such as the recent novel coronavirus or, historically, 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 or disrupt our business. Business disruptions could include disruptions or restrictions on our ability to travel or to distribute our products, as well as temporary closures of our facilities or the facilities of our suppliers and their contract manufacturers, and a reduction in the business hours of hospitals. Any disruption of our suppliers and their contract manufacturers or our customers would likely impact our sales and operating results. In addition, a significant outbreak of epidemic, pandemic, or contagious diseases in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our products. Any of these events 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, WHICH 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 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 that the expected benefits will be 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 that 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.

There can be no assurance that we will realize a return on our strategic investments. Further, if we acquire privately held companies, valuations of such companies are inherently complex due to the lack of readily available market data. If we determined that our investments in privately held companies have experienced a decline in value, we may be required to record impairments, which could be material and have an adverse effect on our results of operations.

The alliances may involve significant expense and divert the focus and 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, 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. In 2019, we acquired certain assets and operations from Schölly Fiberoptic GmbH, a supplier of endoscopes and other visualization equipment. The integration of this acquisition involves complex manufacturing and repair operations across different geographic locations. Therefore, we cannot assure you that we can successfully integrate this acquisition or manufacture robotic endoscopes after the acquisition. Failure to successfully integrate our acquisitions may have a material adverse impact on our business, financial condition, results of operations, or cash flows.

CONTINUED CONSOLIDATION IN THE HEALTHCARE INDUSTRY COULD HAVE AN ADVERSE EFFECT ON OUR SALES AND RESULTS OF OPERATIONS.

The healthcare industry has been consolidating, and organizations continue to consolidate purchasing decisions for many of our healthcare provider customers. Numerous initiatives and reforms by legislators, regulators, and third-party payers to curb the rising cost of healthcare have catalyzed a consolidation of aggregate purchasing power within the markets in which we sell our products. As the healthcare industry consolidates, competition to provide products and services is expected to continue to intensify, resulting in pricing pressures and decreased average selling prices. We expect that market demand, government regulation, third-party coverage and reimbursement policies, government contracting requirements, and societal pressures will continue to change the worldwide healthcare industry, resulting in further consolidation, which may exert further downward pressure on prices of our products and services and 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 DETERMINING OUR FINANCIAL RESULTS AND IN MEASURING THE PROGRESS OF OUR BUSINESS. AS THESE ESTIMATES, JUDGMENTS, AND METHODS CHANGE, OUR RESULTS OF OPERATIONS AND OUR ASSESSMENT OF THE PROGRESS OF OUR BUSINESS COULD VARY.

The methods, estimates, and judgments we use in applying our accounting policies have a significant impact on our results of operations. Such methods, estimates, and judgments are, by their nature, subject to substantial risks, uncertainties, and assumptions, and factors may arise over time that 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, which could adversely impact our business and reputation. 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. It is possible for such vulnerabilities to remain undetected for an extended period, including several years or longer. The costs to us to eliminate or alleviate network security problems, bugs, viruses, worms, ransomware and other 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 different types of personal data and personal information ("Personal Information") and other 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, the General Data Protection Regulation (the "GDPR"), which is in effect across the European Economic Area (the "EEA"), imposes several stringent requirements for controllers and processors of personal data and increased our obligations, 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 to increase and harm our business and financial condition. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EU member states may result in fines of up to 4% of the total worldwide annual turnover of the preceding financial year and other administrative penalties. Compliance with the new data protection rules imposed by GDPR may be onerous and adversely affect our business, financial condition, and results of operations.

California recently passed the California Consumer Privacy Act (the “CCPA”), which is considered by many to be the most far-reaching data privacy law introduced in the US to date and which introduces new compliance burdens on many organizations doing business in California who collect Personal Information about California residents. The CCPA’s definition of Personal Information is very broad and specifically includes biometric information. The CCPA took effect in 2020 and will allow for significant fines by the state attorney general, as well as a private right of action from individuals in relation to certain security breaches. The enactment of the CCPA is prompting a wave of similar legislative developments in other US states and creating the potential for a patchwork of overlapping but different state laws. These developments are increasing our compliance burden and our risk, including risks of regulatory fines, litigation and associated reputational harm.

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 current 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 U.S. 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 Personal Information from Europe to the U.S. is invalidated, or if we are unable to transfer Personal Information 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 Personal Information 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 Personal Information processing to within individual countries could increase our operating costs significantly.

CHANGES IN FUNDING FOR THE FDA OR OTHER GOVERNMENT AGENCIES, INCLUDING 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, or approvals or could 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, the ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Disruptions at the FDA and other agencies, including 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. Although there were some exceptions to the excise tax, this excise tax applied to most of our products sold within the U.S. In December 2015, the Consolidated Appropriations Act, 2016 (the "Appropriations Act") was signed into law. The Appropriations Act included a two-year moratorium on the MDET such that medical device sales in 2016 and 2017 were exempt from the excise tax. This moratorium was extended through December 31, 2019, by the Extension of Continuing Appropriations Act of 2018, signed into law on January 22, 2018. The MDET was repealed in December 2019.

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. Legislation to appropriate funds for CSR payments has been introduced in Congress, but the future of such legislation is uncertain. In addition, CMS has finalized regulations that are effective beginning with the 2020 plan year 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 was 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. 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 pending appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

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 may 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 include 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 that began in 2019, which 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 healthcare 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 to, 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 what 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 that 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 that 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 that 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 that can affect our ability to obtain the manufactured materials that 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, 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 healthcare 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 that 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. Additionally, on October 25, 2018, President Trump signed into law the "Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act" which in part (under a provision entitled "Fighting the Opioid Epidemic with Sunshine") extends the reporting and transparency requirements for physicians in the Physician Payments Sunshine Act to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives (with reporting requirements going into effect in 2022 for payments made in 2021). Failure to submit required information may result in civil monetary penalties of up to an aggregate of $173,436 per year (and up to an aggregate of $1.156 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 with 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. 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 upon 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, lawsuits, and government investigations involving labor and employment. Such claims, lawsuits, 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 SELL 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, either 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 us 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 that 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, revise existing regulations, or take other actions that 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. Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FFDCA. Among other things, the FDA announced that it plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals include plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. In May 2019, the FDA solicited public feedback on these proposals. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

More recently, in September 2019, the FDA finalized guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA intends to develop and maintain a list device types appropriate for the "safety and performance based" pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

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 the 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 that we intend to market in the U.S. in the future. If we do 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 require that manufacturers keep detailed records of investigations or complaints against their devices and 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 the same; and
- the reporting of Corrections and Removals, which requires that manufacturers report to the FDA recalls and field corrective actions taken to reduce a risk to health or to remedy a violation of the FFDCA that may pose a risk to health.

We are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. If the FDA finds that we have failed to comply, it can institute a wide variety of enforcement actions, ranging from inspectional observations (Form FDA 483) to a public Warning Letter to more severe civil and criminal sanctions, including the seizure of our products and equipment or ban on the import or export of our products. The FDA has, in the past, issued and could, in the future, issue Warning Letters or other communications to us. If we fail to satisfy or remediate the matters discussed in any such Warning Letters or communications, the FDA could take further enforcement action, including prohibiting the sale or marketing of the affected product. Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations. The receipt of a Warning Letter places certain limits on the ability to obtain FDA-issued Certificates to Foreign Government ("CFGs") used for new and re-registration of products in certain foreign countries.

The FDA also strictly regulates labeling, advertising, promotion, and other activities relating to the marketing of our products. Medical devices may be promoted only for their cleared or approved indications and in accordance with the provisions of the cleared or approved label. It is possible that federal or state enforcement authorities might take action if they

consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under a variety of statutory authorities, including under the FFDCA as well as laws prohibiting false claims for reimbursement.

In addition, any modification or change of medical devices cleared for market requires the manufacturer to make a determination whether the change is significant enough to require new 510(k) clearance. We have created labeling, advertising, and user training for the da Vinci Surgical System to describe specific surgical procedures that we believe are fully within the scope of our existing 510(k) indications for use stated in our 510(k) clearances. Although we have relied on expert in-house and external staff, consultants, and advisors, some of whom were formerly employed by the FDA and are familiar with the 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 with Mexican authorities. The facility is operated under U.S. and international quality system regulations, including those applicable to Canada, the EU, 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 SELL OUR PRODUCTS IN FOREIGN COUNTRIES.

To be able to sell 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 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 that 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 that 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 that 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 EU 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. Further, Switzerland, which is the country from which we import our products into the EU and where our EU regulatory team is based, has not yet entered into a Mutual Recognition Agreement with the EU that covers the Medical Device Regulation and allows medical devices to move freely between Switzerland and the EU. Therefore, we may be required to adjust the manner in which we bring our products into the EU market. Any such adjustments could cause temporary disruptions in and have adverse financial implications to our business in Europe.

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 procedures. 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 U.S., 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 the 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 to 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 that 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 to 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 significant 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 COMMERCIALLY 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 2017, it reached a high of $403.70 and a low of $209.83; during fiscal 2018, it reached a high of $574.74 and a low of $375.25; and during fiscal 2019, it reached a high of $598.81 and a low of $450.24. 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, 2019, we own approximately 1.0 million square feet of space on 95 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 750,000 square feet for certain engineering, warehousing, and support functions 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 Germany, we own and lease facilities for manufacturing operations, as we integrate and build out operations of our acquisition of certain assets and operations from Schölly Fiberoptic GmbH. In addition, we lease various international facilities for sales and other operations.

ITEM 3. LEGAL PROCEEDINGS

The information included in Note 8 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 17, 2020, there were 188 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, 2019, 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 [2]	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	4,802,150	$ 253.85	7,298,684
Equity compensation plans not approved by security holders [1]	551,413	$ 183.85	—
Total	5,353,563	$ 246.64	7,298,684

(1) Represents options under the Amended and Restated 2009 Employment Commencement Incentive Plan, adopted by the Board in October 2009 and first used in 2010. Options are granted at an exercise price not less than the fair market value of the stock on the date of grant and have a term not to exceed ten years. This plan expired in October 2019 and, therefore, there are no shares reserved for future issuance. However, awards granted prior to the plan's expiration continue to remain outstanding until their original expiration date.

(2) The weighted-average exercise price is calculated based solely on the exercise prices of the outstanding options and does not reflect the shares that will be issued upon the vesting of outstanding awards of RSUs, which have no exercise price.

Material Features of the Amended and Restated 2009 Employment Commencement Incentive Plan

In October 2009, the Board adopted our Amended and Restated 2009 Employment Commencement Incentive Plan, or the 2009 Plan, pursuant to Rule 5653(c)(4) of the Nasdaq Global Market, which was subsequently amended by the Board in February 2011, July 2011, February 2012, July 2012, January 2013, May 2013, December 2013, and April 2015.

Awards granted under the 2009 Plan were intended to constitute "employment inducement awards" under Nasdaq Listing Rule 5635(c)(4) and, therefore, the 2009 Plan was intended to be exempt from the Nasdaq Listing Rules regarding stockholder approval of stock option and stock purchase plans. A total of 4,365,000 shares of our common stock were reserved for issuance under the 2009 Plan. The 2009 Plan provided for the grant of non-qualified stock options, restricted stock units, restricted stock awards, dividend equivalents, or stock appreciation rights. These awards may have been granted to individuals who were then new employees, or were commencing employment with us or one of our subsidiaries following a bona fide period of non-employment with us, and for whom such awards were granted as a material inducement to commencing employment with us or one of our subsidiaries. This plan expired in October 2019 and, therefore, there are no shares reserved for future issuance. However, awards granted prior to the plan's expiration continue to remain outstanding until their original expiration date.

The 2009 Plan is administered by the Compensation Committee or another committee of the Board. The plan administrator has broad discretion to take action under the 2009 Plan, as well as make adjustments to the terms and conditions of existing awards, in the event of certain transactions and events affecting our common stock, including a change in control, stock dividends, stock splits, mergers, acquisitions, consolidations, and other corporate transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders known as "equity restructurings," the plan administrator will make equitable adjustments to the 2009 Plan and outstanding awards.

The Board may amend, suspend, or terminate the 2009 Plan at any time, provided that no such action may impair any rights under any outstanding awards without the consent of the participant.

RECENT SALES OF UNREGISTERED SECURITIES

None.

ISSUER PURCHASES OF EQUITY SECURITIES

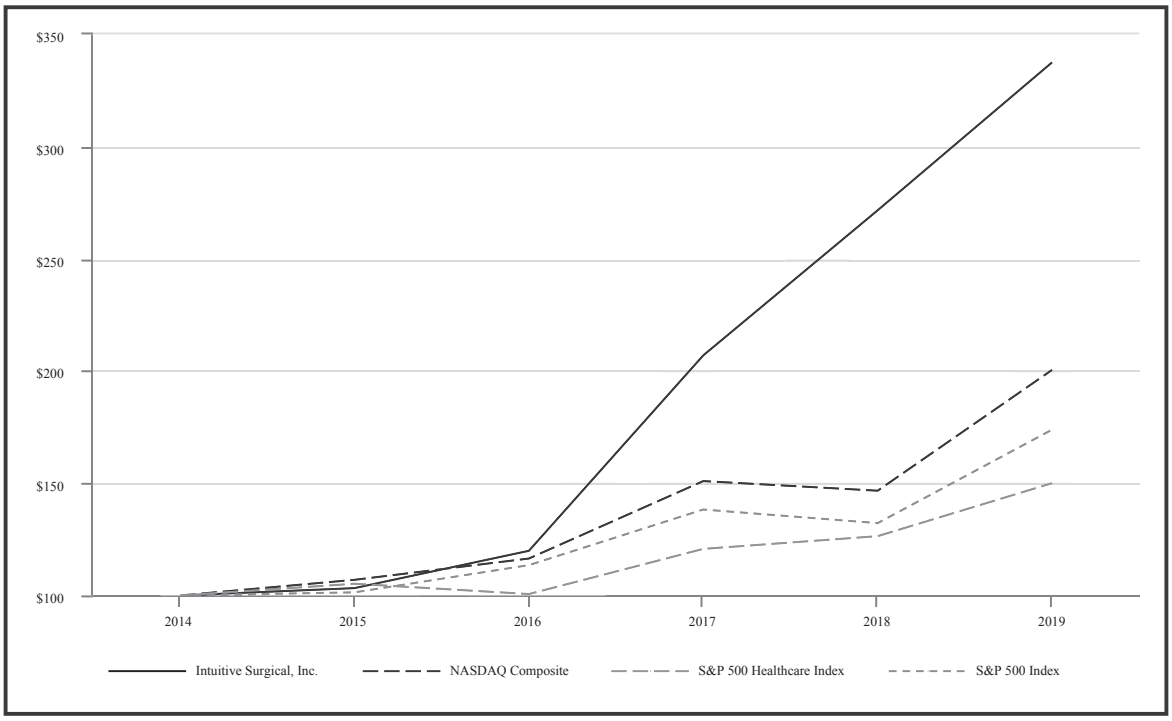
Since March 2009, we have had an active stock repurchase program. As of December 31, 2019, our Board of Directors (the "Board") has authorized an aggregate amount of up to $7.5 billion for stock repurchases, of which the most recent authorization occurred in January 2019 when the Board increased the authorized amount available under our share repurchase program to $2.0 billion. The remaining amount available to repurchase shares under the authorized repurchase program was $1.7 billion as of December 31, 2019. The authorized stock repurchase program does not have an expiration date. During the quarter ended December 31, 2019, we did not purchase any of our securities in the open market.

STOCK PERFORMANCE GRAPH

The graph set forth below compares the cumulative total stockholder return on our common stock between December 31, 2014, and December 31, 2019, with the cumulative total return of (i) the Nasdaq Composite Index, (ii) the S&P 500 Healthcare Index, and (iii) the S&P 500 Index over the same period. This graph assumes an investment of $100.00 on December 31, 2014 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 HEALTHCARE INDEX, AND S&P 500 INDEX



	December 31,					
	2014	2015	2016	2017	2018	2019
Intuitive Surgical, Inc.	$ 100.00	$ 103.26	$ 119.89	$ 206.98	$ 271.63	$ 337.55
Nasdaq Composite	$ 100.00	$ 106.96	$ 116.45	$ 150.96	$ 146.67	$ 200.49
S&P 500 Healthcare Index	$ 100.00	$ 105.21	$ 100.62	$ 120.75	$ 126.42	$ 150.03
S&P 500 Index	$ 100.00	$ 101.38	$ 113.51	$ 138.29	$ 132.23	$ 173.86

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				
	2019	2018	2017 (2)	2016	2015 (1)
	(In millions, except per share amounts and headcount)				
Revenue	$ 4,478.5	$ 3,724.2	$ 3,138.2	$ 2,706.5	$ 2,384.4
Gross profit	$ 3,110.2	$ 2,604.1	$ 2,202.0	$ 1,892.9	$ 1,577.9
Net income attributable to Intuitive Surgical, Inc.	$ 1,379.3	$ 1,127.9	$ 670.9	$ 738.3	$ 588.8
Net income per share attributable to Intuitive Surgical, Inc.:					
Basic	$ 11.95	$ 9.92	$ 6.01	$ 6.43	$ 5.29
Diluted	$ 11.54	$ 9.49	$ 5.77	$ 6.26	$ 5.18
Shares used in computing basic and diluted net income per share:					
Basic	115.4	113.7	111.7	114.9	111.3
Diluted	119.5	118.8	116.3	117.9	113.7
Cash, cash equivalents, and investments	$ 5,845.2	$ 4,834.4	$ 3,846.5	$ 4,837.9	$ 3,347.8
Total assets	$ 9,733.2	$ 7,846.7	$ 5,776.8	$ 6,521.4	$ 4,907.3
Other long-term liabilities	$ 418.3	$ 338.6	$ 333.6	$ 112.1	$ 95.9
Stockholders' equity	$ 8,284.7	$ 6,687.5	$ 4,780.4	$ 5,820.1	$ 4,319.5
Total headcount	7,326	5,527	4,444	3,755	3,211

(1) Does not reflect the impact of the adoption of ASC Topic 606, *Revenue from Contracts with Customers*, effective January 1, 2018, using the full retrospective method, which restated fiscal years 2017 and 2016.

(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 da Vinci products fall into five broad categories: da Vinci Surgical Systems, da Vinci instruments and accessories, 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 approach offering 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 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, commercialized in the third quarter of 2018. We are early in the launch of our da Vinci SP Surgical System, and we have placed 29 da Vinci SP Surgical Systems in 2019 and have an installed base of 44 as of December 31, 2019. Our plans for the rollout of the da Vinci SP Surgical System include putting systems in the hands of experienced da Vinci users first while we optimize training pathways and our supply chain. We received FDA clearances for the da Vinci SP Surgical System for urological and certain transoral procedures. We also received clearance in South Korea where the da Vinci SP Surgical System may be used for a broad set of procedures. We plan to seek FDA clearances for additional indications for da Vinci SP over time. The success of the da Vinci SP Surgical System is dependent on positive experiences and improved clinical outcomes for the procedures for which it has been cleared 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 with 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 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 share the same instruments whereas the da Vinci Si Surgical System uses instruments that are not compatible with X or Xi systems. We currently offer nine core instruments on our da Vinci SP Surgical System. We plan to expand the SP instrument offering over time.

Training technologies include our Intuitive Simulation products, our Intuitive Telepresence remote case observation and telementoring tools, and our dual console for use in surgeon proctoring and collaborative surgery.

During the first quarter of 2019, the FDA cleared our Ion endoluminal system to enable minimally invasive biopsies in the lung. Our Ion system extends our commercial offering beyond surgery into diagnostic procedures with this first application. We are introducing the Ion system in the U.S. in a measured fashion while we optimize training pathways and our supply chain and collect additional clinical data. We are early in the launch and have placed 10 Ion systems for commercial use through December 31, 2019, which are not included in our da Vinci Surgical System installed base. We have also placed 6 Ion systems with hospitals for gathering clinical data.

The success of new product introductions depends on a number of factors including, but not limited to, 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.

Business Model

Overview

We generate revenue from the placements of da Vinci Surgical Systems, in sales or sales-type lease arrangements where revenue is recognized up-front or in operating lease transactions and usage-based models where revenue is recognized over time. We earn recurring revenue from the sales of instruments, accessories, and services, as well as the revenue from operating leases. The da Vinci Surgical System generally sells for 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 generally earn between $700 and $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 or leased at an annual fee between $80,000 and $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 generate revenue from the placements of the Ion endoluminal system in a business model consistent with the da Vinci Surgical System model described above. We generate revenue from the placement of Ion systems, and we earn recurring revenue from the sales of instruments and accessories used in biopsies and ongoing system service. We are introducing the Ion system in the U.S. in a measured fashion. For the year ended December 31, 2019, the associated impact to revenue and gross margin was not significant.

Recurring Revenue

Recurring revenue consists of instrument and accessory revenue, service revenue, and operating lease revenue. Recurring revenue increased to $3.2 billion, or 72% of total revenue in 2019, compared with $2.6 billion, or 71% of total revenue in 2018, and $2.2 billion, or 71% of total revenue in 2017.

Instrument and accessory revenue has grown at a faster rate than systems revenue over time. Instrument and accessory revenue increased to $2.4 billion in 2019, compared with $2.0 billion in 2018 and $1.6 billion in 2017. 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 12% to approximately 5,582 at December 31, 2019; 13% to approximately 4,986 at December 31, 2018; and 13% to approximately 4,409 at December 31, 2017. Service revenue increased to $724 million in 2019, compared with $635 million in 2018 and $573 million in 2017.

Intuitive 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 systems and expand their robotic-assisted programs while leveraging our balance sheet. These leases generally have commercially competitive terms as compared with other third-party entities that offer equipment leasing. We have also entered into usage-based arrangements with larger customers that have committed da Vinci programs where we charge for the system and service as the systems are utilized. We include operating and sales-type leases, and systems placed under usage-based arrangements, in our system shipment and installed base disclosures. We exclude operating lease-related revenue, usage-based revenue, and Ion system revenue from our da Vinci Surgical System average selling price ("ASP") computations.

In the years ended December 31, 2019, 2018, and 2017, we shipped 425, 272, and 139 systems, respectively, under lease and usage-based arrangements, of which 384, 229, and 108 systems, respectively, were operating lease and usage-based arrangements. Revenue from operating lease arrangements is generally recognized on a straight-line basis over the lease term. More recently, we have entered into usage-based arrangements with certain large customers whereby system and service revenue is recognized as the systems are used. We set operating lease and usage-based pricing at a modest premium relative to purchased systems reflecting the time value of money and, in the case of usage-based arrangements, the risk that system utilization may fall short of anticipated levels. The proportion of revenue recognized from usage-based arrangements has not been significant and has been included in our operating lease metrics herein. Operating lease revenue has grown at a faster rate than overall systems revenue and was $106.9 million, $51.4 million, and $25.9 million for the years ended December 31, 2019, 2018, and 2017, respectively. Generally, lease transactions generate similar gross margins as our sale transactions. As of December 31, 2019, a total of 658 da Vinci Surgical Systems were installed at customers under operating lease or usage-based arrangements.

Our system leasing and usage-based models provide customers with flexibility regarding how they acquire or obtain access to our systems. We believe that these alternative financing structures have been effective and well-received, and we are willing to expand the proportion of these structures based on customer demand. As revenue for operating leases and usage-based

systems is recognized over time, total systems revenue growth is reduced in a period when the number of operating lease and usage-based placements increases as a proportion of total system placements.

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 payments; therefore, customers may exit such arrangements without paying a financial penalty to us.

For some operating lease arrangements, our customers are provided with the right to purchase the leased system at certain points during and/or at the end of the lease term. Revenue generated from customer purchases of systems under operating lease arrangements ("Lease Buyouts") was $92.8 million, $48.8 million, and $39.5 million for the years ended December 31, 2019, 2018, and 2017, 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.

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 customer budgets are reset. Systems revenue grew 19% to $1,346 million in 2019; 21% to $1,127 million in 2018; and 16% to $928 million in 2017. Systems revenue is also affected by the proportion of system placements under operating lease and usage-based arrangements, recurring operating lease and usage-based revenue, operating lease buyouts, product mix, ASPs, trade-in activities, and customer mix.

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 and EndoWrist Stapler products, and our Integrated Table Motion product targets the more complex procedure segment. Our da Vinci X Surgical System is targeted towards price sensitive markets and procedures. Our da Vinci SP Surgical System complements the da Vinci Xi and X Surgical Systems by enabling surgeons to access narrow workspaces.

Procedure Seasonality

More than half of da Vinci procedures performed are for benign conditions, most notably hernia repairs, hysterectomies, 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, and most Eastern European countries), China, Japan, South Korea, India, and Taiwan. In May and December 2018, we began direct operations in India and Taiwan, respectively. In January 2019, our Intuitive-Fosun joint venture began direct sales for da Vinci products and services in China. In the remainder of our OUS markets, we provide our products through distributors.

Regulatory Activities

Overview

Our products must meet the requirements of a large and growing body of international standards that govern the product safety, efficacy, advertising, labeling, safety reporting design, manufacture, materials content and sourcing, testing, certification, packaging, installation, use, and disposal of our products. Examples of such standards include electrical safety standards, such as those of the International Electrotechnical Commission, and composition standards, such as the Reduction of Hazardous Substances and the Waste Electrical and Electronic Equipment Directives. Failure to meet these standards could limit our ability to market our products in those regions that require compliance to such standards.

Our products and operations are also subject to increasingly stringent medical device, privacy, and other regulations by regional, federal, state, and local authorities. We anticipate that timelines for the introduction of new products and/or indications may be extended relative to past experience as a result of these regulations.

Clearances and Approvals

We have generally obtained the clearances required to market our products associated with our da Vinci Surgical Multiport Systems (Standard, S, Si, Xi, and X systems) for our targeted surgical specialties within the U.S., South Korea, Japan, and the European markets in which we operate. Between 2017 and 2019, we obtained regulatory clearances for the following products:

- In November 2019, we obtained FDA clearance for our SynchroSeal instrument and E-100 generator.
- In July 2019, we obtained FDA clearance for our SureForm 45 Curved-Tip stapler and SureForm 45 Gray reload, which round out our SureForm 45 portfolio.
- In June 2019, we received CE mark clearance for our da Vinci Endoscope Plus for the da Vinci X/Xi Surgical Systems in Europe. Following the CE mark, in July 2019, we obtained FDA clearance for our da Vinci Endoscope Plus.
- In June 2019, we obtained FDA clearance for our da Vinci Handheld Camera.
- In February 2019, we obtained FDA clearance for our 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. We are introducing the Ion endoluminal system in a measured fashion while we optimize training pathways and our supply chain and collect additional clinical data. We have placed 10 Ion systems for commercial use through December 31, 2019.
- In February 2019, we obtained FDA clearance for our IRIS augmented reality product. IRIS is a service that delivers a 3D image of the patient anatomy (initially targeting kidneys) to aid surgeons in both pre- and intra-operative settings. We are in the early stages of an IRIS pilot study in the field at a small group of U.S. hospitals to gain initial product experience and insights.
- In December 2018, we received regulatory clearance for our da Vinci Xi Surgical System in China. The Xi clearance does not include advanced energy or stapling products that attach to the Xi system. Separate clearances are required for each of these products by China National Medical Products Administration ("NMPA").
- 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. As of December 31, 2019, we have sold 57 da Vinci Surgical Systems under this quota. Future 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 obtained FDA clearance to market SureForm 60, our da Vinci EndoWrist 60mm Stapler. In January 2019, we obtained FDA clearance to market SureForm 45. We have also received regulatory clearance in South Korea and Japan to market SureForm 60 and SureForm 45 and 60.
- In May 2018, we obtained FDA clearance for the da Vinci SP Surgical System for urologic surgical procedures that are appropriate for a single port approach. In March 2019, we obtained FDA clearance for the da Vinci SP Surgical System for certain transoral procedures. We also received regulatory clearance for the da Vinci SP Surgical System in South Korea in May 2018. We continue to introduce the da Vinci SP Surgical System in a measured fashion while we optimize training pathways and our supply chain. We have placed 29 da Vinci SP Surgical Systems in 2019 and have an installed base of 44 as of December 31, 2019.
- In April 2018, we obtained FDA clearance for our da Vinci Vessel Sealer Extend.
- 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 obtained 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. Regulatory clearances for the da Vinci X Surgical System may be received in other markets over time.

Refer to the descriptions of our products that received regulatory clearances in 2019 and 2018 in the New Product Introductions section below.

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. Most prostatectomies and partial nephrectomies were open procedures prior to da Vinci reimbursement. Da Vinci procedure reimbursement for dVP and partial nephrectomy procedures are higher than open procedure reimbursements. 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 12 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 procedures. 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.

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

Worldwide Procedures

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 da Vinci prostatectomy ("dVP") and da Vinci 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 2019, approximately 1,229,000 surgical procedures were performed with da Vinci Surgical Systems, compared with approximately 1,038,000 and 877,000 surgical procedures performed with da Vinci Surgical Systems in 2018 and 2017, respectively. The growth in our overall procedure volume in 2019 was driven by growth in U.S. general surgery procedures and worldwide urology procedures.

U.S. Procedures

Overall U.S. procedure volume with da Vinci Surgical Systems grew to approximately 883,000 in 2019, compared with approximately 753,000 in 2018 and approximately 644,000 in 2017. General surgery was our largest and fastest growing U.S. specialty in 2019 with procedure volume that grew to approximately 421,000 in 2019, compared with approximately 325,000 in 2018 and approximately 246,000 in 2017. Gynecology was our second largest U.S. surgical specialty in 2019 with procedure volume that grew to approximately 282,000 in 2019, compared with approximately 265,000 in 2018 and approximately 252,000 in 2017. Urology was our third largest U.S. surgical specialty in 2019 with procedure volume that grew to approximately 138,000 in 2019, compared with approximately 128,000 in 2018 and approximately 118,000 in 2017.

Procedures Outside of the U.S.

Overall OUS procedure volume with da Vinci Surgical Systems grew to approximately 346,000 in 2019, compared with approximately 285,000 in 2018 and approximately 233,000 in 2017. Procedure growth in most OUS markets was driven largely by urology procedure volume, which grew to approximately 206,000 in 2019, compared with approximately 175,000 in 2018 and approximately 149,000 in 2017. General surgery and gynecology procedures also contributed to OUS procedure growth.

Recent Business Events and Trends

Procedures

Overall. Total da Vinci procedures grew approximately 18% for the year ended December 31, 2019, compared with approximately 18% for the year ended December 31, 2018. U.S. procedure growth was approximately 17% for the year ended December 31, 2019, compared with approximately 17% for the year ended December 31, 2018. 2019 U.S. procedure growth was largely attributable to growth in general surgery procedures, most notably hernia repair, cholecystectomy, colorectal, and bariatric procedures. U.S. procedure growth was also driven by growth in thoracic procedures, as well as moderate growth in more mature urologic and gynecologic procedure categories.

Procedure volume OUS grew approximately 21% for the year ended December 31, 2019, compared with approximately 22% for the year ended December 31, 2018. 2019 OUS procedure growth was driven by continued growth in urologic procedures, including prostatectomies and nephrectomies, and earlier stage growth in general surgery (particularly colorectal), gynecologic, and thoracic 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.

U.S. General Surgery. In 2019, general surgery was our largest and fastest growing specialty in the U.S. with procedure volume that grew to approximately 421,000 in 2019, compared with approximately 325,000 in 2018 and approximately 246,000 in 2017. Inguinal and ventral hernia repairs contributed the most incremental procedures in 2019, as they did 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 surgical complexity associated with treatment of various hernia patient populations and varying surgeon opinion regarding optimal surgical technique, it is difficult to estimate the timing of and to what extent da Vinci hernia repair procedure volume will grow in the future. We expect a large portion of hernia repairs will continue to be performed via different modalities of surgery.

Adoption of da Vinci for colorectal procedures, which includes several underlying procedures including low anterior resections for rectal cancers and certain colon procedures for benign and cancerous conditions, has been ongoing for several years and is supported by our recently launched technologies, such as the EndoWrist Staplers and energy devices and Integrated Table Motion.

During 2019, we have seen increasing contributions to growth from other U.S. general surgery procedures, including cholecystectomy and bariatric procedures. Given the already very high level of laparoscopic techniques used in cholecystectomy, it is unclear whether growth is sustainable and to what extent da Vinci cholecystectomy may be adopted. Our third quarter 2018 introduction of the SureForm 60mm stapler product provides surgeons a better optimized robotic tool set for bariatric procedures.

U.S. Gynecology. In 2019, growth in gynecology procedures in the U.S. increased modestly compared to 2018. Procedure volume was approximately 282,000 in 2019, compared with approximately 265,000 in 2018 and approximately 252,000 in 2017, driven by growth in benign hysterectomy procedures and, to a lesser extent, growth in hysterectomy for cancer. Combining robotic, laparoscopic, and vaginal approaches, MIS represents about 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 have also been a strong contributor to our overall procedure growth. In the U.S., dVP is the standard of care for the surgical treatment of prostate cancer, and we believe growth is largely aligned with surgical volumes of prostate cancer. 2019 growth in U.S. dVP procedures was consistent with growth in 2018. For OUS, dVP is at varying states of adoption in different areas of the world but is the largest overall da Vinci procedure. 2019 growth in OUS dVP procedures was consistent with growth in 2018.

Kidney cancer procedures have also been a strong contributor to our recent global urology procedure growth. Clinical publications have demonstrated that the use of a da Vinci system increases the likelihood that a patient will receive nephron sparing surgery through a partial nephrectomy, which is typically the surgical society guideline recommended therapy.

OUS Procedures. The 2019 OUS procedure growth rate reflects continued da Vinci adoption in European and Asian markets. In 2018 and the first quarter of 2019, procedure growth in China moderated, as the previous systems quota expired at the end of 2015 and the systems installed in China are highly utilized. 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 da Vinci 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 provincial allocation processes and hospitals completing a tender process and receiving associated approvals. In the last three quarters of 2019, procedure growth in China accelerated, as initial systems placed during these quarters provided additional capacity in the field. In Japan, we experienced strong procedure growth after receiving the national reimbursements for dVP and partial nephrectomy in 2012 and 2016, respectively. However, as adoption for these procedures has progressed towards higher levels of penetration, growth in these two urologic procedures has moderated. A total of 12 additional da Vinci procedures were granted national reimbursement status effective April 1, 2018, including gastrectomy, low anterior resection, lobectomy, and hysterectomy, for both malignant and benign conditions. Procedure growth in Japan has accelerated since the new procedures were granted reimbursement status. However, these additional 12 reimbursed procedures have varying levels of conventional laparoscopic penetration and are 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 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 healthcare 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, the following companies: Avatera Medical GmbH; CMR Surgical Limited; Johnson & Johnson (including their wholly-owned subsidiaries Auris Health, Inc. and Verb Surgical Inc.); Medicaroid 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.

Many of the above factors will also impact future demand for our recently cleared Ion system, as we extend our commercial offering into diagnostics, along with additional factors associated with a new product introduction, including, but not limited to, our ability to optimize manufacturing and our supply chain, competition, clinical data to demonstrate value, and market acceptance.

New Product Introductions

SynchroSeal and E-100 Generator. In November 2019, we obtained FDA clearance for our SynchroSeal instrument and E-100 generator. SynchroSeal is a single-use, bipolar, electrosurgical instrument intended for grasping, dissection, sealing, and transection of tissue. With its wristed articulation, rapid sealing cycle, and refined curved jaw, SynchroSeal offers enhanced

versatility to the da Vinci Energy portfolio. The E-100 generator is an electrosurgical generator developed to power two key instruments – Vessel Sealer Extend and SynchroSeal – on the da Vinci X and Xi Surgical Systems. The generator delivers high frequency energy for cutting, coagulation, and vessel sealing of tissues.

SureForm 45 Curved-Tip and Gray Reload. In July 2019, we obtained FDA clearance for the SureForm 45 Curved-Tip stapler and SureForm 45 Gray reload. SureForm 45 Curved-Tip is a single-use, fully wristed stapling instrument with a curved tip intended for resection, transection, and/or creation of anastomoses. SureForm 45 Gray reload is a new, single-use cartridge that contains multiple staggered rows of implantable staples and a stainless steel knife. The SureForm 45 Curved-Tip stapler and Gray reload have particular utility in thoracic procedures and round out our SureForm 45 portfolio. Not all reloads or staplers are available for use on all systems or in all countries.

Da Vinci Endoscope Plus. In June 2019, we received CE mark clearance in Europe for our da Vinci Endoscope Plus, an enhanced 3D endoscope for use with our da Vinci X and Xi Surgical Systems. Following the CE mark, in July 2019, we obtained FDA clearance for our da Vinci Endoscope Plus. The da Vinci Endoscope Plus leverages new sensor technology to allow for increased sharpness and color accuracy. The da Vinci Endoscope Plus is currently available in Europe and is expected to launch in the U.S. later in 2019.

Da Vinci Handheld Camera. In June 2019, we obtained FDA clearance for our da Vinci Handheld Camera, a lightweight, 2D camera head, which can be connected to third-party laparoscopes. This allows the laparoscopic image to be displayed on the da Vinci X/Xi vision cart to address aspects of da Vinci procedures that may require use of a laparoscope, thus eliminating the need for redundant equipment in the operating room and increasing procedure efficiency. We are introducing the da Vinci Handheld Camera in a measured fashion in 2019 with a broad launch expected in early 2020.

Ion endoluminal system. In February 2019, we obtained FDA clearance for 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. The Ion system uses an ultra-thin articulating robotic catheter that can move 180 degrees in all directions. The outer diameter of the catheter is 3.5mm, which allows physicians to navigate through small and tortuous airways to reach nodules in most airway segments within the lung. The Ion system's flexible biopsy needle can also pass through very tight bends via Ion's catheter to collect tissue in the peripheral lung. The catheter's 2mm working channel can also accommodate other biopsy tools, such as biopsy forceps or cytology brushes, if necessary. We are introducing Ion in a measured fashion while we optimize training pathways and our supply chain and collect additional clinical data. We have placed 10 Ion systems for commercial use as of December 31, 2019.

IRIS. In February 2019, we obtained FDA clearance for our IRIS augmented reality product. IRIS is a service that delivers a 3D image of the patient anatomy (initially targeting kidneys) to aid surgeons in both the pre- and intra-operative settings. We are now in the early stages of an IRIS pilot study in the field at a small group of U.S. hospitals to gain initial product experience and insights.

SureForm 60 and SureForm 45 Staplers. In July 2018, we obtained FDA clearance for the SureForm 60 instrument with White, Blue, Green, and Black 60mm reloads. In January 2019, we obtained FDA clearance for the SureForm 45 instrument with White, Blue, Green, and Black 45mm reloads. Additionally, we received regulatory clearance in South Korea for the SureForm 60 instrument and 60mm reloads in June 2018 and July 2018, respectively, and for the SureForm 45 instrument and 45mm reloads in June 2019 and September 2019, respectively. Also, we received regulatory clearance in Japan for the SureForm 60 instrument and 60mm reloads in June 2018 and November 2018, respectively, and for the SureForm 45 instrument and 45mm reloads in September 2019. The SureForm 60 and SureForm 45 Staplers are single-use, fully wristed stapling instruments intended for resection, transection, and/or creation of anastomoses. The SureForm 60 instrument has particular utility in bariatric procedures, while the SureForm 45 instrument has particular utility in colorectal procedures. SureForm 60 and SureForm 45 Staplers broaden our existing stapler product line, which also includes EndoWrist Stapler 45 with White, Blue, and Green 45mm reloads and EndoWrist Stapler 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 SP Surgical System. In May 2018, we obtained FDA clearance for the da Vinci SP Surgical System for urologic surgical procedures that are appropriate for a single port approach. In March 2019, we obtained FDA clearance for the da Vinci SP Surgical System for certain transoral procedures. The da Vinci SP Surgical 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 Surgical System, which uses the same fourth generation surgeon console as the da Vinci X and Xi Surgical Systems. The da Vinci SP Surgical 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 Surgical System, including colorectal applications, broadening the applicability of the SP platform over time. We continue to introduce the da Vinci SP

Surgical System in a measured fashion while we optimize training pathways and our supply chain. We have placed 29 da Vinci SP Surgical Systems in 2019 and have an installed base of 44 as of December 31, 2019.

Da Vinci Vessel Sealer Extend. In April 2018, we obtained 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 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 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 system 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, choosing which system model by considering clinical and economic factors.

The da Vinci X system 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 da Vinci X 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.

Acquisition of Certain Assets from Schölly Fiberoptic

In July 2019, we entered into an agreement to acquire certain assets and operations from Schölly Fiberoptic GmbH (“Schölly”), a supplier of endoscopes and other visualization equipment (the "Schölly Acquisition"). On August 31, 2019, upon the satisfaction of closing conditions, we acquired control of these assets and operations, which collectively met the definition of a business. Total purchase consideration of $101.4 million, as of the acquisition date, consisted of an initial cash payment of $34.4 million and deferred cash payments totaling approximately $67.0 million, of which $37.3 million continues to be deferred as of December 31, 2019. The timing of the future payments is based upon achieving certain integration steps, which are expected to be completed around the end of 2020.

The process to manufacture endoscopes is complex, and there can be no assurance that we can successfully integrate or operate the endoscope manufacturing operations of the acquired business. For example, we may be unable to retain the employees of Schölly or its current suppliers. The integration process will be complex and involves the integration of manufacturing operations across multiple sites globally. The integration may require expenses and time in excess of expectations. Integrating the Schölly Acquisition will also involve getting certain regulatory approvals and re-certification of manufacturing sites. If we cannot successfully integrate or manufacture endoscopes subsequent to the Schölly Acquisition, it may have an adverse impact on our business, financial condition, results of operations, or cash flows.

2019 Operational and Financial Highlights

- Total revenue increased by 20% to $4.5 billion for the year ended December 31, 2019, compared with $3.7 billion for the year ended December 31, 2018.
- Approximately 1,229,000 da Vinci procedures were performed during the year ended December 31, 2019, an increase of 18% compared with approximately 1,038,000 da Vinci procedures for the year ended December 31, 2018.
- Instruments and accessories revenue increased by 23% to $2.4 billion for the year ended December 31, 2019, compared with $2.0 billion for the year ended December 31, 2018.
- Systems revenue increased by 19% to $1.3 billion for the year ended December 31, 2019, compared with $1.1 billion for the year ended December 31, 2018.
- A total of 1,119 da Vinci Surgical Systems were shipped during the year ended December 31, 2019, an increase of 21% compared with 926 systems during the year ended December 31, 2018.
- As of December 31, 2019, we had a da Vinci Surgical System installed base of approximately 5,582 systems, an increase of 12% compared with the installed base of approximately 4,986 systems as of December 31, 2018.
- During the year ended December 31, 2019, we began commercial sales of the Ion system and shipped the first 10 commercial systems.
- Gross profit as a percentage of revenue was 69.4% for the year ended December 31, 2019, compared with 69.9% for the year ended December 31, 2018.
- Operating income increased by 15% to $1.4 billion for the year ended December 31, 2019, compared with $1.2 billion for the year ended December 31, 2018. Operating income included $338 million and $263 million of share-based

compensation expense related to employee stock plans and $67.2 million and $31.6 million of intangible asset charges for the years ended December 31, 2019, and 2018, respectively.

- As of December 31, 2019, we had $5.8 billion in cash, cash equivalents, and investments. Cash, cash equivalents, and investments increased by $1.0 billion compared with December 31, 2018.

Results of Operations

This section of the Form 10-K generally discusses 2019 and 2018 items and year-to-year comparisons between 2019 and 2018. Discussions of 2017 items and year-to-year comparisons between 2018 and 2017 that are not included in this Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

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

	Years Ended December 31,					
	2019	% of total revenue	2018	% of total revenue	2017	% of total revenue
Revenue:						
Product	$ 3,754.3	84 %	$ 3,089.1	83 %	$ 2,565.3	82 %
Service	724.2	16 %	635.1	17 %	572.9	18 %
Total revenue	4,478.5	100 %	3,724.2	100 %	3,138.2	100 %
Cost of revenue:						
Product	1,119.1	25 %	906.2	24 %	756.3	24 %
Service	249.2	6 %	213.9	6 %	179.9	6 %
Total cost of revenue	1,368.3	31 %	1,120.1	30 %	936.2	30 %
Product gross profit	2,635.2	59 %	2,182.9	59 %	1,809.0	58 %
Service gross profit	475.0	10 %	421.2	11 %	393.0	12 %
Gross profit	3,110.2	69 %	2,604.1	70 %	2,202.0	70 %
Operating expenses:						
Selling, general and administrative	1,178.4	26 %	986.6	27 %	810.5	26 %
Research and development	557.3	12 %	418.1	11 %	328.6	10 %
Total operating expenses	1,735.7	38 %	1,404.7	38 %	1,139.1	36 %
Income from operations	1,374.5	31 %	1,199.4	32 %	1,062.9	34 %
Interest and other income, net	127.7	3 %	80.1	2 %	41.9	1 %
Income before taxes	1,502.2	34 %	1,279.5	34 %	1,104.8	35 %
Income tax expense	120.4	3 %	154.5	4 %	433.9	14 %
Net income	1,381.8	31 %	1,125.0	30 %	670.9	21 %
Less: net income (loss) attributable to noncontrolling interest in joint venture	2.5	— %	(2.9)	— %	—	— %
Net income attributable to Intuitive Surgical, Inc.	$ 1,379.3	31 %	$ 1,127.9	30 %	$ 670.9	21 %

Total Revenue

Total revenue increased by 20% to $4.5 billion for the year ended December 31, 2019, compared with $3.7 billion for the year ended December 31, 2018. Total revenue for the year ended December 31, 2018, increased by 19% compared with $3.1 billion for the year ended December 31, 2017. The increase in total revenue for the year ended December 31, 2019, resulted from 23% higher instruments and accessories revenue, driven by approximately 18% higher procedure volume, 19% higher systems revenue, and 14% higher service revenue.

Revenue denominated in foreign currencies as a percentage of total revenue was approximately 20%, 20%, and 17% for the years ended December 31, 2019, 2018, and 2017, respectively. We generally 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, 2019, as compared with 2018, or for the year ended December 31, 2018, as compared with 2017.

Revenue generated in the U.S. accounted for 70%, 71%, and 73% of total revenue for the years ended December 31, 2019, 2018, and 2017, respectively. We believe that U.S. revenue has accounted for the large majority of total revenue due to U.S. patients' ability to choose their provider and method of treatment, reimbursement structures supportive of innovation and minimally invasive surgery, and our initial investments focused on U.S. infrastructure. We have been investing in our business in the OUS markets, 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 system unit shipments for the years ended December 31, 2019, 2018, and 2017, respectively (in millions, except percentages and unit shipments):

	Years Ended December 31,		
	2019	2018	2017
Revenue			
Instruments and accessories	$ 2,408.2	$ 1,962.0	$ 1,636.9
Systems	1,346.1	1,127.1	928.4
Total product revenue	3,754.3	3,089.1	2,565.3
Services	724.2	635.1	572.9
Total revenue	$ 4,478.5	$ 3,724.2	$ 3,138.2
United States	$ 3,129.5	$ 2,633.5	$ 2,285.8
OUS	1,349.0	1,090.7	852.4
Total revenue	$ 4,478.5	$ 3,724.2	$ 3,138.2
% of Revenue - U.S.	70 %	71 %	73 %
% of Revenue - OUS	30 %	29 %	27 %
Instruments and accessories	$ 2,408.2	$ 1,962.0	$ 1,636.9
Services	724.2	635.1	572.9
Operating lease	106.9	51.4	25.9
Total recurring revenue	$ 3,239.3	$ 2,648.5	$ 2,235.7
% of Total revenue	72 %	71 %	71 %
Da Vinci Surgical System Shipments by Region:			
U.S. unit shipments	728	581	417
OUS unit shipments	391	345	267
Total unit shipments*	1,119	926	684
*Systems shipped under operating leases (included in total unit shipments)	384	229	108
Ion System Shipments	10	—	—
Da Vinci Surgical System Shipments involving System Trade-ins:			
Unit shipments involving trade-ins	442	277	163
Unit shipments not involving trade-ins	677	649	521

Product Revenue

Product revenue increased by 22% to $3.8 billion for the year ended December 31, 2019, compared with $3.1 billion for the year ended December 31, 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.

Instruments and accessories revenue increased by 23% to $2.4 billion for the year ended December 31, 2019, compared with $2.0 billion for the year ended December 31, 2018. The increase in instruments and accessories revenue was driven primarily by procedure growth of 18%, incremental sales of our advanced instruments, and customer buying patterns. U.S. procedure growth in 2019 of 17%, compared with 17% in 2018, was driven by strong growth in general surgery procedures, most notably hernia repair, cholecystectomy, colorectal, and bariatric procedures, and thoracic procedures as well as moderate growth in the more mature gynecologic and urologic procedures categories. OUS procedure growth in 2019 was 21% compared with 22% in 2018. Key drivers for OUS procedure growth in both years was driven by continued growth in urologic procedures

and earlier stage growth in general surgery and gynecology procedures. Geographically, OUS procedure growth was driven by procedure expansion in Japan, Germany, Korea, and China with varying results in other countries.

Systems revenue increased by 19% to $1.3 billion for the year ended December 31, 2019, compared with $1.1 billion for the year ended December 31, 2018. Higher systems revenue was primarily driven by higher system shipments, higher 2019 ASPs, higher operating lease revenue, and higher lease buyouts, partially offset by a higher proportion of system shipments under operating lease or usage-based arrangements.

During 2019, a total of 1,119 da Vinci Surgical Systems were shipped compared with 926 systems during 2018. By geography, 728 systems were shipped into the U.S., 169 into Europe, 182 into Asia, and 40 into other markets during 2019, compared with 581 systems shipped into the U.S., 169 into Europe, 116 into Asia, and 60 into other markets during 2018. During 2019, 384 of the 1,119 systems were shipped under operating lease arrangements, compared with 229 of the 926 systems shipped during 2018. The increase in system shipments was primarily driven by procedure growth, the need for hospitals to expand or establish capacity, and more customers trading in older da Vinci models for fourth generation da Vinci Xi and da Vinci X systems.

We shipped 425 and 272 da Vinci Surgical Systems under lease or usage-based arrangements, of which 384 and 229 systems were classified as operating leases for the years ended December 31, 2019, and 2018, respectively. Operating lease revenue was $106.9 million for the year ended December 31, 2019, compared with $51.4 million for the year ended December 31, 2018. Systems placed as operating leases represented 34% of total shipments during 2019, compared with 25% during 2018. A total of 658 da Vinci Surgical Systems were installed at customers under operating lease or usage-based arrangements as of December 31, 2019, compared with 350 as of December 31, 2018. Revenue from Lease Buyouts was $92.8 million for the year ended December 31, 2019, compared with $48.8 million for the year ended December 31, 2018. We expect revenue from Lease Buyouts to fluctuate period to period based on the timing of when, and if, customers choose to exercise the buyout options embedded in their leases.

The da Vinci Surgical System ASP, excluding the impact of systems shipped under operating leases and Ion systems, was approximately $1.52 million for the year ended December 31, 2019, compared with approximately $1.45 million for the year ended December 31, 2018. The higher 2019 ASP was largely driven by favorable geographic and product mix. ASP fluctuates from 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 14% to $724 million for the year ended December 31, 2019, compared with $635 million for the year ended December 31, 2018. Service revenue increased by 11% to $635 million for the year ended December 31, 2018, compared with $573 million for the year ended December 31, 2017. Higher service revenue in 2019 was primarily driven by a larger installed base of da Vinci Surgical Systems producing service revenue.

Gross Profit

Product gross profit for the year ended December 31, 2019, increased 21% to $2.6 billion, representing 70.2% of product revenue, compared with $2.2 billion, representing 70.7% of product revenue, for the year ended December 31, 2018. The higher 2019 product gross profit was primarily driven by higher product revenue, partially offset by lower product gross profit margin. The lower product gross profit margin for the year ended December 31, 2019, was primarily driven by higher intangible assets amortization expense.

The MDET initially became effective on January 1, 2013, and we treated MDET as a reduction in gross profit. 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. This moratorium was extended through December 31, 2019, by the Extension of Continuing Appropriations Act of 2018, signed into law on January 22, 2018. The MDET was repealed in December 2019.

Product gross profit for the years ended December 31, 2019 and 2018, included share-based compensation expense of $46.6 million and $36.4 million, respectively, and intangible assets amortization expense of $31.5 million and $5.3 million, respectively.

Service gross profit for the year ended December 31, 2019, increased 13% to $475 million, representing 65.6% of service revenue, compared with $421 million, representing 66.3% of service revenue, for the year ended December 31, 2018. The higher 2019 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, 2019, was primarily driven by higher share-based compensation expense and intangible assets amortization.

Service gross profit for the years ended December 31, 2019 and 2018, included share-based compensation expense of $20.4 million and $16.8 million, respectively, and intangible assets amortization expense of $3.7 million and $0.8 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, 2019, increased by 19% to $1,178 million, compared with $987 million for the year ended December 31, 2018. The higher selling, general and administrative expenses in 2019 were primarily associated with our expanded Asian and European teams, including establishing our direct organizations in China, India, and Taiwan, increased infrastructure to support our growth, and higher headcount. Also, in the fourth quarters of 2019 and 2018, we made charitable contributions of $5.0 million and $25.2 million, respectively, to the Intuitive Foundation, a 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 net pre-tax litigation charges of $0.8 million and $45.2 million for the years ended December 31, 2019, and 2018, respectively. The litigation charges for the year ended December 31, 2018, were primarily related to the settlement of the Abrams class action lawsuit further described in Note 8 to the Consolidated Financial Statements included in Part II, Item 8.

Selling, general and administrative expenses for the years ended December 31, 2019, and 2018, included share-based compensation expense of $170 million and $133 million, respectively, and intangible assets amortization expense of $5.7 million and $2.2 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, 2019, increased by 33% to $557 million, compared with $418 million for the year ended December 31, 2018. The increase was primarily due to higher personnel-related expenses, intangible asset charges, and other project costs incurred to support a broader set of product development initiatives, including Ion and SP platform investments, informatics, advanced instrumentation, advanced imaging, and future generations of robotics.

Research and development expenses for the years ended December 31, 2019, and 2018, included share-based compensation expense of $101.4 million and $76.2 million, respectively, and intangible asset charges of $26.3 million and $23.3 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 $127.7 million for the year ended December 31, 2019, compared with $80.1 million for the year ended December 31, 2018, and $41.9 million for the year ended December 31, 2017. The increase in interest and other income, net, for the year ended December 31, 2019, was primarily driven by higher interest earned due to higher interest rates and higher cash and investment balances.

Income Tax Expense

Our income tax expense was $120 million, $155 million, and $434 million for the years ended December 31, 2019, 2018, and 2017, respectively. Our effective tax rate for 2019 was approximately 8.0% compared with 12.1% for 2018 and 39.3% for 2017. Our effective tax rate for 2019 and 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, the federal research and development credit benefit, and the release of unrecognized tax benefits from the expiration of statutes of limitations, partially offset by U.S. tax on foreign earnings and state income taxes (net of federal benefit). In addition, our 2019 tax rate reflected a $51.3 million benefit associated with re-measurement of our Swiss deferred tax assets due to a Swiss statutory tax rate increase enacted as part of Swiss tax reform in August 2019.

Our tax rate for 2017 reflected the effect of a one-time discrete item in the amount of $317.8 million associated with the enactment of the 2017 Tax Act. Besides the impact of the 2017 Tax Act, our tax rate for 2017 differs from the U.S. federal statutory rate of 35% due to the effect of income earned by certain overseas entities being taxed at rates lower than the federal statutory rate, excess tax benefits recognized for employee share-based compensation, and the reversal of certain unrecognized tax benefits, partially offset by state income taxes (net of federal benefit).

On December 22, 2017, the U.S. federal government enacted the 2017 Tax Act. The 2017 Tax Act includes a number of changes in existing tax law impacting businesses, including a one-time deemed repatriation of cumulative undistributed foreign earnings and a permanent reduction in the U.S. federal statutory rate from 35% to 21%, effective on January 1, 2018.

Under U.S. GAAP, changes in tax rates and tax law are accounted for in the period of enactment and deferred tax assets and liabilities are measured at the enacted tax rate. In December 2017, 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 of which 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 and reflected a $0.5 million net increase in the 2018 income tax expense.

In June 2018, we repatriated $1.6 billion of our cumulative undistributed foreign earnings back to the U.S. 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.

Our 2019, 2018, and 2017 provisions for income taxes included excess tax benefits associated with employee equity plans of $147 million, $116 million, and $103 million, respectively, which reduced our effective tax rate by 9.8, 9.1, and 9.3 percentage points, respectively. 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, which results in increased income tax expense volatility.

Our 2019, 2018, and 2017 tax provision reflected tax benefits of $8.4 million, $5.2 million, and $62.4 million, respectively, associated with the reversal of unrecognized tax benefits and interest resulting from the expiration of statutes of limitations in multiple jurisdictions and certain audit conclusions.

We file federal, state, and foreign income tax returns in many jurisdictions in the U.S. and abroad. Years prior to 2016 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.

In July 2015, a U.S. Tax Court opinion (the "2015 Opinion") was issued involving an independent third party related to intercompany charges for share-based compensation. Based on the findings of the U.S. Tax Court, we were required to, and did, refund to our foreign subsidiaries the share-based compensation element of certain intercompany charges made in prior periods. Starting in 2015, direct share-based compensation has been excluded from intercompany charges. In June 2019, the Ninth Circuit Court of Appeals (the "Ninth Circuit") reversed the 2015 Opinion (the "Ninth Circuit Opinion"). Subsequently, a re-hearing of the case was requested, but the rehearing request was denied by the Ninth Circuit on November 12, 2019. However, a petition for appeal to the U.S. Supreme Court can be filed within 90 days of the denial. Since the Ninth Circuit Opinion potentially is subject to further judicial review, we continue to treat our share-based compensation expense in accordance with the 2015 Opinion and continue to recognize the related tax benefits in our financial statements based upon our evaluation of the position in light of the present facts. In the event of a final opinion that reverses the 2015 Opinion, there may be an adverse impact to our income tax expense and effective tax rate.

Net Income (Loss) Attributable to Noncontrolling Interest in Joint Venture

The Company's majority-owned joint venture (the "Joint Venture") with Shanghai Fosun Pharmaceutical (Group) Co., Ltd. ("Fosun Pharma"), a subsidiary of Fosun International Limited, was established to research, develop, manufacture, and sell robotic-assisted, catheter-based medical devices. The Joint Venture is owned 60% by us and 40% by Fosun Pharma and is located in China. 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. 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.

In January 2019, the Joint Venture acquired certain assets, including distribution rights, customer relationships, and certain personnel, from Chindex and its affiliates, a subsidiary of Fosun Pharma, and began direct operations for da Vinci products and services in China. As of December 31, 2019, the companies have contributed $55 million of up to $100 million required by the joint venture agreement.

We do not expect the Joint Venture to generate revenue in 2020 related to the sale of robotic-assisted, catheter-based medical devices. There can be no assurance 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 continue to be profitable, or that the acquired Chindex assets will be successfully integrated and the expected benefits will be realized.

Net income (loss) attributable to noncontrolling interest in Joint Venture for the year ended December 31, 2019, was $2.5 million, compared with $(2.9) million for the year ended December 31, 2018. The increase in net income attributable to noncontrolling interest in Joint Venture was primarily due to the increase in sales in China, partially offset by intangible assets amortization expense and higher costs to ramp up operations in China.

Liquidity and Capital Resources

Sources and Uses of Cash

Our principal source of liquidity is cash provided by operations and by the issuance of common stock through the 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 $5.8 billion as of December 31, 2019, from $4.8 billion as of December 31, 2018, primarily from cash provided by our operations, partially offset by capital expenditures and share repurchases. 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 from cash provided by our operations and employee stock option exercises.

As of December 31, 2019, $362 million of our cash, cash equivalents, and investments were held by foreign subsidiaries. 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,		
	2019	2018	2017
(in millions)			
Net cash provided by (used in)			
Operating activities	$ 1,598.2	$ 1,169.6	$ 1,143.9
Investing activities	(1,154.4)	(1,049.6)	378.7
Financing activities	(168.4)	126.3	(1,913.1)
Effect of exchange rates on cash, cash equivalents, and restricted cash	(2.2)	(0.1)	2.1
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 273.2	$ 246.2	$ (388.4)

Operating Activities

For the year ended December 31, 2019, net cash provided by operating activities of $1,598 million exceeded our net income of $1,382 million, primarily due to the following reasons:

1. Our net income included non-cash charges of $537.9 million, consisting primarily of the following significant items: share-based compensation of $335.8 million; depreciation expense and losses on the disposal of property, plant, and equipment of $160.0 million; and amortization of intangible assets of $43.0 million.
2. The non-cash charges outlined above were partially offset by changes in operating assets and liabilities that resulted in $321.5 million of cash used by operating activities during the year ended December 31, 2019. Inventory, including the transfer of equipment from inventory to property, plant, and equipment, increased by $360.5 million, primarily due to the increased number of systems under operating lease and usage-based arrangements and build-up to address the growth in the business as well as to mitigate risks of disruption that could arise from trade, supply, or other matters. Prepaid expenses and other assets increased by $116.9 million, primarily due to an increase in leasing, an increase in deferred commissions, and an increase in prepaid taxes, driven by the timing of tax payments. The unfavorable impact of these items on cash provided by operating activities was partially offset by a $57.4 million increase in accrued compensation and employee benefits, primarily due to higher headcount, a $38.8 million decrease in accounts receivable, primarily due to the timing of collections, and a $35.5 million increase in deferred revenue, primarily due to the increased volume of sales contracts.

For the year ended December 31, 2018, net cash provided by operating activities of $1,170 million exceeded our net income of $1,125 million, primarily due to the following reasons:

1. Our net income included non-cash charges of $428.3 million, consisting primarily of the following significant items: share-based compensation of $261.2 million; depreciation expense and losses on the 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; and amortization of contract acquisitions assets of $10.6 million.
2. The non-cash charges outlined above were partially offset by changes in operating assets and liabilities that resulted in $383.7 million of cash used in operating activities during the year ended December 31, 2018. Inventory, including the transfer of equipment from inventory to property, plant, and equipment, increased by $279.0 million, primarily due to the increased number of systems under operating lease arrangements and build-up to address the growth in the business as well as to mitigate risks of disruption that could arise from trade, supply, or other 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 provided by operating activities was partially 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.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2019, consisted of purchases of investments (net of proceeds from sales and maturities of investments) of $669.1 million, the acquisition of property and equipment of $425.6 million, and the acquisition of businesses, net of cash acquired, of $59.7 million.

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

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

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

Financing Activities

Net cash used in financing activities for the year ended December 31, 2019, consisted primarily of cash used in the repurchase of approximately 0.6 million shares of our common stock in the open market for $269.5 million and taxes paid on behalf of employees related to net share settlements of vested employee equity awards of $159.1 million, partially offset by proceeds from stock option exercises and employee stock purchases of $272.8 million.

Net cash provided by financing activities for the year ended December 31, 2018, consisted primarily of proceeds from stock option exercises and employee stock purchases of $236.6 million, partially offset by taxes paid on behalf of employees related to net share settlements of vested employee equity awards of $120.0 million.

Net cash used in financing activities for the year ended December 31, 2017, consisted primarily of $2.3 billion related to an accelerated share buyback program executed and settled during 2017 and taxes paid on behalf of employees related to net share settlements of vested employee equity awards of $56.6 million, partially offset by proceeds from stock option exercises and employee stock purchases of $415.5 million.

Capital Expenditures

Our business is not capital equipment intensive. However, with the growth of our business and our investments in property and facilities and in manufacturing automation, capital investments in these areas have increased. We expect these capital investments to exceed $400 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 for the foreseeable future.

Contractual Obligations and Commercial Commitments

The following table summarizes our contractual obligations and commercial commitments as of December 31, 2019 (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 (Note 6)	$ 87.7	$ 9.6	$ 34.5	$ 21.2	$ 22.4
Purchase commitments and obligations	844.7	805.6	37.7	1.4	—
Tax Cuts and Jobs Act Toll Tax (Note 11)	225.2	21.4	42.9	93.9	67.0
Total	$ 1,157.6	$ 836.6	$ 115.1	$ 116.5	$ 89.4

Operating leases. We lease spaces for operations in the U.S. as well as in Japan, Mexico, China, South Korea, and other foreign countries. We also lease automobiles for certain sales and field service employees. These leases have varying terms up to 15 years. Operating lease amounts include future minimum lease payments under all of our non-cancellable operating leases with an initial term in excess of one year. Refer to Note 6 for further details.

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, commitments for capital expenditures and construction-related activities for which we have not received the 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. For instances in which 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.

Tax Cuts and Jobs Act Toll Tax. As of December 31, 2019, our obligation associated with the deemed repatriation toll charge is $225.2 million, which is expected to be paid in installments. Refer to Note 11 for further details.

We are unable to make a reasonably reliable estimate as to when payments may occur for our unrecognized tax benefits. Therefore, our liability for unrecognized tax benefits is not included in the table above.

Off-Balance Sheet Arrangements

As of December 31, 2019, 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. Factors considered in determining whether a loss is temporary include the extent and length of time that the investment's fair value has been lower than its cost basis, the financial condition and near-term prospects of the investee, the 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. 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, 2019, 2018, and 2017. As of December 31, 2019, and 2018, net unrealized losses on investments of $20.4 million and $9.8 million, net of tax, respectively, were included in accumulated other comprehensive income/(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 billed at a stated service price. Revenue that is allocated to the 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 that 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 cost 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 intangible assets and goodwill. Identifiable intangible assets include developed technology, patents, distribution rights, customer relationships, licenses, and non-competition arrangements. All of our identifiable intangible assets 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 intangible assets 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, 2019, 2018, and 2017. 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 forfeiture rate adjustments for all expense amortization in the period that the estimated forfeiture rates are 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 the 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 the fair value of stock options and, consequently, the related amount of share-based compensation expense recognized in 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, 2019, 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. From time to time, 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 supporting the Company's liquidity requirements. To achieve this objective, we maintain a diversified 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, 2019, was approximately 1.0 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 $13.5 million as of December 31, 2019. We do not utilize derivative financial instruments to manage our interest rate risks.

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 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, 2019, 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, 2019, our revenue would have decreased by approximately $53.5 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, 2019, would have resulted in an approximately $2.8 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 credit 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

Index To Consolidated Financial Statements

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders 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, 2019 and 2018, and the related consolidated statements of income, of comprehensive income, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2019, including the related notes and schedule of valuation and qualifying accounts for each of the three years in the period ended December 31, 2019 listed in the accompanying index (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 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, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Change in Accounting Principle

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

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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Acquisitions of Chindex and Schölly - Fair value of Intangible Assets and Contingent Consideration

As described in Note 7 to the consolidated financial statements, the Company completed two transactions accounted for as business combinations during the year ended December 31, 2019. During the first quarter of 2019, the Company's majority-owned joint venture with Fosun Pharma acquired certain assets from Chindex and its affiliates ("Chindex"), a subsidiary of Fosun Pharma, for total purchase consideration of $66.0 million, which resulted in $64.7 million of contingent consideration liability and $48.2 million of distribution rights being recorded. Management measured the contingent consideration liability at estimated fair value using a discounted cash flow model, which requires significant inputs not observable in the market. For the contingent consideration, key assumptions included (1) the probability and timing of milestone achievements based on projected future revenues through 2019 and 2020 and (2) the discount rate used to calculate the present value of the milestone payments. For the distribution rights intangible asset, key assumptions included (1) the amount and timing of projected future cash flows, and (2) the discount rate used to determine the present value of these cash flows. During the third quarter of 2019, the Company acquired certain assets and operations from Schölly Fiberoptic GmbH ("Schölly") for total purchase consideration of $101.4 million, which resulted in $28.0 million of a manufacturing process technology intangible asset being recorded. For the manufacturing process technology intangible asset, key assumptions included (1) the amount and timing of projected future cash flows and (2) the discount rate used to determine the present value of these cash flows.

The principal considerations for our determination that performing procedures relating to the acquisitions of Chindex and Schölly, specifically the fair value of the distribution rights intangible asset, contingent consideration liability, and manufacturing process technology intangible asset, is a critical audit matter are there was significant judgment by management in developing the fair value estimates. This in turn led to a high degree of auditor judgment, effort, and subjectivity in performing procedures and evaluating audit evidence relating to management's projected future cash flows, specifically the revenue projections, for the distribution rights intangible asset, contingent consideration liability and manufacturing process technology, and the discount rates for the distribution rights intangible asset and contingent consideration liability. In addition, the audit effort involved the use of professionals with specialized skill and knowledge to assist in performing these procedures and evaluating the audit evidence obtained from these procedures.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the acquisition accounting, including controls over management's valuation of the distribution rights intangible asset and contingent consideration liability for the acquisition of Chindex and the manufacturing process technology intangible asset for the acquisition of Schölly, and controls over the development of the projected future cash flows, specifically revenue projections and discount rates. These procedures also included, among others, (i) reading the purchase agreements, (ii) evaluating management's assessments of the completeness of the identified intangible assets acquired, and (iii) testing management's process for estimating the fair value of the distribution rights, contingent consideration liability, and manufacturing process technology. Testing management's process included evaluating the appropriateness of the methods used to develop the fair value estimates and evaluating the reasonableness of significant assumptions used by management, including the revenue projections and discount rates. Evaluating the reasonableness of the revenue projections included evaluating consistency with evidence obtained in other areas of the audit and considering historical trends of the Company's business. Professionals with specialized skill and knowledge were used to assist in evaluating the reasonableness of the discount rates.

/s/ PricewaterhouseCoopers LLP

San Jose, California
February 7, 2020

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

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

	December 31,	
	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,167.6	$ 857.9
Short-term investments	2,054.1	2,205.2
Accounts receivable, net of allowances of $8.3 and $8.2 as of December 31, 2019, and 2018, respectively	645.2	682.3
Inventory	595.5	409.0
Prepaids and other current assets	200.2	178.8
Total current assets	4,662.6	4,333.2
Property, plant, and equipment, net	1,272.9	812.0
Long-term investments	2,623.5	1,771.3
Deferred tax assets	425.6	428.6
Intangible and other assets, net	441.4	261.0
Goodwill	307.2	240.6
Total assets	$ 9,733.2	$ 7,846.7
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 123.5	$ 100.7
Accrued compensation and employee benefits	251.6	193.8
Deferred revenue	337.8	294.3
Other accrued liabilities	317.3	231.8
Total current liabilities	1,030.2	820.6
Other long-term liabilities	418.3	338.6
Total liabilities	1,448.5	1,159.2
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, 2.5 shares authorized, $0.001 par value, issuable in series; no shares issued and outstanding as of December 31, 2019, and 2018	—	—
Common stock, 300.0 shares authorized, $0.001 par value, 116.0 shares and 114.5 shares issued and outstanding as of December 31, 2019, and 2018, respectively	0.1	0.1
Additional paid-in capital	5,756.8	5,170.3
Retained earnings	2,494.5	1,521.7
Accumulated other comprehensive income/(loss)	12.4	(13.3)
Total Intuitive Surgical, Inc. stockholders' equity	8,263.8	6,678.8
Noncontrolling interest in joint venture	20.9	8.7
Total stockholders' equity	8,284.7	6,687.5
Total liabilities and stockholders' equity	$ 9,733.2	$ 7,846.7

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,		
	2019	2018	2017
Revenue:			
Product	$ 3,754.3	$ 3,089.1	$ 2,565.3
Service	724.2	635.1	572.9
Total revenue	4,478.5	3,724.2	3,138.2
Cost of revenue:			
Product	1,119.1	906.2	756.3
Service	249.2	213.9	179.9
Total cost of revenue	1,368.3	1,120.1	936.2
Gross profit	3,110.2	2,604.1	2,202.0
Operating expenses:			
Selling, general and administrative	1,178.4	986.6	810.5
Research and development	557.3	418.1	328.6
Total operating expenses	1,735.7	1,404.7	1,139.1
Income from operations	1,374.5	1,199.4	1,062.9
Interest and other income, net	127.7	80.1	41.9
Income before taxes	1,502.2	1,279.5	1,104.8
Income tax expense	120.4	154.5	433.9
Net income	1,381.8	1,125.0	670.9
Less: net income (loss) attributable to noncontrolling interest in joint venture	2.5	(2.9)	—
Net income attributable to Intuitive Surgical, Inc.	$ 1,379.3	$ 1,127.9	$ 670.9
Net income per share attributable to Intuitive Surgical, Inc.:			
Basic	$ 11.95	$ 9.92	$ 6.01
Diluted	$ 11.54	$ 9.49	$ 5.77
Shares used in computing net income per share attributable to Intuitive Surgical, Inc.:			
Basic	115.4	113.7	111.7
Diluted	119.5	118.8	116.3
Total comprehensive income attributable to Intuitive Surgical, Inc.	$ 1,405.0	$ 1,130.1	$ 664.3

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,		
	2019	2018	2017
Net income attributable to Intuitive Surgical, Inc.	$ 1,379.3	$ 1,127.9	$ 670.9
Other comprehensive income (loss):			
Change in foreign currency translation gains (losses)	0.3	(2.6)	3.6
Available-for-sale investments (net of tax):			
Change in unrealized gains (losses)	30.7	0.3	(2.7)
Less: Reclassification adjustment for (gains) losses on investments	(0.5)	1.2	—
Net change	30.2	1.5	(2.7)
Derivative instruments (net of tax):			
Change in unrealized gains (losses)	5.8	3.6	(8.6)
Less: Reclassification adjustment for (gains) losses on derivative instruments	(5.3)	(1.0)	1.2
Net change	0.5	2.6	(7.4)
Employee benefit plans (net of tax):			
Change in unrealized gains (losses)	(5.9)	0.4	(0.3)
Less: Reclassification adjustment for losses on employee benefit plans	0.6	0.3	0.2
Net change	(5.3)	0.7	(0.1)
Other comprehensive gains (losses)	25.7	2.2	(6.6)
Total comprehensive income attributable to Intuitive Surgical, Inc.	$ 1,405.0	$ 1,130.1	$ 664.3

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 Income/(Loss)	Total Intuitive Surgical, Inc. Stockholders' Equity	Noncontrolling Interest in Joint Venture	Total Stockholders' Equity
	Shares	Amount						
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 attributable to Intuitive Surgical, Inc.				670.9		670.9		670.9
Other comprehensive loss					(6.6)	(6.6)		(6.6)
Capital contribution from noncontrolling interest						—	2.0	2.0
Net loss attributable to noncontrolling interest in joint venture						—	(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 attributable to Intuitive Surgical, Inc.				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
Net loss attributable to noncontrolling interest in joint venture						—	(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
Issuance of common stock through employee stock plans	2.4		272.8			272.8		272.8
Shares withheld related to net share settlement of equity awards	(0.3)		(7.6)	(151.5)		(159.1)		(159.1)
Share-based compensation expense related to employee stock plans			335.8			335.8		335.8
Repurchase and retirement of common stock	(0.6)		(14.5)	(255.0)		(269.5)		(269.5)
Net income attributable to Intuitive Surgical, Inc.				1,379.3		1,379.3		1,379.3
Other comprehensive income (loss)					25.7	25.7	(0.3)	25.4
Capital contribution from noncontrolling interest						—	10.0	10.0
Net income attributable to noncontrolling interest in joint venture						—	2.5	2.5
Balances at December 31, 2019	116.0	$ 0.1	$5,756.8	$ 2,494.5	$ 12.4	$ 8,263.8	$ 20.9	$ 8,284.7

(1) Represents the adjustments related to the adoptions of Accounting Standards Update ("ASU") 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other than Inventory*, and ASU 2018-02, *Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*.

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,		
	2019	2018	2017
Operating activities:			
Net income	$ 1,381.8	$ 1,125.0	$ 670.9
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and loss on disposal of property, plant, and equipment, net	160.0	108.6	86.2
Amortization of intangible assets	43.0	14.2	12.9
Loss (gain) on investment, accretion of discounts, and amortization of premiums on investments, net	(6.0)	1.8	21.2
Deferred income taxes	(8.0)	31.9	60.2
Share-based compensation expense	335.8	261.2	209.1
Amortization of contract acquisition assets	13.1	10.6	10.9
Changes in operating assets and liabilities, net of effects of acquisitions:			
Accounts receivable	38.8	(161.3)	(81.4)
Inventory	(360.5)	(279.0)	(115.5)
Prepaids and other assets	(116.9)	(77.7)	(38.9)
Accounts payable	12.3	16.7	14.0
Accrued compensation and employee benefits	57.4	26.2	31.2
Deferred revenue	35.5	54.3	43.7
Other liabilities	11.9	37.1	219.4
Net cash provided by operating activities	1,598.2	1,169.6	1,143.9
Investing activities:			
Purchase of investments	(3,346.2)	(2,581.9)	(1,995.0)
Proceeds from sales of investments	107.3	274.0	1,861.3
Proceeds from maturities of investments	2,569.8	1,533.6	703.1
Purchase of property, plant, and equipment and intellectual property	(425.6)	(187.4)	(190.7)
Acquisition of businesses, net of cash	(59.7)	(87.9)	—
Net cash provided by (used in) investing activities	(1,154.4)	(1,049.6)	378.7
Financing activities:			
Proceeds from issuance of common stock relating to employee stock plans	272.8	236.6	415.5
Taxes paid related to net share settlement of equity awards	(159.1)	(120.0)	(56.6)
Repurchase of common stock	(269.5)	—	(2,274.0)
Capital contribution from noncontrolling interest	10.0	10.0	2.0
Payment of deferred purchase consideration	(22.6)	(0.3)	—
Net cash provided by (used in) financing activities	(168.4)	126.3	(1,913.1)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(2.2)	(0.1)	2.1
Net increase (decrease) in cash, cash equivalents, and restricted cash	273.2	246.2	(388.4)
Cash, cash equivalents, and restricted cash, beginning of year	909.4	663.2	1,051.6
Cash, cash equivalents, and restricted cash, end of year	$ 1,182.6	$ 909.4	$ 663.2

The accompanying notes are an integral part of these 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 and the Ion™ endoluminal 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 systems consist 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 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 years ended December 31, 2019 and 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.

Beginning in 2018, the Company adopted Accounting Standards Update ("ASU") No. 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other than Inventory*. The Company adopted this standard using the modified retrospective approach and, as a result, recorded a cumulative adjustment to retained earnings as of January 1, 2018.

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, revenue recognition and the valuation of revenue and allowances for sales returns and doubtful accounts, the estimation of exposures that are able to be hedged and the offsetting hedge transactions, the valuation of inventory, the valuation of and assessment of recoverability of intangible assets and their estimated useful lives, 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 the estimates for legal contingencies. 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, 2019, and 2018, 66% and 71%, respectively, of accounts receivable were from domestic customers. No single customer represented more than 10% of total revenue for the years ended December 31, 2019, 2018, and 2017.

During the years ended December 31, 2019, 2018, and 2017, domestic revenue accounted for 70%, 71%, and 73% of total revenue, respectively, while outside of the U.S. revenue accounted for 30%, 29%, and 27%, 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.

Restricted Cash

As of December 31, 2019, the Company had $15.0 million of restricted cash associated with its insurance programs. As of December 31, 2018, the Company had $51.5 million of restricted cash associated with its insurance programs and a shareholder litigation settlement that was reached in 2018. Restricted cash was included in prepaids and other current assets and intangible and other assets, net on the Consolidated Balance Sheets.

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 90 days 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 that the investment's fair value has been lower than its cost basis, the financial condition and near-term prospects of the investee, the 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, 2019, 2018, and 2017.

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 cost 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, 2019, 2018, and 2017, was $156.7 million, $105.9 million, and $82.1 million, respectively.

Capitalized Software Costs for Internal Use

The Company capitalizes direct costs associated with developing or obtaining internal use software, including enterprise-wide business software, that are incurred during the application development stage. These capitalized costs are recorded as capitalized software within property, plant, and equipment. Costs related to preliminary project activities and post-implementation activities are expensed as incurred. Upon being placed in service, amounts capitalized are amortized over an estimated useful life of up to 5 years, generally on a straight-line basis.

Business Combinations

The Company accounts for business acquisitions in accordance with ASC 805, *Business Combinations*. This standard requires the acquiring entity in a business combination to recognize all of (and only) the assets acquired and liabilities assumed in the transaction and establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed in a business combination. Certain provisions of this standard prescribe, among other things, the determination of acquisition-date fair value of consideration paid in a business combination, including contingent consideration. The Company allocates the acquisition-date fair value to the assets acquired and liabilities assumed based on the estimated fair values. The excess of the acquisition-date fair value of consideration paid 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. The Company includes the results of operations of the businesses that are acquired as of the acquisition date.

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 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.

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

Impairment of Long-lived Assets

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

Revenue Recognition

The Company's revenue consists of product revenue resulting from the 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 separate performance obligations in the arrangement for a system sale. Traded-in systems could 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.

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 $51.5 million and $34.2 million as of December 31, 2019, and 2018, respectively. The Company did not incur any impairment losses during the periods presented.

Intuitive System Leasing

The Company enters into sales-type 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 system or system component, while non-lease elements generally include service, instruments, and accessories. For some lease arrangements, the customers are provided with the right to purchase the leased system at some point during and/or at the end of

the lease term. Except for certain usage-based lease arrangements, lease arrangements generally do not provide rights for the customers to exit or terminate the lease without incurring a penalty. For some leases, lease payments are based on the usage of the systems.

In determining whether a transaction should be classified as a sales-type or operating lease, the Company considers the following terms at lease commencement: (1) whether title of the system transfers automatically or for a nominal fee by the end of the lease term, (2) whether the present value of the minimum lease payments equals or exceeds substantially all of the fair value of the leased system, (3) whether the lease term is for the major part of the remaining economic life of the leased system, (4) whether the lease grants the lessee an option to purchase the leased system that the lessee is reasonably certain to exercise, and (5) whether the underlying system is of such a specialized nature that it is expected to have no alternative use to the Company 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 related to lease elements from sales-type leases is presented as product revenue. Revenue related to lease elements from operating lease arrangements is generally recognized on a straight-line basis over the lease term or based upon system usage and is presented as product revenue.

Other Leasing Arrangements

The Company determines if an arrangement contains a lease at inception. For arrangements where the Company is the lessee, operating leases are included in intangible and other assets, net, other accrued liabilities, and other long-term liabilities on the Consolidated Balance Sheet as of December 31, 2019. The Company currently does not have any finance leases.

Operating lease right-of-use ("ROU") assets and operating leases liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities, as the Company's leases generally do not provide an implicit rate. Lease terms may include options to extend or terminate when the Company is reasonably certain the option will be exercised. Lease expense is recognized on a straight-line basis over the lease term.

The Company also has lease arrangements with lease and non-lease components. The Company elected the practical expedient not to separate non-lease components from lease components for the Company's real estate and automobile leases. Additionally, the Company applied a portfolio approach to effectively account for the operating lease ROU assets and lease liabilities for the Company's automobile leases. The Company also elected to apply the short-term lease measurement and recognition exemption in which ROU assets and lease liabilities are not recognized for leases with terms of 12 months or less.

Allowances 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 the estimate, 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 that 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 actively traded options with expirations greater than one year on the Company’s common stock. The extent to which the Company relies on market-based volatility when valuing options depends, 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 date 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 hedging or non-hedging 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 that 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 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.

The Company recognizes excess tax benefits and tax deficiencies in the provision for income taxes as discrete items in the period when the awards vest or are settled. The Company accounts for Global Intangible Low-Taxed Income ("GILTI") as period costs when incurred.

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, 2019, and 2018, 85% 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

From time to time, 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 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 that are 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.

Recently Adopted Accounting Pronouncements

Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, *Leases (Topic 842)* ("Topic 842"), which amended prior accounting standards for leases. The Company adopted Topic 842 on January 1, 2019, using the alternative modified transition method, which requires a cumulative-effect adjustment, if any, to the opening balance of retained earnings to be recognized on the date of adoption with prior periods not restated. There was no cumulative-effect adjustment recorded on January 1, 2019. Please see the description of the Company's "Intuitive System Leasing" and "Other Leasing Arrangements" accounting policies above. Also, see "Note 6. Leases" for further information.

As permitted by the new standard, the Company elected the following practical expedients when assessing the transition impact from both the lessee and lessor perspectives: (i) not to reassess whether any expired or existing contracts as of January 1, 2019, are or contain leases; (ii) not to reassess the lease classification for any expired or existing leases as of January 1, 2019; (iii) not to reassess initial direct costs for any existing leases as of January 1, 2019; and (iv) not to reassess whether land easements meet the definition of a lease.

The primary impact for the Company was the balance sheet recognition of ROU assets and lease liabilities for operating leases as a lessee.

Customer's 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 standard also requires customers to amortize the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. The Company early adopted this standard, as of January 1, 2019, on a prospective basis for all applicable implementation costs.

The Company recorded these capitalized implementation costs within intangible and other assets, net in the accompanying Consolidated Balance Sheets and recognized the related amortization expenses generally over the fixed, non-cancellable term of the associated arrangement on a straight-line basis. The adoption did not have a material impact on the Company's financial position and the results of operations in 2019.

Recent Accounting Pronouncements Not Yet Adopted

Financial Instruments (Topic 326)

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"),* which requires an entity to measure expected credit losses for certain financial instruments and financial assets, including trade receivables. This standard also modifies the impairment model for available-for-sale debt securities and requires that credit losses be recorded through an allowance for credit losses and limits the credit loss to the amount by which fair value is below amortized cost. The Company will adopt ASU 2016-13 as of January 1, 2020, using the modified retrospective transition method. The adoption of ASU 2016-13 is not expected to have a material impact on the Company's financial position and the results of operations.

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, 2019, and 2018 (in millions):

					Reported as:		
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Cash and Cash Equivalents	Short-term Investments	Long-term Investments
December 31, 2019							
Cash	$ 413.1	$ —	$ —	$ 413.1	$ 413.1	$ —	$ —
Level 1:							
Money market funds	726.8	—	—	726.8	726.8	—	—
U.S. treasuries	1,935.8	9.7	(0.4)	1,945.1	—	890.8	1,054.3
Subtotal	2,662.6	9.7	(0.4)	2,671.9	726.8	890.8	1,054.3
Level 2:							
Commercial paper	165.1	—	—	165.1	25.5	139.6	—
Corporate securities	2,096.1	16.8	(0.2)	2,112.7	—	798.5	1,314.2
U.S. government agencies	418.3	1.1	(0.2)	419.2	—	209.6	209.6
Non-U.S. government securities	4.5	—	—	4.5	—	4.5	—
Municipal securities	58.4	0.3	—	58.7	2.2	11.1	45.4
Subtotal	2,742.4	18.2	(0.4)	2,760.2	27.7	1,163.3	1,569.2
Total assets measured at fair value	$ 5,818.1	$ 27.9	$ (0.8)	$ 5,845.2	$ 1,167.6	$ 2,054.1	$ 2,623.5

	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 connection with a concluded legal matter in prepaids and other current assets in the accompanying Consolidated Balance Sheets.

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, 2019 (in millions):

	Amortized Cost	Fair Value
Mature in less than one year	$ 2,082.4	$ 2,087.7
Mature in one to five years	2,595.8	2,617.6
Total	$ 4,678.2	$ 4,705.3

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

As of December 31, 2019, and 2018, net unrealized gains/(losses) on investments of $20.4 million and $(9.8) million, net of tax, respectively, were included in accumulated other comprehensive income/(loss) in the accompanying Consolidated Balance Sheets.

The following tables present the breakdown of the available-for-sale investments with unrealized losses at December 31, 2019, and 2018 (in millions):

	Unrealized losses less than 12 months		Unrealized losses 12 months or greater		Total	
December 31, 2019	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate securities	$ 237.0	$ (0.2)	$ —	$ —	$ 237.0	$ (0.2)
U.S. treasuries	236.5	(0.2)	87.5	(0.2)	324.0	(0.4)
U.S. government agencies	45.9	(0.1)	45.5	(0.1)	91.4	(0.2)
Total	$ 519.4	$ (0.5)	$ 133.0	$ (0.3)	$ 652.4	$ (0.8)
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)
Total	$ 1,434.1	$ (2.8)	$ 1,427.6	$ (11.1)	$ 2,861.7	$ (13.9)

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, the 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 unrealized after-tax gain or loss from the hedge as a component of accumulated other comprehensive income/(loss) in stockholders' equity and reclassifies the amount 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, Indian Rupee, and New Taiwan Dollar.

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,		
	2019	2018	2017
Recognized gains (losses) in interest and other income, net	$ 6.4	$ 8.7	$ (9.2)
Foreign exchange gains (losses) related to balance sheet re-measurement	$ (1.5)	$ (2.6)	$ 9.7

The notional amounts for derivative instruments provide one measure of the transaction volume. Total gross notional amounts (in USD) for derivatives and the 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, 2019	December 31, 2018	December 31, 2019	December 31, 2018
Notional amounts:				
Forward contracts	$ 154.5	$ 183.0	$ 227.2	$ 182.7
Gross fair value recorded in:				
Prepaid and other current assets	$ 1.3	$ 3.1	$ 2.2	$ 4.1
Other accrued liabilities	$ 0.5	$ 0.9	$ 0.7	$ 1.1

NOTE 4. CONSOLIDATED FINANCIAL STATEMENT DETAILS

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

	December 31,	
	2019	2018
Inventory:		
Raw materials	$ 211.0	$ 164.1
Work-in-process	75.9	40.0
Finished goods	308.6	204.9
Total inventory	$ 595.5	$ 409.0

	December 31,	
	2019	2018
Property, plant, and equipment, net:		
Land	$ 248.0	$ 184.6
Building and building/leasehold improvements	408.3	266.2
Machinery and equipment	357.2	280.1
Operating lease assets—Intuitive System Leasing	293.8	150.2
Computer and office equipment	74.0	52.6
Capitalized software	182.2	157.8
Construction-in-process	272.5	156.7
Gross property, plant, and equipment	1,836.0	1,248.2
Less: Accumulated depreciation*	(563.1)	(436.2)
Total property, plant, and equipment, net	$ 1,272.9	$ 812.0
*Accumulated depreciation associated with operating lease assets—Intuitive System Leasing	(62.2)	(32.1)

	December 31,	
	2019	2018
Other accrued liabilities—short-term		
Taxes payable	$ 37.9	$ 39.1
Litigation-related accruals	5.8	55.0
Current portion of deferred purchase consideration payments	35.7	4.6
Current portion of contingent consideration	44.5	—
Other accrued liabilities	193.4	133.1
Total other accrued liabilities—short-term	$ 317.3	$ 231.8

	December 31,	
	2019	2018
Other long-term liabilities:		
Income taxes—long-term	$ 258.6	$ 270.2
Deferred revenue—long-term	27.4	33.0
Other long-term liabilities	132.3	35.4
Total other long-term liabilities	$ 418.3	$ 338.6

Supplemental Cash flow Information

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

	Years Ended December 31,		
	2019	2018	2017
Income taxes paid	$ 158.6	$ 179.2	$ 147.5
Supplemental non-cash investing and financing activities:			
Equipment transfers from inventory to property, plant, and equipment	$ 210.6	$ 125.7	$ 65.8
Deferred payments and contingent consideration related to business combinations	$ 86.6	$ 16.7	$ —

NOTE 5. REVENUE

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

	Years Ended December 31,		
U.S.	**2019**	**2018**	**2017**
Instruments and accessories	$ 1,790.4	$ 1,485.2	$ 1,263.1
Systems	830.7	692.2	603.5
Services	508.4	456.1	419.2
Total U.S. revenue	$ 3,129.5	$ 2,633.5	$ 2,285.8
Outside of U.S. ("OUS")			
Instruments and accessories	$ 617.8	$ 476.8	$ 373.8
Systems	515.4	434.9	324.9
Services	215.8	179.0	153.7
Total OUS revenue	$ 1,349.0	$ 1,090.7	$ 852.4
Total			
Instruments and accessories	$ 2,408.2	$ 1,962.0	$ 1,636.9
Systems	1,346.1	1,127.1	928.4
Services	724.2	635.1	572.9
Total revenue	$ 4,478.5	$ 3,724.2	$ 3,138.2

Remaining Performance Obligations

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. In addition, non-lease elements associated with the Company's lease arrangements are primarily comprised of service contracts that will be satisfied and recognized as revenue in future periods. The transaction price allocated to the remaining performance obligations and the non-lease elements associated with the lease arrangements were $1,597 million as of December 31, 2019. The remaining performance obligations are expected to be satisfied over the term of the individual sales arrangements, which generally are 5 years. Service revenue associated with the lease arrangements will generally be recognized over the service period, which generally coincides with the lease term.

Contract Assets and Liabilities

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

	As of	
	December 31, 2019	**December 31, 2018**
Contract assets	$ 20.8	$ 12.4
Deferred revenue	$ 365.2	$ 327.3

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, 2019, the Company recognized $307 million of revenue that was included in the deferred revenue balance as of December 31, 2018. During the year ended December 31, 2018, the Company recognized $269 million of revenue that was included in the deferred revenue balance as of December 31, 2017.

Intuitive System Leasing

The following table presents revenue from Intuitive System Leasing arrangements (in millions):

	Years Ended December 31,		
	2019	2018	2017
Sales-type lease revenue	$ 81.6	$ 69.8	$ 49.5
Operating lease revenue	$ 106.9	$ 51.4	$ 25.9

NOTE 6. LEASES

Lessor Information related to Intuitive System Leasing

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

	December 31,	
	2019	2018
Gross lease receivables	$ 191.9	$ 150.4
Unearned income	(10.1)	(6.3)
Allowance for credit loss	(1.2)	(1.0)
Net investment in sales-type leases	$ 180.6	$ 143.1
Reported as:		
Prepaids and other current assets	$ 63.1	$ 51.2
Intangible and other assets, net	117.5	91.9
Total, net	$ 180.6	$ 143.1

Contractual maturities of gross lease receivables as of December 31, 2019, are as follows (in millions):

Fiscal Year	Amount
2020	$ 63.5
2021	52.9
2022	36.2
2023	22.1
2024	15.4
2025 and thereafter	1.8
Total	$ 191.9

Operating Leases. The Company's operating lease terms are generally less than seven years. Future minimum lease payments related to the non-cancellable portion of operating leases (which excludes contingent payments related to usage-based arrangements) as of December 31, 2019, are as follows (in millions):

Fiscal Year	Amount
2020	$ 146.5
2021	134.2
2022	116.0
2023	86.6
2024	40.6
2025 and thereafter	10.8
Total	$ 534.7

Contingent rental revenue relating to operating lease arrangements was not material for the years ended December 31, 2019, 2018, and 2017.

Lessee Information

The Company enters into operating leases for real estate, automobiles, and certain equipment. Operating lease expense was $19.1 million for the year ended December 31, 2019. For leases with terms of 12 months or less, the related expense for the year ended December 31, 2019 was not material.

Supplemental cash flow information for the year ended December 31, 2019, related to operating leases was as follows (in millions):

	Amount
Cash paid for leases that were included within operating cash outflows	$ 18.8
Right-of-use assets recognized related to new lease obligations	$ 21.5

Supplemental balance sheet information, as of December 31, 2019, related to operating leases was as follows (in millions, except lease term and discount rate):

Reported as:	Amount
Intangible and other assets, net (Right-of-use assets)	$ 74.4
Other accrued liabilities	$ 7.7
Other long-term liabilities	68.7
Total lease liabilities	$ 76.4
Weighted average remaining lease term	6.1 years
Weighted average discount rate	3.4 %

As of December 31, 2019, the future payments related to the Company's operating lease liabilities are scheduled as follows (in millions):

Fiscal Year	Amount
2020	$ 9.6
2021	19.7
2022	14.7
2023	12.8
2024	8.4
2025 and thereafter	22.4
Total lease payments	$ 87.6
Less imputed interest	(11.2)
Total operating lease liabilities	$ 76.4

ASC 840 Disclosures

The Company elected the alternative modified transition method and is required to present previously disclosed information under the prior accounting standards for leases.

Lessor Information

Sales-type Leases. Contractual maturities of gross lease receivables as of December 31, 2018, are as follows (in millions):

Fiscal Year	Amount
2019	$ 50.8
2020	46.5
2021	29.7
2022	14.9
2023	7.5
2024 and thereafter	1.0
Total lease payments	$ 150.4

Operating Leases. Future minimum lease payments related to the non-cancellable portion of operating leases (which excludes contingent payments related to usage-based arrangements) as of December 31, 2018, are as follows (in millions):

Fiscal Year	Amount
2019	$ 88.0
2020	85.8
2021	68.8
2022	51.3
2023	25.4
2024 and thereafter	1.9
Total lease payments	$ 321.2

Lessee Information

Operating Leases. Future minimum lease commitments under the Company's operating leases as of December 31, 2018, are as follows (in millions):

Fiscal Year	Amount
2019	$ 15.1
2020	14.5
2021	12.7
2022	11.2
2023	11.0
2024 and thereafter	30.9
Total lease payments	$ 95.4

NOTE 7. GOODWILL AND INTANGIBLE ASSETS

Acquisitions in 2019

Chindex

During the first quarter of 2019, the Company's majority-owned Joint Venture with Fosun Pharma acquired certain assets from Chindex and its affiliates, a subsidiary of Fosun Pharma, including distribution rights, customer relationships, and certain personnel on January 5, 2019, which collectively met the definition of a business. Chindex was the Company's distributor of da Vinci products and services in China. The transaction enhances the Company's ability to serve patients, surgeons, and hospitals in China.

The total purchase consideration of $66.0 million, as of the acquisition date, included a contingent consideration liability of $64.7 million and an upfront cash payment of $1.3 million. The amount and timing of the future contingent consideration payments are based upon the underlying performance of the business in 2019 and 2020. As of the acquisition date, the estimated total undiscounted contingent consideration was approximately $81 million. As of December 31, 2019, the estimated total undiscounted contingent consideration has decreased by approximately $6 million due to a change in the timing of the milestone achievements. The contingent consideration liability was measured at estimated fair value using a discounted cash flow model, which requires significant inputs not observable in the market and, thus, represents a Level 3 measurement. Key assumptions included (1) the probability and timing of milestone achievements based on projected future revenues through 2019 and 2020, and (2) the discount rate used to calculate the present value of the milestone payments. At each reporting period until the contingent consideration is settled, the Company remeasures the contingent consideration liability and records changes in fair value within selling, general and administrative expenses. For the year ended December 31, 2019, the contingent consideration liability changed due to payments of $16.5 million and net additional expenses of $7.2 million, primarily related to accretion due to the passage of time. Changes to the contingent consideration estimate can result from adjustments to discount rates, accretion due to the passage of time, or change in estimates in the performance of the business. The assumptions related to determining the fair value of contingent consideration include a significant amount of judgment, and any changes in the underlying estimates could have a material impact on the amount of contingent consideration adjustment recorded in any given period.

The Company recorded $1.7 million of net tangible assets, $58.6 million of intangible assets, and $5.7 million of residual goodwill. Intangible assets included distribution rights of $48.2 million and customer relationships of $10.4 million, which are being amortized over a weighted-average period of 2.9 years. Key assumptions included (1) the amount and timing of projected

future cash flows, and (2) the discount rate used to determine the present value of these cash flows. The goodwill is not amortizable for income tax purposes. The allocation of purchase consideration was completed in the third quarter of 2019. There were no adjustments to the provisional amounts in the measurement period.

Schölly

During the third quarter of 2019, the Company acquired certain assets and operations from Schölly Fiberoptic GmbH ("Schölly"), including manufacturing process technology, a non-compete agreement, certain personnel, and net tangible assets on August 31, 2019, which collectively met the definition of a business. The Company believes that the transaction strengthens the Company's supply chain and manufacturing capacity for imaging products used in the Company's da Vinci systems. The total purchase consideration of $101.4 million consists of an initial cash payment of $34.4 million and deferred cash payments totaling approximately $67.0 million, of which $37.3 million continues to be deferred as of December 31, 2019. The timing of the future payments is based upon achieving certain integration steps, which occur during 2020 and are expected to be completed around the end of 2020.

The Company preliminarily recorded $10.7 million of net tangible assets, which included $6.7 million of inventory and $1.4 million of cash, $31.0 million of intangible assets, and $59.7 million of residual goodwill. The balances include the net impact of adjustments to the preliminary allocation of the purchase price within the one year measurement period, which increased intangible assets and goodwill by $0.5 million and $0.4 million, respectively, during the fourth quarter of 2019. There was no significant impact to the Consolidated Statements of Income as result of these adjustments. Intangible assets included manufacturing process technology of $28.0 million and non-compete provisions of $3.0 million, which are being amortized over a weighted-average period of 6.6 years. Key assumptions included (1) the amount and timing of projected future cash flows, and (2) the discount rate used to determine the present value of these cash flows. The allocation of purchase consideration is considered preliminary with provisional amounts primarily related to working capital. Goodwill primarily consists of the manufacturing and other synergies of the combined operations and the value of the assembled workforce. The majority of goodwill is not deductible for income tax purposes.

In 2019, the Company has included the results of the acquired businesses, since their acquisition dates, in its Consolidated Financial Statements, and the revenues and earnings were not material in the year. Pro forma results of operations related to the acquisitions have not been presented, because the operating results of the acquired businesses are not considered material to the Consolidated Financial Statements.

Acquisitions in 2018

During the second quarter of 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. After the net impact of measurement-period adjustments of $2.5 million, the purchase consideration consisted of $36.2 million in cash and the Company recorded $4.1 million of net tangible assets, $24.2 million of intangible assets, and $7.3 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 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 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 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.

In 2018, the Company has included the results of the acquired businesses, since their acquisition dates, in its Consolidated Financial Statements, and the revenues and earnings were not material in the year. Pro forma results of operations related to the acquisitions have not been presented, because the operating results of the acquired businesses are not material to the Consolidated Financial Statements.

Goodwill

The following table summarizes the changes in the carrying amount of goodwill (in millions):

	Amount
Balance at December 31, 2017	$ 201.1
Acquisition activity	40.2
Translation and other	(0.7)
Balance at December 31, 2018	240.6
Acquisition activity	65.4
Translation and other	1.2
Balance at December 31, 2019	$ 307.2

The Company completed its annual goodwill impairment test and determined that no impairment existed. As of December 31, 2019, there has been no impairment of goodwill.

Intangible Assets

The following table summarizes the components of gross intangible asset, accumulated amortization, and net intangible asset balances as of December 31, 2019, and 2018 (in millions):

	December 31, 2019			December 31, 2018		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents and developed technology	$ 186.7	$ (149.0)	$ 37.7	$ 158.7	$ (144.7)	$ 14.0
Distribution rights and others	91.3	(44.9)	46.4	40.2	(12.9)	27.3
Customer relationships	57.7	(29.7)	28.0	48.5	(23.1)	25.4
Total intangible assets	$ 335.7	$ (223.6)	$ 112.1	$ 247.4	$ (180.7)	$ 66.7

Amortization expense related to intangible assets was $43.0 million, $14.2 million, and $12.9 million for the years ended December 31, 2019, 2018, and 2017, respectively.

The estimated future amortization expense related to intangible assets as of December 31, 2019, is as follows (in millions):

Fiscal Year	Amount
2020	$ 46.1
2021	18.7
2022	16.0
2023	11.5
2024	9.4
2025 and thereafter	10.4
Total	$ 112.1

The preceding expected amortization expense is an estimate. Actual amounts of amortization expense may differ from estimated amounts due to additional intangible asset acquisitions, changes in foreign currency exchange rates, impairment of intangible assets, accelerated amortization of intangible assets, and other events.

NOTE 8. COMMITMENTS AND CONTINGENCIES

COMMITMENTS

Our commitments include an estimated amount of approximately $845 million relating to the Company's open purchase orders and contractual obligations that occur in the ordinary course of business, including commitments with contract manufacturers and suppliers for which the Company has not received the goods or services, commitments for capital expenditures and construction-related activities for which the Company has not received the services, and acquisition and licensing of intellectual property. 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. For instances in which the achievement of these milestones is neither probable nor reasonably estimable, such contingencies are not included in the estimated amount.

CONTINGENCIES

From time to time, 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 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 the 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, 2019, 2018, and 2017, the Company recorded pre-tax litigation charges of $0.5 million, $45.2 million, and $16.3 million, respectively, related to the securities class action lawsuits and the tolled product liability claims described below. A total of $4.2 million and $53.0 million associated with these matters were included in other accrued liabilities in the accompanying Consolidated Balance Sheets as of December 31, 2019, and 2018, 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, the payment was made in 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, 2019, the majority of the "tolled claims" have either been resolved or the matters have been filed.

During the years ended December 31, 2019, 2018, and 2017, the Company recorded $0.5 million, $2.7 million, and $16.3 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, 2019, and 2018, a total of $4.2 million and $10.5 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 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. A claim construction hearing occurred on October 1, 2018, and the court issued a scheduling order on December 28, 2018. On March 20, 2019, the court granted the Company's Motion to Stay pending an Inter Parties Review to be held at the Patent Trademark and Appeals Board to review patentability of six of the seven patents noted above and vacated the trial date. On August 1, 2019, the court granted the parties' joint stipulation to modify the stay in light of Ethicon's U.S. International Trade Commission ("USITC") complaint against Intuitive involving U.S. Patent Nos. 8,479,969 and 9,113,874, discussed below.

On August 27, 2018, 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. On March 19, 2019, Ethicon filed a Motion for Leave to File a First Amended Complaint, removing allegations related to U.S. Patent No. 9,326,770 and adding allegations related to U.S. Patent Nos. 9,844,379 and 8,479,969. On July 17, 2019, the court entered an order denying the amendment, without prejudice, and granting the parties' joint stipulation to stay the case in its entirety in light of the USITC investigation involving U.S. Patent Nos. 9,844,369 and 7,490,749, discussed below.

On May 30, 2019, Ethicon filed a complaint with the USITC, asserting infringement of U.S. Patent Nos. 9,884,369, 7,490,749, 9,844,379, 9,113,874, and 8,479,969. On June 28, 2019, the USITC voted to institute an investigation (No. 337-TA-1167) with respect to claims in this complaint. The accused products include the Company's EndoWrist 30, EndoWrist 45, SureForm 45, and SureForm 60 Staplers, as well as the stapler reload cartridges. The evidentiary hearing is set for April 20-24, 2020, and the target for completion of the investigation is December 7, 2020. An unfavorable ruling by the USITC could have an adverse effect on our results of operations, including a prohibition on importing the accused products into the U.S. or necessitating workarounds that may limit certain features of our products.

Based on currently available information, the Company is unable to make a reasonable estimate of losses or range of losses, if any, arising from these matters.

Commercial Litigation

On February 27, 2019, Restore Robotics LLC and Restore Robotics Repair LLC ("Restore") filed a Complaint alleging anti-trust claims against the Company. On May 13, 2019, Restore filed an Amended Complaint alleging anti-trust claims relating to the da Vinci Surgical System and EndoWrist service, maintenance, and repair processes. On September 16, 2019, the Court partially granted and partially denied the Company's Motion to Dismiss the Amended Complaint.

On September 30, 2019, the Company filed an Answer denying the anti-trust allegations and a Counterclaim against Restore. The Company filed Amended Counterclaims after the Court partially granted and partially denied Restore's Motion to Dismiss the Counterclaim. The Amended Counterclaims allege that Restore violated the Federal Lanham Act, the Federal Computer Fraud and Abuse Act, and Florida's Deceptive and Unfair Trade Practices Act and that Restore is also liable to the Company for Unfair Competition and Tortious Interference with Contract. On January 7, 2020, the Court denied Restore's Motion to Dismiss the Amended Counterclaims.

In its initial scheduling order, the Court stated that it anticipate trial in this case to occur on or before February 2022. Based on currently available information, the Company is unable to make a reasonable estimate of loss or range of losses, if any, arising from these matters.

NOTE 9. STOCKHOLDERS' EQUITY

STOCK REPURCHASE PROGRAM

Through December 31, 2019, the Company's Board of Directors (the "Board") has authorized an aggregate of $7.5 billion of funding for the Company's common stock repurchase program (the "Repurchase Program") since its establishment in March 2009. The most recent authorization occurred in January 2019 when the Board increased the authorized amount available under the Repurchase Program to $2.0 billion. As of December 31, 2019, the remaining amount of share repurchases authorized by the Board under the Repurchase Program was approximately $1.7 billion.

The following table provides the stock repurchase activities during the years ended December 31, 2019, 2018, and 2017 (in millions, except per share amounts):

	Years Ended December 31,		
	2019	2018	2017
Shares repurchased	0.6	—	7.3
Average price per share	$ 481.35	$ —	$ 310.32
Value of shares repurchased	$ 269.5	$ —	$ 2,274.0

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, 2019, 2018, and 2017, the Company reduced common stock and additional paid-in capital by an aggregate of $14.5 million, zero, and $152 million, respectively, and charged $255 million, zero, $2,122 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, 2019, and 2018, are as follows (in millions):

	Year Ended December 31, 2019				
	Gains (Losses) on Hedge Instruments	Unrealized Gains (Losses) on Available-for-Sale Securities	Foreign Currency Translation Gains (Losses)	Employee Benefit Plans	Total
Beginning balance	$ 0.2	$ (9.8)	$ (0.3)	$ (3.4)	$ (13.3)
Other comprehensive income (loss) before reclassifications	5.8	30.7	0.3	(5.9)	30.9
Reclassified from accumulated other comprehensive (loss)	(5.3)	(0.5)	—	0.6	(5.2)
Net current-period other comprehensive income (loss)	0.5	30.2	0.3	(5.3)	25.7
Ending balance	$ 0.7	$ 20.4	$ —	$ (8.7)	$ 12.4

	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)

NOTE 10. 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 2029. In April 2019, 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 24,450,000 to 28,450,000. As of December 31, 2019, approximately 5.9 million shares were reserved for future issuance under the 2010 Plan. A maximum of 2.6 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. The New Hire Plan expired in October 2019 and, therefore, there are no shares reserved for future issuance under the New Hire Plan. However, awards granted prior to the plan's expiration continue to remain outstanding until their original expiration date.

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 of 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 of 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 vested over a three-year period with 12/36 of the shares vesting after one year from the date of grant and 1/36 of the shares vesting monthly thereafter. Annual stock option grants vested 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, 2019, approximately 0.1 million shares were reserved for future issuance under the Directors' Plan. However, the Company no longer intends to issue grants from the Directors' Plan in the future and instead plans to utilize the 2010 Plan to make grants to non-employee directors.

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 $56.4 million, $46.8 million, and $38.3 million in employee contributions for the years ended December 31, 2019, 2018, and 2017, respectively. As of December 31, 2019, there were approximately 1.2 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. The RSUs to existing non-employee directors vest one year from the date of grant or at the next Annual Shareholders Meeting, whichever comes first. 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 2019 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, 2018	6.2	$ 200.79
Options granted	0.6	$ 523.30
Options exercised	(1.3)	$ 159.46
Options forfeited/expired	(0.1)	$ 381.82
Balance at December 31, 2019	5.4	$ 246.64

The aggregate intrinsic value of stock options exercised under the Company's stock plans determined as of the date of option exercise was $512.0 million, $526.6 million, and $379.9 million during the years ended December 31, 2019, 2018, and 2017, respectively. Cash received from option exercises and employee stock purchase plans for the years ended December 31, 2019, 2018, and 2017, was $272.8 million, $236.6 million, and $415.5 million, respectively. The income tax benefit from stock options exercised was $109.7 million for the year ended December 31, 2019.

The following table summarizes significant ranges of outstanding and exercisable options as of December 31, 2019 (number of shares and aggregate intrinsic value in millions):

	Options Outstanding				Options Exercisable			
Range of Exercise Prices	Number of Shares	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (1)	Number of Shares	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value (1)
$86.88-$148.03	1.1	2.8	$ 127.46		1.1		$ 127.46	
$150.50-$172.44	1.4	3.6	$ 166.28		1.4		$ 166.29	
$172.76-$231.00	1.2	5.1	$ 194.42		1.2		$ 193.89	
$231.11-$505.36	1.1	8.1	$ 376.53		0.5		$ 334.67	
$508.19-$585.57	0.6	9.0	$ 536.41		0.1		$ 531.66	
Total	5.4	5.3	$ 246.64	$1,844.4	4.3	4.4	$ 195.76	$1,702.4

(1) The aggregate intrinsic value represents the total pre-tax intrinsic value, based on the Company's closing stock price of $591.15 at December 31, 2019, 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, 2019, a total of 5.2 million shares of stock options vested and expected to vest had a weighted-average remaining contractual life of 5.2 years, an aggregate intrinsic value of $1,833.1 million, and a weighted-average exercise price of $241.65.

Restricted Stock Units Information

RSU activity for the year ended December 31, 2019, was as follows (in millions, except per share amounts):

	Shares	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2018	2.0	$ 295.70
Granted	0.8	541.36
Vested	(0.8)	258.87
Forfeited	(0.1)	382.52
Unvested balance at December 31, 2019	1.9	410.09

As of December 31, 2019, 1.7 million shares of RSUs were expected to vest with an aggregate intrinsic value of $1,032 million. The aggregate vesting date fair value of RSUs vested was $433.2 million, $334.3 million, and $144.2 million during the years ended December 31, 2019, 2018, and 2017, respectively.

Share-Based Compensation Expense

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

	Years Ended December 31,		
	2019	2018	2017
Cost of sales—products	$ 46.6	$ 36.4	$ 28.1
Cost of sales—services	20.4	16.8	14.0
Total cost of sales	67.0	53.2	42.1
Selling, general and administrative	169.5	133.2	111.8
Research and development	101.4	76.2	56.0
Share-based compensation expense before income taxes	337.9	262.6	209.9
Income tax effect	70.2	54.3	49.2
Share-based compensation expense after income taxes	$ 267.7	$ 208.3	$ 160.7

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 under the ESPP, 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, 2019, 2018, and 2017, were as follows:

	Years Ended December 31,		
STOCK OPTION PLANS	2019	2018	2017
Risk-free interest rate	2.0 %	2.7 %	1.8 %
Expected term (years)	4.1	4.3	4.1
Volatility	30 %	33 %	25 %
Fair value at grant date	$ 142.53	$ 146.30	$ 67.03
EMPLOYEE STOCK PURCHASE PLAN			
Risk-free interest rate	2.1 %	2.1 %	1.2 %
Expected term (years)	1.2	1.3	1.2
Volatility	29 %	32 %	28 %
Fair value at grant date	$ 148.99	$ 135.84	$ 79.77
RESTRICTED STOCK UNITS			
Fair value at grant date	$ 541.36	$ 431.11	$ 249.34

As share-based compensation expense recognized in the Consolidated Statements of Income during the years ended December 31, 2019, 2018, and 2017, is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures.

As of December 31, 2019, there was a total of $110.1 million, $493.6 million, and $31.4 million of total unrecognized compensation expense related to unvested stock options, restricted stock units, and employee stock purchases, respectively. The unrecognized compensation expense is expected to be recognized over a weighted-average period of 2.5 years for unvested stock options, 2.2 years for unvested restricted stock units, and 1.4 years for rights granted to acquire common stock under the ESPP.

NOTE 11. INCOME TAXES

Income before provision for income taxes for the years ended December 31, 2019, 2018, and 2017, consisted of the following (in millions):

	Years Ended December 31,		
	2019	2018	2017
U.S.	$ 1,053.7	$ 852.7	$ 774.7
Foreign	448.5	426.8	330.1
Total income before provision for income taxes	$ 1,502.2	$ 1,279.5	$ 1,104.8

The provision for income taxes for the years ended December 31, 2019, 2018, and 2017, consisted of the following (in millions):

	Years Ended December 31,		
	2019	2018	2017
Current			
Federal	$ 82.0	$ 89.5	$ 352.1
State	26.5	21.1	13.0
Foreign	18.0	9.9	8.7
	$ 126.5	$ 120.5	$ 373.8
Deferred			
Federal	$ 8.5	$ (4.1)	$ 62.8
State	3.2	(0.3)	(0.3)
Foreign	(17.8)	38.4	(2.4)
	$ (6.1)	$ 34.0	$ 60.1
Total income tax expense	$ 120.4	$ 154.5	$ 433.9

Income tax expense differs from amounts computed by applying the statutory federal income rate of 21% for the years ended December 31, 2019, and 2018, and 35% for the year ended December 31, 2017, as a result of the following (in millions):

	Years Ended December 31,		
	2019	2018	2017
Federal tax at statutory rate	$ 315.5	$ 268.7	$ 386.7
Increase (reduction) in tax resulting from:			
State taxes, net of federal benefits	29.7	20.8	16.0
Foreign rate differential	(56.2)	(44.7)	(115.7)
U.S. tax on foreign earnings	55.0	43.7	8.4
Research and development credit	(32.7)	(25.2)	(15.3)
Share-based compensation not benefited	13.5	9.9	10.8
Domestic production activities deduction	—	—	(7.9)
Reversal of unrecognized tax benefits	(8.4)	(5.2)	(62.4)
Tax Cuts and Jobs Act impact	—	0.5	317.8
Excess tax benefits related to share-based compensation arrangements	(146.5)	(116.2)	(102.8)
Deferred tax remeasurement due to Swiss Tax Reform	(51.3)	—	—
Other	1.8	2.2	(1.7)
Total income tax expense	$ 120.4	$ 154.5	$ 433.9

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,	
	2019	2018
Deferred tax assets:		
Share-based compensation expense	$ 95.6	$ 87.2
Expenses deducted in later years for tax purposes	42.0	29.1
Intangible assets	362.3	351.9
Research and other credits	56.1	40.1
Other	10.4	9.0
Gross deferred tax assets	$ 566.4	$ 517.3
Valuation allowance	(57.2)	(42.3)
Deferred tax assets	$ 509.2	$ 475.0
Deferred tax liabilities:		
Fixed assets	$ (75.3)	$ (42.2)
Intangible assets	(8.3)	(7.5)
Other	—	(0.1)
Deferred tax liabilities	$ (83.6)	$ (49.8)
Net deferred tax assets	$ 425.6	$ 425.2

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 due to the re-measurement of its net deferred tax assets at a reduced U.S. federal statutory rate of 21%. 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 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.

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 years ended December 31, 2019, and 2018, were insignificant, while for the year ended December 31, 2017, was approximately $10.9 million, or $0.09 per diluted share.

In August 2019, Swiss tax reform was enacted, which resulted in a higher statutory rate for the Company's Swiss entity for years after 2019. The Company remeasured its Swiss deferred tax asset at the enacted tax rate and recorded an income tax benefit of $51.3 million in its 2019 tax provision.

As of December 31, 2019, and 2018, the Company had valuation allowances of $57.2 million and $42.3 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 $17.9 million during the year ended December 31, 2019. The net increase was primarily due to increases related to 2019 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 and an audit conclusion. The Company had gross unrecognized tax benefits of approximately $96.7 million, $78.8 million, and $65.4 million as of December 31, 2019, 2018, and 2017, 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, 2019, 2018, and 2017, gross interest related to unrecognized tax benefits accrued was $2.9 million, $2.6 million, and $1.8 million, respectively. A majority of the Company's net unrecognized tax benefits and related interest is presented in other long-term 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, 2019, 2018, and 2017, are as follows (in millions):

	Years Ended December 31,		
	2019	2018	2017
Beginning balance	$ 78.8	$ 65.4	$ 106.0
Increases related to tax positions taken during the current year	26.5	22.5	21.1
Increases related to tax positions taken during a prior year	1.2	—	—
Decreases related to tax positions taken during a prior year	—	(0.9)	(46.5)
Decreases related to settlements with tax authorities	(3.8)	—	(0.5)
Decreases related to expiration of statute of limitations	(6.0)	(8.2)	(14.7)
Ending balance	$ 96.7	$ 78.8	$ 65.4

The Company files federal, state, and foreign income tax returns in many U.S. and OUS jurisdictions. Years before 2016 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.

In July 2015, a U.S. Tax Court opinion (the "2015 Opinion") was issued involving an independent third party related to intercompany charges for share-based compensation. Based on the findings of the U.S. Tax Court, the Company was required to, and did, refund to its foreign subsidiaries the share-based compensation element of certain intercompany charges made in prior periods. Starting in 2015, direct share-based compensation has been excluded from intercompany charges. In June 2019, the Ninth Circuit Court of Appeals (the "Ninth Circuit") reversed the 2015 Opinion (the "Ninth Circuit Opinion"). Subsequently, a re-hearing of the case was requested, but the rehearing request was denied by the Ninth Circuit on November 12, 2019. However, a petition for appeal to the U.S. Supreme Court can be filed within 90 days of the denial. Since the Ninth Circuit Opinion potentially is subject to further judicial review, the Company continues to treat its share-based compensation expense in accordance with the 2015 Opinion and continues to recognize the related tax benefits in its financial statements based upon its evaluation of the position in light of the present facts. In the event of a final opinion that reverses the 2015 Opinion, there may be an adverse impact to the Company's income tax expense and effective tax rate.

NOTE 12. 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,		
	2019	2018	2017
Numerator:			
Net income attributable to Intuitive Surgical, Inc.	$ 1,379.3	$ 1,127.9	$ 670.9
Denominator:			
Weighted average shares outstanding used in basic calculation	115.4	113.7	111.7
Add: dilutive effect of potential common shares	4.1	5.1	4.6
Weighted average shares outstanding used in diluted calculation	119.5	118.8	116.3
Net income per share attributable to Intuitive Surgical, Inc.:			
Basic	$ 11.95	$ 9.92	$ 6.01
Diluted	$ 11.54	$ 9.49	$ 5.77

Share-based compensation awards of approximately 0.7 million, 0.4 million, and 0.2 million shares for the years ended December 31, 2019, 2018, and 2017, 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 13. 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.

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

	Three Months Ended			
	December 31, 2019	September 30, 2019	June 30, 2019	March 31, 2019
Revenue	$ 1,277.7	$ 1,128.2	$ 1,098.9	$ 973.7
Gross profit	$ 896.0	$ 785.6	$ 759.0	$ 669.6
Net income attributable to Intuitive Surgical, Inc. [(1)(2)(3)]	$ 357.7	$ 396.8	$ 318.3	$ 306.5
Net income attributable to Intuitive Surgical, Inc. per share:				
Basic	$ 3.09	$ 3.44	$ 2.76	$ 2.67
Diluted	$ 2.99	$ 3.33	$ 2.67	$ 2.56
(1) Includes discrete tax benefits as follows:				
Excess tax benefits related to share-based compensation arrangements	$ 33.7	$ 28.8	$ 11.3	$ 72.7
One-time tax benefit related to the enactment of Swiss tax reform	$ —	$ 51.3	$ —	$ —
(2) Includes acquisition-related benefits (charges)	$ (3.1)	$ 3.0	$ (4.1)	$ (3.0)
(3) Includes charitable foundation contribution expense	$ (5.0)	$ —	$ —	$ —

	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)	$ —	$ —	$ —

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, 2019	$ 20.4	$ 46.9	$ (45.9)	$ 21.4
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

(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, 2019.

The effectiveness of our internal control over financial reporting as of December 31, 2019, has been audited by an independent registered public accounting firm, as stated in their report, which is included 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, 2019, 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, 2019.

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 A ND 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.
4.2	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
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. *
10.14	Consulting Agreement between Intuitive Surgical, Inc. and Sal Brogna. *
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, 2019, formatted in Inline XBRL (Inline 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.
104	The cover page from Intuitive Surgical, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2019, formatted in Inline XBRL and contained in Exhibit 101.

(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 7, 2020

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

Signature	Title	Date
/S/ GARY S. GUTHART **Gary S. Guthart, Ph.D.**	President, Chief Executive Officer, and Director (Principal Executive Officer)	February 7, 2020
/S/ MARSHALL L. MOHR **Marshall L. Mohr**	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	February 7, 2020
/S/ JAMIE E. SAMATH **Jamie E. Samath**	Senior Vice President, Finance (Principal Accounting Officer)	February 7, 2020
/S/ LONNIE M. SMITH **Lonnie M. Smith**	Chairman of the Board of Directors	February 7, 2020
/S/ CRAIG H. BARRATT **Craig H. Barratt, Ph.D.**	Director	February 7, 2020
/S/ AMAL M. JOHNSON **Amal M. Johnson**	Director	February 7, 2020
/S/ DON R. KANIA **Don R. Kania, Ph.D.**	Director	February 7, 2020
/S/ AMY L. LADD **Amy L. Ladd, Ph.D.**	Director	February 7, 2020
/S/ KEITH R. LEONARD JR. **Keith R. Leonard Jr.**	Director	February 7, 2020
/S/ ALAN J. LEVY **Alan J. Levy, Ph.D.**	Director	February 7, 2020
/S/ JAMI DOVER NACHTSHEIM **Jami Dover Nachtsheim**	Director	February 7, 2020
/S/ MARK J. RUBASH **Mark J. Rubash**	Director	February 7, 2020

Exhibit 21.1

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

Subsidiaries of the Registrant	State or Other Jurisdiction of Incorporation
Intuitive Surgical AB	Sweden
Intuitive Surgical ApS	Denmark
Intuitive Surgical Australia Proprietary Limited	Australia
Intuitive Surgical B.V.	Netherlands
Intuitive Surgical Brasil Importacao E Comercio De Equipamentos Cirurgicos Ltda.	Brazil
Intuitive Surgical Canada Inc.	Canada
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 B.V.	Netherlands
Intuitive Surgical International Finance LLC	Delaware, U.S.
Intuitive Surgical Ireland Limited	Ireland
Intuitive Surgical Korea Limited	South Korea
Intuitive Surgical Limited	United Kingdom
Intuitive Surgical Medical Device Science & Technology (Shanghai) Co., Ltd.	China
Intuitive Surgical Medical Device Taiwan Ltd.	Taiwan
Intuitive Surgical Operations, Inc.	Delaware, U.S.
Intuitive Surgical Optics GmbH	Germany
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 Sarl Taiwan Branch	Taiwan
Intuitive Surgical Spain, S.L.	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
Schoelly, Inc.	Massachusetts, U.S.
Schölly Micro Optics GmbH	Germany

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-232829, 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 7, 2020 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 7, 2020

Exhibit 31.1

Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Gary S. Guthart, 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 7, 2020

By: /s/ Gary S. Guthart

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

Exhibit 31.2

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 7, 2020

By: /s/ Marshall L. Mohr

Marshall L. Mohr
Executive Vice President and Chief Financial Officer

Exhibit 32.1

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, 2019 (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 7, 2020

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, 2019 (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 7, 2020

INTUITIVE