INTUITIVE SURGICAL INC
Form 10-K
February 04, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(MARK ONE)
x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018
OR
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM TO
COMMISSION FILE NUMBER 000-30713

Intuitive Surgical, Inc.

(Exact name of Registrant as Specified in its Charter)

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

1020 KIFER RD
SUNNYVALE, CA 94086
(Address of Principal Executive Offices) (Zip Code)
(408) 523-2100
(Registrant's Telephone Number, Including Area Code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Name of Each Exchange on which Registered
Common Stock, par value $0.001 per share	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No ¨
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨
Indicate by check mark whether the registrant has submitted electronically 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 x No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See definition of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	x	Accelerated filer	¨
Non-accelerated filer	¨	Smaller reporting company	¨
		Emerging growth company	¨

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates on June 30, 2018, based upon the closing price of Common Stock on such date as reported on The Nasdaq Global Select Market, was approximately $53.9 billion. Shares of voting stock held by each officer and director have been excluded in that such persons may be deemed to be affiliates. This assumption regarding affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant’s common stock as of January 18, 2019, was 114,488,602.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference to the definitive proxy statement for the Company’s Annual Meeting of Stockholders to be held on or about April 25, 2019, to be filed within 120 days of the registrant’s fiscal year ended December 31, 2018.

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FORWARD-LOOKING STATEMENTS

This report contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as "estimates," "projects," "believes," "anticipates," "plans," "expects," "intends," "may," "will," "could," "should," "would," "targeted" and similar word expressions are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements related to our expected business, new product introductions, procedures and procedure adoption, future results of operations, future financial position, our ability to increase our revenues, the anticipated mix of our revenues between product and service revenues, our financing plans and future capital requirements, anticipated costs of revenue, anticipated expenses, our potential tax assets or liabilities, the effect of recent accounting pronouncements, our investments, anticipated cash flows, our ability to finance operations from cash flows and similar matters, and statements based on current expectations, estimates, forecasts and projections about the economies and markets in which we operate and our beliefs and assumptions regarding these economies and markets. These forward-looking statements should, therefore, be considered in light of various important factors including, but not limited to, the following: the impact of global and regional economic and credit market conditions on healthcare spending; healthcare reform legislation in the U.S. and its impact on hospital spending, reimbursement and fees levied on certain medical device revenues; changes in hospital admissions and actions by payers to limit or manage surgical procedures; the timing and success of product development and market acceptance of developed products; the results of any collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships; procedure counts; regulatory approvals, clearances and restrictions or any dispute that may occur with any regulatory body; guidelines and recommendations in the healthcare and patient communities; intellectual property positions and litigation; competition in the medical device industry and in the specific markets of surgery in which we operate; unanticipated manufacturing disruptions or the inability to meet demand for products; the results of legal proceedings to which we are or may become a party; product liability and other litigation claims; adverse publicity regarding us and the safety of our products and adequacy of training; our ability to expand into foreign markets; the impact of changes to tax legislation, guidance, and interpretations; and other risk factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which are based on current expectations and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those risk factors described throughout this filing and particularly in Part I, "Item 1A. Risk Factors." Our actual results may differ materially and adversely from those expressed in any forward-looking statement. We undertake no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.

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PART I

ITEM 1. BUSINESS

In this report, "Intuitive Surgical," "Intuitive," the "Company," "we," "us," and "our" refer to Intuitive Surgical, Inc. and its wh and majority-owned subsidiaries. Intuitive®, Intuitive Surgical®, da Vinci®, da Vinci S®, da Vinci S HD Surgical System®, da Vinci Si®, da Vinci Si HD Surgical System®, da Vinci Xi®, da Vinci SP®, EndoWrist®, Firefly®, InSite®, da Vinci Connect®, Intuitive Surgical EcoSystem®, da Vinci X®, SureForm™, Single-Site®, and Ion™ are trademarks or registered trademarks of the Company.

Company Background

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

With the aim of entering the body less invasively, seeing anatomy more clearly, interacting with tissue more precisely, and enabling surgical skill, Intuitive launched its first da Vinci Surgical System in 1999. In 2000, it was cleared by the U.S. Food and Drug Administration ("FDA") for general laparoscopic surgery. The da Vinci Surgical System is designed to enable complex surgery using a minimally invasive approach. It consists of: an ergonomic surgeon console or consoles; a patient-side cart with interactive arm or arms; a high-performance vision system; and proprietary instruments and accessories. Surgeons using the da Vinci system operate while seated comfortably at a console viewing a three dimensional high definition ("3DHD") image of the surgical field. This immersive visualization connects surgeons to the surgical field and their instruments. While seated at the console, the surgeon manipulates instrument controls in a natural manner, similar to the open surgery approach. Our technology is designed to provide surgeons with a range of motion analogous to the motions of a human wrist, while filtering out the tremors inherent in a surgeon's hands. In designing our products, we focus on making our technology easy and safe to use.

Our systems provide the following features and benefits to surgeons:

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

Precise and Tremor-Free Endoscope Control. Our imaging system also incorporates our proprietary camera control technology that allows the surgeon to easily change, move, zoom, and rotate his or her field of vision. Surgeons can reposition the surgical camera quickly with foot controls or zoom in, out, up, down, left and right by moving their hands while maintaining a stable image.

Advanced Instruments. We offer a comprehensive suite of stapling, energy and core instrumentation for our surgical systems. Most of our proprietary instruments feature EndoWrist technology, incorporating "wrist" joints. Inspired by the human hand, our wristed instruments enable surgeons to orient the instruments carefully relative to tissue and suture with precision, just as they can in open surgery.

Intuitive Instrument Movements. Our technology is designed to transform the surgeon's natural hand movements outside the body into corresponding micro-movements inside the patient's body. For example, with the da Vinci Surgical System, a hand movement to the right outside the body causes the instrument inside the patient to be moved to the right. In contrast, conventional minimally invasive surgery ("MIS") instruments are long rigid levers that rotate around a fulcrum, or pivot point, located at the port created in the body wall. In conventional MIS, the instrument tip moves in the opposite direction from the surgeon's hand and surgeons must adjust their hand-eye coordination to compensate for the direction reversal by the pivot.

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

control for delicate tasks. In addition, our technology filters the tremor inherent in a surgeon's hands.

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

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

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

Products

da Vinci Surgical Systems

Intuitive's primary platform for robotic-assisted surgery is our family of da Vinci Surgical Systems. We have commercialized the following four generational platforms of da Vinci Surgical Systems: our fourth generation da Vinci X, da Vinci Xi and da Vinci SP Surgical Systems, our third generation da Vinci Si Surgical System, our second generation da Vinci S Surgical System, and our first generation da Vinci standard Surgical System. Da Vinci Surgical Systems are comprised of the following components:

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

Patient-Side Cart. The patient-side cart holds electromechanical arms that manipulate the instruments inside the patient. Up to four arms attached to the cart can be positioned, as appropriate, and then locked into place. At least two arms hold surgical instruments, one representing the surgeon's left hand and one representing the surgeon's right hand. A third arm positions the endoscope, allowing the surgeon to easily move, zoom, and rotate the field of vision. A fourth instrument arm extends surgical capabilities by enabling the surgeon to add a third instrument to perform additional tasks. The fourth instrument arm is a standard integrated feature on da Vinci X, Xi, and Si Surgical Systems. Our da Vinci SP Surgical System includes a single arm with three, multi-jointed, wristed instruments and the first da Vinci fully wristed 3DHD camera. The instruments and the camera all emerge through a single cannula and are triangulated around the target anatomy to avoid external instrument collisions that can occur in narrow surgical workspaces.

3DHD Vision System. Our vision system includes our InSite 3D endoscope with two separate vision channels linked to two separate color monitors through high performance video cameras and specialized image processing hardware. The resulting 3DHD image has high resolution, high contrast, low flicker, and low cross fading. A digital zoom feature in the 3DHD vision system allows surgeons to magnify the surgical field of view without adjusting the endoscope position and thereby reduces interference between the endoscope and instruments. The 3DHD vision is a standard integrated feature on da Vinci X, Xi, SP, Si, and S Surgical Systems.

Da Vinci Skills Simulator. The Skills Simulator is a practice tool that gives a user the opportunity to practice their skills and gain familiarity with the surgeon console controls. The Skills Simulator incorporates 3D, physics-based computer simulation technology to immerse the user within a virtual environment. The user navigates through the environment and completes exercises by controlling virtual instruments from the surgeon console. Upon completion of a skills exercise, the Skills Simulator provides a quantitative assessment of user performance based on a variety of task-specific metrics. The Skills Simulator is intended to augment, not replace, existing training programs for the da Vinci X, Xi, and SP Surgical Systems.

Da Vinci Xi Integrated Table Motion. Integrated Table Motion coordinates the movements of the da Vinci robot arms with an advanced operating room table, the TruSystem® 7000dV sold by Trumpf Medical™, to enable managing the patient's position in real-time while the da Vinci surgical robotic arms remain docked. This gives operating room teams the capability to optimally position the operating table during da Vinci System procedures. Integrated Table Motion enables surgeons to maximize reach, facilitate access, and choose the angle of approach to target anatomy, as well as reposition the table during the procedure to enhance anesthesiologists' management of the patient.

Firefly Fluorescence Imaging. Firefly is a standard feature of the da Vinci X and Xi Surgical System and available on our da Vinci Si Surgical System. This imaging capability combines a fluorescent dye with a specialized da Vinci camera head,

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endoscope and laser-based illuminator to allow surgeons to identify vasculature, tissue perfusion, or biliary ducts in three dimensions beneath tissue surfaces to visualize critical anatomy. Firefly is typically used in the categories of urology, gynecology, and general surgery.

Instruments and Accessories

Da Vinci Instruments. We manufacture a variety of instruments, most of which incorporate EndoWrist technology with wristed joints for natural dexterity, and tips customized for various surgical procedures. Da Vinci instruments are offered in a variety of diameters, of which 5mm and 8mm diameter sizes are the most commonly sold. Various da Vinci instrument tips include forceps, scissors, electrocautery tools, scalpels, and other surgical tools that are familiar to the surgeon from open surgery and conventional MIS. A variety of instruments may be selected and used interchangeably during a surgery. Most instruments are sterilizable at the hospital, while others are provided sterile, and most are reusable for a defined number of procedures. A programmed memory chip inside each instrument performs several functions that help determine how the da Vinci system and instruments work together. In addition, the chip will generally not allow the instrument to be used for more than the prescribed number of procedures to help ensure that its performance meets specifications during each procedure.

Da Vinci Stapling. The EndoWrist Stapler is a wristed, stapling instrument intended for resection, transection, and/or creation of anastomoses. This instrument enables operators to precisely position and fire the stapler. We market three types of staplers: the EndoWrist Stapler 45 and 30, and the SureForm 60 where the numeric designation indicates the length of the staple line. The EndoWrist Stapler 45 is used in general, gynecologic, and urologic surgery.

The EndoWrist Stapler 30, available with the da Vinci X and Xi Surgical System, is intended to deliver particular utility with fine tissue interaction in lobectomy and other thoracic procedures. The SureForm 60 is a single-use, fully wristed, stapling instrument intended for resection, transection, and/or creation of anastomoses, with particular utility in bariatric procedures.

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

Da Vinci Single-Site. Da Vinci Single-Site is a set of non-wristed and wristed instruments and accessories that allow da Vinci Surgical Systems to work through a single incision, typically in the umbilicus, rather than multiple incisions. Single incision surgery is intended to minimize trauma to patients by reducing the number of ports required to enter the body and is typically utilized for less complex surgery than multi-port surgery.

Accessory Products. We sell various accessory products which are used in conjunction with the da Vinci Surgical System as surgical procedures are performed. Accessory products include sterile drapes used to help ensure a sterile field during surgery, vision products such as replacement 3D stereo endoscopes, camera heads, light guides, and other items that facilitate use of the da Vinci Surgical System.

Business Strategy

Our goal is to fundamentally improve surgery and other acute interventions by enabling physicians and hospitals to improve outcomes for their patients, improve their patient’s experience and the care team experience, and lower total cost to treat per patient episode. Through the use of smart, connected systems, robotic technologies, advanced imaging, and informatics, our objective is to create value for patients, surgeons, and hospitals as summarized below:

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

by the relative patient value and total treatment costs of da Vinci procedures compared to alternative treatment options for the same disease state. We believe most patients will place higher value on procedures that are not only more efficacious, but also less invasive than alternative treatments. Our goal is to provide products to surgeons who in turn provide patients with procedure options that are both highly effective and less invasive than other surgical options.

Surgeon Value. We offer surgeons and their operating room staff training on the technical use of our products. We provide an ergonomic platform for surgeons to perform their procedures. We seek to provide surgeons with reliable and easy to use products.

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Hospital Value. We assist hospitals in building value by offering patient value using da Vinci products, thereby increasing surgical revenue and reducing costs through lower complication rates and reduced length of patient stay. We believe robotic-assisted surgery with the da Vinci Surgical System is a cost effective approach to many surgeries as compared to alternative treatment options, as recognized in many published studies.

Clinical Applications

We are the beneficiaries of productive collaborations with leading surgeons in exploring and developing new techniques and applications for robotic-assisted surgery with the da Vinci Surgical System—an important part of our creative process. We primarily focus our development efforts on those procedures in which we believe our products bring the highest patient value, surgeon value, and hospital value. We currently focus on five surgical specialties: gynecologic surgery, urologic surgery, general surgery, cardiothoracic surgery, and head and neck surgery. Key procedures which we are focused on include da Vinci hysterectomy ("dVH"), da Vinci prostatectomy ("dVP"), da Vinci for hernia repair, da Vinci for colon and rectal procedures, da Vinci for partial nephrectomy, da Vinci for sacrocolpopexy, da Vinci for lobectomy, da Vinci for transoral robotic surgery, and da Vinci for mitral valve repair. Representative surgical applications are described below.

Gynecologic Surgery

Hysterectomy. Removal of the uterus is one of the most commonly performed surgeries in gynecology and is performed for a variety of underlying benign and cancerous conditions. Hysterectomies can be performed using open surgery (laparotomy), or MIS techniques, which include vaginal, laparoscopic, and robotic approaches. Prior to the clearance of da Vinci Surgical System for use in gynecological procedures in 2005, the majority of hysterectomies performed were open surgeries. We believe that robotic-assisted surgery with the da Vinci Surgical System provides patients the opportunity to receive a minimally invasive treatment as an alternative to an open hysterectomy. Hysterectomies for benign conditions can be performed using either multi-port or Single-Site technology and we estimate that a majority of robotic-assisted surgery with a da Vinci Surgical System is performed using multi-port techniques. Single-Site instruments enable surgeons to perform surgery through a single port via the patient's umbilicus, allowing for significantly reduced scarring.

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

Urologic Surgery

Prostatectomy. Radical prostatectomy is the removal of the prostate gland in patients diagnosed with clinically localized prostate cancer. The standard approach to removal of the prostate was via an open surgical procedure. The conventional laparoscopic approach is an option but is difficult and poses challenges to even the most skilled urologist. The da Vinci Surgical System has enabled a large number of surgeons to convert from using an open surgical technique to a minimally invasive technique.

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

General Surgery

Hernia Repair. A hernia occurs when an organ or other tissue squeezes through a weak spot in a surrounding muscle or connective tissue. During a hernia repair surgery, the weakened tissue is secured and defects are repaired. Common types of hernia are ventral and inguinal. Ventral, or abdominal hernia, may occur through a scar after surgery in the abdomen. Inguinal hernia is a bulge in the groin and is more common in men. Hernia repair can be performed using traditional open surgery or MIS. There is a wide-range of complexity in hernia repair surgeries and varying surgeon opinion regarding optimal surgical approach. The benefits of minimally invasive and robotic hernia repair surgery vary by patient.

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Colorectal Surgery. These procedures typically involve benign or cancerous conditions of the lower digestive system, in particular the rectum or colon. Common procedures in this area include hemicolectomy, sigmoidectomy, low anterior resection, and abdominoperineal resection. Surgeons have reported that the use of robotic-assisted surgery with a da Vinci Surgical System and our latest technologies, such as the da Vinci Xi Surgical System, EndoWrist Stapler, and EndoWrist Vessel Sealer, have enabled them to offer MIS approaches to a broader range of colorectal surgery patients.

Cholecystectomy. Cholecystectomy, or the surgical removal of the gall bladder, is a commonly performed general surgery procedure. Cholecystectomy is the primary method for the treatment of gallstones and other gall bladder diseases. Most cholecystectomies are performed using multi-port MIS techniques, although some surgeons choose to perform cholecystectomy using manual single-port instrumentation. Using da Vinci Single-Site instruments, many of the technical challenges of manual single-port MIS are reduced as surgeons benefit from additional precision, control, and improved ergonomics. Multi-port da Vinci techniques are also being used for certain cases, and Firefly technology can be used to visualize biliary anatomy in three dimensions beneath tissue surfaces during Single-Site and multi-port da Vinci cholecystectomies.

Bariatric Surgery. A body of literature points to the benefit of surgery to treat patients for morbid obesity and its secondary effects, such as diabetes. Sleeve gastrectomy and roux-en-Y gastric bypass ("RYGB") are commonly performed surgical procedures for morbid obesity in the U.S. The body habitus of morbidly obese patients can make laparoscopic surgery physically challenging for the surgeon, and certain surgeons have found value in using the da Vinci Surgical System to improve upon the ergonomics when performing MIS in morbidly obese patients. In addition, RYGB can be a technically challenging procedure because of the suturing, stapling, and tissue (bowel) manipulation that is required. Surgeons using the da Vinci Surgical System have reported a reduction in a critical complication (anastomotic leaks) relative to laparoscopic RYGB. We believe SureForm 60 may have particular utility in bariatric procedures.

Cardiothoracic Surgery

Thoracic Surgery. Conventional approaches to surgical procedures in the thorax include both open and video-assisted thoracoscopic approaches. Procedures performed via these methods include pulmonary wedge resection, pulmonary lobectomy, thymectomy, mediastinal mass excision, and esophagectomy. Many thoracic procedures remain open procedures. Surgeons have reported that the use of robotic-assisted surgery with a da Vinci Surgical System in thoracic surgery has enabled them to offer MIS approaches to a broader range of thoracic surgery patients and improved clinical outcomes compared to open and video-assisted thoracic surgery in published single-center, multi-center and national database clinical studies. We believe the EndoWrist Stapler 30 may have particular utility in thoracic procedures.

Mitral Valve Repair. When patients are diagnosed with mitral valve disease, there are typically two surgical treatment options from which they can choose: mitral valve replacement or mitral valve repair. Mitral valve repairs are generally preferred over mitral valve replacement for a number of reasons, which include longevity and durability of the repaired valve over a replacement valve and the elimination or reduction of the patient's post-surgical pharmaceutical regimen. Because mitral valve repairs are considered to be more technically challenging than mitral valve replacements, they are only performed approximately 50% of the time. Several of our surgeon customers have reported an improvement in their mitral valve repair rates over mitral valve replacements when using the da Vinci Surgical System.

Head and Neck Surgery

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

conventional transoral surgery.

Procedure Mix

Our procedure business is broadly split into two categories: (1) cancer procedures and (2) procedures for benign conditions. Cancer and other highly complex procedures tend to be reimbursed at higher rates than less complex procedures. Thus, hospitals are more sensitive to the costs associated with treating less complex benign conditions. Our strategy is to provide hospitals with attractive clinical and economic solutions in each of these categories. Our fully featured da Vinci Xi system with advanced instruments including the EndoWrist One Vessel Sealer, EndoWrist Stapler products, and our Integrated Table Motion product cover a wide range of procedures, from complex to those that are less so. Our da Vinci X Surgical System and Single-Site instruments are targeted towards price sensitive markets and procedures.

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Clinical Summary

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

Sales and Customer Support

Sales Model

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

Our direct sales organization is composed of a capital sales team, responsible for selling da Vinci Surgical Systems, and a clinical sales team, responsible for supporting da Vinci Surgical System use in surgical procedures performed at our hospital accounts. Our hospital accounts include both individual hospitals and health care facilities and hospitals and health care facilities that are part of an integrated delivery network ("IDN groups"). The initial da Vinci Surgical System sale into an account as a major capital equipment purchase by our customers typically has a lengthy sales cycle that can be affected by macroeconomic factors, capital spending prioritization, timing of budgeting cycles, and competitive bidding processes. Capital sales activities include educating surgeons and hospital staff across multiple surgical specialties on the benefits of robotic-assisted surgery with a da Vinci Surgical System, total treatment costs, and the clinical applications that our technology enables. We also train our sales organization to educate hospital management on the potential benefits of adopting our technology, including clinical benefits of robotic-assisted surgery with a da Vinci Surgical System, potential reductions in complications and length of stay, and the resulting potential for increased patient satisfaction, surgeon recruitment, and procedure volume.

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

Our customers place orders to replenish their supplies of instruments and accessories on a regular basis. Orders received are typically shipped within one business day. New direct customers who purchase a new da Vinci Surgical System typically place an initial stocking order of instruments and accessories soon after they receive their system.

Our business is subject to seasonal fluctuations. Historically, our sales of da Vinci Surgical Systems have tended to be heaviest during the third month of each fiscal quarter, lighter in the first fiscal quarter and heavier in the fourth fiscal quarter. In addition, we have historically experienced lower procedure volume in the first and third fiscal quarters and higher procedure volume in the second and fourth fiscal quarters. In the U.S., procedure volumes for procedures associated with benign conditions are typically seasonally higher in the fourth quarter when more patients have met

annual deductibles and lower in the first quarter when deductibles are reset. Seasonality outside the U.S. varies and is generally more pronounced around local holidays and vacation periods. The timing of procedures and changes in procedure volume impact the timing of instrument and accessory and capital purchases.

Customer Support and Training Programs

We have a network of field service engineers across the U.S., Europe, and Asia and maintain relationships with various distributors around the globe. This infrastructure of service and support specialists offers a full complement of services for our customers, including 24/7 support, installation, repair, and maintenance. We generate service revenue by providing these services to our customers through comprehensive service contracts and time and material programs.

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We provide basic system training that teaches the fundamental operating principles of the da Vinci Surgical System to surgeons, surgical assistants, and operating room nurses. We have established training centers where system training and ongoing surgical procedural training are provided, the latter led by expert surgeons. Training technologies include our Simulation program which provides for independent da Vinci skills development through interactive VR exercises, and our telementoring program which provides real-time surgeon-to-surgeon learning and collaboration during robotic-assisted surgery.

Research and Development

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

We establish strategic alliances with other medical and technology companies to complement our research and development effort. To date, these alliances have taken several forms, including cooperation in the areas of product development, training, procedure development, and marketing activities. We have formed alliances with several companies including, but not limited to, 3D Systems, Inc., Bolder Surgical Holdings, Inc. (formerly JustRight Surgical, LLC), Erbe Elektromedizin GmbH, InTouch Technology Inc., Johnson & Johnson, Mimic Technologies, Inc., Novadaq Technologies, Inc., Olympus Corporation, Schoelly Fiberoptic GmbH, and Trumpf Medical (a division of Hill-Rom Holdings, Inc.).

Manufacturing

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

We purchase both custom and off-the-shelf components from a large number of suppliers and subject them to stringent quality specifications and processes. Some of the components necessary for the assembly of our products are currently provided to us by sole-sourced suppliers (the only recognized supply source available to us) or single-sourced suppliers (the only approved supply source for us among other sources). We purchase the majority of our components and major assemblies through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of finished goods relative to our anticipated demand.

Competition

We face competition in the forms of existing open surgery, conventional MIS, drug therapies, radiation treatment, and emerging interventional surgical approaches. Our success depends on continued clinical and technical innovation, quality and reliability as well as educating hospitals, surgeons, and patients on the demonstrated results associated with robotic-assisted surgery using da Vinci Surgical Systems and its value relative to other techniques. We also face competition from several companies that are developing new approaches and products for the MIS market. We believe that many companies are focused on adding capability to manual MIS systems. Because many of these developments are aimed at MIS, we believe that our da Vinci Surgical Systems may prove complementary to some of these new technologies.

Moreover, as we add new robotically controlled products (e.g. da Vinci Stapling and da Vinci Vessel Sealer Extend) that compete with product offerings traditionally within the domains of open surgery and/or conventional MIS, we face greater competition from larger and well established companies such as Ethicon Endo-Surgery, Inc. and Medtronic PLC.

Furthermore, a number of companies have introduced products in the field of robotic surgery or have made explicit their intention to enter the field of robotic surgery including, but not limited to: Auris Health, Inc.; Avatera Medical GmbH; CMR Surgical Limited; Johnson & Johnson and Google Inc. and their joint venture, Verb Surgical Inc.; 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, as well as confidentiality procedures and contractual provisions, to protect our proprietary technology. For example, we have trademarks, both registered and unregistered, that provide distinctive identification of our products in the marketplace. We also have exclusive and non-exclusive patent licenses with various third parties to supplement our own robust patent portfolio.

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

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

Government Regulation

Our products and operations are subject to regulation by the FDA, the State of California, and countries or regions in which we market our products. In addition, our products must meet the requirements of a large and growing body of international standards which govern the design, manufacture, materials content and sourcing, testing, certification, packaging, installation, use, and disposal of our products. We must continually keep abreast of these standards and requirements and integrate our compliance into the development and regulatory documentation for our products. Failure to meet these standards could limit our ability to market our products in those regions which require compliance to such standards. Examples of standards to which we are subject include electrical safety standards such as those of the International Electrotechnical Commission (e.g. IEC 60601-ss series of standards), and composition standards such as the Reduction of Hazardous Substances ("RoHS") and the Waste Electrical and Electronic Equipment ("WEEE") Directives.

United States

The FDA regulates the development, testing, manufacturing, labeling, storage, recordkeeping, promotion, marketing, distribution, and service of medical devices in the U.S. to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical devices manufactured in the U.S. to markets outside of the U.S. and the importation of medical devices manufactured abroad.

Under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Our current products are Class II medical devices.

Class II devices are those which are subject to general controls and most require premarket demonstration of adherence to certain performance standards or other special controls, as specified by the FDA, and clearance by the FDA. Premarket review and clearance by the FDA for these devices is accomplished through the 510(k) premarket notification process. Unless a Class II device is exempt from premarket review, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the device is "substantially equivalent" in intended use and technology to a "predicate device" that is either:

- a device that has grandfather marketing status because it was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted; or
- a device that has previously been cleared through the 510(k) process.

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

After a device receives FDA 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA application approval. The FDA requires each manufacturer to make the determination of whether a modification requires a new 510(k) notification or PMA application in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance or PMA approval for a particular change, the FDA may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease U.S. marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

In addition, after a device is placed on the market, numerous FDA and other regulatory requirements continue to apply. These include establishment registration and device listing with the FDA; compliance with medical device reporting regulations, which

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

Our manufacturing processes are required to comply with the FDA's Good Manufacturing Practice ("GMP") requirements contained in its Quality System Regulation ("QSR") and associated regulations and guidance. The QSR covers, among other things, the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all medical devices intended for human use. The QSR also requires maintenance of extensive records which demonstrate compliance with FDA regulation, the manufacturer's own procedures, specifications, and testing as well as distribution and post-market experience. Compliance with the QSR is necessary to receive FDA clearance or approval to market new products and is necessary for a manufacturer to be able to continue to market cleared or approved product offerings in the U.S. A company's facilities, records, and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA, which may issue reports known as Forms FDA 483 or Notices of Inspectional Observations which list instances where the FDA investigator believes the manufacturer has failed to comply with applicable regulations and/or procedures. If the observations are sufficiently serious or the manufacturer fails to respond appropriately, the FDA may issue Warning Letters, or Untitled Letters, which are notices of potential enforcement actions against the manufacturer. If a Warning Letter or Untitled Letter is not addressed to the satisfaction of the FDA, or if the FDA becomes aware of any other serious issue with a manufacturer's products or facilities, it could result in fines, injunctions, civil penalties, delays, suspension or withdrawal of clearances, seizures or recalls of products, operating restrictions, total shutdown of production facilities, prohibition on export or import and criminal prosecution. Such actions may have further indirect consequences for the manufacturer outside of the U.S., and may adversely affect the reputation of the manufacturer and the product.

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

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

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

California Regulation

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

Foreign Regulation

In order for us to market our products in countries outside the United States, we must obtain regulatory approvals and comply with extensive product and quality system regulations in other countries. These regulations, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. Some countries have regulatory review

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processes which are substantially longer than U.S. processes. Failure to obtain regulatory approval in a timely manner and to meet all local requirements including language and specific safety standards in any foreign country in which we plan to market our products could prevent us from marketing products in such countries or subject us to sanctions and fines.

To be sold in Japan, most medical devices must undergo thorough safety examinations and demonstrate medical efficacy before they receive regulatory approval. We obtained from the Japanese Ministry of Health, Labor, and Welfare ("MHLW") approval for our da Vinci Si Surgical Systems in October 2012 and approval for our da Vinci Xi Surgical Systems in March 2015, and approval for our da Vinci X Surgical Systems in April 2018. National reimbursement status was received in Japan for dVP procedures, effective April 2012 and for da Vinci partial nephrectomy procedures in April 2016. An additional 12 da Vinci procedures were granted reimbursement effective April 1, 2018, including gastrectomy, anterior resection, lobectomy and hysterectomy, for both malignant and benign conditions. These additional 12 reimbursed procedures have varying levels of conventional laparoscopic penetration and will be reimbursed at rates equal to the conventional laparoscopic procedures. Given the reimbursement level and laparoscopic penetration for these procedures, there can be no assurance that adoption will occur or, that the adoption pace for these procedures will be similar to any other da Vinci procedure. If these procedures are not adopted and we are not successful in obtaining adequate procedure reimbursements for additional procedures, then the demand for our products in Japan could be limited. We are currently seeking reimbursement for additional procedures through the MHLW's Senshin Iryo processes as well as alternative reimbursement processes. Our Senshin Iryo approvals require in-country clinical data and are considered for reimbursed status in April of even numbered years.

Commercialization of medical devices in Europe is regulated by the European Union ("EU"). The EU presently requires that all medical products bear the Conformité Européenne ("CE") mark, for compliance with the Medical Device Directive (93/42/EEC) as amended. The CE mark is an international symbol of adherence to certain essential principles of safety and performance mandated in applicable European medical device directives, which once affixed, enables a product to be sold in member countries of the EU and those affiliated countries which accept the CE mark. The CE mark is also recognized in many countries outside of the EU, such as Australia, and can assist in the clearance process. In order to affix the CE mark on products, a recognized European Notified Body must certify a manufacturer's quality system and design dossier for compliance with international and European requirements. We have received authorization from Presafe Denmark A/S (formerly DGM Denmark A/S), a recognized European Notified Body and part of Nemko Presafe A/S, to affix the CE mark to our da Vinci Surgical System and EndoWrist instruments and accessories. To maintain authorization to apply the CE mark, we are subject to annual surveillance audits and periodic re-certification audits. In September 2013, the European Commission adopted a recommendation indicating that all Notified Bodies, including Presafe, should carry out unannounced audits, at least once every third year, of the manufacturers whose medical devices they have certified. These unannounced audits can also extend to the manufacturer's critical suppliers or sub-contractors (those that supply a critical input or perform a critical function for the manufacturer).

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

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

Regulations in other countries, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. Certain countries, such as China and South Korea, have their own

regulatory agencies. These countries typically require regulatory approvals and compliance with extensive safety and quality system regulations. Failure to obtain regulatory approval in any foreign country in which we plan to market our products, or failure to comply with any regulation in any foreign country in which we market our products, may negatively impact our ability to generate revenue and harm our business. Our system sales into China are also dependent on obtaining importation authorizations, provincial approvals, and hospitals completing a tender process under the authorization. In October 2018, the China National Health Commission published on its official website the quota for major medical equipment to be imported and sold in China through 2020. The government will allow the sale of 154 new surgical robots into China, which could include da Vinci Surgical Systems as well as surgical systems introduced by others. Da Vinci Surgical systems sales under the quota are uncertain. In addition, local regulations may apply which govern the use of our products and which could have an adverse effect on our product utilization if they are unfavorable. All such regulations are revised from time to time and in general are increasing in complexity, and in the scope and degree of documentation and testing required. There can be no assurance the outcomes from such documentation and testing will be acceptable to any particular regulatory agency or will continue to be acceptable over time. There are further regulations governing the importation,

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marketing, sale, distribution, use, and service as well as the removal and disposal of medical devices in the regions in which we operate and market our products. Failure to comply with any of these regulations could result in sanctions or fines and could prevent us from marketing our products in these regions.

Other Healthcare Laws

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payors that are false or fraudulent. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals may share in amounts paid by the entity to the government in fines or settlement;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal Physician Payment Sunshine Act, which requires (i) manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals, and teaching hospitals, and (ii) applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians described above and their immediate family members, and payments or other "transfers of value" to such physician owners. Manufacturers are required to submit reports to CMS by the 90th day of each calendar year; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other "transfers of value" to physicians and other healthcare providers or marketing expenditures and pricing information; and laws governing the privacy and security of health information in certain circumstances, including the E.U. General Data Protection Regulation ("GDPR"), many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

attention from the operation of our business.

Third-Party Coverage and Reimbursement

In the U.S. and most markets OUS where we sell our products, the government and health insurance companies together are responsible for hospital and surgeon reimbursement for virtually all covered surgical procedures. Governments and insurance companies generally reimburse hospitals and physicians for surgery when the procedure is considered medically necessary. In the

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U.S., CMS administers the Medicare and Medicaid programs (the latter, along with applicable state governments). Many other third-party payors model their reimbursement methodologies after the Medicare program. As the single largest payor, this program has a significant impact on other payors' payment systems.

Generally, reimbursement for professional services performed at a facility by physicians is reported under billing codes issued by the American Medical Association ("AMA"), known as Current Procedural Terminology ("CPT") codes. Physician reimbursement under Medicare generally is based on a fee schedule and determined by the relative values of the professional service rendered. In addition, CMS and the National Center for Health Statistics ("NCHS") are jointly responsible for overseeing changes and modifications to billing codes used by hospitals to report inpatient procedures, ICD-10-PCS codes. For Medicare, CMS generally reimburses hospitals for services provided during an inpatient stay based on a prospective payment system that is determined by a classification system known as Medicare-Severity Diagnostic Related Groupings ("MS-DRGs"). MS-DRGs are assigned using a number of factors including the principal diagnosis, major procedures, discharged status, patient age, and complicating secondary diagnoses among other things. Hospital outpatient services, reported by CPT codes, are assigned to clinically relevant Ambulatory Payment Classifications ("APCs") used to determine the payment amount for services provided.

Since October 1, 2015, a new family of ICD-10-PCS codes can be used-in conjunction with other applicable procedure codes-to describe various robotic-assisted procedures. An inpatient surgical procedure, completed with or without robotic assistance, continues to be assigned to the clinically relevant MS-DRG.

Governments and insurance companies carefully review and increasingly challenge the prices charged for medical products and surgical services. Reimbursement rates from private companies vary depending on the procedure performed, the third-party payor, contract terms, and other factors. Because both hospitals and physicians may receive the same reimbursement for their respective services, with or without robotics, regardless of actual costs incurred by the hospital or physician in furnishing the care, including for the specific products used in that procedure, hospitals and physicians may decide not to use our products if reimbursement amounts are insufficient to cover any additional costs incurred when purchasing our products.

Domestic institutions typically bill various third-party payors, such as Medicare, Medicaid, and other government programs and private insurance plans for the primary surgical procedure that includes our products. Because our da Vinci Surgical System has been cleared for commercial distribution in the U.S. by the FDA, coverage and reimbursement by payors are generally determined by the medical necessity of the primary surgical procedure. We believe that the additional procedures we intend to pursue are established surgical procedures that are generally already reimbursable by government agencies and insurance companies for appropriately selected patients. If hospitals do not obtain sufficient reimbursement from third-party payors for procedures performed with our products, or if governmental and private payors' policies do not cover surgical procedures performed using our products, we may not be able to generate the revenues necessary to support our business.

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

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

passed in January 2018 such that MDET will be delayed until January 1, 2020.

The PPACA also appropriated funding to research the comparative effectiveness of health care treatments and strategies. It remains unclear how this research will influence future Medicare coverage and reimbursement decisions, as well as influence other third-party payor coverage and reimbursement policies. The PPACA, as well as other federal or state health care reform measures that may be adopted in the future, could have a material adverse effect on our business. The taxes imposed by PPACA and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits, lower reimbursement from payors for procedures that use our products, and/or reduced procedural volumes, all of which may adversely affect our business, financial condition, and results of operations.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes included an aggregate reduction in Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and

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will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers. The Medicare Access and CHIP Reauthorization Act of 2015, enacted on April 16, 2015 ("MACRA"), repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. Individual states in the U.S. have also become increasingly aggressive in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints and discounts, and require marketing cost disclosure and transparency measures.

There have also been judicial and congressional challenges to certain aspects of the PPACA, as well as efforts by the U.S. administration to modify, repeal, or otherwise invalidate all, or certain provisions of, the PPACA. Since January 2017, the U.S. President has signed two Executive Orders designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. The current U.S. administration has also announced that it will discontinue the payment of cost-sharing reduction ("CSR") payments to insurance companies until Congress approves the appropriation of funds for the CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the PPACA. A bipartisan bill to appropriate funds for CSR payments has been introduced in the Senate, but the future of that bill is uncertain. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the PPACA for plans sold through such marketplaces. Because of the Tax Cuts and Jobs Act ("2017 Tax Act") enacted on December 22, 2017, the PPACA's individual mandate penalty for not having health insurance coverage will be eliminated starting in 2019. Further, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the PPACA. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the 2017 Tax Act, the remaining provisions of the ACA are invalid as well. While the current White House Administration and CMS have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the ACA will impact the ACA and our business. Although the majority of these measures have not been enacted by Congress to date, Congress will likely continue to consider other legislation to repeal or repeal and replace elements of the PPACA. Any regulatory or legislative developments in domestic or foreign markets that eliminate or reduce reimbursement rates for procedures performed with our products could harm our ability to sell our products or cause downward pressure on the prices of our products, either of which would adversely affect our business, financial condition, and results of operations.

Employees

As of December 31, 2018, we had 5,527 employees, 771 of whom were engaged directly in research and development, 2,341 in manufacturing and service, and 2,415 in marketing, sales, and administrative activities. None of our employees are covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

General

We make our periodic and current reports, including our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports, available free of charge, on our website as soon as practicable after such material is electronically filed or furnished with the Securities and Exchange Commission (the "SEC"). Our website address is www.intuitive.com and the reports are filed under "SEC Filings," on the Company—Investor Relations portion of our website. Periodically, we webcast Company announcements, product launch events, and executive presentations which can be viewed via our Investor Relations page on our website. In addition, we provide notifications of our material news including SEC filings, investor events, and press releases as part of our Investor Relations page on our website. The contents of our website are not intended to be incorporated by reference into this report or in any other report or document we file and any references to our website are intended to

be inactive textual references only. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. The contents of these websites are not incorporated into this filing. Further, references to the URLs for these websites are intended to be inactive textual references only.

We operate our business as one segment as defined by U.S. generally accepted accounting principles. Our financial results for the years ended December 31, 2018, 2017, and 2016 are discussed in “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Item 8. Financial Statements and Supplementary Data” of this Annual Report.

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

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ITEM 1A. RISK FACTORS

RISKS RELATING TO OUR BUSINESS

IF OUR PRODUCTS DO NOT ACHIEVE MARKET ACCEPTANCE, WE WILL NOT BE ABLE TO GENERATE THE REVENUE NECESSARY TO SUPPORT OUR BUSINESS.

The da Vinci Surgical System and our other products represent a fundamentally new way of performing surgery. Achieving physician, patient, and third-party payor acceptance of robotic-assisted surgery as a preferred method of performing surgery is crucial to our success. If our products fail to achieve market acceptance, customers will not purchase our products and we will not be able to generate the revenue necessary to support our business. We believe that physicians' and third-party payors' acceptance of the benefits of procedures performed using our products will be essential for acceptance of our products by patients. Physicians will not recommend the use of our products unless we can demonstrate that they produce results comparable or superior to existing surgical techniques. Even if we can prove the effectiveness of our products through clinical trials, surgeons may elect not to use our products for any number of other reasons. For example, cardiologists may continue to recommend conventional heart surgery simply because such surgery is already widely accepted. In addition, surgeons may be slow to adopt our products because of the perceived liability risks arising from the use of new products and the uncertainty of reimbursement from third-party payors, particularly in light of ongoing health care reform initiatives and the evolving U.S. health care environment.

We expect that there will be a learning process involved for surgical teams to become proficient in the use of our products. Broad use of our products will require training of surgical teams. Market acceptance could be delayed by the time required to complete this training. We may not be able to rapidly train surgical teams in numbers sufficient to generate adequate demand for our products.

ECONOMIC CONDITIONS COULD MATERIALLY ADVERSELY AFFECT OUR COMPANY.

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

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

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

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

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

will use our products to replace or supplement established treatments or that our products will continue to be competitive with current or future technologies.

Additionally, we face or expect to face competition from companies that develop or have developed wristed, robotic, or computer-assisted surgical systems and products. Companies have introduced products in the field of robotic surgery or have made explicit statements about their efforts to enter the field including, but not limited to: Auris Health, Inc.; Avatera Medical GmbH; CMR Surgical Limited; Johnson & Johnson and Google Inc. and their joint venture, Verb Surgical Inc.; Medicaroid Inc.; MedRobotics Corp.; Medtronic PLC; meerecompany Inc.; Olympus Corp.; Samsung Corporation; Smart Robot Technology Group

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Co. Ltd.; Titan Medical Inc.; TransEnterix Inc.; and Wego Holding Co., Ltd. Other companies with substantial experience in industrial robotics could potentially expand into the field of surgical robotics and become competitors. Our revenues may be reduced due to pricing pressure or eliminated if our competitors develop and market products that are more effective or less expensive than our products. If we are unable to compete successfully, our revenues will suffer, which could have a material adverse effect on our business, financial condition, result of operations, or cash flows. We may not be able to maintain or improve our competitive position against current or potential competitors, especially those with greater resources.

In addition, third-party service providers that provide services to da Vinci Surgical System operators may emerge and compete with us on price or offerings. To date, substantially all of our customers have sourced services on their da Vinci Surgical Systems from us through service contract commitments or time and materials contracts. Furthermore, there are third-party service providers offering consulting services targeted at analyzing the cost-effectiveness of hospitals' robotic surgery programs, including procedures performed, placement of systems, and consumption of instruments and accessories. We currently provide similar services and analysis to our customers, but it is difficult to assess the impact that this may have on our business. If we are unable to compete successfully with any third-party service providers, our revenues may suffer.

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

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

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

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

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

Our products are subject to various regulatory processes, and we must obtain and maintain regulatory approvals in order to sell our new products. If a potential purchaser believes that we plan to introduce a new product in the near

future or if a potential purchaser is located in a country where a new product that we have introduced has not yet received regulatory clearance, planned purchases may be deferred or delayed. We have in the past experienced a slowdown in demand for existing products in advance of new product introductions and may experience a slowdown in demand in the future as well. It is also possible that a new product introduction could cause downward pressure on the prices of our existing products or require us to change how we sell our products, either of which could have material adverse effect on our revenues.

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

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

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

- changes in customer, geographic, or product mix, including mix of da Vinci Surgical System models sold or leased;
- changes in the portion of sales involving a trade-in of another system and the amount of trade-in credits given;
- introduction of new products, which may have lower margins than our existing products;
- our ability to maintain or reduce production costs;
- changes to our pricing strategy;
- changes in competition;
- changes in production volume driven by demand for our products;
- changes in material, labor, or other manufacturing-related costs, including the impact of foreign exchange rate fluctuations for foreign-currency denominated costs;
- changes to U.S. and foreign trade policies, such as the enactment of tariffs on goods imported into the U.S. including, but not limited to, goods imported from Mexico where we manufacture a majority of our instruments that we sell;
- inventory obsolescence and product recall charges; and
- market conditions.

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

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

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

We have experienced procedure growth for a number of benign conditions, including hysterectomies for benign conditions, sacrocolpopexies, hernia repairs, cholecystectomies, and certain other surgeries. Many of these types of surgeries may be postponed in the short term by patients to avoid vacation periods and for other personal scheduling reasons. Patients may also accelerate procedures to take advantage of insurance funding cut-off dates. Historically, we have experienced lower procedure volume in the first and third fiscal quarters and higher procedure volume in the second and fourth fiscal quarters. Timing of procedures and changes in procedure growth directly affect the timing of instrument and accessory purchases and capital purchases by customers.

The above factors may contribute to substantial fluctuations in our quarterly operating results. Because of these fluctuations, it is possible that in future periods our operating results will fall below the expectations of securities analysts or investors. If that happens, the market price of our stock would likely decrease. These fluctuations, among other factors, also mean that our operating results in any particular period may not be relied upon as an indication of future performance.

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

We manufacture, perform research and development activities, and distribute our products in OUS markets. Revenue from OUS markets accounted for approximately 29%, 27%, and 28% of our revenue for the years ended December 31, 2018, 2017, and 2016, respectively. Our OUS operations are, and will continue to be, subject to a number of risks including:

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

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- local or national regulations that make it difficult or impractical to market or use our products;
- U.S. relations with the governments of the foreign countries in which we operate;
- inability or regulatory limitations on our ability to move goods across borders;
- the risks associated with foreign currency exchange rate fluctuations;
- difficulty in establishing, staffing, and managing OUS operations;
- the expense of establishing facilities and operations in new foreign markets;
- building and maintaining an organization capable of supporting geographically dispersed operations;
- anti-corruption laws, such as the U.S. Foreign Corrupt Practices Act, and other local laws prohibiting corrupt payments to governmental officials;
- antitrust and anti-competition laws;
- economic weakness, including inflation, or political instability in particular foreign economies and markets; and
- business interruptions due to natural disasters, outbreak of disease, and other events beyond our control.

On June 23, 2016, the United Kingdom (the "UK") held a referendum in which voters approved an exit from the European Union (the "EU"), commonly referred to as "Brexit." On March 29, 2017, the UK formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The commencement of the official withdrawal process by the UK has created uncertainties affecting business operations in the UK and the EU. Until the terms of the UK's exit from the EU on March 29, 2019 are determined, including any transition period, it is difficult to predict its impact. It is possible that the withdrawal could, among other things, affect the legal and regulatory environments to which our business is subject, impose greater restrictions on imports and exports between the UK and the EU and other parties, and create economic and political uncertainty in the region.

In addition, the U.S. federal government has made changes to U.S. trade policy, including signing an executive order to withdraw from the negotiating process of the Trans-Pacific Partnership, renegotiate the terms of NAFTA, and imposing border taxes on imports into the U.S. On November 30, 2018, the leaders of the U.S., Mexico and Canada signed a replacement to NAFTA, which remains subject to the ratification by the legislatures of each country. We manufacture a majority of the instruments we sell in Mexico and any legislation enacted that impacts the relationship between the U.S. and Mexico and/or the continuity of NAFTA could adversely affect our operations and financial results. In addition, the U.S. federal government has implemented, or is considering the imposition of, tariffs on certain foreign goods. Such tariffs, and, if enacted, any further legislation or actions taken by the U.S. federal government that restrict trade, such as additional tariffs, trade barriers, and other protectionist or retaliatory measures taken by governments in Europe, Asia, and other countries, could adversely impact our ability to sell products and services in our OUS markets. Tariffs could increase the cost of our products and the components and raw materials that go into making them. These increased costs could adversely impact the gross margin that we earn on our products. Tariffs could make our products more expensive for customers, which could make our products less competitive and reduce consumer demand. Countries may also adopt other protectionist measures that could limit our ability to offer our products and services.

Furthermore, a large portion of our OUS sales are denominated in U.S. dollars. As a result, an increase in the value of the U.S. dollar relative to foreign currencies could make our products less competitive and/or less affordable in OUS markets.

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

WE UTILIZE DISTRIBUTORS FOR A PORTION OF OUR SALES, WHICH SUBJECTS US TO A NUMBER OF RISKS THAT COULD HARM OUR BUSINESS.

We have strategic relationships with a number of key distributors for sales and service of our products in certain foreign countries. If these strategic relationships are terminated and not replaced, our revenues and/or ability to sell or service our products in the markets serviced by these distributors could be adversely affected. In addition, we may be named as a defendant in lawsuits against our distributors related to sales or service of our products performed by them. Please see our risk factor below titled "We Are Subject to Product Liability and Negligence Claims Relating to the Use of Our Products and Other Legal Proceedings That Could Materially Adversely Affect Our Financial

Condition, Divert Management's Attention, and Harm Our Business." The actions of our distributors may affect our ability to effectively market our products in certain foreign countries or regulatory jurisdictions if a distributor holds the regulatory authorization in such countries or within such regions and causes, by action or inaction, the suspension of such marketing authorization or sanctions for non-compliance. It may be difficult, expensive, and time consuming for us to re-establish market access or regulatory compliance in such case.

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

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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 procedures on systems leased under usage-based arrangements, or return or terminate leases prematurely, it could have a material adverse effect on our business, financial condition, result of operations, or cash flows.

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

Our operating results are subject to volatility due to fluctuations in foreign currency exchange rates. Our primary exposure to fluctuations in foreign currency exchange rates relates to revenue and operating expenses denominated in currencies other than the U.S. dollar. The weakening of foreign currencies relative to the U.S. dollar adversely affects our foreign currency-denominated revenue. Margins on OUS revenue could also be materially adversely affected by foreign currency exchange rate fluctuations as we may not be able to raise local prices to fully offset the strengthening of the U.S. dollar. Conversely, the strengthening of foreign currencies relative to the U.S. dollar, while generally beneficial to our foreign currency-denominated revenue and earnings, may cause us to reduce pricing on our products in our OUS markets and may cause us to incur losses on our foreign currency hedging instruments, thereby limiting the benefit that strengthened foreign currencies could have on our results of operations.

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

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

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

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

IF DEFECTS ARE DISCOVERED IN OUR PRODUCTS, WE MAY INCUR ADDITIONAL UNFORESEEN COSTS, HOSPITALS MAY NOT PURCHASE OUR PRODUCTS, AND OUR REPUTATION MAY SUFFER. Our success depends on the quality and reliability of our products. While we subject components sourced and products manufactured to stringent quality specifications and processes, our products incorporate mechanical parts, electrical components, optical components, and computer software, any of which may contain errors or exhibit failures, especially when products are first introduced. In addition, new products or enhancements may contain undetected errors or performance problems that, despite testing, are discovered only after commercial shipment. Because our products are designed to be used to perform complex surgical procedures, due to the serious and costly consequences of product failure, we and our customers have an increased sensitivity to such defects. In the past, we have voluntarily recalled certain products. Although our products are subject to stringent quality

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processes and controls, we cannot provide assurance that our products will not experience component aging, errors, or performance problems. If we experience product flaws or performance problems, any or all of the following could occur:

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

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

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

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

In particular, our business exposes us to significant risks of product liability claims, which are inherent to the medical device industry. Product liability claims have been brought against us by or on behalf of individuals alleging that they have sustained personal injuries and/or death as a result of purported product defects, the alleged failure to warn, and/or the alleged inadequate training by us of physicians regarding the use of the da Vinci Surgical System. The individuals who have brought the product liability claims seek recovery for their alleged personal injuries and in many cases, punitive damages. Current product liability claims have resulted in negative publicity regarding our Company, and these and any other product liability or negligence claims or product recalls also could harm our reputation. Please see our risk factor below titled "Negative Publicity, Whether Accurate or Inaccurate, Concerning Our Products or Our Company Could Reduce Market Acceptance of Our Products and Could Result in Decreased Product Demand and a Decline in Revenues" for additional risks related to the potential effects of negative publicity on our business.

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

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

There have been articles published and reports questioning patient safety and efficacy associated with robotic-assisted surgery with the da Vinci Surgical System and its cost relative to other disease management methods, and the adequacy of surgeon training. Negative publicity, including statements made by public officials, whether accurate or inaccurate, concerning our products or our Company could reduce market acceptance of our products and could result

in decreased product demand and a decline in revenues. In addition, significant negative publicity could result in an increased number of product liability claims, regardless of whether these claims are meritorious. The number of claims could be further increased by plaintiffs' law firms that use a wide variety of media to advertise their services and solicit clients for product liability cases against us.

WE ARE SUBJECT TO SIGNIFICANT, UNINSURED LIABILITIES.

For certain risks, we do not maintain insurance coverage because of cost and/or availability. For example, we self-insure our product liability risks and we indemnify our directors and officers for third-party claims and do not carry insurance to cover that indemnity or the related underlying losses. We also do not carry, among other types of coverage, earthquake, and cyber insurance.

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In addition, in the future, we may not continue to maintain certain existing insurance coverage or adequate levels of coverage. Premiums for many types of insurance have increased significantly in recent years, and depending on market conditions and our circumstances, in the future, certain types of insurance such as directors' and officers' insurance may not be available on acceptable terms, or at all. Because we retain some portion of our insurable risks, and in some cases we are self-insured completely, unforeseen or catastrophic losses in excess of insurance coverage could require us to pay substantial amounts, which may have a material adverse impact on our business, financial condition, results of operations, or cash flows.

WE MAY ENCOUNTER MANUFACTURING PROBLEMS OR DELAYS THAT COULD RESULT IN LOST REVENUE.

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

- problems involving production yields;
- quality control and assurance;
- component supply shortages;
- import or export restrictions on components, materials or technology;
- shortages of qualified personnel; and
- compliance with state, federal, and foreign regulations.

If demand for our products exceeds our manufacturing capacity, we could develop a substantial backlog of customer orders. If we are unable to maintain larger-scale manufacturing capabilities, our ability to generate revenues will be limited and our reputation in the marketplace could be damaged, which may have a material adverse impact on our business, financial condition, results of operations, or cash flows.

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

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

IF INSTITUTIONS OR SURGEONS ARE UNABLE TO OBTAIN COVERAGE AND REIMBURSEMENT FROM THIRD-PARTY PAYORS FOR PROCEDURES USING OUR PRODUCTS, OR IF REIMBURSEMENT IS INSUFFICIENT TO COVER THE COSTS OF PURCHASING OUR PRODUCTS, WE MAY BE UNABLE TO GENERATE SUFFICIENT SALES TO SUPPORT OUR BUSINESS.

In the U.S., hospitals generally bill for the services performed with our products to various third-party payors, such as Medicare, Medicaid, and other government programs and private insurance plans. If hospitals do not obtain sufficient reimbursement from third-party payors for procedures performed with our products, or if government and private payors' policies do not cover surgical procedures performed using our products, we may not be able to generate the revenues necessary to support our business. Our success in OUS markets also depends upon the eligibility of our products for coverage and reimbursement through government-sponsored health care payment systems and third-party payors. Reimbursement practices vary significantly by country. Many OUS markets have government-managed healthcare systems that control reimbursement for new products and procedures. Other foreign markets have both private insurance systems and government-managed systems that control reimbursement for new products and procedures. Market acceptance of our products may depend on the availability and level of coverage and

reimbursement in any country within a particular time. In addition, health care cost containment efforts similar to those in the U.S. are prevalent in many of the other countries in which we intend to sell our products and these efforts are expected to continue. Please see our risk factor below titled “Changes in Healthcare Legislation and Policy May Have a Material Adverse Effect on Our Financial Condition and Results of Operations” for additional risks related to the ability of institutions or surgeons to obtain reimbursements.

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IF WE LOSE OUR KEY PERSONNEL OR ARE UNABLE TO ATTRACT AND RETAIN ADDITIONAL PERSONNEL, OUR ABILITY TO COMPETE WILL BE HARMED.

We are highly dependent on the principal members of our management and scientific staff. For example, our product development plans depend, in part, on our ability to attract and retain engineers with experience in mechanics, electronics, software and optics. Attracting and retaining qualified personnel will be critical to our success, and competition for qualified personnel is intense. We may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among technology and healthcare companies and universities. The loss of any of these persons or our inability to attract and retain qualified personnel could harm our business and our ability to compete.

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

Natural disasters, terrorist activities, and other business disruptions including, but not limited to, internet security threats, could seriously harm our revenue and financial condition and increase our costs and expenses. For example, the March 2011 earthquake and tsunami in Japan and their aftermath created economic uncertainty and disrupted economic activities in Japan, including a reduction in hospital spending. Furthermore, our corporate headquarters and many of our operations, including certain of our manufacturing facilities, are located in California, which in the past has experienced both severe earthquakes and other natural disasters. We do not have multiple-site capacity for all of our operations in the event of a business disruption. Furthermore, parties in our supply chain and our customers are similarly vulnerable to natural disasters or other sudden, unforeseen, and severe adverse events. A natural disaster in any of our major markets, or an unanticipated business disruption caused, for example, by internet security threats, damage to global communication networks, or similar events could have a material adverse impact on our business, financial condition, results of operations, or cash flows.

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

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

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

From time to time, we enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships to complement or augment our research and development, product development, training, procedure development, and marketing efforts. For example, in 2016, we entered into an agreement to form the Joint Venture. In January 2019, the Joint Venture acquired certain assets related to the da Vinci distribution business of Chindex, a subsidiary of Fosun Pharma, which has been our distribution partner for da Vinci Surgical Systems in China since 2011, following which the Joint Venture began direct distribution operations for da Vinci products and services in China. There can be no assurance that we and the Joint Venture can successfully complete the development of the robotic-assisted catheter-based medical devices; or that we and the Joint Venture will successfully commercialize such products. There can also be no assurance that the Joint Venture will not require additional contributions to fund its business; that the Joint Venture will become profitable; or that the acquired Chindex assets will be successfully integrated and the expected benefits realized. Proposing, negotiating, and implementing collaborations, in-licensing agreements, joint ventures, strategic alliances, or partnerships may be a lengthy and complex process. In addition, other companies, including those with substantially greater financial, marketing, sales, technology, or other business resources, may compete with us for these opportunities or arrangements. As a result, we may not identify, secure, or complete any such arrangements in a timely manner, on a cost-effective basis or on otherwise favorable terms, if it all.

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

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

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

We need to grow our businesses in response to changing technologies, customer demands, and competitive pressures. In some circumstances, we may decide to grow our business through the acquisition of complementary businesses, products, or technologies rather than through internal development.

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

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

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

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

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

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

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

field employee, and other factors. In addition, from time to time, we may change the method for determining market sizes and the number and type of da Vinci procedures, causing variation in our reporting.

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

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

- the jurisdictions in which profits are determined to be earned and taxed;

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

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

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

Information technology helps us operate efficiently, interface with customers, maintain financial accuracy and efficiency, and accurately produce our financial statements. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology infrastructure, we could be subject to transaction errors, processing inefficiencies, the loss of customers, business disruptions, or the loss of or damage to intellectual property through security breach. If our data management systems do not effectively collect, store, process, and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, or human error, our ability to effectively plan, forecast, and execute our business plan and comply with applicable laws and regulations will be impaired, perhaps materially. Any such impairment could materially and adversely affect our financial condition, results of operations, cash flows, and the timeliness with which we report our internal and external operating results.

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

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

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

While we devote significant resources to network security, data encryption, and other security measures to protect our systems and data, these security measures cannot provide absolute security. We may experience a breach of our systems and may be unable to protect sensitive data. The costs to us to eliminate or alleviate network security problems, bugs, viruses, worms, malicious software programs, and security vulnerabilities could be significant. Our

efforts to address these problems may not be successful and could result in unexpected interruptions, delays, cessation of service, and harm to our business operations. Moreover, if a computer security breach affects our systems or results in the unauthorized release of PII, our reputation and brand could be materially damaged and use of our products and services could decrease. We would also be exposed to a risk of loss or litigation and potential liability, which could have a material adverse impact on our business, financial condition, results of operations, or cash flows.

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

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

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

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

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

A PROLONGED GOVERNMENT SHUTDOWN MAY ADVERSELY AFFECT OUR BUSINESS.

Hospital, health systems, and physicians depend on a number of government agencies and services to effectively deliver healthcare to their patients. A prolonged government shutdown could impact inspections, regulatory review and certifications, grants, approvals, or cause other situations that could impede their ability to effectively deliver healthcare, including attempts to reduce payments and other reimbursements to hospitals by federal healthcare

programs. These situations could adversely affect our customers' ability to perform procedures with our devices and/or their decisions to purchase additional products from us. In addition, a prolonged government shutdown may cause significant regulatory delays, and therefore, delay our efforts to seek clearances from the FDA, and adversely affect business travel and import and export of products, all of which could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

RISKS RELATING TO OUR REGULATORY ENVIRONMENT

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

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

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The PPACA contained a number of provisions designed to generate the revenues necessary to fund health insurance coverage expansions among other things. This includes fees or taxes on certain health-related industries, including medical device manufacturers. For sales between January 1, 2013, and December 31, 2015, medical device manufacturers were required to pay an excise tax (or sales tax) of 2.3% of certain U.S. medical device revenues. Though there were some exceptions to the excise tax, this excise tax did apply to all or most of our products sold within the U.S. In December 2015, the former U.S. President signed into law the Appropriations Act. The Appropriations Act included a two-year moratorium on the medical device excise tax such that medical device revenues in 2016 and 2017 were exempt from the excise tax. Subsequent legislation was passed in January 2018 such that MDET will be delayed until January 1, 2020.

The PPACA also implemented a number of Medicare payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models, and appropriated funding for comparative effectiveness research.

The taxes imposed by the PPACA and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursement by payors for our products, and/or reduced medical procedure volumes, all of which may have a material adverse impact on our business, financial condition, results of operations, or cash flows.

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

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. MACRA repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what impact new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations, or cash flows. Individual states in the U.S. have also become increasingly aggressive in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, and discounts, and require marketing cost disclosure and transparency measures.

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

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

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

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

The Medicare and Medicaid anti-kickback laws, and several similar state laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, prohibit payments, or other remuneration that could be considered to induce hospitals, physicians, or other potential purchasers of our products either to refer patients or to purchase, lease or order, or arrange for or recommend the purchase, lease or order, of healthcare products or services for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid and any other third-party payor programs. Further, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it. The government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. The federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. Although we would not submit claims directly to government payors, manufacturers can be held liable under the federal false claim act if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. These laws may affect our sales, marketing, and other promotional activities by limiting the kinds of financial arrangements we may have with hospitals, physicians, or other potential purchasers of our products. They particularly impact how we structure our sales offerings, including discount practices, customer support, education and training programs, physician consulting, and other service arrangements. These laws are broadly written, and it is often difficult to determine precisely how these laws will be applied to specific circumstances. Violating anti-kickback laws can result in civil and criminal fines and penalties, which can be substantial and include monetary damages and penalties, imprisonment, and exclusion from government healthcare programs for non-compliance. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to defend, and thus could harm our business and results of operations.

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The federal Physicians Payments Sunshine Act imposes reporting and disclosure requirements on device manufacturers for any "transfer of value" made or distributed to physicians (including family members), certain other healthcare providers and teaching hospitals. Such information must be made publicly available in a searchable format. In addition, device manufacturers are required to report and disclose any ownership or investment interests held by physicians and their immediate family members, as well as any transfers of value made to such physician owners and investors, during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $165,786 per year (and up to an aggregate of $1.105 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Device manufacturers are required to submit reports to CMS by the 90th day of each calendar year.

In addition, there has been increased federal and state regulation of payments made to physicians, including the tracking and reporting of gifts, compensation, and other remuneration to physicians. Certain states mandate implementation of commercial compliance programs to ensure compliance with these laws, impose restrictions on device manufacturer marketing practices, and/or require the tracking and reporting of gifts, compensation, and other remuneration to physicians or marketing expenditures and pricing information. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may be found out of compliance of one or more of the requirements, subjecting us to significant civil monetary penalties.

Compliance with complex foreign and U.S. laws and regulations that apply to our OUS operations increases our cost of doing business in foreign jurisdictions and could expose us or our employees to fines and penalties in the U.S. and/or abroad. These numerous and sometimes conflicting laws and regulations include U.S. laws such as the Foreign Corrupt Practices Act, and similar laws in foreign countries, such as the U.K. Bribery Act of 2010, which became effective on July 1, 2011. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, prohibitions on the conduct of our business and damage to our reputation. Although we have implemented policies and procedures designed to ensure compliance with these laws, there can be no assurance that our employees, contractors, or agents will not violate our policies.

Our operations are subject to certain antitrust and competition laws in the jurisdictions in which we conduct our business, in particular the U.S. and the EU. These laws prohibit, among other things, anticompetitive agreements and practices. If any of our commercial agreements or practices are found to violate or infringe such laws, we may be subject to civil and other penalties. We may also be subject to third-party claims for damages. Further, agreements that infringe these antitrust and competition laws may be void and unenforceable, in whole or in part, or require modification in order to be lawful and enforceable. If we are unable to enforce our commercial agreements, whether at all or in material part, our results of operations, financial position, and cash flows could be adversely affected.

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

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

Our products and operations are subject to extensive regulation in the U.S. by the FDA. The FDA regulates the development and clinical testing, manufacturing, labeling, storage, record keeping, promotion, sales, distribution, and post-market support and medical device reporting in the U.S. to ensure that medical products distributed domestically are safe and effective for their intended uses. In order for us to market products for use in the U.S., we generally must first obtain clearance from the FDA pursuant to Section 510(k) of the Federal Food Drug and Cosmetic Act ("FFDCA"). Clearance under Section 510(k) requires demonstration that a new device is substantially equivalent to another device with 510(k) clearance or grandfathered ("pre-amendment") status. If we significantly modify our products after they receive FDA clearance, the FDA may require us to submit a separate 510(k) or premarket approval application ("PMA") for the modified product before we are permitted to market the products in the U.S. In addition, if we develop products in the future that are not considered to be substantially equivalent to a device with 510(k) clearance or

grandfathered status, we will be required to obtain FDA approval by submitting a PMA. A PMA is typically a much more complex, lengthy and burdensome application than a 510(k). To support a PMA, the FDA would likely require that we conduct one or more clinical studies to demonstrate that the device is safe and effective. In some cases such studies may be requested for a 510(k) as well. The FDA may not act favorably or quickly in its review of our 510(k) or PMA submissions, or we may encounter significant difficulties and costs in our efforts to obtain FDA clearance or approval, all of which could delay or preclude the sale of new products in the U.S. Moreover, we may not be able to meet the requirements to obtain 510(k) clearance or PMA approval, in which case the FDA may not grant any necessary clearances or approvals. In addition, the FDA may place significant limitations upon the intended use of our products as a condition to a 510(k) clearance or PMA approval. Product applications can also be denied or withdrawn due to failure to comply with regulatory requirements or the occurrence of unforeseen problems following clearance or approval. Any delays or failure to obtain FDA clearance or approvals of new products we develop, any limitations

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imposed by the FDA on new product use, or the costs of obtaining FDA clearance or approvals could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

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

In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a medical device, a company must, among other things, apply for and obtain Institutional Review Board ("IRB") approval of the proposed investigation. In addition, if the clinical study involves a "significant risk" (as defined by the FDA) to human health, the sponsor of the investigation must also submit and obtain FDA approval of an Investigational Device Exemption ("IDE") application. Many of our products to date have been or would be considered significant risk devices requiring IDE approval prior to investigational use. We may not be able to obtain FDA and/or IRB approval to undertake clinical trials in the U.S. for any new devices we intend to market in the U.S. in the future. If we obtain such approvals, we may not be able to conduct studies which comply with the IDE and other regulations governing clinical investigations or the data from any such trials may not support clearance or approval of the investigational device. Failure to obtain such approvals or to comply with such regulations could have a material adverse effect on our business, financial condition and results of operations. Certainty that clinical trials will meet desired endpoints, produce meaningful or useful data and be free of unexpected adverse effects, or that the FDA will accept the validity of foreign clinical study data cannot be assured, and such uncertainty could preclude or delay market clearance or authorizations resulting in significant financial costs and reduced revenue.

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

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

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

- continued compliance to the QSR, which requires manufacturers to follow design, testing, control, documentation, and other quality assurance procedures during the development and manufacturing process;
- labeling regulations;
- the FDA's general prohibition against false or misleading statements in the labeling or promotion of products for unapproved or "off-label" uses;
- stringent complaint reporting and Medical Device Reporting ("MDR") regulations, which requires that manufacturers keep detailed records of investigations or complaints against their devices and to report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- adequate use of the Corrective and Preventive Actions process to identify and correct or prevent significant systemic failures of products or processes or in trends which suggest same; and
- the reporting of Corrections and Removals, which requires that manufacturers report to the FDA recalls and field corrective actions taken to reduce a risk to health or to remedy a violation of the FFDCA that may pose a risk to health.

We are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. If the FDA finds that we have failed to comply, it can institute a wide variety of enforcement actions, ranging from inspectional observations (Form FDA 483) to a public Warning Letter to more severe civil and criminal sanctions including the seizure of our products and equipment or ban on the import or export of our products. The FDA has in the past issued and could in the future issue Warning Letters or other communications to us. If we fail to satisfy or remediate the matters discussed in any such Warning Letters or communications, the FDA could take further enforcement action, including prohibiting the sale or marketing of the affected product. Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse

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

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

In addition, any modification or change of medical devices cleared for market requires the manufacturer to make a determination whether the change is significant enough to require new 510(k) clearance. We have created labeling, advertising, and user training for the da Vinci Surgical System to describe specific surgical procedures that we believe are fully within the scope of our existing 510(k) indications for use stated in our 510(k) clearances. Although we have relied on expert in-house and external staff, consultants and advisors, some of whom were formerly employed by FDA and familiar with FDA perspective, we cannot provide assurance that the FDA would agree that all such specific procedures are within the scope of the existing general clearance or that we have compiled adequate information to support the safety and efficacy of using the da Vinci Surgical System for all such specific procedures. From time to time we modify our products, including the hardware and software in the da Vinci Surgical System, after we obtain 510(k) clearance from the FDA for the devices in ways that we do not believe require new 510(k) clearance. We cannot provide assurance that the FDA would agree in all cases with our determinations not to seek new 510(k) clearance for any of these changes. If the FDA disagrees with our assessments that a new 510(k) clearance was not required prior to commercializing the devices with these changes or modifications, then the FDA could impose enforcement sanctions and/or require us to obtain 510(k) clearance for any modification to our products. We may be prohibited from marketing the modified device until such 510(k) clearance is granted.

We have a wholly owned manufacturing facility located in Mexicali, Mexico which manufactures reusable and disposable surgical instruments. This facility is registered with the FDA as well as Mexican authorities. The facility is operated under U.S. and international quality system regulations including those applicable to Canada, the European Union, and Japan among others. Our wholly owned manufacturing facility in Mexicali, Mexico has an FDA Establishment Registration but has not been inspected by the FDA to date. If the FDA were to identify non-conformances in our product documentation or quality system compliance, it could hold indefinitely the importation of instruments at the border which would deprive us of the ability to sell and supply the majority of our customers until the FDA requirements have been satisfied. Similar supply disruptions could occur if key suppliers outside of the U.S. were to encounter non-conformances with their documentation or quality system compliance.

OUR PRODUCTS ARE SUBJECT TO VARIOUS INTERNATIONAL REGULATORY PROCESSES AND APPROVAL REQUIREMENTS. IF WE DO NOT OBTAIN AND MAINTAIN THE NECESSARY INTERNATIONAL REGULATORY APPROVALS, WE WILL NOT BE ABLE TO PROVIDE OUR PRODUCTS IN FOREIGN COUNTRIES.

To be able to provide our products in other countries, we must obtain regulatory approvals and comply with the regulations of those countries which may differ substantially from those of the U.S. These regulations, including the requirements for approvals and the time required for regulatory review, vary from country to country. Obtaining and maintaining foreign regulatory approvals is complex, and we cannot be certain that we will receive regulatory approvals in any foreign country in which we plan to market our products, or to obtain such approvals on a favorable schedule. If we fail to obtain or maintain regulatory approval in any foreign country in which we plan to market our products, our ability to generate revenue will be harmed. In particular, if the FDA refuses to provide CFGs our ability to register products or renew such registrations may be delayed or denied.

The EU requires that manufacturers of medical products obtain the right to affix the CE mark, for compliance with the Medical Device Directive (93/42/EEC), as amended, to their products before selling them in member countries of the EU. The CE mark is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain the authorization to affix the CE mark to products, a

manufacturer must obtain certification that its processes and products meet certain European quality standards. In January 1999, we received permission to affix the CE mark to our da Vinci Surgical System and EndoWrist instruments and have maintained this authorization continuously since that time. From time to time we seek the authorization to affix the CE mark to new or modified products. Subsequent products and accessories have received marketing authorization by our Notified Body, Presafe.

As we modify existing products or develop new products in the future, including new instruments, we currently plan to apply for authorization to affix the CE mark to such products. In addition, we are subject to annual regulatory audits in order to maintain the CE mark authorizations we have already obtained including inspection of our compliance to required standards and directives. We cannot be certain we will be able to affix the CE mark for new or modified products or that we will continue to meet the quality and performance standards required to maintain the authorizations we have already received. If we are unable to maintain permission to affix the CE mark to our products, we will no longer be able to sell our products in member countries of the EU and many affiliated countries that accept the CE mark, which would have a material adverse effect on our results of operations. Some member

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states of the EU have additional requirements for registration and notification which may add to the time and effort to obtain market access. In addition, the regulations applied to end users of our products may increase over time, forcing us to provide additional solutions to regulations which do not apply directly to us, but which apply indirectly as they may limit our customers' ability to use our products.

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

To date, we received approvals from the Japanese Ministry of Health, Labor and Welfare ("MHLW") for our da Vinci S, Si, Xi, and X Surgical Systems and various associated instruments and accessories for use in certain da Vinci procedures. We may seek additional approvals for other products and/or indications; however, there can be no assurance that such approvals will be granted. In addition, because not all of our instruments have received product approvals, and reimbursement is an additional process to generate market acceptance, it is possible that procedures will be adopted slowly or not at all. Sales of our products depend, in part, on the extent to which the costs of our products are reimbursed by governmental health administration authorities. In April 2012 and April 2016, we have received reimbursement approval for prostatectomy and partial nephrectomy, respectively. An additional 12 procedures were granted reimbursement for Japan in April 2018, including gastrectomy, anterior resection, lobectomy and hysterectomy, for both malignant and benign conditions. These additional 12 reimbursed procedures have varying levels of conventional laparoscopic penetration and will be reimbursed at rates equal to the conventional laparoscopic procedures. Given the reimbursement level and laparoscopic penetration for these procedures, there can be no assurance that adoption will occur or, that the adoption pace for these procedures will be similar to any other da Vinci procedure. There are multiple pathways to obtain reimbursement for procedures including those that require in-country clinical data and which are considered for reimbursed status in April of even numbered years. If we are not successful in obtaining the necessary reimbursement approvals or obtaining approvals for future products and procedures, then the demand for our products could be limited. These limitations could eliminate a significant market opportunity for our products in Japan.

Our capital sales in China are subject to importation authorizations and purchasing tender processes. In October 2018, the China National Health Commission published on its official website the quota for major medical equipment to be imported and sold in China through 2020. The government will allow the sale of 154 new surgical robots into China, which could include da Vinci Surgical Systems. Future system sales and our ability to grow future procedure volumes are dependent on the completion of these purchasing tender authorizations. The timing and magnitude of these future authorizations, which may determine our system placements in future years, is not certain and we expect to continue to experience variability in the timing of capital sales in China.

IF OUR MANUFACTURING FACILITIES DO NOT CONTINUE TO MEET FEDERAL, STATE, OR OTHER MANUFACTURING STANDARDS, WE MAY BE REQUIRED TO TEMPORARILY CEASE ALL OR PART OF OUR MANUFACTURING OPERATIONS, IMPORT/EXPORT OF OUR PRODUCTS, AND/OR RECALL SOME PRODUCTS WHICH WOULD RESULT IN SIGNIFICANT PRODUCT DELIVERY DELAYS AND LOST REVENUE.

Our manufacturing facilities are subject to periodic inspection by regulatory authorities, and our operations will continue to be regulated and inspected by the FDA and other regulatory agencies for compliance with Good Manufacturing Practice requirements contained in the QSR and other regulatory requirements. We are also required to comply with International Organization for Standardization ("ISO") quality system standards as well as European Directives and norms in order to produce products for sale in the EU. In addition, many countries such as Canada and Japan have very specific additional regulatory requirements for quality assurance and manufacturing. If we fail to continue to comply with Good Manufacturing Practice requirements, as well as ISO or other regulatory standards, we may be required to cease all or part of our operations until we comply with these regulations.

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

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

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

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

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

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

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

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

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

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

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

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

As we continue to introduce and commercialize new products and technologies, there may be U.S. and foreign patents issued to third parties that relate to our products. Some of these patents may be broad enough to cover one or more aspects of our products. We do not know whether any of these patents, if challenged, would be held valid, enforceable and infringed. From time to time, we receive, and likely will continue to receive, letters from third parties accusing us

of infringing and/or inviting us to license their patents. We may be sued by, or become involved in an administrative proceeding with, one or more of these third parties.

We cannot be certain that a court or administrative body would agree with any arguments or defenses we may have concerning invalidity, unenforceability or non-infringement of any third-party patent. In addition, other parties may have filed or will file patent applications covering products that are similar or identical to ours. We cannot be certain that patents issuing from our own patent application covering our products will have a priority date over any patents issuing from applications filed by a third party.

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

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

OUR PRODUCTS RELY ON LICENSES FROM THIRD PARTIES, 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 2016, it reached a high of $241.61 and a low of $169.09; during fiscal 2017, it reached a high of $403.70 and a low of $209.83; and during fiscal 2018, it reached a high of $574.74 and a low of $375.25. Our stock price can fluctuate for a number of reasons, including:

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

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

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- changes in accounting policies;
- economic changes and overall market volatility;
- litigation;
- media coverage, whether accurate or inaccurate, fair or misleading;
- political uncertainties;