NUVASIVE INC
Form 10-K
February 20, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number: 000-50744

NUVASIVE, INC.

(Exact name of registrant as specified in its charter)

Delaware	33-0768598
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
7475 Lusk Boulevard San Diego, California	92121 (Zip Code)
(Address of principal executive offices)	

(858) 909-1800

(Registrant’s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act

Title of Class:	Name of Exchange on which Registered:
Common Stock, par value $0.001 per share	The NASDAQ Stock Market LLC (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 of 1933, as amended. YES NO

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended. YES NO

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $2.7 billion as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2018), based upon the closing sale price for the registrant's common stock on that day as reported by the NASDAQ Global Select Market. Shares of common stock held by each officer and director on June 30, 2018 have been excluded in that such persons may be deemed to be affiliates.

As of February 18, 2019, there were 51,635,602 shares of the registrant's common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Form 10-K incorporates information by reference to portions of the definitive Proxy Statement for the registrant's 2019 Annual Meeting of Stockholders, which will be filed with the U.S. Securities and Exchange Commission not later than 120 days after December 31, 2018.

NuVasive, Inc.

Annual Report on Form 10-K for the Fiscal Year ended December 31, 2018

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PART I

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements that involve risks, uncertainties, assumptions and other factors which, if they do not materialize or prove correct, could cause our results to differ from historical results or those expressed or implied by such forward-looking statements. In some cases, you can identify these forward-looking statements by words like "may", "will", "should", "could", "expect", "plan", "anticipate", "believes", "estimates", "predicts", "potential", "intends", or "continues" (or the negative of those words and other comparable words). Forward-looking statements include, but are not limited to, statements about:

- our intentions, beliefs and expectations regarding our expenses, sales, operations and future financial performance;
- our operating results;
- our plans for future products and enhancements of existing products;
- anticipated growth and trends in our business;
- the timing of and our ability to maintain and obtain regulatory clearances or approvals;
- our belief that our cash and cash equivalents and investments will be sufficient to satisfy our anticipated cash requirements;
- our expectations regarding our revenues, customers and distributors;
- our beliefs and expectations regarding our market penetration and expansion efforts;
- our expectations regarding the benefits and integration of recently-acquired businesses and our ability to make future acquisitions and successfully integrate any such future-acquired businesses;
- our anticipated trends and challenges in the markets in which we operate; and
- our expectations and beliefs regarding and the impact of investigations, claims and litigation.

These statements are not guarantees of future performance or events. Our actual results may differ materially from those discussed in this Annual Report and the documents incorporated by reference to this Annual Report. The potential risks and uncertainties that could cause actual results to differ materially include, but are not limited to, those set forth in Part I, Item 1(A) under the heading "Risk Factors", Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this Annual Report and in any other documents incorporated by reference to this Annual Report. Readers are cautioned not to place undue reliance on such forward-looking statements. We assume no obligation to update any forward-looking statements to reflect new information, future events or circumstances or otherwise, except as required by law.

This Annual Report and the documents incorporated by reference into this Annual Report refer to trademarks, such as Absolute Responsiveness®, Acuity®, Affix®, Armada®, AttraX®, Back Pact®, Bendini®, Better Back Alliance®, Better Insight. Better Decisions. Better Medicine®, Brigade®, CerPass®, COALESCE™, COHERE®, CoRoent®, Creative Spine Technology®, DBR®, Embody®, Embrace®, ExtenSure®, Formagraft®, Gradient Plus®, Halo®, iGA™, ILIF®, InStim®, LessRay®, Leverage®, MAGEC®, MAGEC-EOS™, MAS®, MaXcess®, Modulus®, NeoDisc™, Nerve Avoidance Leader™, NuvaLine™, NuvaMap™ O.R., NuVasive®, NVM5®, Osteocel®, Precept®, PRECICE®, PROPEL®, Pulse™, Radian®, Reline™, Speed of Innovation®, SpheRx®, Surgical Intelligence™, The Better Way Back®, Traverse®, Triad®, VuePoint®, X360™, X-Core®, and XLIF®, which are protected under applicable intellectual property laws and are our property or the property of our subsidiaries. Solely for convenience, our trademarks and tradenames referred to in this Annual Report may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames.

Item 1.Business

Overview

We are a leading medical device company in the global spine surgery market, focused on developing minimally disruptive surgical products and procedurally integrated solutions for spine surgery. Our currently marketed product portfolio is focused on applications for spine fusion surgery, including ancillary products and services used to aid in the surgical procedure. Our procedurally integrated solutions use innovative, technological advancements and a minimally disruptive surgical platform called Maximum Access Surgery, or MAS, to provide surgical efficiency, operative reliability, and procedural versatility. For the year ended December 31, 2018, we generated global revenues of $1.1 billion, including sales in over 50 countries.

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Our principal product offering includes the MAS platform which combines three categories of solutions that collectively minimize soft tissue disruption during spine fusion surgery, provide maximum visualization and are designed to enable safe and reproducible outcomes for the surgeon and the patient. The platform includes our proprietary software-driven nerve detection and avoidance systems, and Intraoperative Monitoring, or IOM, services and support offered by NuVasive Clinical Services; MaXcess, an integrated split-blade retractor system; and a wide variety of specialized implants and biologics. Many of our products, including the individual components of our MAS platform can also be used in open or traditional spine surgery. Our spine surgery product line offerings, which include products for the thoracolumbar and the cervical spine, are primarily used to enable surgeon access to the spine to perform restorative and fusion procedures in a minimally disruptive fashion. To assist with surgical procedures, we offer a platform called Integrated Global Alignment, or iGA, in which products and computer assisted technology under our MAS platform help achieve more precise spinal alignment.

Our MAS platform and its related offerings are designed to provide a unique and comprehensive solution for the safe and reproducible minimally disruptive surgical treatment of spine disorders by enabling surgeons to access the spine in a manner that affords both direct visualization and detection and avoidance of critical nerves along with intraoperative reconciliation. The fundamental difference between our MAS platform, which is sometimes referred to in the industry as “minimally invasive surgery” or “MIS”, is the ability to customize safe and reproducible access to the spine while allowing surgeons to continue to use instruments that are familiar to them and effective during surgery. Accordingly, the MAS platform does not force surgeons to reinvent or learn new approaches that add complexity and undermine safety, ease of use and/or efficacy. We have dedicated and continue to dedicate significant resources toward training spine surgeons around the world; both those who are new to our MAS and other product platforms, as well as ongoing education for MAS-trained surgeons attending advanced courses. An important ongoing objective of ours has been to maintain a leading position in access and nerve avoidance, as well as to pioneer and remain the ongoing leader in minimally invasive spine surgery. Our MAS platform, with the unique advantages provided by our neuromonitoring systems, enables innovative lateral procedures, including a procedure known as eXtreme Lateral Interbody Fusion, or XLIF, in which surgeons access the spine for a fusion procedure from the side of the patient’s body, rather than from the front or back. It has been demonstrated clinically that XLIF and other procedures facilitated by our MAS platform decrease trauma and blood loss, and lead to faster overall patient recovery times compared to open spine surgery.

We offer a range of implants for spinal surgery, which include our porous titanium and polyetheretherketone, or PEEK, implants under our Advanced Materials Science portfolio, fixation devices such as customizable rods, plates and screws, bone allograft in patented saline packaging, allogeneic and synthetic biologics, and disposables used in IOM. We also design and sell expandable growing rod implant systems that can be non-invasively lengthened following implantation with precise, incremental adjustments via an external remote controller using magnetic technology called MAGnetic External Control, or MAGEC, which allows for the minimally invasive treatment of early-onset and adolescent scoliosis. This technology is also the basis for our PRECICE limb lengthening system, which allows for the correction of long bone limb length discrepancy, as well as enhanced bone healing in patients that have experienced traumatic injury. The PRECICE limb lengthening system is sold by NuVasive Specialized Orthopedics.

We intend to continue development on a wide variety of projects intended to broaden our MAS and other product platforms and advance the applications of our unique technology into procedurally integrated surgical solutions designed to improve clinical and economic outcomes. In 2019, we expect to commercially launch Pulse, a surgical automation platform which will incorporate LessRay, neuromonitoring, surgical planning, rod bending, imaging, navigation, and other automation capabilities. Pulse is a combined hardware and software platform designed to achieve surgical efficiencies via real-time feedback to aid in clinical decision making and to optimize the procedural workflow in the operating room.

We expect to continue to pursue business and technology acquisition targets and strategic relationships to identify opportunities to broaden participation along the spine care continuum. Top priorities include opportunities that complement our technology leadership position in spine, targeted geographic expansion, technology that makes procedures even safer, as well as opportunities for surgical automation.

Our corporate headquarters is located in San Diego, California where we currently occupy approximately 169,000 square feet, including a six-suite state-of-the-art cadaver operating theatre designed to accommodate the training of spine surgeons. In August 2017, we entered into a 17 year operating lease agreement for the purpose of expanding and restructuring our corporate headquarters located in San Diego, California, from approximately 145,000 square feet to approximately 252,000 square feet. Our location in Amsterdam, the Netherlands, serves as our international headquarters. Our primary distribution and warehousing operations are located in our facility in Memphis, Tennessee. Our business is facilitated by rapid delivery of products and surgical instruments for surgeries involving our products. Because of its location and proximity to overnight third-party transporters, our Memphis facility enhances our ability to meet demanding delivery schedules and provide a greater level of customer service. Additionally, our primary self-manufacturing facility which produces spinal implants is located in West Carrollton, Ohio.

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Our Strategy

We are a leading provider of innovative medical products that provide comprehensive solutions for the surgical treatment of spine disorders. We continue to pursue the following business strategies in order to improve our competitive position:

- Establish our MAS Platform as the Standard of Care. We believe our MAS platform has the potential to become the standard of care for spine surgery as hospitals, providers and spine surgeons continue to recognize its many benefits and adopt our products and procedures. We also believe our MAS platform has the potential to dramatically improve the clinical results of spine surgery. Because of this belief, we dedicate significant resources to researching clinical outcomes data as well as educating spine surgeons, hospitals, and other providers and their patients on the clinical and financial benefits of our products, and we intend to capitalize on the growing demand for minimally disruptive surgical procedures.
- Continue to Develop and Introduce Procedurally-Integrated Solutions and New Innovative Products. One of our core competencies is our ability to rapidly develop and commercialize innovative spine surgery products and procedures to fulfill an unmet clinical need. In the past several years, we have introduced a continual flow of new products and product enhancements. We have additional products and procedural offerings currently under development that should expand our presence in fusion surgery. With our comprehensive portfolio of product and service offerings, we believe we can offer our customers a comprehensive procedural solution for spine surgery that distinguishes us from traditional spine implant companies. We intend to continue to build upon our procedural solution with new and enhanced technology offerings, as well as product expansions. We believe through continued innovation and a focus on providing comprehensive procedural solutions for our customers, we will increase our market share while at the same time improving patient care. As part of this strategy, we must continue to protect and defend the intellectual property related to our innovative products.
- Expand the Reach of Our Exclusive Sales Force. We believe having a sales force dedicated to selling only our products is critical to achieving continued growth across our various product lines, driving greater market penetration and increasing our revenues. In the United States, we have a sales force consisting of a mix of directly-employed sales representatives and exclusive sales agents who are responsible for particular geographic regions of the country. Outside of the United States, our sales force consists of directly-employed sales representatives, independent sales agents and territory-based distributors.
- Provide Tailored Solutions in Response to Surgeon Needs. Responding quickly to the needs of spine surgeons is central to our culture, critical to our success, and we believe differentiates us from our competition. We solicit information and feedback from our surgeon customers and clinical advisors regarding the utility of, and potential improvements to, our products. For example, we have an on-site machine shop to allow us to rapidly manufacture product prototypes and a cadaver operating theatre in San Diego, California to provide clinical training and validate new ideas through prototype testing. We also maintain regional training facilities and centers for excellence in strategic locations around the globe. Responding quickly goes beyond product development to include active support in all areas, including clinical research and payer relations. Continuing to remain connected and responsive to the collective voices of the surgeon community should allow us to increase our market share and drive adoption of our procedurally-integrated spine solutions.
- Selectively License or Acquire Complementary Products and Technologies and Drive our International Presence. In addition to building our company through internal product development and global expansion efforts, we intend to selectively license or acquire complementary products and technologies and enter into strategic relationships that should keep us on the forefront of innovation and to pursue opportunities that allow us to expand our presence in international markets. With the 2016 acquisition of Ellipse Technologies, we offer innovative products based on the MAGEC technology platform. With this acquisition, we accelerated our entry into the pediatric and idiopathic spine deformity segment and expanded our international presence. With the 2016 acquisition of the LessRay software technology suite, we now help surgeons and hospital staff manage radiation exposure, without compromising intra-operative images or visual accuracy. With the acquisition of Vertera Spine in 2017, which developed patented

porous PEEK technology, we now offer porous interbody technology across both PEEK and titanium materials, thereby addressing the spectrum of surgeons' needs and preferences for interbody implants. In 2018, we entered into a Spine Precision Partnership with Siemens Healthineers to advance operating room workflow efficiency and provide increased precision in the delivery of minimally-disruptive spine surgery technologies through the integration of our Pulse surgical automation platform with Siemens Healthineers' mobile 3D C-arm. By acquiring complementary products, entering into strategic relationships, and executing on domestic and international footprint expansion opportunities, we believe we can leverage our expertise of bringing new products to market that are intended to improve patient outcomes, simplify or better integrate techniques, reduce hospitalization and rehabilitation times across the globe, and, as a result, reduce overall costs to the healthcare system and continue to grow our global presence.

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- Provide Intraoperative Monitoring Capabilities. Monitoring the health of the nervous system during spinal surgery has been a key component of our strategy of product differentiation since early in our development. Over time, surgeon and hospital demand for neuromonitoring has increased along with the advancement of technologies and techniques used in IOM. We believe our proprietary neuromonitoring platform is a differentiator in the market and is unique in its ability to provide information about the directionality and proximity of nerves. With our acquisitions of Biotronic NeuroNetwork in 2016 and SafePassage in 2018, we have expanded the scale of our IOM services business and solidified our position as the largest provider of outsourced IOM services and are driving increased utilization of our neuromonitoring platform. We intend to continue to expand the utility of such platforms and broaden our IOM product and services offerings to further our value to our customers and increase adoption and usage.

Industry Background and Market

The spine is the core of the human skeleton, and provides a crucial balance between structural support and flexibility. It consists of 33 separate bones called vertebrae that are connected together by connective tissue (defined as bone, muscle, or ligament) to form a column and to permit a normal range of motion. The spinal cord, the body's central nerve system, is enclosed within the spinal column. Vertebrae are paired into what are called motion segments that move by means of three joints: two facet joints and one spine disc. The four major categories of spine disorders are degenerative conditions, deformities, trauma and tumors. The largest market and the focus of our business historically are degenerative conditions of the facet joints and the intervertebral disc space. These two conditions can result in instability and pressure on the nerve roots as they exit the spinal column, causing back or neck pain or radiating pain in the arms or legs.

The prescribed treatment for back or neck pain depends on the severity and duration of the disorder. Initially, physicians will prescribe non-operative, conservative procedures including bed rest, medication, lifestyle modification, exercise, physical therapy, chiropractic care and steroid injections. In many cases, non-operative treatment options are effective; however, some patients eventually require spine fusion surgery. The vast majority of spine fusion surgeries are done using traditional open surgical techniques from either the front or back of the patient. These traditional open surgical approaches generally require a large incision in the patient's abdomen or back in order to enable the surgeon to access and see the spine and surrounding area. These open procedures are invasive, lengthy and complex, and typically result in significant blood loss, extensive tissue damage and lengthy patient hospitalization and rehabilitation.

We believe the market for procedurally integrated spine surgery solutions will continue to grow over the long term, and we also believe our market share will increase, because of the following market dynamics:

- Demand for Surgical Alternatives with Less Tissue Disruption. As has been proven in other surgical markets, we anticipate the broader acceptance of surgical treatments with less tissue disruption and patient trauma will result in increased demand.
- Favorable Domestic Demographics. The population segment most likely to experience back pain is expected to increase as a result of aging "baby boomers" (people born between 1946 and 1965). This large population segment is expected to increasingly demand a quicker return to activities of daily living following surgery than prior generations.
- Access to Care in Emerging Markets. Healthcare reforms in many emerging markets are expanding access to treatments to a greater proportion of their populations, which is expected to continue to drive strong increases in demand for healthcare-related product volumes. Increasing economic affluence in key developing regions will further drive demand for healthcare treatments.
- Vendor/Hospital Consolidation. Given the continued economic pressures facing hospitals and healthcare systems, we anticipate broader consolidation of vendors in the spine space. We believe we are well-positioned to benefit from this vendor consolidation given our size and scale and the breadth of our portfolio.

Although the market for procedurally-integrated spine surgery solutions should continue to grow over the long term, economic, political and regulatory influences are subjecting our industry to significant changes that may slow the growth rate of the spine surgery market.

Surgical Alternatives with Less Tissue Disruption

The benefits of minimally invasive surgical procedures in other areas of orthopedics have significantly contributed to the strong and growing demand for surgical alternatives with less tissue disruption of the spine. Surgeons and hospitals seek spine procedures that result in fewer operative and postoperative complications and decreased patient hospitalization periods. At the same time, patients seek procedures that reduce trauma, allow for faster recovery times and result in more favorable and predictable clinical outcomes. Despite patient and doctor demands, the rate of adoption of alternative surgical procedures with less tissue disruption has been relatively slow with respect to the spine. Currently, the majority of spine surgery patients are treated with traditional open and invasive techniques.

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A principal factor contributing to spine surgeons' slow adoption of traditional minimally invasive spine procedure alternatives has been inconsistent outcomes driven by the limited or lack of direct access to and visibility of the surgical anatomy, and the associated complex instruments that have been required to perform these procedures. Most traditional minimally invasive spine surgery systems do not allow the surgeon to directly view the spine and the relevant pathology point and, as such, provide only restrictive visualization through a camera system or endoscope, while also requiring the use of complex surgical techniques. In addition, most traditional minimally invasive spine surgery systems use complex or highly customized surgical instruments that require special training and the completion of a large number of trial cases before the surgeon becomes proficient using the system, which is an impediment and/or deterrent to their adoption.

Our Commercial Products

Our MAS platform allows surgeons to perform a wide range of minimally disruptive spine procedures in all regions of the spine and from various surgical approaches, while overcoming the shortcomings of traditional minimally invasive spine surgical techniques. The MAS platform is designed to treat a wide range of spinal pathologies while accommodating a surgeon's preferred surgical technique. We believe our approach improves clinical results and should continue to drive an expanded number of minimally disruptive procedures performed, lead the market away from open surgery, and make less invasive techniques the standard of care in spine fusion and non-fusion surgery.

Our products facilitate minimally disruptive applications of the following spine surgery procedures, among others:

- Lumbar and thoracic fusion procedures in which the surgeon approaches the spine through the patient's back, side or abdomen;
- Cervical fusion procedures for either the posterior occipito-cervico-thoracic region or the anterior cervical region; and
- Decompression, which is removal of a portion of bone or disc from over or under the nerve root to relieve pinching of the nerve.

Our MAS platform combines three product categories: our MaXcess retractors, our specialized implants and fixation products, and our neuromonitoring systems and service offerings that collectively enable surgeons to detect and navigate around nerves while directing customized access to the spine for implant delivery. Biologics are used to complement procedures by promoting bone fusion. In addition to our MAS platform and biologics, our comprehensive procedural solutions include our IOM services, Integrated Global Alignment, or iGA, and Pulse, our surgical automation platform.

MaXcess

MaXcess retractors have a split-blade design consisting of three blades that can be positioned to customize the surgical exposure in the shape and size specific to the surgical requirements rather than the more traditional fixed tube or two-blade designs of traditional minimally invasive spine surgical systems. This split-blade design also provides customizable access to the spine, which allows surgeons to perform surgical procedures using instruments that are similar to those used in open procedures but with a smaller incision and less tissue disruption. The ability to use familiar instruments reduces the learning curve for our procedures and facilitates the adoption of our products. Our system's illumination of the operative corridor aids in providing surgeons with better direct visualization of the patient's anatomy, without the need for additional technology or other special equipment such as endoscopes. Over the years, several improvements to our MaXcess systems have been made, including incorporating integrated neuromonitoring technology and improving the blade systems, and the MAS approach has broadened from the lumbar to the thoracic region. Our MaXcess products are used in the cervical spine for posterior application and anterior retraction, the lumbar spine for decompressions, transforaminal lumbar interbody fusions, or TLIFs, posterior lumbar interbody fusions, or PLIFs, the thoracolumbar spine for eXtreme Lateral Interbody Fusion, or XLIFs, and the thoracic region

for tumors and trauma, as well as in adult degenerative scoliosis procedures.

Implants and Fixation Products

We have many implants and fixation devices designed to be used with our MAS platform. Our portfolio of implants used for interbody disc height restoration include implants made from allograft, titanium, and PEEK. Our titanium and PEEK implants are available in both porous and non-porous formats and come in a variety of shapes, sizes, and lordosis options to accommodate specific approach, pathology, alignment restoration, and anatomical requirements of the patient and the particular fusion procedure. Our implants are designed for insertion into the smallest possible space while maximizing surface area contact for fusion. Our fixation products, including pedicle screws, rods and plates, have been uniquely designed and include a highly differentiated percutaneous minimally invasive solution with advanced guide technology, superior rod insertion options, and multiple reduction capabilities to be delivered through our procedures to provide stabilization of the spine. Our fixation offerings include our Armada, Precept and Reline posterior fixation portfolios.

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Neuromonitoring

Our neuromonitoring systems utilize electromyography, or EMG, as well as proprietary software hunting algorithms and graphical user interfaces to provide surgeons with an enhanced and intuitive nerve avoidance system. Our systems function by monitoring changes in electrical signals across muscle groups, which allows us to detect underlying changes in nerve activity. Through our neuromonitoring platforms, we give surgeons the option to connect their instruments to a computer system that provides discrete, real-time, surgeon directed and surgeon controlled feedback about the directionality and relative proximity of nerves during surgery. We believe our proprietary neuromonitoring platforms are a differentiator in the market and are unique in their ability to provide information about the directionality and proximity of nerves. Our systems analyze and then translate complex neurophysiologic data into simple, useful information to assist the surgeon's clinical decision-making process. The health and integrity of the spinal cord and related nerves can also be assessed using motor evoked potentials, or MEPs, and somatosensory evoked potentials, SSEPs. Both of these methods of IOM involve applying stimulation and recording the response that must travel along the motor or sensory paths of the spinal cord. Surgeons can connect certain instruments to our neuromonitoring systems, thus creating an interactive set of instruments that better enable the safe navigation through the body's nerve anatomy during surgery. The connection is accomplished using a clip that is attached to the instrument, effectively providing the benefits of our neuromonitoring systems through an instrument already familiar to the surgeon. Our proprietary software and easy to use graphical user interfaces allow the surgeon to make critical decisions in real time to help enable safer, faster, and more reproducible procedures to achieve improved patient outcomes.

Biologics

Biologics are used to aid in the spinal fusion process or bone healing process. The global biologics market in spine surgery consists of autograft (autologous human tissue), allograft (donated human tissue), and a varied offering of synthetic products and growth factors. Our allograft biologics product offerings include Osteocel Plus and Pro – a cellular bone matrix designed to mimic the biologic profile of autograft including mesenchymal stem cells and osteoprogenitor cells to aid in spinal fusion and Propel DBM (highly moldable demineralized bone matrix putty and gel). Our synthetic biologics product offerings include Formagraft (collagen-based synthetic bone substitute) and AttraX (synthetic bone graft material delivered in putty and other forms).

Intraoperative Monitoring Services

Monitoring the health of the nervous system during spinal surgery has been a key component of our strategy of product differentiation since early in our development. Over time, surgeon and hospital demand for neuromonitoring has increased along with the advancement of technologies and techniques used in IOM. Through our IOM services business, we provide onsite and remote monitoring of the neurological systems of patients undergoing spinal and brain-related surgeries. Our neurophysiologists are present in the operating room during procedures and work in partnership with supervising physicians who remotely oversee and interpret neurophysiological data gathered via broadband transmission over the internet. Through this service, data can be analyzed in real time by healthcare professionals for additional interpretation of intraoperative information and oversight, which we believe further improves the safety and reproducibility of the vast array of our spine procedures.

Integrated Global Alignment

Current and emerging data illustrates a direct correlation between proper spinal alignment and long-term clinical outcomes. Our iGA platform offers a global approach for assessing, preserving, and restoring spinal alignment in an effort to promote surgical effectiveness and efficiencies, lasting patient outcomes, and improved quality of life. Using our NuvaPlanning portfolio of software products for integrated operative solutions, surgeons can preoperatively

calculate and evaluate alignment parameters and implant integration by accurately modeling surgery to create a reliable plan with clear results, and then conduct a real-time intraoperative assessment in order to correct the anterior and posterior column alignment in line with the surgical plan. Following a procedure, surgeons can use our solutions to confirm the success of the procedure and effect on alignment by reviewing surgical results and easily comparing those results to the surgical plan. In addition to our software solutions, we also offer specific products that are designed to restore alignment, including our Reline posterior fixation portfolio, our VuePoint occipito-cervico-thoracic fixation system, and our Bendini spinal rod bending system.

Imaging Technology

Our LessRay system is a software technology platform designed to help surgeons and hospital staff manage radiation exposure associated with x-ray and other imaging technology, without compromising intraoperative images or visual accuracy. This is achieved through digital imaging processing technology that generates high resolution images of the surgical field from low resolution fluoroscopy (or x-ray) images. We currently offer LessRay as a standalone product but anticipate incorporating the LessRay technology into our Pulse surgical automation platform in the future.

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Integrated Surgical Automation Platform

Pulse is our modular surgical automation platform which will incorporate LessRay, neuromonitoring, surgical planning, rod bending, imaging, navigation, and other automation capabilities. Pulse is a combined hardware and software platform designed to achieve surgical efficiencies via real-time feedback to aid in clinical decision making and to optimize the procedural workflow in the operating room. In 2018, Pulse received 510(k) clearance from the United States Food and Drug Administration and we expect to commercially launch Pulse in 2019.

MAGEC-EOS Spinal Bracing and Distraction System

Early onset scoliosis, or EOS, refers to severely deformed curvatures of the spine diagnosed before the age of ten. EOS is a challenging health issue and can lead to more severe progressive deformities. Surgical treatments for EOS include the use of surgically adjustable expandable rods to control the spine deformity while still allowing the spine to grow until a child reaches an appropriate size or age for a more permanent solution, such as spinal fusion. Surgeries to adjust traditional growing rods are typically performed every six to nine months and are associated with scarring, elevated infection rates, postoperative pain, and impaired mobility as the child heals from surgery. Additionally, these surgeries involve repetitive exposure to general anesthesia, which can delay development and impair long-term cognitive function. The MAGEC-EOS system is designed to overcome the limitations of conventional adjustable rod treatments for EOS and reduce the number of surgical procedures required throughout childhood. Once our MAGEC growing rods are surgically implanted in a patient, they can be adjusted non-invasively using the external remote controller. The ability to adjust growing rods without surgical intervention means that EOS patients can be treated with fewer planned surgeries. Our non-invasive adjustment technology enables physicians to perform more frequent adjustments in a non-surgical outpatient setting, thereby improving deformity correction and allowing for optimal spinal growth.

PRECICE Limb Lengthening System

Limb length discrepancies, or LLDs, refer to a congenital deformity or injury resulting in one leg being shorter than the other. Large LLDs often require complex treatments including limb lengthening surgery to create equal limb length. The traditional limb lengthening surgical procedure includes the creation of a gap in the bone, or osteotomy, the attachment of wires or pins to the fractured bones, and the passing of the wires or pins through the skin to an external fixator, a scaffold-like frame that surrounds the limb. The external fixator distracts the bone when the patient or a family member manually turns the knobs on the fixator. These adjustments must be performed several times each day such that the bone is lengthened approximately one millimeter per day. Adjustments of the external fixator are very painful and associated with soft tissue disruption, disturbance of the wound healing process of the skin and soft tissue and high rates of pin site infection. In addition, traditional external fixation can result in significant psychosocial comorbidities that reduce quality of life for patients undergoing treatment, including anxiety, social disengagement, sleep disorders, depression and addiction to pain medication. The PRECICE LLD system uses the MAGEC technology to enable non-invasive and painless adjustments using a pre-programmed external remote controller. As a result, PRECICE LLD enables physicians to customize therapy to the needs of the patient over time without the need for surgical re-intervention and provides improved quality of life and satisfaction for patients in need of surgical limb lengthening.

Research and Development

Our research and development efforts are primarily focused on developing our new technology platforms and further enhancing our existing products to improve and further integrate our procedural solutions to address unmet clinical needs while improving patient and economic outcomes. Our research and development group has extensive experience in developing products to treat spine pathologies. This group continues to work closely with our clinical

advisors and spine surgeon customers to design products and procedural solutions designed to improve patient outcomes, simplify techniques, and reduce patient trauma including subsequent hospitalization and rehabilitation times; and as a result reduce overall costs to patients and the healthcare system.

International

As the spine market shifts towards minimally invasive surgery and international access to healthcare increases, it should provide us with an opportunity for accelerated growth outside the United States. Because our procedurally-integrated solutions and technologies treat similar pathologies around the world, we are focused on expanding our operations in select developed and emerging international markets. We are investing to tailor our products and technologies to meet varying international patient, surgeon and market requirements. We are also investing in expanding our global infrastructure to adapt to alternative distribution channels, to support differing language and customer service requirements, and to provide training and surgeon education in our MAS surgical techniques, our surgical instruments and our implants to our international customers. We intend to continue to make targeted investments in select international markets in order to increase our commercial reach outside of the United States. Our international revenue, which excludes Puerto Rico, was $205.6 million or 19% of total revenue for the year ended December 31, 2018.

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Sales and Marketing

In the United States, we currently sell our procedurally-integrated solutions through a combination of exclusive and non-exclusive independent sales agents and directly-employed sales force. Each member of our United States sales force is responsible for a defined territory, with our independent sales agents acting as our sole representative in their respective territories. The determination of whether to engage a directly-employed sales representative or an independent sales agent is made on a territory–by-territory basis, with a focus on aligning the sales team with the best skills and experience with local surgeons' needs. Our international sales force is comprised of directly-employed sales representatives, as well as exclusive distributors and independent sales agents. Directly-employed sales representatives make up the majority of our overall sales force.

Surgeon Training and Education

We devote significant resources to training and educating surgeons regarding the safety and reproducibility of our surgical techniques and our instruments and implants. We maintain state-of-the-art cadaver operating rooms and training facilities to help educate surgeons regarding our products at our corporate headquarters in San Diego, California. We continue to train surgeons on our lateral techniques, including XLIF, and our other MAS platform products including: our proprietary neuromonitoring systems, MaXcess, biologics, and specialized implants. Our surgeon education program includes a Clinical Professional Development global platform, which integrates surgical training with professional development.

Manufacturing and Supply

As our business has continued to scale, we significantly expanded our self-manufacturing capabilities in 2017 as we increased production at our approximately 180,000 square foot manufacturing facility in West Carrollton, Ohio. As we increase our self-manufacturing capabilities, we will look to maintain adequate raw materials suppliers, sourcing alternatives and adequate supply to support our operations. We have identified or are in the process of identifying and qualifying additional suppliers, on a per product basis, for our highest volume products to best enable us to be able to maintain consistent supply to our customers. Our outsourcing strategy is targeted at companies that meet U.S. Food and Drug Administration ("FDA"), International Organization for Standardization (ISO), and quality standards supported by internal policies and procedures. Supplier performance is maintained and managed through a supplier qualification, performance management and corrective action program intended to ensure that all of our product requirements are met or exceeded.

Our products are inspected, packaged and labeled, as needed, at our San Diego headquarters, our Memphis distribution facility or our Aliso Viejo facility. Under our existing contracts with third-party manufacturers, we reserve the exclusive right to inspect and assure conformance of each product and product component to our specifications.

We currently rely on several tissue banks as our suppliers of allograft tissue implants, including for our Osteocel Plus and Osteocel Pro product lines. Like our relationships with our device manufacturing suppliers, we subject our tissue processing suppliers to the same quality criteria in terms of selection, qualification, and verification of processed tissue quality upon receipt of goods, as well as hold them accountable to compliance with FDA regulations, state requirements, and as-voluntary industry standards (such as those put forward by the American Association of Tissue Banks).

We rely on two suppliers for PEEK, which comprises many of our partial vertebral body replacement and interbody product lines. We rely on one, exclusive supplier for our neuromonitoring platforms, and rely on one, exclusive supplier for our neuromonitoring equipment that is used outside of the NVM5 and Pulse platforms.

We, and our third-party manufacturers, are subject to the quality system regulations of the FDA, state regulations (such as the regulations promulgated by the California Department of Health Services), and regulations promulgated by foreign regulatory bodies (such as in the European Union). For tissue products, we are FDA registered and licensed in the States of California, New York, Florida, Maryland and Oregon. For our device implants and instruments, we are FDA registered, California licensed, CE marked and ISO certified. CE is an abbreviation for “Conformité Européenne” or European Conformity, and is the registration marking designating that a device can be commercially distributed throughout Europe. Our facilities and the facilities of our third-party manufacturers are subject to periodic announced and unannounced inspections by regulatory authorities, and may undergo compliance inspections conducted by the FDA, state, and/or international regulatory agencies.

Surgical Instrument, Implant Sets and Equipment Sales

For many of our customers, we provide surgical instrumentation sets, including both implants and instruments, as well as our neuromonitoring systems in a manner tailored to fulfill our customer’s obligations to meet surgery schedules. We do not generally receive separate economic value specific to the surgical instrument sets from the surgeons or hospitals that utilize them. In many cases, once the surgery is finished, the surgical instrument sets are returned to us, and we prepare them for shipment to meet future surgeries.

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We complement this implant and instrument shipment model with field-based instrument assets. This hybrid strategy is designed to improve customer service, minimize backlogs, increase asset turns, optimize freight costs, and maximize cash flow. Our pool of surgical equipment that we make available to hospitals continues to increase as we increase our product offering, expand our distribution channels and increase the market penetration of our products. These surgical instrumentation and implant sets are important to the growth of our business, and we anticipate additional investments in such assets going forward.

In certain cases we will sell either surgical instruments, implant sets or both to our customers. While this does not constitute a material component of our business, as customer penetration and volume increases, these sales of sets allows our customers to increase the amount of surgical volume performed locally. Additionally, LessRay units are sold as a capital sale or as a lease. We also intend to offer the Pulse platform through a capital sales and leasing model. We do not have a long history of selling, leasing or servicing capital equipment, and we have recently invested and intend to continue to invest in building resources and expertise in this area.

Intellectual Property

We rely on a combination of patent, trademark, copyright, trade secret and other intellectual property laws, nondisclosure agreements and other measures to protect our intellectual property rights. In order to have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. We require our employees (who we refer to as “shareowners”), consultants and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationships with us. We also require our shareowners, consultants and advisors who we expect to work on our products to agree to disclose and assign to us all inventions conceived using our property or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary.

Patents

As of December 31, 2018, we had over 1,125 issued and pending patents world-wide, including over 530 U.S. issued patents. Our issued and pending patents cover, among other things:

- MAS surgical access instrumentation and methodology, including our XLIF procedure and aspects thereof;
- Neurophysiology enabled instrumentation and methodology, including pedicle screw test systems, software hunting algorithms, navigated guidance, rod bending and surgical access systems;
- Implants and related instrumentation and targeting systems;
- Biologics, including Osteocel Plus and Osteocel Pro, Formagraft and AttraX;
- Magnetic technology for non-invasive distraction of an implanted device, including the MAGEC technology platform;
- Digital imaging processing technology that generates high resolution images of the surgical field from low resolution scans, including the LessRay technology platform; and
- Porous PEEK technology, included in our Cohere, Coalesce and Coalesce Straight interbody implants.

Our issued patents began to expire in 2018. We do not believe that the expiration of any single patent is likely to significantly affect our intellectual property position.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Patent litigation can involve complex factual and legal questions and its outcome is uncertain. Our success will depend in part on our not infringing patents issued to others, including our competitors and potential competitors. As the number of entrants into our market increases, the possibility of future patent infringement claims against us grows. While we make extensive efforts to ensure that our products do not infringe other parties’ patents and proprietary rights, our products and methods may be covered by patents held by our

competitors. There are numerous risks associated with our intellectual property. For a complete discussion of these risks, please see the “Risk Factors” section of this Annual Report.

Trademarks

As of December 31, 2018, we had over 265 trademark registrations in both domestic and foreign regions.

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Competition

Competition within the industry is primarily based on technology, innovation, quality, reputation and customer service. Our significant competitors are Medtronic Sofamor Danek, or Medtronic, DePuy/Synthes, a Johnson & Johnson company, Stryker Spine, Globus Medical, and Zimmer Biomet Spine, which together represent a significant portion of the spine market. We also face competition from a significant number of smaller companies with more limited product offerings and geographic reach than our larger competitors. These companies, who represent intense competition in specific markets, include Orthofix International N.V., Alphatec Spine, and others. With respect to our neuromonitoring systems, we primarily compete with Medtronic, and Cadwell Industries. Our IOM services business competes with SpecialtyCare and numerous smaller and regional neuromonitoring companies. We also face competition from physician owned distributorships, or PODs, which are medical device distributors that are owned, directly or indirectly, by physicians. However, these PODs have come under scrutiny by the Office of Inspector General, or OIG as the associated physicians derive a portion of their revenue from selling or arranging for the sale of medical devices for use in procedures they perform on their own patients. The prevalence of these PODs may impact our ability to grow.

The United States Government Regulation

Our products are medical devices and human tissue products subject to extensive regulation by the FDA and other regulatory bodies both inside and outside of the United States. Each of these agencies requires us - to varying degrees - to comply with laws and regulations governing the development, testing, manufacturing, storage, labeling, marketing and distribution of our products.

FDA’s Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device that we market and sell in the United States must first receive either premarket clearance (by submitting a 510(k) notification) or premarket approval (by filing a premarket approval application, or PMA) from the FDA. In addition, certain modifications to marketed devices may require 510(k) clearance or approval of a PMA supplement. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products (referred to as a predicate device). The FDA’s 510(k) clearance process usually takes between three and six months from the date the application is completed, but may last longer. The process of obtaining PMA approval is much more costly, lengthy and uncertain than the 510(k) clearance process and generally takes between one and three years, or even longer, from the time the application is submitted to the FDA until any approval is obtained. In addition, a clinical trial is almost always required to support a PMA application and may be required for a 510(k) premarket notification.

In 2018, the FDA issued draft guidance and announced steps to modernize the 510(k) clearance pathway that, if finalized and implemented, could impact the ability of medical device manufacturers to obtain or maintain 510(k) clearance for devices. Among other initiatives, the FDA has proposed to “sunset” the use of older predicate devices for purposes of comparison in new device 510(k) clearance submissions. If we cannot establish that a new or modified product is substantially equivalent to a predicate device, we may be required to seek pre-market approval through the PMA process. There are numerous risks associated with the PMA process, which typically requires conducting clinical trials with high costs and uncertain outcomes. For a complete discussion of these risks, please see the “Risk Factors” section of this Annual Report.

Human Cell, Tissue, and Cellular and Tissue Based Products

Our allograft products, including our Triad and ExtenSure, and our Osteocel Plus and Osteocel Pro products, are regulated by the FDA as Human Cell, Tissue, and Cellular and Tissue Based Products. FDA regulations do not

currently require these minimally manipulated human tissue-based products to be subjected to a premarket approval or pre-market notification process before they are marketed if they are deemed to meet the requirements of a “361” product under the Public Health Safety Act.

We are, however, required to register with the FDA as a provider of such products and to list these products with the FDA and comply with its Current Good Tissue Practices for Human Cell, Tissue, and Cellular- and Tissue-Based Product Establishments. The FDA periodically inspects tissue facilities to determine compliance with these requirements. Entities that provide us with allograft bone tissue are responsible for performing donor recovery, donor screening, donor testing, processing, and packaging and our compliance with those aspects of the Current Good Tissue Practices regulations that regulate those functions are dependent upon the actions of these independent entities.

The procurement and transplantation of allograft bone tissue is subject to United States federal law pursuant to the National Organ Transplant Act (NOTA), a criminal statute that prohibits the purchase and sale of human organs used in human transplantation - including bone and related tissue - for “valuable consideration” (as defined in the NOTA). The NOTA permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human bone tissue. With the exception of removal and implantation, we provide services, directly or indirectly, in all of these areas. We make payments to vendors in consideration for the services they provide in connection with the recovery and screening of donors. Failure to comply with the requirements of NOTA could result in enforcement action against us.

The procurement of human tissue is also subject to state anatomical gift acts and some states have statutes similar to NOTA. In addition, some states require that tissue processors be licensed by that state. Failure to comply with state laws could also result in enforcement action against us.

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Continuing FDA Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. These regulatory requirements include, but are not limited to, the following:

- product listing and establishment registration;
- adherence to the Quality System Regulation which requires stringent design, testing, control, documentation and other quality assurance procedures;
- labeling requirements and FDA prohibitions against the promotion of off-label uses or indications;
- adverse event reporting;
    - post-approval restrictions or conditions, including post-approval clinical trials or other required testing;
- post-market surveillance requirements;
- the FDA's recall authority, whereby it can ask for, or require, the recall of products from the market; and
- requirements relating to voluntary corrections or removals.

Failure to comply with applicable regulatory requirements can result in fines and other enforcement actions by the FDA, which could adversely impact our business.

We are also subject to announced and unannounced inspections by the FDA, the California Food and Drug Branch, American Association of Tissue Banking, as well as other regulatory agencies overseeing the implementation and adherence of applicable state and federal device and tissue licensing regulations. These inspections may include our manufacturing and subcontractors' facilities.

Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although surgeons are permitted to use medical devices for indications other than those cleared or approved by the FDA based on their medical judgment, we are prohibited from promoting products for such "off-label" uses.

Healthcare Regulation and Commercial Compliance

The healthcare industry is highly regulated and changes in laws and regulations can be significant. The federal government and all states in which we currently operate regulate various aspects of our business. Changes in the law or new interpretation of existing laws can have a material effect on our permissible activities, the relative costs associated with doing business and the amount of reimbursement by government and other third-party payers.

Anti-kickback Statute

We are subject to the federal anti-kickback statute which, among other things, prohibits the knowing and willful solicitation, offer, payment or receipt of any remuneration, direct or indirect, in cash or in kind, in return for, or to induce the referral of patients for, items or services covered by Medicare, Medicaid and certain other governmental health programs. Under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (ACA), neither knowledge of the anti-kickback statute nor the specific intent to violate the law is a requirement for being found in violation of such laws. Violation of the anti-kickback statute may result in civil or criminal penalties and exclusion from Medicare, Medicaid and other federal healthcare programs, and - according to ACA - now provides a basis for liability under the False Claims Act. Many states have enacted similar statutes, which are not limited to items and services paid for under Medicare or a federally funded healthcare program. We believe our operations materially comply with the anti-kickback statutes; however, because these provisions are interpreted broadly by regulatory authorities, we cannot be assured that law enforcement officials or others will not challenge our operations under these statutes.

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Federal False Claims Act

The Federal False Claims Act (in particular -its “qui tam” or “whistleblower” provisions) allow(s) private individuals to bring actions in the name of the United States government alleging that a defendant has made false claims for payment from federal funds. In addition, various states are considering enacting or have enacted laws modeled after the Federal False Claims Act, penalizing false claims against state funds. In 2013, we received a federal administrative subpoena from the OIG in connection with an investigation into possible false or otherwise improper claims submitted to Medicare and Medicaid. The subpoena sought discovery of documents for the period January 2007 through April 2013. In July 2015, we entered into a definitive settlement agreement with the U.S. Department of Justice, or DOJ, to settle this matter. Under the terms of the agreement, we paid $13.5 million plus fees and accrued interest of approximately $0.3 million to resolve this matter. The settlement was not an admission of liability or wrongdoing by us, and we were not required to enter into a corporate integrity agreement with the OIG as part of the settlement. In August 2015, we received a civil investigative demand, or CID, issued by the DOJ pursuant to the federal False Claims Act. The CID requires the delivery of a wide range of documents and information related to an investigation by the DOJ concerning allegations that we assisted a physician group customer in submitting improper claims for reimbursement and made improper payments to the physician group in violation of the Anti-Kickback Statute. We are cooperating with the DOJ in regards to this matter. Any adverse findings related to this investigation could result in material financial penalties against the Company.

Health Insurance Portability and Accountability Act

Under the Health Insurance Portability and Accountability Act of 1996, as was amended in 2005 and in 2009, or HIPAA, a Covered Entity, as further defined under HIPAA, is required to adhere to certain requirements regarding the use, disclosure and security of protected health information, or PHI. In the past, HIPAA has generally affected us indirectly, as NuVasive is generally neither a Covered Entity nor a Business Associate, as further defined under HIPAA, to Covered Entities, except that our provision of IOM services through various subsidiaries may create a Business Associate relationship; additionally, we treat our Puerto Rico subsidiary as a Covered Entity. Regardless of Covered Entity status under HIPAA, in those cases where patient data is received, NuVasive is committed to maintaining the security and privacy of PHI. The potential for enforcement action against us is now greater, as the U.S. Department of Health and Human Services (HHS) can take action directly against Business Associates. Thus, while we believe we are and will be in compliance with all required HIPAA standards, there is no guarantee that the government will agree. Enforcement actions can be costly and interrupt regular operations of our business.

Foreign Corrupt Practices Act

The United States and foreign government regulators have increased regulation, enforcement, inspections and governmental investigations of the medical device industry, including increased United States government oversight and enforcement of the Foreign Corrupt Practices Act. If the United States or another foreign governmental authority were to conclude that we are not in compliance with applicable laws or regulations, such governmental authority can impose fines, delay or suspend regulatory clearances, institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil penalties against us or our officers or employees, and can recommend criminal prosecution to the Department of Justice. Moreover, governmental authorities can ban or request the recall, repair, replacement or refund of the cost of any device or product we manufacture or distribute. We are also potentially subject to the UK Bribery Act, which would also subject us to the imposition of civil and criminal fines. Any of the foregoing actions could result in decreased sales as a result of negative publicity and product liability claims, and could have a material adverse effect on our financial condition, results of operations and prospects.

Physician Payments Sunshine Act of 2009 (Sunshine Act)

The Sunshine Act was enacted into law in 2010 and requires public disclosure to the United States government of payments to physicians and teaching hospitals, including in-kind transfers of value such as free gifts or meals. The Act also provides penalties for non-compliance. The Sunshine Act requires that we file an annual report on March 31 of a calendar year for the transfers of value incurred for the prior calendar year. This law, along with various international and individual state reporting requirements, such as in Massachusetts and Vermont, increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Compliance Program

A compliance program is a set of internal controls established by a company to prevent and/or detect any non-compliant activities and to address properly those issues that may be discovered. The United States government has recommended that healthcare companies, among others, develop and maintain an effective compliance program to reduce the likelihood of any such non-compliance by the company, its employees, agents and contractors. In addition, some states, such as Massachusetts and California, now require certain healthcare companies to have a formal compliance program in place in order to do business within the state. For years, we have maintained a compliance program structured to meet the requirements of the federal sentencing guidelines for an effective compliance program and the model compliance program guidance promulgated by HHS over the years. Our program includes, but is not limited to, a Code of Ethical Business Conduct, designation of a compliance officer, oversight by a designated committee of our Board of Directors, policies and procedures, a confidential disclosure method (a hotline), and conducting periodic audits to ensure compliance.

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Foreign Government Regulation

Sales of medical devices outside the United States are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ.

The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Additionally, certain countries (such as Switzerland), have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear "CE" conformity marking, and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body". This third-party assessment consists of an audit of the manufacturer's quality system and technical review of the manufacturer's product. We have now successfully passed several Notified Body audits since our original certification in 2001, granting us ISO certification and allowing the CE conformity marking to be applied to certain of our devices under the European Union Medical Device Directive.

In 2017, the European Union adopted the EU Medical Device Regulation (Council Regulations 2017/745) which imposes stricter requirements for the marketing and sale of medical devices, including new quality system and post-market surveillance requirements. The regulation has a three-year implementation period to May 2020 and will replace the existing directives on medical devices in the European Union. After May 2020, medical devices marketed in the European Union will require certification according to these new requirements, except that devices with valid CE certificates, issued pursuant to the Medical Device Directive before May 2020, may be placed on the market until 2024. Complying with this new regulation will require us to incur significant costs and failure to meet the requirements of the regulation could adversely impact our business in the European Union and other countries that utilize or rely on European Union requirements for medical device registrations.

In 2014, the Japanese government made revisions to the Pharmaceutical Affairs Law (now called PMD Act) that made significant changes to the preapproval regulatory systems. These changes have - in part - stipulated that, in addition to obtaining a manufacturing or import approval from the Ministry of Health, Labor and Welfare, certain low-risk medical devices can now be evaluated by third-party organizations. Based on the risk-based classification, manufacturers are provided three procedures for satisfying the PMD Act requirements prior to placing products on the market: Pre-market Submission, or Todokede; Pre-market Certification, or Ninsho; and Pre-market Approval, or Shonin. NuVasive markets devices in Japan that are assessed by both government entities and third-party organizations using all three procedures in place for manufacturers. The level of review and time line for medical device approval will depend on the risk-based classification and subsequent regulatory procedure that the medical device is aligned based on assessment against the current PMD Law. Manufacturers must also obtain a manufacturing or import license from the prefectural government prior to importing medical devices. We also pursue authorizations required by the prefectural government as required.

Device and tissue premarket approval and/or registration and/or facility licensing requirements also exist in other markets where international NuVasive facilities are established and/or where we may conduct business, including, but not limited to, Southeast Asia, Australia, and Latin America. Such requirements vary by country and NuVasive has established procedures to drive its compliance with these requirements.

Data protection laws, including the EU General Data Protection Regulation ("GDPR"), also apply to our international operations. The GDPR requires, among other things, obligations and restrictions on the ability to collect, analyze and transfer EU personal data and the prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances. These data protection regulations create a range of compliance obligations and permit substantial fines

for noncompliance.

Third-Party Reimbursement

Broadly speaking, payer pushback on spine surgery and IOM services in the United States has increased in the recent past, and we believe this has had an overall dampening effect on spine procedure volumes and prices.

We expect that sales volumes and prices of our products and services will continue to be largely dependent on the availability of reimbursement from third-party payers, such as governmental programs, for example, Medicare and Medicaid, private insurance plans, accountable care organizations and managed care programs. Reimbursement is contingent on established coding for a given procedure, coverage of the codes by the third-party payers, and adequate payment for the resources used.

Physician coding for procedures is established by the American Medical Association, or AMA. For coding related to spine surgery, the North American Spine Society, or NASS, is the primary liaison to the AMA. In July of 2006, NASS established the proper physician coding for the XLIF procedure by declaring it to be encompassed in existing codes that describe an anterolateral approach to the spine. This position was confirmed in a formal statement by NASS in January 2010. Hospital coding is established by the Centers for Medicare & Medicaid Services. XLIF is included in the nomenclature for hospital codes as an additional descriptor under long standing codes. All physician and hospital coding is subject to change which could impact reimbursement and physician practice behavior.

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Independent of the coding status, third-party payers may deny coverage based on their own criteria, including if they feel that a device or procedure is not well established clinically, is not the most cost-effective treatment available, or is used for an unapproved indication. At various times in the past, certain insurance providers have adopted policies of not providing reimbursement for the XLIF procedure. We have worked with our surgeon customers and NASS who, in turn, have worked with these insurance providers to supply the information, explanation and clinical data they require to categorize the XLIF procedure as a procedure entitled to reimbursement under their policies. At present, the majority of insurance companies provide reimbursement for XLIF procedures.

However, certain carriers, large and small, may have policies significantly limiting coverage of XLIF, Interlaminar Lumbar Interbody Fusion, or ILIF, Osteocel Plus and Osteocel Pro, cervical interbody implants, and/or other procedures, products or services that we offer. We will continue to provide resources to patients, surgeons, hospitals, and insurers in order to ensure optimum patient care and clarity regarding reimbursement and work to remove any and all non-coverage policies. National and regional coverage policy decisions are subject to unforeseeable change and have the potential to impact physician behavior and reimbursement for physician services. We cannot offer definitive time frames or final outcomes regarding reversal of the coverage-limiting policies, as the process is dictated by the third-party insurance providers. For a discussion of these risks, please see the “Risk Factors” section of this Annual Report.

Payment amounts are established by government and private payer programs and are subject to fluctuations which could impact physician practice behavior. Third-party payers are increasingly challenging the prices charged for a wide range of medical products and services, including those in spine and intraoperative monitoring where we participate.

In international markets, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific product lines. There can be no assurance that our products will be accepted by third-party payers, that reimbursement will be available, and/or that the third-party payers’ reimbursement policies (if available) will not adversely affect our ability to sell our products profitably.

In the United States, as a result of healthcare reform, third-party payers are increasingly required to demonstrate they can improve quality and reduce costs; we accordingly see an increase in pre-approval/prior authorizations and non-coverage policies citing higher levels of evidence required for medical therapies and technologies. In addition, insured individuals are facing increased premiums and higher out–of-pocket costs for medical coverage which can lead a patient to delay medical treatment. An increasing number of insured individuals receive their medical care through managed care programs, which monitor and often require pre-approval of the services that a member will receive. The percentage of individuals covered by managed care programs is expected to grow in the United States over the next decade.

Overall escalating costs of medical products and services has led to, and is expected to continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. There can be no assurance that third-party reimbursement and coverage will be available or adequate, or that future legislation, regulation, or reimbursement policies of third-party payers will not adversely affect the demand for our products and services or our ability to sell these products and services on a profitable basis. The unavailability or inadequacy of third-party payer coverage or reimbursement could have a material adverse effect on our business, operating results and financial condition. For a discussion of these risks, please see the “Risk Factors” section of this Annual Report.

Shareowners (our employees)

We refer to our employees as “shareowners.” As of December 31, 2018, we have approximately 2,600 shareowners. In addition to our shareowners, we partner with independent sales agents and independent distributors who sell our

products in the United States and internationally. None of our shareowners or sales agents are represented by a labor union, and we believe our shareowner and agency relations are good.

Corporate Information

Our business was incorporated in Delaware in July 1997. Our principal executive offices are located at 7475 Lusk Boulevard, San Diego, California 92121, and our telephone number is (858) 909-1800. Our website is located at www.nuvasive.com.

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to those reports, electronically with the Securities and Exchange Commission (the Commission). We make these reports available free of charge on our website under the investor relations page as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Commission. All such reports were made available in this fashion during 2018.

The public can also obtain any documents that we file with the Commission at http://www.sec.gov.

This report may refer to brand names, trademarks, service marks or trade names of other companies and organizations, and these brand names, trademarks, service marks and trade names are the property of their respective holders.

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Item 1A.Risk Factors

An investment in our common stock involves a high degree of risk. Risk factors that could cause actual results to differ from our expectations and that could negatively impact our financial condition and results of operations are set forth below and elsewhere in this report. If any of these risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. Under these circumstances, the trading price of our common stock could decline, and you may lose all or part of your investment. Further, additional risks not currently known to us or that we currently believe are immaterial also may impair our business, operations, liquidity and stock price materially and adversely. You should consider carefully the risks and uncertainties described below and elsewhere in this report before you decide to invest in our common stock.

Risks Related to Our Business and Industry

To be commercially successful, we must effectively demonstrate to spine surgeons the value proposition of our products and procedural solutions compared to those of our competitors.

We focus on marketing our products and procedural solutions to spine surgeons, because of the role that they play in determining the course of patient treatment. Spine surgeons may not widely adopt our products and procedural solutions unless we are able to effectively educate and train them as to the distinctive characteristics, perceived benefits, safety and cost-effectiveness of our offerings as compared to those of our competitors. We believe that the most effective way to introduce and build market demand for our products and procedural solutions is by directly training spine surgeons in their use. If surgeons are not properly trained, they may misuse or ineffectively use our products and procedural solutions. This may also result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us, any of which could have a significant adverse effect on our business, financial condition and results of operations.

Surgeons may be hesitant to use our products and procedural solutions for the following reasons, among others:

- lack of surgeon experience with minimally disruptive surgical products and procedures;
- lack or perceived lack of evidence supporting additional patient benefits;
- perceived liability risks generally associated with the use of new products and procedures;
- existing relationships with competitors and distributors;
- limited or lack of availability of coverage and reimbursement within healthcare payment systems;
- increased competition in procedural offerings;
- lack or perceived lack of differentiation among procedures;
- costs associated with the purchase of new products and equipment; and
- the time commitment that may be required for training.

If we are not able to effectively demonstrate to spine surgeons the value proposition of our products and procedural solutions, or if spine surgeons adopt competing products into their practice, our sales could significantly decrease or fail to increase, which could adversely impact our profitability and cash flow. In addition, we believe recommendations and support of our offerings by influential spine surgeons and other key opinion leaders are essential for market acceptance and adoption. If we are not successful in obtaining such support, surgeons may not use our products and procedural solutions, and we may not achieve expected sales or profitability.

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Our future success depends on our strategy of obsoleting our products and our ability to timely acquire, develop and introduce new products or product enhancements that will be accepted by the market.

An important part of our business strategy is to stay ahead of our competitors by obsoleting our current offerings with new and enhanced products and technologies. As such, our success will depend in part on our ability to acquire, develop and introduce new products and enhancements to our existing products to keep pace with changes in technology and market demand, as well as physician, hospital and healthcare provider practices. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to:

- properly identify and anticipate surgeon and patient needs;
- develop and introduce new products or product enhancements in a timely and cost-effective manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and efficacy of new products through clinical investigations or the collection of existing relevant clinical data;
- qualify for adequate reimbursement from third-party payers; and
- obtain the necessary regulatory clearances or approvals for new products or product enhancements.

In addition, our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial or technical viability of a new product, technology, or other innovation. Even if we are able to develop enhancements or new generation products successfully, these enhancements or new generation products may not generate sufficient demand or produce sales in excess of the costs of development, which would cause our results of operations to suffer. It is also important that we carefully manage our introduction of new and enhanced products. If potential customers delay purchases until new or enhanced products are available, it could negatively impact our sales. In addition, to the extent we have excess or obsolete inventory as we transition to new products, it would result in margin reducing write-offs and charges for obsolete inventory, and our results of operations may suffer.

Furthermore, our product development strategy is based on certain assumptions, including assumptions about various demographic trends and trends in the treatment of spine disorders, which could affect the demand for our products and procedural solutions. However, these trends are uncertain and actual demand for our products and procedural solutions could differ materially from projected demand if our assumptions regarding these trends prove to be incorrect or do not materialize, or if alternative treatments to those offered by our products gain widespread acceptance.

We operate in a highly competitive market segment that is subject to rapid change, and if we are unable to compete successfully, our sales and operating results may suffer.

The market for spine surgery products and procedures is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. Our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, receive adequate reimbursement and are safer, less invasive and less expensive than those of our competitors. With respect to our neuromonitoring systems, we primarily compete with Medtronic and Cadwell Industries. Our IOM services business competes with Specialty Care and numerous smaller and regional neuromonitoring companies. With respect to MaXcess, our minimally disruptive surgical system, our largest competitors are Medtronic, DePuy/Synthes, Stryker Spine, Globus Medical, and Zimmer Biomet Spine. We compete with many of the same companies with respect to our other products. We also compete with numerous smaller companies with respect to our implant products, many of whom have a significant regional market presence. At any time, these companies and other potential market entrants may develop alternative treatments, products or procedures for the treatment of spine disorders that compete directly or indirectly with our offerings. In addition, they may gain a market advantage by developing and patenting competitive products or processes earlier than we can or by obtaining regulatory clearances or market registrations more rapidly than we can.

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Many of our competitors have greater resources than we have.

Many of our larger competitors are either publicly traded or divisions or subsidiaries of publicly traded companies, and enjoy several competitive advantages over us, including:

- significantly greater name recognition;
- established relationships with a greater number of spine surgeons, hospitals, other healthcare providers and third-party payers;
- larger and more well-established distribution networks domestically and/or internationally;
- products supported by long-term clinical data;
- greater experience in obtaining and maintaining FDA and other regulatory approvals or clearances for products and product enhancements;
- greater experience in, and resources for, launching, marketing, distributing and selling products, including capital equipment;
- greater ability to cross-sell their products or create bundled offerings to incentivize hospitals and surgeons to use their products;
- more expansive portfolios of intellectual property rights; and
- greater financial assets, cash flow, capital markets access and other resources for product research and development, sales and marketing, and litigation.

Because of the significant size of the potential market for spine surgery products and procedures, we anticipate that existing competitors will continue to dedicate substantial resources to developing competing products. If we are unable to compete effectively, our sales and operating results may suffer.

Third-party reimbursement policies and practices, including non-coverage decisions, can negatively impact our ability to sell our products and services.

Sales of our products and procedural solutions depend on the availability of adequate reimbursement from third-party payers. Future third-party reimbursement for healthcare costs may be subject to changes in policies and practices, such as more restrictive criteria to qualify for surgery coverage or reduction in payment amounts to hospitals and surgeons for approved surgery and IOM services, both in the United States and internationally. Further, certain third-party payers have stated non-coverage decisions concerning our technologies and services. These actions could significantly alter our ability to sell our products and procedural solutions. The continuing efforts of governmental authorities, insurance companies, and other payers of healthcare costs to contain or reduce costs could lead to patients being unable to obtain approval for payment from these third-party payers. Changes in legislation, regulation or reimbursement policies of third-party payers may adversely affect the demand for our products and services as healthcare providers generally rely on third-party payers to reimburse all or part of the costs and fees associated with the procedures performed with these devices and services. Likewise, spine surgeons, neurophysiologists and their supervising physicians rely primarily on third-party reimbursement for the surgical or monitoring fees they earn. Spine surgeons are unlikely to use our products and services if they do not receive reimbursement adequate to cover the cost of their involvement in surgical procedures.

Further, as we continue to grow our international business, market acceptance of our products and procedural solutions in a particular foreign market may also depend, in part, upon the availability of coverage and reimbursement within the applicable healthcare payment system. Reimbursement and healthcare payment systems in international markets vary significantly by country. As in the United States, our products and procedural solutions may not obtain coverage and reimbursement approvals in a timely manner, if at all, in a particular foreign market. In addition, even if we are able to obtain country-specific coverage and reimbursement approvals, the amount of such coverage and reimbursement may not be adequate and we could incur considerable expense in seeking such approvals. Our failure to obtain such coverage and approvals would negatively affect market acceptance of our products and procedural

solutions in the international markets in which such failure occurs and the expenses incurred in connection with obtaining such coverage and approvals could outweigh the benefits of obtaining them.

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Pricing pressure from our competitors, hospital customers and insurance providers can negatively impact our ability to sell our products and services.

The market for spine surgery products is large and has attracted numerous new companies and technologies. As some companies have sought to compete based on price, it has created pricing pressure, which we expect to continue in the future. In addition, we may experience decreasing prices for our products due to pricing pressure from our hospital customers and insurance providers. Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms have resulted in efforts to drive down prices. As hospitals look to reduce costs, including by aggregating purchasing decisions and through industry consolidation, they may demand lower pricing and limit their number of suppliers. If competitive forces drive down the prices we are able to charge for our products, our profit margins will shrink, which will adversely affect our ability to maintain our profitability and to invest in and grow our business.

In addition, as we expand our procedural solutions offerings to include new technologies, we expect that sales and leases of capital equipment will become a larger portion of our revenues. Demand for capital equipment can be affected by changes in the budgets of healthcare organizations, the timing of spending under these budgets and conflicting spending priorities. In addition, the implementation of healthcare reform in the United States, which may reduce or eliminate the amount that healthcare organizations may be reimbursed for capital equipment, could further impact demand. Any such decreases in expenditures by these healthcare organizations and decreases in demand for our capital equipment could have an adverse effect on our results of operations and financial condition.

The proliferation of physician-owned distributorships, as well as aggressive competitive tactics to attract away key customers, could result in increased pricing pressure and harm our ability to maintain or grow revenue.

Physician-owned distributorships, or PODs, are medical device distributors that are owned, directly or indirectly, by physicians. These physicians derive revenue from selling or arranging for the sale of medical devices via their PODs that are used in the procedures they perform on their patients. We do not sell or distribute any of our products to PODs. However, the proliferation of PODs may reduce our market opportunities and may hamper our ability to grow or maintain revenue. PODs can have significant market knowledge and access to the surgeons who use our products, and we have seen increasingly aggressive competitive tactics from PODs focused on attracting customers away from us. To the extent these tactics are successful, our revenue may materially suffer.

Quality or safety issues affecting our products could harm our reputation, result in liability and adversely impact our business.

In the course of conducting our business, we must adequately address quality and safety issues that may arise with our products, as well as defects in third-party components included in our products. Although we have established internal procedures to minimize risks that may arise from quality and safety issues, we may not be able to eliminate or mitigate occurrences of these issues and associated liabilities. Manufacturing flaws, component failures, design defects, or inadequate disclosure of product-related information could result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall of, or issuance of a safety alert relating to our products and result in significant costs and negative publicity. An adverse event involving one of our products could result in reduced market acceptance and demand for our products, and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our applications for new product approvals or clearances. We may also voluntarily undertake a recall of our products, temporarily shut down production lines, or place products on a shipping hold based on internal safety and quality monitoring and testing data.

While we have a network of quality systems throughout our business lines and facilities, quality and safety issues may occur with respect to any of our products. A quality or safety issue may result in a public warning letter or consent decree from the FDA or an equivalent action by a governmental health authority in an international jurisdiction. In addition, we may be subject to product recalls or seizures, monetary sanctions, injunctions to halt manufacturing and distribution of products, civil or criminal sanctions, refusal of a government to grant clearances or approvals or delays in granting such clearances or approvals, import detentions of products made outside the United States, restrictions on operations or withdrawal or suspension of existing approvals. Any of the foregoing events could disrupt our business and have an adverse effect on our results of operations and financial condition.

The safety of many of our products is not yet supported by long-term clinical data and many of our products may therefore prove to be less safe and effective than initially thought.

As a consequence of our strategy to obsolete our own products with new technologies, many of our products do not have a long history of use. Further, many of our products are subject to the FDA's 510(k) premarket notification clearance process in the United States and similar regulatory processes in other countries, which typically do not require clinical data. Accordingly, many of our products currently lack the breadth of published long-term clinical data supporting their safety and effectiveness. For these reasons, spine surgeons may be slow to adopt our products, we may not have comparative data that our competitors have or are generating, and we may be subject to greater regulatory and product liability risks.

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Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes. Such results would reduce demand for our products, affect sustainable reimbursement from third-party payers, significantly reduce our ability to achieve expected revenue and could prevent us from sustaining or increasing profitability. Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to significant legal liability and harm to our business reputation. The spine medical device market has been particularly prone to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices and products for spine surgery procedures.

We may engage in strategic transactions, including acquisitions, investments, joint development agreements or divestitures that may have an adverse effect on our business.

We may pursue transactions, including acquisitions of complementary businesses, technology licensing arrangements, strategic relationships, and joint development agreements to expand our product offerings and geographic presence as part of our business strategy, which could be material to our financial condition and results of operations. We may also consider divesting non-core product lines or out-licensing our technology. We may not complete transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the expected benefits of any acquisition, license arrangement, strategic relationship, joint development agreement or divestiture. Other companies may compete with us for these strategic opportunities. We also could experience negative effects on our results of operations and financial condition from charges related to acquisitions and investments, amortization of intangible assets and asset impairment charges, and other issues that could arise in connection with, or as a result of, the acquisition of an acquired company or business, including issues related to internal control over financial reporting, regulatory or compliance issues and potential adverse short-term effects on results of operations through increased costs or otherwise. Acquisitions involve numerous risks, including the following:

- difficulties in finding suitable partners or acquisition candidates;
- difficulties in obtaining financing on favorable terms, if at all;
- difficulties in completing transactions on favorable terms, if at all;
- the possibility that we will pay more than the value we derive from the acquisition, which could result in future non-cash impairment charges and/or a dilution of future earnings per share;
- difficulties in integration of the operations, technologies, personnel, and products of acquired companies, which may require significant attention of our management team that otherwise would be available for the ongoing development of our business;
- the applicability of additional laws, regulations and policies that have particular application to our acquisitions, including those relating to patient privacy, insurance fraud and abuse, false claims, prohibitions against self-referrals, anti-kickbacks, direct billing practices, HIPAA compliance, and prohibitions against the corporate practice of medicine and fee-splitting;
- the assumption of certain known and unknown liabilities of acquired companies;
    - the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill;
- difficulties in retaining key relationships with employees, customers, partners and suppliers of an acquired company; and
- difficulties in operating in different business markets where we may not have historical experience.

Any of these factors could have a negative impact on our business, results of operations or financial position. Further, past and potential acquisitions entail risks, uncertainties and potential disruptions to our business, especially where we have limited experience as a company developing or marketing a particular product or technology. Following any acquisition, we must integrate the new business, which can be expensive and time-consuming. Failure to timely and successfully integrate acquired businesses may result in non-compliance with regulatory or other requirements and may result in unexpected costs, including as a result of inadequate cost containment and failure to fully realize

expected synergies. As a result of any of the foregoing, we may not realize the expected benefit from any acquisition or investment. If we cannot integrate acquired businesses, products or technologies, our business, financial conditions and results of operations could be materially and adversely affected.

In addition, we may face additional risks related to foreign acquisitions and investments. Foreign acquisitions and investments involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Any divestitures may result in a dilutive impact to our future earnings, as well as significant write-offs, including those related to goodwill and other intangible assets, which could have a material adverse effect on our results of operations and financial condition. Divestitures could involve additional risks, including difficulties in the separation of operations, services, products and personnel, the diversion of management's attention from other business concerns, the disruption of our business and the potential loss of key employees. We may not be successful in managing these or any other significant risks that we encounter in divesting a product or technology.

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Healthcare policy changes may have a material adverse effect on us.

Political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. In March 2010, comprehensive healthcare reform legislation was signed into law in the United States through the passage of the Patient Protection and Affordable Health Care Act and the Health Care and Education Reconciliation Act ("ACA"). Among other initiatives, the legislation implemented a 2.3% annual excise tax on the sales of certain medical devices in the United States, effective January 2013. This excise tax was suspended for years 2016 through 2019, but will be reinstated as of January 1, 2020, absent further legislative action to repeal – or extend the suspension of – the tax. As this excise tax is recorded as a selling, general and administrative expense, it would have an adverse effect on our operating expenses and results of operations. In addition, the ACA significantly alters Medicare and Medicaid reimbursements for medical services and medical devices, which could result in downward pricing pressure and decreased demand for our products. We anticipate that Congress, regulatory agencies and certain state legislatures will continue to review and assess alternative healthcare delivery systems and payment methods with an objective of ultimately reducing healthcare costs and expanding access. We cannot predict with certainty what healthcare initiatives, if any, will be implemented at the state level, or what ultimate effect federal healthcare reform or any future legislation or regulation may have on our customers' purchasing decisions regarding our products and services. However, the implementation of new legislation and regulation may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business, possibly materially.

Our IOM business exposes us to risks inherent with the sale of services.

Our IOM services and support business exposes us to different risks than our other products and technologies. Through our NuVasive Clinical Services business, including the Biotronic NeuroNetwork business acquired in July 2016 and the SafePassage business acquired in January 2018, we provide onsite and remote monitoring of the neurological systems of patients undergoing spinal and brain-related surgeries. Our neurophysiologists are present in the operating room during procedures and work in partnership with supervising physicians who remotely oversee and interpret neurophysiological data gathered via broadband transmission over the Internet. Providing this service subjects us to malpractice exposure. In addition, given the reliance on technology, any disruption to our neuromonitoring equipment or the Internet could harm our service operations and our reputation among our customers. Further, any disruption to our information technology systems could adversely impact the performance of our neurophysiologists.

In addition, IOM services are directly billed to Medicare and commercial payers, which brings with it additional risks associated with proper billing practice regulations, HIPAA compliance, corporate practice of medicine laws, and new collections risk associated with third-party payers. Due to the breadth of many healthcare laws and regulations, our IOM business could also be subject to healthcare fraud regulation and enforcement by both the federal government and the states in which we conduct our business, including under the Anti-Kickback Statute, the federal false claims laws and state law equivalents. If our operations are found to be in violation of any of the laws described in the previous sentence or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results.

As we expand our offerings to include capital equipment and invest in related resources and expertise, we are exposed to additional risks.

As we expand our procedural solutions offerings to include new technologies, including Pulse and LessRay, we expect that sales and leases of capital equipment will become a larger portion of our revenues. We do not have a long history of selling, leasing or servicing capital equipment, and we intend to continue to invest in building resources and

expertise in this area. We may not generate sufficient revenue to offset the expenses associated with this investment. There can be no assurance that our capital equipment strategy will be successful and will not materially adversely affect our financial condition and operating results.

In addition, approval processes of healthcare organizations for the purchase or lease of capital equipment can be lengthy, and such organizations may delay or accelerate system purchases or leases in conjunction with their budget timelines. As a result, it is difficult for us to predict the length of capital sales cycles and, therefore, the exact timing of capital sales, which may cause fluctuations in our financial results. Further, demand for capital equipment can be affected by changes in the budgets of healthcare organizations and conflicting spending priorities. Any such decreases in expenditures by these healthcare organizations and decreases in demand for our capital equipment could have an adverse effect on our results of operations and financial condition.

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Our employee shareowners, consultants, distributors and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employee shareowners, consultants, distributors and other commercial partners may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the regulations of the FDA and non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by employees, sales agents, distributors and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

Risks Related to our Commercial Operations and Plans for Future Growth

If we are unable to maintain and expand our network of direct and independent sales representatives, we may not be able to generate anticipated sales.

In the United States, we sell our products through a combination of independent sales agents and directly-employed sales personnel. Our international sales force is comprised of independent sales agents, directly-employed sales personnel, as well as exclusive and non-exclusive independent third-party distributors. We expect these sales representatives to develop long-lasting relationships with the customers they serve. If our sales representatives fail to adequately promote, market and sell our products, or fail to develop lasting relationships with customers, our sales could significantly decrease or fail to increase. Further, we may terminate sales representatives from time to time, which could subject us to claims and lawsuits. Asserting or defending against these types of claims and lawsuits may result in significant legal fees and expenses, and if we are unsuccessful, we could be liable for damages.

We face significant challenges and risks in managing our geographically dispersed distribution network and retaining the individuals who make up that network. In the past, we have experienced departures of sales representatives, which have had a negative impact on our results. If sales representatives were to depart and be retained by one of our competitors, we may be unable to prevent them from helping competitors solicit business from our existing customers, which could further adversely affect our sales. In addition, as we expand into new markets, it may be difficult to find sales representatives with the appropriate expertise or it may take time for new sales representatives to reach full operational effectiveness and generate expected revenue. Because of the intense competition for their services, we may be unable to recruit or retain sales representatives to work with us. Failure to hire or retain qualified sales representatives would prevent us from expanding our business and generating sales.

We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy.

We intend to grow our business operations and we may experience periods of rapid growth and expansion. This anticipated future growth could create a strain on our organizational, administrative and operational infrastructure, including manufacturing operations, quality control, technical support and customer service, sales force management and general and financial administration. We may not be able to maintain the quality or delivery timelines of our products or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures.

If our commercial operations and sales volume grow, we will need to continue to increase our workflow capacity for manufacturing, customer service, billing and general process improvements and expand our internal quality assurance program, among other things. We will also need to purchase additional equipment, some of which can take several months or more to procure, set up and validate, and increase our manufacturing, maintenance, software and computing capacity to meet increased demand. These increases in scale, expansion of personnel, purchases of equipment or process enhancements may not be successfully implemented.

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Our reliance on a limited number of suppliers and manufacturers could limit our ability to meet demand for our products in a timely manner or within our budget.

While we are increasing our capacity to self-manufacture many of our products, we continue to rely on a limited number of third-party suppliers and manufacturers to supply and manufacture our products, and we may not be able to find replacements or immediately transition to alternative suppliers or manufacturers. Many of our key products are manufactured at single locations, with limited alternate facilities, and it could take considerable time and resources for us to replace the capacity of such vendors in the event of disruptions. In addition, if we are required to change the manufacturer of a critical component of our products, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner.

Further, for reasons of quality assurance or cost effectiveness, we purchase certain components and raw materials from sole suppliers. To be successful, we rely on our suppliers to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable cost and on a timely basis. In the event we experience delays, shortages, or stoppages of supply with any supplier, we would be forced to identify a suitable alternative supplier which could take significant time and result in significant expense. In addition, our anticipated growth could strain the ability of suppliers to deliver an increasingly large supply of products, materials and components. If we are required to transition to new third-party suppliers for certain components of our products, the use of components or materials furnished by these alternative suppliers could require us to alter our operations. Any such interruption or alteration could harm our reputation, business, financial condition and results of operations. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our products or could require that we modify the design of those systems.

Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any products, it could be costly to replace such products in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our products on a timely basis.

Manufacturing risks may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our operating results.

In 2017, we significantly expanded our self-manufacturing capabilities as we increased production at our approximately 180,000 square foot manufacturing facility in West Carrollton, Ohio. As part of our business strategy, we intend to continue to expand our ability to manufacture our current and new products with exceptional quality and in sufficient quantities to meet demand, while complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks relating to our manufacturing capabilities, including both those of our own manufacturing facilities and those of our third party suppliers, such as:

- problems with quality control and assurance;
- defects in product components that we source from third-party suppliers;

- delays in obtaining components from third-party suppliers and component supply shortages;
- failing to predict demand accurately, resulting in a failure to increase production of products to meet demand;
- potential adverse effects on existing business relationships with current third-party suppliers as we expand our in-house manufacturing capabilities;
- maintaining control over manufacturing expenses as production expands;
- difficulties associated with compliance with local, state, federal and foreign regulatory requirements;
- shortages of qualified personnel or workforce disruptions;
- the inability to modify production lines to enable the efficient manufacture of new products or to quickly implement changes to current products in response to regulatory requirements; and
- potential damage to or destruction of our, or our suppliers' manufacturing equipment or manufacturing facilities.

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These risks may be exacerbated by our limited experience with self- manufacturing processes and procedures. In addition, as we seek to expand our manufacturing capabilities, we will have to continue to invest additional resources to hire and train personnel and enhance our production processes. If we fail to increase our manufacturing capacity efficiently, our profit margins will shrink, which will negatively affect our operating results.

The loss of key employee shareowners, or our inability to recruit, hire and retain skilled and experienced personnel, could negatively impact our ability to effectively manage and expand our business.

Our success depends on the skills, experience and performance of the members of our executive management team and other key employee shareowners. Their individual and collective efforts will be important as we continue to develop our products and as we expand our commercial activities. The loss or incapacity of existing members of our executive management team could negatively impact our operations, particularly if we experience difficulties in hiring qualified successors. We do not maintain key man life insurance with respect to any of our employee shareowners.

Our research and development programs and operations depend on our ability to attract and retain highly skilled engineers and technicians. We may not be able to attract or retain qualified managers, engineers and technicians in the future due to the competition for qualified personnel among medical device businesses, particularly in California. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified personnel. Recruiting and retention difficulties can limit our ability to support our commercial, manufacturing and research and development programs. All of our U.S. employee shareowners are employed on an at-will basis, which means that either we or the employee shareowner may terminate his or her employment at any time. The loss of key employee shareowners, the failure of any key employee shareowners to perform or our inability to attract and retain skilled employee shareowners, as needed, or an inability to effectively plan for and implement a succession plan for key employee shareowners could harm our business.

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We face risks associated with our international business.

During the year ended December 31, 2018, $205.6 million or approximately 19% of our net revenue was attributable to our international customers. We are seeking to increase our international sales over the foreseeable future. Our international business operations are subject to a variety of risks, including:

- difficulties in staffing and managing foreign and geographically dispersed operations;
- having to comply with various U.S. and international laws, including the U.S. Foreign Corrupt Practices Act of 1977, or the FCPA, and anti-money laundering laws;
    - having to comply with U.S. and foreign trade, import and export and customs regulations and laws, including, but not limited to, the Export Administration Regulations and trade sanctions against embargoed countries, which are administered by the Office of Foreign Assets Control within the Department of the Treasury, as well as the laws and regulations administered by the Department of Commerce;
- differing complex regulatory requirements for obtaining clearances or approvals to market our products, including the EU Medical Device Regulation (Council Regulations 2017/745);
- changes in, or uncertainties relating to, foreign rules and regulations that may impact our ability to sell our products, perform services or repatriate profits to the United States;
- tariffs and trade barriers, export regulations and other regulatory and contractual limitations on our ability to sell our products in certain foreign markets;
- fluctuations in foreign currency exchange rates;
- limitations on or increase of withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures;
- differing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- differing labor laws and standards;
- changes in, or uncertainties relating to foreign laws around VAT/GST or permanent establishment that may impact our international indirect and income tax expense and related compliance costs;
- complex data privacy requirements, including the EU General Data Protection Regulation;
- economic, political or social instability in foreign countries and regions;
- an inability, or reduced ability, to protect our intellectual property, including any effect of compulsory licensing imposed by government action;
- potential changes to U.S. trade policy, including new legislation that could restrict international trade, or protectionist or retaliatory measures taken by governments of other countries; and
- availability of government subsidies or other incentives that benefit competitors in their local markets that are not available to us.

The FCPA and similar anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business. The FCPA also imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments. Because of the predominance of government-sponsored healthcare systems around the world, many of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws. Our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employee shareowners, distributors or agents. In recent years, both the United States and foreign government regulators have increased regulation, enforcement, inspections and governmental investigations of the medical device industry, including increased United States government oversight and enforcement of the FCPA. Despite implementation of a comprehensive global healthcare compliance program, we may be subject to more regulation, enforcement, inspections and investigations by governmental authorities in the future.

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Any failure to comply with applicable legal and regulatory obligations in the United States or abroad could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities, disgorgement and other remedial measures, disruptions of our operations, and significant management distraction. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities. Any reduction in international sales, or our failure to further develop our international markets, could have a material adverse effect on our business, results of operations and financial condition.

Our results may be impacted by changes in foreign currency exchange rates.

As we increasingly compete in markets outside of the United States, we are and will be exposed to foreign currency exchange risk related to our foreign operations. A significant portion of our foreign subsidiaries' operating expenses are incurred in foreign currencies. If the U.S. dollar weakens, our consolidated operating expenses would increase. An increase in the value of the U.S. dollar relative to foreign currencies could require us to reduce our selling price or risk making our products less competitive in international markets or our costs could increase. Also, as our international sales continue to increase, we may enter into a greater number of transactions denominated in non-U.S. dollars, which could increase our exposure to foreign currency risks, including changes in currency exchange rates. If we are unable to address these risks and challenges effectively, our international operations may not be successful and our business could be harmed.

If we fail to properly manage our anticipated international growth, our business could suffer.

We have invested, and expect to increase our investment for the foreseeable future, in our expansion into international markets. To execute our anticipated growth in international markets we must:

- manage the complexities associated with a larger, faster growing and more geographically diverse organization;
- expand our clinical development resources to manage and execute increasingly global, larger and more complex clinical trials and studies;
- manage our directly-employed sales personnel as well as independent distributors and sales agents operating in international markets often pursuant to laws, regulations and customs that may be different than those that are customary for our United States operations;
- expand our sales and marketing presence in international markets generally to avoid revenue concentration in a small number of markets that would subject us to the risk of business disruption as a result of economic or political problems in concentrated locations;
- upgrade our internal business processes and capabilities (e.g., information technology platform and systems, product distribution and tracking) to create scalability and properly handle the transaction volumes that our growing geographically diverse organization demands;
- expend time and resources to receive product approvals and clearances to sell and promote products; and
- incur significant costs to comply with new and complex regulatory requirements such as the EU Medical Device Regulation (Council Regulations 2017/745).

We expect that our operating expenses will continue to increase as we continue to expand into international markets. International markets may be slower than domestic markets in adopting our products and are expected, in many instances, to yield lower profit margins when compared to our domestic operations. We have only limited experience in expanding into international markets as well as marketing and operating our products and services in such markets.

Additionally, our international endeavors may involve significant risks and uncertainties, including distraction of management from domestic operations, insufficient revenue to offset the expenses associated with our international

strategy, and issues not discovered in our due diligence of new markets or ventures. Because expansion into international markets is inherently risky, no assurance can be given that such strategies and initiatives will be successful and will not materially adversely affect our financial condition and operating results. Even if our international expansion is successful, our expenses may increase at a greater pace than our revenue and our operating results could be harmed.

Further, our anticipated growth internationally will place additional strain on our suppliers and manufacturers, resulting in increased need for us to carefully monitor quality assurance. Any failure by us to manage our international growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

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Cybersecurity risks and the failure to maintain the confidentiality, integrity, and availability of our computer hardware, software, and Internet applications and related tools and functions could result in harm to our business and/or subject us to costs, fines or lawsuits.

We rely on sophisticated information technology systems and network infrastructure to operate and manage our business. We also maintain personally identifiable information (PII) about our employee shareowners, and given the nature of our business, we have access to protected health information (PHI). Our business therefore depends on the continuous, effective, reliable, and secure operation of our computer hardware, software, networks, Internet servers, and related infrastructure. To the extent that our hardware or software malfunctions or access to our data by internal personnel, suppliers or customers through the Internet is interrupted or compromised, our business could suffer.

The integrity and protection of our customer, personnel, financial, research and development, and other confidential data is critical to our business, and our customers and employees have a high expectation that we will adequately protect their personal information. The regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve and a number of states have adopted laws and regulations that may affect our privacy and data security practices regarding the use, disclosure and protection of PII. For example, California recently enacted legislation, the California Consumer Privacy Act, that will, among other things, create new individual privacy rights and impose increased obligations on companies handling PII, when it goes into effect on January 1, 2020.

Although our computer and communications hardware is protected through physical and software safeguards, it is still vulnerable to system malfunction, computer viruses, malware and ransomware, and other cybersecurity threats such as phishing and social engineering attacks. These events could lead to the unauthorized access of our information technology systems and result in financial loss and the misappropriation or unauthorized disclosure of confidential information belonging to us, our employee shareowners, partners, customers, or our suppliers. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. If our information technology systems are compromised we could be subject to fines, damages, litigation and enforcement actions, incur financial losses, suffer reputational damage, and lose trade secrets or other confidential information, each of which could significantly harm our business.

We rely on the performance of our information technology systems, the failure of which could have an adverse effect on our business and performance.

Our business requires the continued operation of sophisticated information technology systems and network infrastructure. These systems are vulnerable to interruption by fire, floods, earthquakes, power loss, system malfunction, computer viruses, security breaches and other events, which are beyond our control. Systems interruptions could reduce our ability to manufacture and provide service for our products, and could have an adverse effect on our operations and financial performance. The level of protection and disaster-recovery capability varies from site to site, and there can be no guarantee that any such plans, to the extent they are in place, will be totally effective. Loss of data could interrupt our operations, including our ability to bill our customers, provide customer support services, conduct research and development activities, process and prepare company financial information, manage various general and administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

Our operations are vulnerable to interruption or loss due to natural or other disasters, power loss, strikes and other events beyond our control.

We conduct a significant portion of our activities, including administration and data processing, at facilities located in Southern California, an area that has experienced major earthquakes, fires and other natural disasters. In addition, our primary self-manufacturing facility is located in West Carrollton, Ohio, an area that has experienced tornados, winter storms and other natural disasters. A major earthquake, fire, tornado or other disaster (such as a major flood, tsunami, storm or terrorist attack) affecting these or other NuVasive facilities, or those of our suppliers, could significantly disrupt our operations, and delay or prevent product shipment or installation during the time required to repair, rebuild or replace our facilities or those of our suppliers. These delays could be lengthy and costly. If our manufacturing facilities or any of our customers' facilities are negatively impacted by a disaster, shipments of our products could be delayed. Additionally, customers may delay purchases of our products until operations return to normal. Even if we are able to quickly respond to a disaster, the ongoing effects of the disaster could create some uncertainty in the operations of our business. In addition, our facilities may be subject to a shortage of available electrical power and other energy supplies. Any shortages may increase our costs for power and energy supplies or could result in blackouts, which could disrupt the operations of our affected facilities and harm our business. In addition, concerns about terrorism, the effects of a terrorist attack, political turmoil or an outbreak of epidemic diseases could have a negative effect on our operations, those of our suppliers and customers and the ability to travel, which could harm our business, financial condition and results of operations.

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Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, foreign liability, employee benefits liability, property, umbrella, workers' compensation, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

We bear the risk of warranty claims on our products.

We bear the risk of express and implied warranty claims on products we supply, including equipment and component parts manufactured by third parties. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or that any recovery from such vendor or supplier would be adequate. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expire, which could result in additional costs to us. There is a risk that warranty claims made against us will exceed our warranty reserve and our business, financial condition and results of operations could be harmed.

Risks Related to Litigation and Intellectual Property

Defending against litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money, and if we are unsuccessful, we may be obligated to pay damages and halt sales of our products.

Significant litigation regarding patent rights occurs in our industry and our commercial success depends in part on not infringing the patents or violating the other proprietary rights of others. We have received in the past, and expect to receive in the future, claims from our competitors alleging infringement of their intellectual property rights as part of business strategies designed to impede our successful commercialization of updated and new products and entry into new markets. A patent infringement suit brought against us or any of our strategic partners or licensees may force us or such strategic partners or licensees to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third-party's intellectual property, unless that party grants us or our strategic partners or licensees rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all, and any licenses may require substantial royalties or other payments by us. Even if our strategic partners, licensees or we were able to obtain rights to the third-party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

Moreover, we may become party to future adversarial proceedings regarding our patent portfolio or the patents of third parties. Such proceedings could include supplemental examination or contested post-grant proceedings such as inter partes review, reexamination, interference or derivation proceedings before the U.S. Patent and Trademark Office and challenges in U.S. District Court. Patents may be subjected to opposition, post-grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these

legal actions than we can.

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Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;
- pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and/or infeasible; or
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. In addition, we generally indemnify our customers and distributors with respect to infringement by our products of the proprietary rights of third parties. If third parties assert infringement claims against our customers or distributors, we may be required to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

We are currently, and may in the future be, subject to claims and lawsuits that could cause us to incur significant legal expenses and result in harm to our business.

We are currently party to various commercial, personal injury, and intellectual property litigation and have previously been subject to a purported securities class action lawsuit, shareholder derivative litigation, and intellectual property infringement lawsuits, and we may be subject to additional claims and lawsuits in the future. In addition, we, as well as certain of our officers and sales representatives, are subject to claims or lawsuits from time to time. Regardless of the outcome, these lawsuits may result in significant legal fees and expenses and could divert management's time and other resources. If the claims contained in these lawsuits are successfully asserted against us, we could be liable for damages and be required to alter or cease certain of our business practices or product lines. Any of these outcomes could cause our business, financial performance and cash position to be negatively impacted. Litigation may also harm our relationships with existing customers and subject us to negative publicity, each of which could harm our business and financial results.

Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain.

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products and procedural solutions. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

Our pending U.S. and foreign patent applications may not issue as patents at all or not in a form that will be advantageous to us or may issue and be subsequently successfully challenged by others and invalidated. Our existing patents and any patents issued in the future may not have claims with a scope sufficient to protect our products, any additional features we develop for our products or any new products. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Other parties may have developed technologies that may be related or competitive to our technology, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. Further, competitors may also be able to design around our patents or develop products that provide outcomes that are comparable to our products but fall outside of the scope of our patent protection.

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We rely on our trademarks, trade names and brand names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. We cannot assure you that our trademark applications will be approved. Third parties may also oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks.

If we seek to enforce our intellectual property rights through litigation or other proceedings, it could require us to spend significant time and money, with uncertain results.

In the event a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time consuming. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against a challenge. Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. It is not unusual for parties to exchange letters surrounding allegations of intellectual property infringement and licensing arrangements. In addition, the patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we have or may obtain cannot be predicted with certainty.

Changes in U.S. patent laws may limit our ability to obtain, defend and/or enforce our patents.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and also affect patent litigation. The U.S. Patent and Trademark Office developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, which became effective in March 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. Additionally, the pool of prior art available to inhibit or limit our ability to obtain issued patents on the technology utilized in our products has expanded and the grace period for filing a patent application has been reduced in some ways. It is now possible for a situation to arise in which a competitor is able to obtain patent rights to technology which we invented first. Furthermore, the Leahy-Smith Act has expanded the types of post grant challenges of issued patents and these proceedings may provide our competitors with additional opportunities to challenge the validity of our issued patents.

Additionally, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the enforcement and defense of our issued patents. For example, the Leahy-Smith Act provides that an administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, provides a venue for challenging the validity of patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long-term impact the Leahy-Smith Act will have on the operation of our business, proceedings before the PTAB have resulted in several of our patents being challenged. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them.

Further, competitors may challenge our issued patents through post-grant challenge procedures (domestically) and/or opposition proceedings (internationally). The Leahy-Smith Act amended the post-grant challenge procedures in the U.S. to eliminate inter partes reexamination, maintain ex parte reexamination, and add inter partes review making it easier for third-parties to challenge issued patents. We are currently engaged in various such proceedings with respect to our issued patents and the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the enforcement or defense of our issued patents.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

We rely upon non-disclosure agreements and invention assignment agreements with our employee shareowners, consultants and third parties to protect our confidential and proprietary information and trade secrets. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed.

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We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property.

Third parties may assert ownership or commercial rights to inventions we develop.

We enter into agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations and product development initiatives. These collaborators and other third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. In addition, we may face claims by third parties that our agreements with employee shareowners, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in that intellectual property. Either outcome could harm our business and competitive position.

In addition, in certain instances we have agreed to pay consultants royalties, milestones and other payments in connection with their product development efforts. There can be no assurance that these consultants will not claim to be entitled to a royalty, milestone or other payment, even if we do not believe that it is warranted. Any such claim against us, even those without merit, may cause us to incur substantial costs, and could place a strain on our financial resources, divert the attention of management from our core business and harm our reputation.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets or are in breach of non-competition or non-solicitation agreements with our competitors.

We employ individuals who previously worked with other companies, including our competitors or potential competitors. Although we try to ensure that our employee shareowners and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our personnel, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third party. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement with a third party. Litigation may be necessary to defend against these

claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and/or be a distraction to management and other employee shareowners.

If personal injury lawsuits are brought against us, our business may be harmed, and we may be required to pay damages that exceed our insurance coverage.

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for surgical procedures, as well as potential malpractice claims that are inherent in the provision of IOM services. Surgical procedures using our products and services often involve significant risk of serious complications, including bleeding, nerve injury, paralysis and even death. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients. Furthermore, our biologics products may expose us to additional potential product liability claims, including due to the risk of transmitting disease to human recipients. Additionally, our IOM services business could become the subject of medical malpractice lawsuits alleging negligence on the part of our neurophysiologists and/or oversight physicians.

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We have had, and continue to have, personal injury claims relating to our products and clinical services and in the future, we may be subject to additional claims, some of which may have a negative impact on our business, results of operations or financial position. Regardless of the merit or eventual outcome, these claims may result in:

- decreased demand for our products;
- injury to our reputation;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients;
- product recalls;
- material defense costs;
- loss of revenue;
- increased insurance costs;
- the inability to commercialize new products or product candidates; and
- diversion of management attention from pursuing our business strategy.

Our existing insurance coverage for personal injury claims may be inadequate to protect us from any liabilities we might incur. If a personal injury claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage, our business could suffer. In addition, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources and adversely affect or eliminate the prospects for commercialization of our IOM business or sales of a product or product candidate that is the subject of any such claim.

Risks Related to Regulatory and Compliance

We are subject to rigorous FDA and other governmental regulations regarding the development, manufacture, and sale of our products and we may incur significant expenses to comply with these regulations and develop products that satisfy these regulations.

The medical devices we manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities, including regulations that cover, among other things, the composition, labeling, testing, clinical study, manufacturing, packaging, marketing and distribution of our products.

We are required to register with the FDA as a device manufacturer and tissue bank. As a result, we are subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation (QSR) and Good Tissue Practices requirements, which require manufacturers of medical devices and tissue banks to adhere to certain regulations, including testing, quality control and documentation procedures. Our compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. In the European Community, we are required to maintain certain ISO certifications in order to sell our products, and are subject to periodic inspections by Notified Bodies to obtain and maintain these certifications. If we or our suppliers fail to adhere to QSR, ISO or other applicable regulations and standards, it could negatively impact product production and regulatory clearances and could result in fines. Further our products could be subject to recall by the FDA or other regulatory bodies, or voluntarily by us, in the event of a material deficiency or defect in design, manufacture, labeling of a product or in the event that a product poses an unacceptable risk to health. These and other consequences could have a material adverse effect on our sales and results of operations.

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Most medical devices must receive FDA clearance or approval before they can be commercially marketed. In addition, the FDA may require testing and surveillance programs to monitor the effects of approved products that have been commercialized, and can prevent or limit further marketing of a product based upon the results of such post-marketing programs. In addition, the Federal Medical Device Reporting Regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, that could cause or contribute to a death or serious injury. Furthermore, most major markets for medical devices outside the United States require clearance, approval or compliance with certain standards before a product can be commercially marketed. The process of obtaining regulatory approvals to market a medical device, particularly from the FDA and certain foreign governmental authorities, can be costly and time-consuming, and approvals may not be granted for future products or product improvements on a timely basis, if at all. Delays in receipt of, or failure to obtain, approvals for future products or product improvements could result in delayed realization of product revenue or in substantial additional costs, which could have a material adverse effect on our business or results of operations or prospects. At any time after approval of a product, the FDA may conduct periodic inspections to determine compliance with both QSR requirements and/or current Medical Device Reporting regulations. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in clearance of future products. Product clearances or approvals by the FDA can be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial clearance or approval.

Also, the procurement and transplantation of allograft bone tissue is subject to the criminal statute National Organ Transplant Act and state rules and regulations which govern, among other things, payments we make to vendors in consideration for the services they provide in connection with the recovery and screening of donors. Failure to comply with such laws could result in enforcement action against us and a disruption to these product lines (and the revenue associated therewith).

Failure or alleged failure to comply with FDA and other governmental regulations can result in investigations and other regulatory proceedings, which are expensive and could divert management attention.

If the FDA or other governmental authorities in the United States or abroad believes we are not conducting our business in compliance with applicable laws or regulations, such governmental authority can initiate investigations or other regulatory proceedings. Responding to such investigations and proceedings may cause us to incur substantial costs, and could place a significant strain on our financial resources and divert the attention of management from our core business. We could be subject to proceedings to detain or seize our products, recall our products, or restrict our operations. Moreover, governmental authorities can ban or request the recall, repair, replacement or refund of the cost of any device or product we manufacture or distribute. Any of the foregoing actions could result in decreased sales as a result of negative publicity and product liability claims, and could have a material adverse effect on our financial condition, results of operations and prospects.

We are subject to federal, state and foreign fraud and abuse laws and health information privacy and security laws, which, if violated, could subject us to substantial penalties.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our relationships with physicians, providers and hospitals are subject to scrutiny under these laws. We may also be subject to patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business.

Healthcare fraud and abuse laws are broad in scope and are subject to evolving interpretation, which could require us to incur substantial costs to monitor compliance or to alter our practices if they are found not to be in compliance.

Violations of these laws may be punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in governmental healthcare programs. Despite implementation of a comprehensive global healthcare compliance program, we cannot provide assurance that any of the healthcare fraud and abuse laws will not change or be interpreted in the future in a manner which restricts or adversely affects our business activities or relationships with healthcare professionals, nor can we make any assurances that authorities will not challenge or investigate our current or future activities under these laws.

In July 2015, we entered into a settlement agreement with the U.S. Department of Justice, or DOJ, pursuant to which we paid $13.5 million to resolve an investigation into possible false or otherwise improper claims submitted to Medicare and Medicaid. We admitted no wrongdoing as part of the settlement. In August 2015, we received a civil investigative demand, or CID, issued by the DOJ pursuant to the federal False Claims Act. The CID requires the delivery of a wide range of documents and information related to an investigation by the DOJ concerning allegations that we assisted a physician group customer in submitting improper claims for reimbursement and made improper payments to the physician group in violation of the Anti-Kickback Statute. We are cooperating with the DOJ.

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No assurance can be given as to the timing or outcome of this investigation. Responding to government requests and investigations requires considerable resources, including the time and attention of management. If we were to become the subject of an enforcement action, including any action resulting from the investigation by the DOJ, it could result in negative publicity, penalties, fines, the exclusion of our products from reimbursement under federally-funded programs and/or prohibitions on our ability to sell our products, which could have a material adverse effect on our results of operations, financial condition and liquidity.

We may fail to obtain or maintain foreign regulatory approvals to market our products in other countries.

We currently market our products internationally and intend to continue to expand our operations in select developed and emerging international markets. International jurisdictions require separate regulatory approvals and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing. Clearance or approval by the FDA does not ensure approval or certification by regulatory authorities in other countries or jurisdictions, and approval or certification by one foreign regulatory authority does not ensure approval or certification by regulatory authorities in other foreign countries or by the FDA.

The European Union requires that manufacturers of medical devices obtain the right to bear the “CE” conformity marking which designates compliance with existing directives and standards regulating the design, manufacture and distribution of medical devices in member countries of the European Union. In 2017, the European Union adopted the EU Medical Device Regulation (Council Regulations 2017/745) which imposes stricter requirements for the marketing and sale of medical devices, including new quality system and post-market surveillance requirements. The regulation has a three-year implementation period to May 2020 and will replace the existing directives on medical devices in the European Union. After May 2020, medical devices marketed in the European Union will require certification according to these new requirements, except that devices with valid CE certificates, issued pursuant to the Medical Device Directive before May 2020, may be placed on the market until 2024. Complying with this new regulation will require us to incur significant costs and failure to meet the requirements of the regulation could adversely impact our business in the European Union and other countries that utilize or rely on European Union requirements for medical device registrations.

The global regulatory environment is becoming increasingly complex and we expect the time and expense of obtaining and maintaining foreign regulatory approvals for our products to increase. We cannot be certain that we will receive necessary approvals or certifications to commercialize our products in foreign jurisdictions on a timely basis, or at all. If we fail to receive or maintain necessary approvals or certifications to commercialize our products in foreign jurisdictions our business, results of operations and financial condition could be adversely affected.

If we fail to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our future products or product enhancements, our ability to commercially distribute and market our products could suffer.

The process of obtaining regulatory clearances or approvals to market a medical device, particularly from the FDA, can be costly and time consuming, and there can be no assurance that such clearances or approvals will be granted on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new, non-exempt, non-Class I medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or receives approval under the premarket approval application (PMA) process. If clinical trials of our current or future product candidates do not produce results necessary to support regulatory approval, we will be unable to commercialize these products, which could have a material adverse effect on our financial results.

The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. Additionally, any modification to a 510(k)-cleared device that could

significantly affect its safety or efficacy, or that would constitute a major change in its intended use, requires a new 510(k) clearance or, possibly, a PMA. The FDA may not agree with any of our decisions regarding whether new clearances or approvals are necessary. Our failure to comply with such regulations could lead to the imposition of injunctions, suspensions or loss of regulatory approvals, product recalls, termination of distribution, or product seizures. In the most egregious cases, criminal sanctions or closure of our manufacturing facilities are possible.

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Legislative or regulatory reforms in the United States may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to produce, market or distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices or the reimbursement thereof in the United States. In addition, the FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. For example, in 2018 the FDA issued draft guidance and announced steps to modernize the 510(k) clearance pathway that, if finalized and implemented, could impact the ability of medical device manufacturers to obtain or maintain 510(k) clearances for devices. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to manufacture, market or distribute our products or future products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- additional testing prior to obtaining clearance or approval;
- changes to manufacturing methods;
- recall, replacement or discontinuance of our products or future products; or
- additional record keeping.

Any of these changes could require substantial time and cost and could harm our business and our financial results.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although physicians are permitted to use medical devices for indications other than those cleared or approved by the FDA based on their medical judgment, we are prohibited from promoting products for such off-label uses. We train our marketing personnel and independent sales representatives and distributors to not promote our products for uses outside of the FDA-cleared indications. Although we believe our marketing, promotional materials and training programs for physicians do not constitute promotion of unapproved uses of our products, if the FDA or any foreign regulatory body determines that our marketing, promotional materials or training programs constitute promotion of an off-label use, we could be subject to significant fines in addition to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, there may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those cleared by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If we or our suppliers fail to comply with the FDA’s quality system regulations or equivalent regulations and standards internationally, the manufacture and processing of our products could be delayed and we may be subject to an enforcement action by the FDA or other government agencies.

We and our suppliers are required to comply with the QSR and other applicable standards and requirements, which cover the methods and documentation of the design, testing, production or processing, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA and other regulatory bodies enforce compliance with regulatory requirements and standards through periodic inspections. If we or one of our suppliers fail an inspection or if any corrective action plan is not sufficient, the release of our products could be delayed. We have undergone inspections by the FDA and other regulatory bodies regarding our allograft business and FDA inspections regarding our medical device activities. In connection with these inspections as well as prior inspections, regulatory agencies have requested minor corrective actions, which we have implemented. There can be no assurance that the FDA will not subject us to further enforcement action and the FDA and other regulatory agencies may impose additional inspections at any time.

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Additionally, we are the legal manufacturer of record for the products that are distributed and labeled by us, regardless of whether the products are manufactured by us or our suppliers. Thus, a failure by us or our suppliers to comply with applicable regulatory requirements can result in enforcement action against us by the FDA, which may include any of the following sanctions:

- fines, injunctions, and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for 510(k) clearance or premarket approval of new products;
- withdrawing 510(k) clearance or premarket approvals that are already granted; and
- criminal prosecution.

We or our suppliers may be the subject of claims for non-compliance with FDA regulations in connection with the processing or distribution of allograft products.

It is possible that allegations may be made against us or against donor recovery groups or tissue banks, including those with which we have a contractual relationship, claiming that the acquisition or processing of tissue for allograft products does not comply with applicable FDA regulations or other relevant statutes and regulations. Allegations like these could cause regulators or other authorities to take investigative or other action against us, or could cause negative publicity for us or our industry in general. These actions or any negative publicity could cause us to incur substantial costs, divert the attention of management from our business, harm our reputation and cause the market price of our shares to decline.

Compliance with SEC regulations relating to “conflict minerals” may increase our costs and adversely affect our business.

We are subject to SEC regulations that require us to determine whether our products contain certain specified minerals, referred to under the regulations as “conflict minerals”, and, if so, to perform an extensive inquiry into our supply chain, in an effort to determine whether or not such conflict minerals originate from the Democratic Republic of Congo (“DRC”), or an adjoining country. Compliance with these regulations has increased our costs, and we expect our costs may increase in the future. We have determined that certain of our products contain such specified minerals. As of the date of our conflict minerals report for the 2017 calendar year, we were unable to determine whether or not such minerals originate from the DRC or an adjoining country. We are continuing to conduct inquiries into our supply chain in connection with the preparation of our conflict minerals report for 2018. Compliance with these requirements has been time-consuming for management and our supply chain personnel (as well as time-consuming for our suppliers), and we expect that compliance will continue to require the expenditure of significant amounts of time and money by us and them. In addition, to the extent any of our disclosures are perceived by the market to be “negative,” it may cause customers to refuse to purchase our products. Further, if we determine to make any changes to products, processes, or sources of supply, it may result in additional costs, which may adversely affect our business.

Our relationships with physicians could be subject to additional scrutiny from regulatory enforcement authorities and could subject us to possible administrative, civil or criminal sanctions.

Federal and state laws and regulations impose restrictions on our relationships with physicians. We have entered into consulting agreements, license agreements and other agreements with physicians in which we provided equity awards or cash or both as compensation. Some of the physicians with which we have such consulting and other agreements are affiliated with some of our customers. Finally, we have other arrangements with physicians, including for research and development grants and for other purposes as well.

We could be adversely affected if regulatory agencies were to interpret our financial relationships with these physicians, who may be in a position to influence the ordering of and use of our products for which governmental reimbursement may be available, as being in violation of applicable laws. If our relationships with physicians are found to be in violation of the laws and regulations that apply to us, we may be required to restructure the arrangements and could be subject to administrative, civil and criminal penalties, including exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations, any of which could negatively impact our ability to operate our business and our results of operations.

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Our business involves the use of hazardous materials and we and our third-party manufacturers must comply with environmental laws and regulations, which may be expensive and restrict how we do business.

Our third-party manufacturers' activities and our own activities involve the controlled storage, use and disposal of hazardous materials. We and our manufacturers are subject to federal, state, local and foreign laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these hazardous materials. We currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials, but we do reserve funds to address these claims at both the federal and state levels. Although we believe that our safety procedures for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, state or federal or other applicable authorities may curtail our use of these materials and interrupt our business operations. In addition, if an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines. If such unexpected costs are substantial, this could significantly harm our financial condition and results of operations.

Risks Related to Our Financial Results and Need for Financing

We may be unable to grow our revenue or earnings as anticipated, which may have a material adverse effect on our future operating results.

We have experienced rapid growth since our inception, and have increased our revenue from $38.4 million in 2004, the year of our initial public offering, to $1.1 billion in 2018. Our ability to achieve future growth will depend upon, among other things, the success of our growth strategies, which we cannot assure will be successful. In addition, we may have more difficulty maintaining our prior rate of growth of revenue or recent levels of profitability and cash flow. Our future success will depend upon various factors, including the strength of our brand image, the market success of our current and future products, competitive conditions and our ability to manage increased revenue, if any, or implement our growth strategy. In addition, we anticipate significantly expanding our infrastructure and adding personnel in connection with our anticipated growth, which we expect will cause our selling, general and administrative expenses to increase in absolute dollars and as a percentage of revenue. Because these expenses are generally fixed, particularly in the short-to-medium term, our operating and financial results may be adversely impacted if we do not achieve our anticipated growth.

We have a significant amount of outstanding indebtedness, and our financial condition and results of operations could be adversely affected if we do not efficiently manage our liabilities.

As of December 31, 2018, we had outstanding $650.0 million aggregate principal amount of our 2.25% Convertible Senior Notes due 2021 (the "2021 Notes"). This significant amount of debt has important risks to us and our investors, including:

- requiring a portion of our cash flow from operations to make interest payments on this debt;
- increasing our vulnerability to general adverse economic and industry conditions;
- reducing the cash flow available to fund capital expenditures and other corporate purposes and to grow our business;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry; and
- limiting our ability to borrow additional funds as needed or take advantage of business opportunities as they arise.

In addition, to the extent we draw on our $500.0 million revolving senior credit facility (the "2017 Facility") or otherwise incur additional indebtedness, the risks described above could increase. Further, if we increase our indebtedness, our actual cash requirements in the future may be greater than expected. Our cash flow from operations may not be sufficient to repay all of the outstanding debt as it becomes due, and we may not be able to borrow money,

sell assets or otherwise raise funds on acceptable terms, or at all, to refinance our debt. Further, there are a large number of shares of common stock reserved for issuance upon the potential conversion of our 2021 Notes and the warrants that we issued as part of the related bond hedge transactions related to the 2021 Notes. The issuance of these shares may depress the market price of our common stock.

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If we fail to comply with the covenants and other obligations under our credit facility, the lenders may be able to accelerate amounts owed under the facilities and may foreclose upon the assets securing our obligations.

In April 2017, we entered into an Amended and Restated Credit Agreement (the "2017 Credit Agreement") with respect to the 2017 Facility, which replaced the previous Credit Agreement we had entered into in February 2016. The 2017 Credit Agreement provides for secured revolving loans, multicurrency loan options and letters of credit in an aggregate amount of up to $500.0 million. The 2017 Credit Agreement also contains an expansion feature, which allows us to increase the aggregate principal amount of the 2017 Facility provided we remain in compliance with the underlying financial covenants, including but not limited to, compliance with the consolidated interest coverage ratio and certain consolidated leverage ratios. All of our assets and the assets of our material subsidiaries are pledged as collateral under the 2017 Facility (subject to customary exceptions) and each of our material domestic subsidiaries guarantee the 2017 Facility. The covenants set forth in the 2017 Credit Agreement restrict, among other things, our ability to: create liens on assets, incur additional indebtedness, make investments, make acquisitions and other fundamental changes, sell and dispose of property or assets, pay dividends and other distributions, change the business conducted, engage in certain transactions with affiliates, enter into burdensome agreements, limit certain use of proceeds, amend organizational documents, change accounting policies or reporting practices, modify or terminate documents related to certain indebtedness, enter into sale and leaseback transactions, fund any person or business that is the subject of sanctions, and use proceeds for any breach of anti-corruption laws. If we fail to comply with the covenants and our other obligations under the 2017 Facility, the lenders would be able to accelerate the required repayment of amounts due under the 2017 Credit Agreement and, if they are not repaid, could foreclose upon our assets securing our obligations under the 2017 Facility.

We may need additional financing in the future to meet our capital needs or to make opportunistic acquisitions and such financing may not be available on favorable terms, if at all, and may be dilutive to existing stockholders.

In furtherance of our growth strategy and global expansion efforts, we intend to continue to invest in our business, including through acquisitions and strategic transactions. These investments will be expensive, and we may need to seek additional financing in the future to meet our capital needs. As of December 31, 2018, we had $117.8 million in cash and cash equivalents and the ability to draw $500.0 million on our 2017 Facility. We may seek to raise capital from public and private debt and equity offerings, borrowings under our existing or future credit facilities or other sources. We may be unable to obtain any desired additional financing on terms favorable to us, if at all. If adequate funds are not available on acceptable terms, we may be unable to fund our expansion, successfully develop or enhance products or respond to competitive pressures, any of which could negatively affect our business. If we raise additional funds through the issuance of equity securities, our stockholders will experience dilution of their ownership interest. If we raise additional funds by issuing debt, we may be subject to limitations on our operations due to restrictive covenants. Additionally, our ability to make scheduled payments or refinance our obligations will depend on our operating and financial performance, which in turn is subject to prevailing economic conditions and financial, business and other factors beyond our control.

We could be subject to changes in tax rates, the adoption, evolution or change of new and/or amended U.S. or international tax legislation or exposure to additional tax liabilities.

We are subject to taxes in the United States and numerous foreign jurisdictions, including the Netherlands, where a number of our subsidiaries are located. Significant judgment is required to determine and estimate our worldwide tax liabilities. Due to economic and political conditions, tax rates in various jurisdictions may be subject to significant change. Our effective income tax rates have been, and could in the future be adversely affected by changes in tax laws or interpretations of those tax laws, by stock-based compensation and other non-deductible expenses, by changes in the mix of earnings in countries with differing statutory tax rates, or by changes in the valuation of our deferred tax assets and liabilities.

As part of our globalization initiative, we have centralized international operations in the Netherlands and have entered into intercompany transfer pricing arrangements, including the licensing of intangibles. We continue to streamline our international operations to better align with and support our international business activities and markets through changes in how we develop, license and use our intangible property and how we structure our international procurement and customer service functions. We have experienced a negative impact to our effective tax rate over the last few years as we've invested in our expansion and expect continued but declining pressure on the tax rate over the next several years until we achieve our net profitability goals outside the U.S. and see the long-term benefits of expansion on our effective tax rate. There can be no assurance that the taxing authorities of the jurisdictions in which we operate or will operate or to which we are otherwise deemed to have sufficient tax presence will not challenge the tax benefits that we ultimately expect to realize as a result of our international structure. In addition, current and future changes to U.S. and non-U.S. tax laws, including recently enacted U.S. tax reform of international business, could negatively impact the anticipated tax benefits of our international structure. Any long term benefits to our tax rate will also depend on our ability to achieve our anticipated international growth projections and to operate our business in a manner consistent with our international structure and intercompany transfer pricing arrangements. If we do not operate our business consistent with the structure and applicable tax provisions, we may fail to achieve the financial efficiencies that we anticipate as a result of the structure and our future operating results and financial condition may be negatively impacted.

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Finally, we may be subject in the future to examination of our income tax returns by the Internal Revenue Service and other taxing authorities which may result in the assessment of additional income taxes. We regularly assess the likelihood of an adverse outcome resulting from these examinations to determine the adequacy of our provision for taxes. There can be no assurance as to the outcome of these examinations. If our effective tax rates were to increase, particularly in the U.S. or the Netherlands or if the ultimate determination of our taxes owed is for an amount in excess of amounts previously accrued, our financial condition, cash flows or results of operations could be adversely affected.

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Risks Related to the Securities Markets and Ownership of Our Common Stock

We expect that the price of our common stock will fluctuate substantially, potentially adversely affecting the ability of investors to sell their shares.

The market price of our common stock may be subject to wide fluctuations, which may negatively affect the ability of investors to sell our shares at consistent prices. Fluctuation in the stock price may occur due to many factors, including, without limitation:

- general market conditions and other factors related to the economy or otherwise, including factors unrelated to our operating performance or the operating performance of our competitors;
- people's expectations, favorable or unfavorable, as to the likely unit growth of the spine sector;
- negative stock market reactions to the results of litigation;
- negative publicity regarding spine surgeon's practices or outcomes, whether warranted or not, that cast the sector in a negative light;
- the introduction of new products or product enhancements by us or our competitors;
- changes in the availability of third-party reimbursement in the United States or other countries;
- disputes or other developments with respect to intellectual property rights or other potential legal actions;
- our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis;
- quarterly variations in our or our competitor's results of operations;
- sales of large blocks of our common stock, including sales by our executive officers and directors;
- announcements of technological or medical innovations for the treatment of spine pathology;
- changes in governmental regulations or in the status of our regulatory approvals, clearances or applications;
- the acquisition or divestiture of businesses, products, assets or technology by us or by our competitors;
- litigation (including intellectual property litigation) and any associated negative verdicts or ruling;
- announcements of actions by the FDA or other regulatory agencies; and
- changes in earnings or operating margin estimates or recommendations by us or by securities analysts.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

- authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, with rights senior to those of the common stock;
- provide for a classified board of directors, with each director serving a staggered three-year term;
- provide that our stockholders may remove our directors only for cause;
- prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent;
- prohibit our stockholders from making certain changes to our certificate of incorporation or bylaws except with 66 2/3% stockholder approval; and
- require advance written notice of stockholder proposals and director nominations.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, our bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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We do not intend to pay cash dividends.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, the terms of any future debt or credit facility may preclude us from paying any dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' source of potential gain for the foreseeable future.

Item 1B.Unresolved Staff Comments

None.

Item 2.Properties

The following table sets forth our principal properties as of December 31, 2018, all of which are leased unless otherwise noted as owned:

Primary Use	Square Footage	Location
Manufacturing facilities (1)	180,000	West Carrollton, OH
Corporate headquarters	169,000	San Diego, CA
Fulfillment and warehouse operations (1)	100,000	Memphis, TN
Office facilities	53,000	Aliso Viejo, CA
Office facilities and warehouse	38,000	Japan
Office facilities and warehouse	22,000	Netherlands
Office facilities	21,000	Columbia, MD
Office facilities and warehouse	16,000	Australia
Office facilities and warehouse	15,000	Germany
Office facilities	10,000	Brazil
Office facilities	7,000	UK

(1) Owned by the Company

Item 3.Legal Proceedings

For a description of our material pending legal proceedings, refer to "Note 10. Contingencies" in the Notes to Consolidated Financial Statements included in this Annual Report.

Item 4.Mine Safety Disclosures

Not applicable.

PART II

Item 5.Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Common Stock Market Price

Our common stock is traded on the NASDAQ Global Select Market under the symbol “NUVA.”

We had approximately 74 stockholders of record as of January 31, 2019. The number of beneficial owners is substantially greater than the number of record holders because a large portion of our common stock is held of record through brokerage firms in “street name.”

Recent Sales of Unregistered Securities

During the fourth quarter of 2018, we did not issue any securities that were not registered under the Securities Act of 1933, as amended (the Securities Act).

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, for development of our business and do not anticipate that we will declare or pay cash dividends on our capital stock in the foreseeable future.

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Equity Compensation Plan Information

The following table provides certain information with respect to all of our compensation plans in effect as of December 31, 2018:

Plan Category	(A) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights		(B) Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	(C) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column(A))	
Equity Compensation Plans approved by stockholders	2,232,740	(1)	$ 35.76	4,844,041	(2)(3)
Equity Compensation Plans not approved by stockholders	—		—	—	
Total	2,232,740		$ 35.76	4,844,041	

(1) Consists of shares subject to outstanding stock options, restricted stock units and performance restricted stock units under the NuVasive 2004 Amended and Restated Equity Incentive Plan, the NuVasive 2014 Equity Incentive Plan, and the Ellipse Technologies 2015 Incentive Award Plan, some of which are vested and some of which remain subject to the vesting and/or performance criteria of the respective equity award.

(2) Consists of shares available for future issuance under the NuVasive 2014 Equity Incentive Plan, the Ellipse Technologies 2015 Incentive Award Plan, and the Amended and Restated 2004 Employee Stock Purchase Plan (ESPP). As of December 31, 2018, an aggregate of 2,707,704 shares of common stock were available for issuance under the NuVasive 2014 Equity Incentive Plan, 1,043,514 shares of common stock were available for issuance under the Ellipse Technologies 2015 Incentive Award Plan, and 1,092,823 shares of common stock were available for issuance under the 2004 Amended and Restated Employee Stock Purchase Plan.

(3) The NuVasive 2004 Amended and Restated Equity Incentive Plan terminated in February 2014, upon the tenth anniversary of its effective date, and we are no longer granting awards under that plan. However, awards granted under the plan will remain outstanding until they are exercised, issued, terminated, cancelled or they expire. Pursuant to the terms of the plan, shares subject to awards granted under the NuVasive 2004 Amended and Restated Equity Incentive Plan may be utilized for future grants of awards under the NuVasive 2014 Equity Incentive Plan, to the extent such awards are terminated, cancelled or they expire, or shares subject thereto are withheld to cover taxes. During the year ended December 31, 2016, we registered 2,200,637 of such shares for re-use under the NuVasive 2014 Equity Incentive Plan.

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PERFORMANCE GRAPH

The following graph compares the cumulative total stockholder return data on our common stock with the cumulative return of (i) The NASDAQ Stock Market Composite Index, and (ii) NASDAQ Medical Equipment Index over the five-year period ending December 31, 2018. The graph assumes that $100 was invested on December 31, 2013 in our common stock and in each of the comparative indices. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

The following graph and related information shall not be deemed “soliciting material” or be deemed to be “filed” with the Commission, nor shall such information be incorporated by reference into any future filing, except to the extent that we specifically incorporate it by reference into such filing.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

AMONG NUVASIVE, INC.,

THE NASDAQ COMPOSITE INDEX

AND THE NASDAQ MEDICAL EQUIPMENT INDEX

*$100 invested on December 31, 2013 in stock or index, including reinvestment of dividends.

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Purchases of Equity Securities

In October 2017, we announced that our Board of Directors had approved a share repurchase program authorizing the repurchase of up to $100 million of our common stock over a three-year period. Under this program, we are authorized to repurchase our shares in open market purchases, privately negotiated purchases or other transactions through October 2020. As of December 31, 2018, we have not repurchased any shares under this program.

Item 6. Selected Financial Data

The selected consolidated financial data set forth in the table below has been derived from our audited financial statements. The data set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited financial statements and notes thereto appearing elsewhere in this report.

	Year Ended December 31,				
	2018 (1)	2017 (2)(3)	2016 (3)(4)	2015	2014
	(In thousands, except per share amounts)				
Statement of Operations Data:					
Total revenues	$1,101,714	$1,026,685	$962,132	$811,113	$762,415
Gross profit	790,555	758,244	722,027	616,634	580,057
Consolidated net income (loss)	12,479	79,855	35,471	65,290	(17,496)
Net income (loss) attributable to NuVasive, Inc.	12,479	81,598	37,192	66,291	(16,720)
Net income (loss) per share attributable to NuVasive, Inc.:					
Basic	$0.24	$1.60	$0.74	$1.36	$(0.36)
Diluted	$0.24	$1.48	$0.69	$1.26	$(0.36)

	December 31,				
	2018 (1)	2017 (2)(3)	2016 (3)(4)	2015	2014
	(In thousands, except per share amounts)				
Balance Sheet Data:					
Working capital	$438,749	$398,668	$335,155	$603,210	$490,972
Total assets	1,707,859	1,640,140	1,573,993	1,289,649	1,343,459
Senior Convertible Notes (net of current portion)	602,526	582,920	564,412	376,542	360,746
Non-current liabilities (excluding convertible notes)	91,348	96,409	64,208	111,288	119,456
Total equity (5)	834,525	799,416	702,194	718,843	648,358

(1) The selected consolidated financial data set forth for the year ended December 31, 2018 includes the operations and results of our 2018 acquisitions from their respective dates of acquisition. See Note 4 to the Consolidated Financial Statements included in this Annual Report for further discussion.

(2) The selected consolidated financial data set forth for the year ended December 31, 2017 includes the operations and results of our 2017 acquisitions from their respective dates of acquisition.

(3) Amounts for 2017 and 2016 have been recasted and presented based on our full retrospective method of adoption of Accounting Standards Codification 606 Revenue from Contracts with Customers ("ASC 606"). See Note 1 to the Consolidated Financial Statements included in this Annual Report for further discussion.

(4)

The selected consolidated financial data set forth for the year ended December 31, 2016 includes the operations and results of Ellipse Technologies, Inc., BNN Holdings Corp. and our other acquisitions from their respective dates of acquisition.

(5) The Company elected to early adopt Accounting Standards Update 2016-09, Improvements to Employee Share-Based Payment Accounting in the second quarter of 2016. As a result, the Company recorded a modified retrospective adjustment of $16.6 million to deferred tax assets and accumulated deficit as of January 1, 2016.

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Item 7.Management's Discussion and Analysis of Financial Condition and Results of Operations

As noted earlier, this Annual Report, including the following discussion and analysis, may contain forward-looking statements that involve risks, uncertainties, assumptions and other factors which, if they do not materialize or prove correct, could cause our results to differ from historical results or those expressed or implied by such forward-looking statements. Please review this Annual Report and the following discussion and analysis in light of the forward-looking statements provisions outlined at the outset of Part I.

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the Consolidated Financial Statements and the Notes to those statements included in this Annual Report.

Overview

We are a leading medical device company in the global spine surgery market, focused on developing minimally disruptive surgical products and procedurally integrated solutions for spine surgery. Our currently marketed product portfolio is focused on applications for spine fusion surgery, including ancillary products and services used to aid in the surgical procedure. Our procedurally integrated solutions use innovative, technological advancements and a minimally disruptive surgical platform called Maximum Access Surgery, or MAS, to provide surgical efficiency, operative reliability, and procedural versatility. For the year ended December 31, 2018, we generated global revenues of $1.1 billion, including sales in over 50 countries.

Our principal product offering includes the MAS platform which combines three categories of solutions that collectively minimize soft tissue disruption during spine fusion surgery, provide maximum visualization and are designed to enable safe and reproducible outcomes for the surgeon and the patient. The platform includes our proprietary software-driven nerve detection and avoidance systems, and Intraoperative Monitoring, or IOM, services and support offered by NuVasive Clinical Services; MaXcess, an integrated split-blade retractor system; and a wide variety of specialized implants and biologics. Many of our products, including the individual components of our MAS platform can also be used in open or traditional spine surgery. Our spine surgery product line offerings, which include products for the thoracolumbar and the cervical spine, are primarily used to enable surgeon access to the spine to perform restorative and fusion procedures in a minimally disruptive fashion. To assist with surgical procedures, we offer a platform called Integrated Global Alignment, or iGA, in which products and computer assisted technology under our MAS platform help achieve more precise spinal alignment.

Our MAS platform and its related offerings are designed to provide a unique and comprehensive solution for the safe and reproducible minimally disruptive surgical treatment of spine disorders by enabling surgeons to access the spine in a manner that affords both direct visualization and detection and avoidance of critical nerves along with intraoperative reconciliation. The fundamental difference between our MAS platform, which is sometimes referred to in the industry as "minimally invasive surgery" or "MIS", is the ability to customize safe and reproducible access to the spine while allowing surgeons to continue to use instruments that are familiar to them and effective during surgery. Accordingly, the MAS platform does not force surgeons to reinvent or learn new approaches that add complexity and undermine safety, ease of use and/or efficacy. We have dedicated and continue to dedicate significant resources toward training spine surgeons around the world; both those who are new to our MAS and other product platforms, as well as ongoing education for MAS-trained surgeons attending advanced courses. An important ongoing objective of ours has been to maintain a leading position in access and nerve avoidance, as well as to pioneer and remain the ongoing leader in minimally invasive spine surgery. Our MAS platform, with the unique advantages provided by our neuromonitoring systems, enables innovative lateral procedures, including a procedure known as eXtreme Lateral Interbody Fusion, or XLIF, in which surgeons access the spine for a fusion procedure from the side of the patient's body, rather than from the front or back. It has been demonstrated clinically that XLIF and other procedures facilitated

by our MAS platform decrease trauma and blood loss, and lead to faster overall patient recovery times compared to open spine surgery.

We offer a range of implants for spinal surgery, which include our porous titanium and polyetheretherketone, or PEEK, implants under our Advanced Materials Science portfolio, fixation devices such as customizable rods, plates and screws, bone allograft in patented saline packaging, allogeneic and synthetic biologics, and disposables used in IOM. We also design and sell expandable growing rod implant systems that can be non-invasively lengthened following implantation with precise, incremental adjustments via an external remote controller using magnetic technology called MAGnetic External Control, or MAGEC, which allows for the minimally invasive treatment of early-onset and adolescent scoliosis. This technology is also the basis for our PRECICE limb lengthening system, which allows for the correction of long bone limb length discrepancy, as well as enhanced bone healing in patients that have experienced traumatic injury. The PRECICE limb lengthening system is sold by NuVasive Specialized Orthopedics.

We intend to continue development on a wide variety of projects intended to broaden our MAS and other product platforms and advance the applications of our unique technology into procedurally integrated surgical solutions that improve clinical and economic outcomes. In 2019, we expect to commercially launch Pulse, a surgical automation platform which will incorporate neuromonitoring, surgical planning, rod bending, imaging, navigation, and other automation. Pulse is a combined hardware and software platform designed to achieve surgical efficiencies via real-time feedback to aid in clinical decision making and to optimize the procedural workflow in the operating room. We intend to continue to pursue business and technology acquisition targets and strategic relationships.

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Recent Developments

On October 15, 2018, our Board of Directors (the "Board") approved the appointment of J. Christopher Barry to succeed Gregory T. Lucier as Chief Executive Officer and the election of Mr. Barry to the Board, effective November 5, 2018. Mr. Lucier will continue to serve as Chairman of the Board.

Revenues and Operations

The majority of our revenues are derived from the sale of implants, biologics and disposables and we expect this trend to continue for the foreseeable future. Additionally, with our recent acquisitions of IOM service providers, we expect our IOM service and support revenue to increase compared to previous periods. Our implants, biologics and disposables are currently sold and shipped from our distribution and warehousing operations. We generally recognize revenue for implants, biologics and disposables upon notice that our products have been used in a surgical procedure or upon shipment to a third-party customer assuming control of the products. Revenue from IOM services is recognized in the period the service is performed for the amount of payment we expect to receive. We make available MAS instrument sets, MaXcess and neuromonitoring systems to hospitals to facilitate surgeon access to the spine to perform restorative and fusion procedures using our implants and fixation devices. We sell MAS instrument sets, MaXcess devices, and our proprietary software-driven neuromonitoring systems, however this does not make up a material part of our business. Currently, sales and leases of capital equipment, including our LessRay software technology suite, represent a small portion of our consolidated revenues.

The majority of our operations are located and the majority of our sales have been generated in the United States. We sell our products in the United States through a sales force comprised primarily of independent sales agents and directly-employed sales representatives. Our sales force provides a delivery and consultative service to our surgeon and hospital customers and is compensated based on sales and product placements in their territories. Sales force commissions are reflected in the sales, marketing and administrative operating expense line item within our Consolidated Statements of Operations. We continue to invest in international expansion with a focus on European, Asia-Pacific and Latin American markets. Our international sales force is comprised of directly-employed sales personnel, independent sales agents, as well as exclusive and non-exclusive independent third-party distributors.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based upon our audited Consolidated Financial Statements, which have been prepared in accordance with generally accepted accounting principles in the United States (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates including those related to revenue recognition, bad debts, inventories, valuation of financial instruments, goodwill, intangibles, property and equipment, contingent liabilities, stock-based compensation, income taxes, and legal proceedings. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates.

The following accounting policies are critical to the judgments and estimates used in the preparation of our Consolidated Financial Statements.

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Revenue Recognition

In accordance with Accounting Standards Codification 606 Revenue from Contracts with Customers ("ASC 606") guidance, we recognize revenue upon the transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. The principles in ASC 606 are applied using the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) we satisfy our performance obligation(s). Specifically, revenue from the sale of implants and disposables is generally recognized at an amount that reflects the expected consideration upon notice that our products have been used in a surgical procedure or upon shipment to a third-party customer assuming control of the products. Revenue from neuromonitoring services is recognized in the period the service is performed for the amount of consideration expected to be received. Revenue from the sale of instrument sets is generally recognized upon receipt of a purchase order and the subsequent shipment to a customer who assumes control. In certain cases, we offer the ability for customers to lease instrumentation primarily on a non-sales type basis. Instrument sales and leasing revenue represent an immaterial amount of our total revenue. Revenue associated with products holding rights of return or trade-in are recognized when we conclude there is not a risk of significant revenue reversal in future periods for the expected consideration in the transaction. Our costs incurred associated with sales contracts with customers are deferred over the performance obligation period and recognized in the same period as the related revenue, with the exception of contracts that complete within one year or less, in which case the associated costs are expensed as incurred.

Allowance for Doubtful Accounts and Sales Return Reserve

We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. The allowance for doubtful accounts is reviewed quarterly and is estimated based on the aging of account balances, collection history and known trends with current customers and in the economy in general. As a result of this review, the allowance is adjusted on a specific identification basis for significant accounts and a general reserve approach for non-significant accounts. We also review the overall quality and age of those invoices not specifically identified. In determining the provision for invoices not specifically reviewed, we analyze historical collection experience and current economic trends. An increase to the allowance for doubtful accounts results in a corresponding charge to sales, marketing and administrative expenses. If the historical data used to calculate the allowance provided for doubtful accounts does not reflect our future ability to collect outstanding receivables or if the financial condition of customers were to deteriorate, resulting in impairment of their ability to make payments, an increase in the provision for doubtful accounts may be required. We maintain a relatively large customer base that mitigates the risk of concentration with any one particular customer. Historically, our reserves have been adequate to cover losses.

In addition, we establish a liability for estimated sales returns and a reserve for price adjustments that are recorded as a reduction to revenue. The liability and reserve are maintained to account for future product returns and price adjustments of products sold in the current period. This reserve is reviewed quarterly and is estimated based on an analysis of our historical experience and expected future trends. Historically, our reserves have been adequate to account for returns and pricing adjustments.

Inventory

Net inventory as of December 31, 2018 consisted of $259.4 million of finished goods, $5.0 million of work in progress, and $8.8 million of raw materials. Net inventory as of December 31, 2017 consisted of $232.3 million of finished goods, $9.8 million of work in progress, and $5.0 million of raw materials. Finished goods include specialized implants and disposables and are stated at the lower of cost or market determined by utilizing a standard

cost method, which includes assessment of capitalized variances, which approximates the weighted average cost. Work in progress and raw materials represent the underlying material, and labor for work in progress, that ultimately yield finished goods upon completion and are stated at lower of cost or market. We review the components of our inventory on a periodic basis for excess and obsolescence and adjust inventory to its net realizable value as necessary.

Excess and Obsolete Inventory

We provide an inventory reserve for estimated obsolescence and excess inventory based upon historical turnover and assumptions about future demand for our products and market conditions. Our allograft products have shelf lives ranging from two to five years and are subject to demand fluctuations based on the availability and demand for alternative products. Our inventory, which consists primarily of disposables and specialized implants, is at risk of obsolescence following the introduction and development of new or enhanced products. Our estimates and assumptions for excess and obsolete inventory are reviewed and updated on a quarterly basis. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our revenue forecasts. Increases in the reserve for excess and obsolete inventory result in a corresponding charge to cost of products sold. Historically our reserves have been adequate to cover losses.

A stated goal of our business is to focus on continual product innovation and to obsolete our own products. While this provides a competitive edge, it also results in the risk that our products and related capital instruments will become obsolete prior to sale or to the end of their anticipated useful lives.

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Fair Value of Financial Instruments

ASC Topic 820, Fair Value Measurements and Disclosures, defines fair value and requires us to establish a framework for measuring fair value and disclosure about fair value measurements. The framework requires the valuation of assets and liabilities subject to fair value measurements using a three tiered approach and fair value measurement be classified and disclosed in one of the following three categories. Inputs to valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions.

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available.

Carrying value of the financial instruments measured and classified within Level 1 is based on quoted prices.

The types of instruments that trade in markets that are not considered to be active, but are valued based on quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency are generally classified within Level 2 of the fair value hierarchy.

Certain contingent consideration liabilities are classified within Level 3 of the fair value hierarchy because they use unobservable inputs. For those liabilities, fair value is determined using a discounted cash flow model or probability simulation model. The significant inputs of such models that are not observable in the market include financial metric growth rates, volatility rates, projections associated with milestones, the discount rate, and the related probabilities and payment structure in the contingent consideration arrangement.

Valuation of Goodwill and Intangible Assets with Indefinite Lives

Our goodwill represents the excess of the cost over the fair value of net assets acquired from our business combinations. The determination of the value of goodwill and intangible assets arising from business combinations and asset acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the fair value of the net tangible and intangible assets acquired, including capitalized in-process research and development, or IPR&D. Intangible assets acquired in a business combination that are used for IPR&D activities are considered indefinite lived until the completion or abandonment of the associated research and development efforts. Upon commercialization of the relevant research and development project, we will amortize the acquired in-process research and development over its estimated useful life or expense the acquired in-process research and development should the research and development project be unsuccessful with no future alternative use.

Goodwill and IPR&D are not amortized; however, they are assessed for impairment using fair value measurement techniques on an annual basis or more frequently if facts and circumstance warrant such a review. The goodwill or IPR&D are considered to be impaired if we determine that the carrying value of the reporting unit or IPR&D exceeds its respective fair value.

We perform our goodwill impairment analysis at the reporting unit level, which aligns with our reporting structure and availability of discrete financial information. We perform our annual impairment analysis by either doing a qualitative assessment of a reporting unit’s fair value from the last quantitative assessment to determine if there is potential impairment, or comparing a reporting unit’s estimated fair value to its carrying amount. We may do a qualitative

assessment when the results of the previous quantitative test indicated the reporting unit's estimated fair value was significantly in excess of the carrying value of its net assets and we do not believe there have been significant changes in the reporting unit's operations that would significantly decrease its estimated fair value or significantly increase its net assets. If a quantitative assessment is performed the evaluation includes management estimates of cash flow projections based on internal future projections and/or use of a market approach by looking at market values of comparable companies. Key assumptions for these projections include revenue growth, future gross and operating margin growth, and its weighted cost of capital and terminal growth rates. The revenue and margin growth is based on increased sales of new and existing products as we maintain our investment in research and development. Additional assumed value creators may include increased efficiencies from capital spending. The resulting cash flows are discounted using a weighted average cost of capital. Operating mechanisms and requirements to ensure that growth and efficiency assumptions will ultimately be realized are also considered in the evaluation, including timing and probability of regulatory approvals for our products to be commercialized. Our market capitalization is also considered as a part of this analysis.

Our annual evaluation for impairment of goodwill consists of one reporting unit. In accordance with our policy, we completed our most recent annual evaluation for impairment as of October 1, 2018 using the qualitative method and determined that no impairment existed. In addition, no indicators of impairments were noted through December 31, 2018 and consequently, no impairment charge was recorded during the year.

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Valuation of Intangible Assets

Our intangible assets are comprised primarily of purchased technology, customer relationships, manufacturing know-how and trade secrets, and trade name and trademarks. We make significant judgments in relation to the valuation of intangible assets resulting from business combinations and asset acquisitions.

Intangible assets are generally amortized on a straight-line basis over their estimated useful lives of 1 to 17 years. We base the useful lives and related amortization expense on the period of time we estimate the assets will generate revenues or otherwise be used by the Company. We also periodically review the lives assigned to our intangible assets to ensure that our initial estimates do not exceed any revised estimated periods from which we expect to realize cash flows from the technologies. If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase.

We evaluate our intangible assets with finite lives for indications of impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that could trigger an impairment review include significant under-performance relative to expected historical or projected future operating results, significant changes in the manner of our use of the acquired assets or the strategy for our overall business or significant negative industry or economic trends. If this evaluation indicates that the value of the intangible asset may be impaired, we make an assessment of the recoverability of the net carrying value of the asset over its remaining useful life. If this assessment indicates that the intangible asset is not recoverable, based on the estimated undiscounted future cash flows of the technology over the remaining amortization period, we reduce the net carrying value of the related intangible asset to fair value and may adjust the remaining amortization period.

Significant judgment is required in the forecasts of future operating results that are used in the discounted cash flow valuation models. It is possible that plans may change and estimates used may prove to be inaccurate. If our actual results, or the plans and estimates used in future impairment analyses, are lower than the original estimates used to assess the recoverability of these assets, we could incur additional impairment charges.

Valuation of Stock-Based Compensation

Stock-based compensation expense for equity-classified awards, principally related to restricted stock units, or RSUs, and performance restricted stock units, or PRSUs, is measured at the grant date based on the estimated fair value of the award. The fair value of equity instruments that are expected to vest is recognized and amortized over the requisite service period. We have granted awards with up to five year graded or cliff vesting terms (in each case, with service through the date of vesting being required). No exercise price or other monetary payment is required for receipt of the shares issued in settlement of the respective award; instead, consideration is furnished in the form of the participant’s service to the Company.

The fair value of RSUs including PRSUs with pre-defined performance criteria is based on the stock price on the date of grant whereas the expense for PRSU with pre-defined performance criteria is adjusted with the probability of achievement of such performance criteria at each period end. The fair value of the PRSUs that are earned based on the achievement of pre-defined market conditions for total shareholder return, is estimated on the date of grant using a Monte Carlo valuation model. The key assumptions in applying this model are an expected volatility and a risk-free interest rate.

Stock-based compensation expense is adjusted from the grant date to exclude expense for awards that are expected to be forfeited. The forfeiture estimate is adjusted as necessary through the vesting date so that full compensation cost is recognized only for awards that vest. We assess the reasonableness of the estimated forfeiture rate at least annually, with any change to be made on a cumulative basis in the period the estimated forfeiture rates change. We considered

our historical experience of pre-vesting forfeitures on awards by each homogenous group of shareowners as the basis to arrive at our estimated annual pre-vesting forfeiture rates.

We estimate the fair value of stock options issued under our equity incentive plans and shares issued to shareowners under our employee stock purchase plan, or ESPP, using a Black-Scholes option-pricing model on the date of grant. The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and risk-free interest rates. The expected volatility is based on the historical volatility of our common stock over the most recent period commensurate with the estimated expected term of our stock options and ESPP offering period which is derived from historical experience. The risk-free interest rate for periods within the contractual life of the option is based on the U.S. Treasury yield in effect at the time of grant. We have never declared or paid dividends and have no plans to do so in the foreseeable future.

Stock-based compensation expense was $25.7 million, $22.4 million, and $26.9 million for 2018, 2017, and 2016, respectively. Stock-based compensation expense increased $3.3 million in 2018 compared to 2017. Stock-based compensation expense decreased $4.5 million in 2017 compared to 2016. The decreased expense in 2017 was primarily attributed to an increase in award forfeitures, including forfeitures on awards held by certain executives who exited the Company during 2017.

As of December 31, 2018, there was approximately $25.1 million and $14.4 million of unrecognized compensation expense for RSUs and PRSUs, respectively, which is expected to be recognized over a weighted-average period of approximately 1.9 years and 2.6 years, respectively. In addition, as of December 31, 2018, there was $0.9 million of unrecognized compensation expense for shares expected to be issued under the ESPP which is expected to be recognized through April 2019. There was no unrecognized amortization expense for stock options as of December 31, 2018.

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Accounting for Income Taxes

The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Tax law and rate changes are reflected in income in the period such changes are enacted. We include interest and penalties related to income taxes, including unrecognized tax benefits, within income tax expense.

During 2018 we completed our tax accounting in connection with the Tax Cuts and Jobs Act (the "Act") which was enacted into law on December 22, 2017. In 2018, we recorded approximately $0.3 million of tax expense attributable to 2017 during the Staff Accounting Bulletin 118 measurement period, which would have increased the 2017 effective tax rate by 0.5%. We have elected an accounting policy to treat the tax impact of the global intangible low taxed income provision of the Act as a future period charge rather than a current component of deferred taxes.

Our income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations. We recognize liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While we believe we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcomes of examinations by tax authorities in determining the adequacy of our provision for income taxes. We continually assess the likelihood and amount of potential revisions and adjust the income tax provision, income taxes payable and deferred taxes in the period in which the facts that give rise to a revision become known.

Significant judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and the valuation allowance recorded against our net deferred tax assets. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting.

Based on our review, we concluded that it was more likely than not that we would be able to realize the future benefits of our domestic and foreign deferred tax assets, with the exceptions of the state of California, Malta and Brazil. This conclusion was based on historical and projected operating performance, as well as our expectation that our operations will generate sufficient taxable income in future periods to realize the tax benefits associated with the deferred tax assets well within the statutory carryover periods. Due to low state apportionment, large net operating losses and the generation of sizeable research credits in California, we concluded that it is not more likely than not that we will be able to utilize our California deferred tax assets. Therefore, we have maintained a full valuation allowance on our California deferred tax assets as of December 31, 2018. Due to a history of losses in Malta and Brazil, and the lack of alternative sources of future taxable income, we have established a full valuation allowance against these entities' deferred tax assets as of December 31, 2018.

We will continue to assess the need for a valuation allowance on our deferred tax assets by evaluating both positive and negative evidence that may exist. Any adjustment to the net deferred tax asset valuation allowance would be recorded in the statement of operations for the period that the adjustment is determined to be required.

Legal Proceedings

We are involved in a number of legal actions arising out of the normal course of our business. The outcomes of these legal actions are not within our complete control and may not be known for prolonged periods of time. In some actions, the claimants seek damages as well as other relief, including injunctions barring the sale of products that are the subject of the lawsuit, that could require significant expenditures or result in lost revenues. In accordance with authoritative guidance, we disclose information regarding each material claim where the likelihood of a loss contingency is probable or reasonably possible. An estimated loss contingency is accrued in our financial statements if it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. If a loss is reasonably possible and can be reasonably estimated, the estimated loss or range of loss is disclosed in the notes to the Consolidated Financial Statements. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded. Our significant legal proceedings are discussed in Note 10 to the Consolidated Financial Statements included in this Annual Report.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. See our Consolidated Financial Statements and Notes thereto included in this Annual Report, which contain accounting policies and other disclosures required by GAAP.

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Results of Operations

Revenue

	Year Ended December 31,			2017 to 2018		2016 to 2017	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Spinal Hardware	$788,650	$737,534	$683,703	$51,116	7 %	$53,831	8 %
Surgical Support	313,064	289,151	278,429	23,913	8 %	10,722	4 %
Total revenue	$1,101,714	$1,026,685	$962,132	$75,029	7 %	$64,553	7 %

Our spinal hardware product line offerings include our implants and fixation products. Our surgical support product line offerings include IOM services, disposables and biologics, all of which are used to aid spinal surgery.

The continued adoption of minimally invasive procedures for spine has led to the expansion of our procedure volume. In addition, increased market acceptance in our international markets contributed to the increase in revenues for the periods presented. We expect continued adoption of our innovative minimally invasive procedures and deeper penetration into existing accounts and international markets as our sales force executes on our strategy of selling the full mix of our products and services. However, the continued consolidation and increased purchasing power of our hospital customers and group purchasing organizations, the continued existence of physician-owned distributorships, continued changes in the public and private insurance markets regarding reimbursement, and ongoing policy and legislative changes in the United States have created less predictability in the lumbar portion of the spine market. Although the market for procedurally-integrated spine surgery solutions should continue to grow over the long term, economic, political and regulatory influences are subjecting our industry to significant changes that may slow the growth rate of the spine surgery market. Our growth in revenue in 2019 is expected to come primarily from market share gains in the shift toward less invasive spinal surgery, revenue from new products and services, and international growth.

Our total revenues increased $75.0 million in 2018 compared to 2017 and $64.6 million in 2017 compared to 2016, representing total revenue growth of 7% in both years. To date, foreign currency fluctuations have not materially impacted our overall revenues as a percentage of growth year over year.

Revenue from our spinal hardware product line offerings increased $51.1 million, or 7%, in 2018 compared to 2017. Product volume for our spinal hardware business increased our revenue by approximately 9%, offset by unfavorable pricing impacts of approximately 2% for the year ended December 31, 2018, as compared to 2017. Foreign currency fluctuation from 2017 to 2018 did not have a material impact on spinal hardware revenue.

Revenue from our spinal hardware product line offerings increased $53.8 million, or 8%, in 2017 compared to 2016. Revenue associated with our 2016 acquisitions accounted for approximately 1% of the increase in spinal hardware revenue for the year ended December 31, 2017. Product volume for our spinal hardware business, excluding the impact from our 2016 acquisitions, increased our revenue by approximately 10%, offset by unfavorable changes in price of approximately 3% for the year ended December 31, 2017, as compared to 2016. Foreign currency fluctuation from 2016 to 2017 did not have a material impact on spinal hardware revenue

Revenue from our spinal hardware product line offerings for the year ended December 31, 2016 included a $4.8 million purchase order, which did not recur during the year ended December 31, 2017, from an organization established by certain former stockholders of Ellipse Technologies with their stated purpose to be donated for use in spinal deformity procedures for children in underprivileged communities.

Revenue from our surgical support product line offerings increased $23.9 million, or 8%, in 2018 compared to 2017. Revenue associated with our 2018 acquisitions accounted for approximately 7% of the increase in surgical support revenue for the year ended December 31, 2018, as compared to 2017. Product and service volume for our surgical support business, excluding the impact from our 2018 acquisitions, increased our revenue by approximately 3% for the year ended December 31, 2018, offset by unfavorable pricing impacts of approximately 2% for the year ended December 31, 2018, as compared to 2017. Foreign currency fluctuation from 2017 to 2018 did not have a material impact on surgical support revenue.

Revenue from our surgical support product line offerings increased $10.7 million, or 4%, in 2017 compared to 2016. Revenue associated with our 2016 acquisitions accounted for approximately 10% of the increase in surgical support revenue for the year ended December 31, 2017, as compared to 2016. Product and service volume for our surgical support business, excluding the impact from our 2016 acquisitions, decreased our revenue by approximately 3% for the year ended December 31, 2017, as compared to 2016. We also realized unfavorable changes in price of approximately 3% which includes lower reimbursement rates on our IOM services for the year ended December 31, 2017, as compared to 2016. Foreign currency fluctuation from 2016 to 2017 did not have a material impact on surgical support revenue.

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Cost of Revenue, Excluding Below Amortization of Intangible Assets

	Year Ended December 31,			2017 to 2018		2016 to 2017	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Cost of revenue	$311,159	$268,441	$240,105	$42,718	16 %	$28,336	12 %
% of total revenue	28 %	26 %	25 %				

Cost of revenue consists primarily of purchased goods, raw materials, labor and overhead associated with product manufacturing, inventory-related costs and royalty expenses, as well as the cost of providing IOM services, which includes personnel and physician oversight costs. We primarily procure and manufacture our goods in the United States, and accordingly, foreign currency fluctuations have not materially impacted our cost of revenue.

Cost of revenue increased $42.7 million, or 16%, during the year ended December 31, 2018, compared to 2017. The cost of revenue associated with the operations of our 2018 acquisitions accounted for approximately 4% of the total increase during the year ended December 31, 2018, compared to 2017. Cost of revenue for our business, excluding our 2018 acquisitions, increased primarily due to growth in volume, additional excess and obsolete inventory reserve, and production related costs, for an overall increase of approximately 12% during the year ended December 31, 2018, compared to 2017.

Cost of revenue increased $28.3 million, or 12%, during the year ended December 31, 2017, compared to 2016. The cost of revenue associated with the operations of our 2016 acquisitions accounted for approximately 9% of the total increase during the year ended December 31, 2017, compared to 2016. Cost of revenue for our business, excluding our 2016 acquisitions, increased primarily due to growth in volume, but also includes unfavorable shifts in inventory costing and product mix, for an overall increase of approximately 11% for the year ended December 31, 2017. These increases were partially offset by royalty obligations for certain product lines and other non-recurring inventory related items, including write-offs and reserves from both manufacturing and obsolescing products, which accounted for approximately a 2% decrease to cost of revenue for the year ended December 31, 2017, compared to 2016. The year ended December 31, 2017 did not include the non-recurring inventory expense associated with the purchase accounting for our acquisition of Ellipse Technologies, which accounted for 6% of total cost of revenue in 2016.

On a long-term basis, we expect cost of revenue, as a percentage of revenue, to decrease moderately due to our manufacturing insourcing efforts.

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Operating Expenses

	Year Ended December 31,			2017 to 2018		2016 to 2017	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Sales, marketing, and administrative	$575,836	$539,507	$533,600	$36,329	7 %	$5,907	1 %
% of total revenue	52 %	53 %	55 %				
Research and development	61,695	50,425	47,999	11,270	22 %	2,426	5 %
% of total revenue	6 %	5 %	5 %				
Amortization of intangibles	50,670	48,039	42,001	2,631	5 %	6,038	14 %
Purchase of in-process research and development	8,913	—	—	8,913	*	—	—
Litigation liability loss (gain)	27,800	4,500	(43,310)	23,300	518 %	47,810	110 %
Business transition costs	11,473	4,287	18,138	7,186	168 %	(13,851)	76 %

Sales, Marketing and Administrative

Sales, marketing and administrative expenses consist primarily of compensation costs, commissions and training costs for our employees (who we refer to as “shareowners”) engaged in sales, marketing and customer support functions. The expense also includes commissions to sales representatives, freight expenses, surgeon training costs, depreciation expense for property and equipment such as surgical instrument sets, and administrative expenses for both shareowners and third party service providers.

Sales, marketing and administrative expenses increased by $36.3 million, or 7% during the year ended December 31, 2018, compared to 2017. The increase during the year ended December 31, 2018 is primary due to increased shareowner compensation and other expenses resulting from increased headcount as compared to 2017. Other costs that increased as a function of the increase in revenue and international expansion included consulting, travel, equipment and freight. Additionally, during the year ended December 31, 2018, legal expenses increased compared to 2017 due to the ongoing litigation with a former Board member and his current employer related to various matters, including infringement of our intellectual property. Sales, marketing and administrative expenses associated with our 2018 acquisitions, which is included in the results discussed herein, accounted for approximately 1% of the increase in sales, marketing and administrative expenses for the year ended December 31, 2018, compared to 2017.

Sales, marketing and administrative expenses increased by $5.9 million, or 1%, during the year ended December 31, 2017 as compared to 2016 due to increases in shareowner compensation and other expenses resulting from increased headcount, offset by the reversal of stock-based compensation expense previously recognized on unvested equity awards forfeited during the year. Other costs which increased as a function of the increase in revenue and expansion included consulting, facilities, travel and equipment, which were partially offset by decreased distributor commissions due to increased sales mix to our direct sales force in 2017 as compared to 2016 and decreased legal expense in 2017 due to the settlement of the Medtronic litigation in 2016. Sales, marketing and administrative expenses associated with our 2016 acquisitions, which are included in the results discussed herein, accounted for approximately 2% of the increase in sales, marketing and administrative expenses for the year ended December 31, 2017, compared to 2016.

Sales, marketing and administrative expenses as a percentage of revenue decreased during the year ended December 31, 2018 compared to 2017. On a long-term basis, we expect total sales, marketing and administrative costs, as a percentage of revenue, to decrease moderately. To date, foreign currency fluctuations have not materially impacted our sales, marketing and administrative expenses.

Research and Development

Research and development expense consists primarily of product research and development, clinical trial and study costs, regulatory and clinical functions, and compensation and other shareowner related expenses. In the last several years, we have introduced numerous new products and product enhancements that have significantly expanded our MAS platform, including iGA, and our comprehensive product portfolio. We have also acquired complementary and strategic assets and technology, particularly in the area of spinal hardware products. We continue to invest in research and development programs.

Research and development expense increased by $11.3 million, or 22% during the year ended December 31, 2018, compared to the 2017. The increase in spending is primarily due to increased headcount and increased spending for further enhancement and functionality of our current and future product offerings, including Pulse, our surgical automation platform which we expect to commercially launch in 2019.

Research and development expense increased by $2.4 million, or 5%, in 2017 compared to 2016. The increase in spending is primarily due to increased headcount and increased spending for our integrated operative solutions technologies, partially offset by non-recurring research and development expenses associated with our 2016 acquisitions.

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Research and development costs as a percentage of revenue increased as compared with the previous year. On a long-term basis, we expect total research and development costs as a percentage of revenue to increase in support of our ongoing development and regulatory approval efforts.

Amortization of Intangible Assets

Amortization of intangible assets relates to the amortization of finite-lived intangible assets acquired. Amortization expense increased $2.6 million in 2018 compared to 2017, primarily due to our 2017 and 2018 acquisitions. Amortization expense increased $6.0 million in 2017 compared to 2016, primarily due to our 2016 and 2017 acquisitions. During the year ended December 31, 2018, we acquired $26.2 million in definite-lived intangible assets, and began amortizing the assets over their respective useful lives.

We expect future amortization of our current intangible assets as a percentage of revenue to be relatively consistent, excluding future acquisitions.

Purchase of In-Process Research and Development

During the year ended December 31, 2018, we expensed $8.9 million for a purchased in-process research and development asset which had no future alternative use.

Litigation Liability Loss (Gain)

During the year ended December 31, 2018, we settled our ongoing litigation with Madsen Medical, Inc. for $27.8 million. We paid the settlement amount and no longer have any remaining liability related to this matter as of December 31, 2018. See Note 10 to the Consolidated Financial Statements included in this Annual Report for further discussion.

During the year ended December 31, 2017, we paid $4.5 million for the settlement of fees associated with the outcome of the Medtronic litigation matter.

During the year ended December 31, 2016, we agreed to settle our ongoing litigation with Medtronic. As a result of the settlement, we paid $45.0 million to Medtronic and accordingly recorded a gain of $43.3 million related to the settlement by reducing our previous accrual of $88.3 million related to the matter.

Business Transition Costs

We incur certain costs related to acquisition, integration and business transition activities, which include severance, relocation, consulting, leasehold exit costs, third-party merger and acquisition costs, contingent consideration fair value adjustments and other costs directly associated with such activities.

We incurred $11.5 million of such costs during the year ended December 31, 2018, which consisted primarily of business transition activities, but also includes $(1.5) million of fair value adjustments on contingent consideration liabilities associated with our 2017 and 2016 acquisitions.

During the year ended December 31, 2017, we incurred $4.3 million of business transition costs, which consisted primarily of acquisition and integration activities, and $(1.3) million of fair value adjustments on contingent consideration liabilities associated with our 2017 and 2016 acquisitions.

During the year ended December 31, 2016, we incurred $18.1 million of such costs, which consisted primarily of acquisition and integration activities, and $7.3 million of fair value adjustments on contingent consideration liabilities associated with our 2016 acquisitions.

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Interest and Other Expense, Net

	Year Ended December 31,			2017 to 2018		2016 to 2017	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Interest income	$586	$440	$1,091	$146	33 %	$(651)	60 %
Interest expense	(37,857)	(38,021)	(40,520)	164	0 %	2,499	6 %
Loss on repurchases of convertible notes	—	—	(19,085)	—	—	19,085	100 %
Other income (expense), net	(8,174)	(1,542)	(305)	(6,632)	430 %	(1,237)	406 %
Total interest and other expense, net	$(45,445)	$(39,123)	$(58,819)	$(6,322)	16 %	$19,696	33 %
% of total revenue	4 %	4 %	6 %				

Total interest and other expense, net for the year ended December 31, 2018 increased $6.3 million, compared to 2017 primarily due to strategic investments, foreign currency impacts, and our pro rata allocation of net income or loss from our equity method investments during the year ended December 31, 2018.

Total interest and other expense, net for the year ended December 31, 2017 decreased $19.7 million, compared to 2016, primarily due to a loss of $19.1 million recognized during the year ended December 31, 2016 related to the repurchase of a portion of the Senior Convertible Notes due 2017. Additionally, we settled the remaining Senior Convertible Notes due 2017 on July 1, 2017 resulting in decreased interest expense in 2017.

Total interest and other expense, net for the years presented also included gains and losses from derivative instruments and foreign currency impacts on settled receivables and payables.

Income Tax (Benefit) Expense

	Year Ended December 31,			2017 to 2018		2016 to 2017	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Income tax (benefit) expense	$(3,756)	$(7,492)	$29,309	$(3,736)	50 %	$36,801	126 %
Effective income tax rate	43 %	10 %	45 %				

The provision for income tax expense as a percentage of pre-tax income from continuing operations reflected a tax benefit of 43% for the year ended December 31, 2018 compared with a tax benefit of 10% on pre-tax income for the year ended December 31, 2017. The tax benefit was higher in 2018 primarily due to permanent tax benefits from research credits, tax planning related deductions and reorganization of its international intellectual property company structure. While the 2017 permanent tax benefits for worthless stock and U.S. tax reform were significantly larger than the permanent tax benefits realized in 2018, the percentage impact of the 2018 tax benefits were larger due to the lower pretax earnings in 2018.

The provision for income tax expense as a percentage of pre-tax income from continuing operations reflected a tax benefit of 10% for the year ended December 31, 2017 compared with a tax expense of 45% for the year ended December 31, 2016. The effective tax rate for 2017 is lower than 2016 primarily due to one-time tax benefits from the worthless stock deduction of one of our wholly-owned U.S. subsidiaries and the revaluation of deferred taxes due to the enactment of U.S. tax reform in 2017. In addition, during 2017, there were lower losses in jurisdictions where we do not receive benefit as well as lower non-deductible acquisition costs, offset by a reduction in share-based compensation windfall tax benefits.

We are subject to audits by federal, state, local, and foreign tax authorities. We believe that adequate provisions have been made for any adjustments that may result from tax examinations. However, the outcome of tax audits cannot be predicted with certainty. Should any issues addressed in our tax audits be resolved in a manner not consistent with our expectations, we could be required to adjust our provision for income taxes in the period such resolution occurs.

We expect our future effective income tax rate to be in-line with the U.S federal and statutory income tax rates due to the large concentration of earnings in the U.S. and foreign statutory tax rates being, on average, comparable to that in the U.S. We continue to streamline our international operations, including procurement, logistics and customer service functions, in an effort to improve overall operational efficiencies. U.S. tax reform has lessened the tax benefit associated with foreign earnings due to a reduced federal corporate tax rate and the forced U.S. inclusion of certain foreign intangible related earnings. As international tax rules and regulations change, we may be subjected to higher taxes on foreign earnings.

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Liquidity, Cash Flows and Capital Resources

Liquidity and Capital Resources

Our principal sources of liquidity are our existing cash, cash equivalents and marketable securities, cash generated from operations, proceeds from our convertible notes issuances, and access to our revolving line of credit. We expect that cash provided by operating activities may fluctuate in future periods as a result of a number of factors, including fluctuations in our operating results, working capital requirements and capital deployment decisions. We have historically invested our cash primarily in the U.S. treasuries and government agencies, corporate debt, and money market funds. Certain of these investments are subject to general credit, liquidity and other market risks. The general condition of the financial markets and the economy may increase those risks and may affect the value and liquidity of investments and restrict our ability to access the capital markets.

Our future capital requirements will depend on many factors including our rate of revenue growth, the timing and extent of spending to support development efforts, the expansion of sales, marketing and administrative activities, the timing of introductions of new products and enhancements to existing products, successful vertical integration of our manufacturing process, the continuing market acceptance of our products, the expenditures associated with possible future acquisitions or other business combination transactions, the outcome of current and future litigation, the evolution of our globalization initiative, and continuous international expansions of our business. Our cash flow from operations and growing operations should continue to fund the ongoing core business. As current borrowing sources become due, we may be required to access the capital markets for additional funding. As we assess inorganic growth strategies, we may need to supplement our internally generated cash flow with outside sources. In the event that we are required to access the debt market, we should be able to secure reasonable borrowing rates. As part of our liquidity strategy, we will continue to monitor our current level of earnings and cash flow generation as well as our ability to access the market in light of those earning levels.

A substantial portion of our operations are located in the United States, and the majority of our sales and cash generation since inception have been made in the United States. Accordingly, we do not have material net cash flow exposures to foreign currency rate fluctuations. However, as our business in markets outside of the United States continues to increase, we will be exposed to foreign currency exchange risk related to our foreign operations. Fluctuations in the rate of exchange between the United States dollar and foreign currencies, primarily in the pound sterling, the euro, the Australian dollar, the Brazilian real, the Singapore dollar, and the yen, could adversely affect our financial results, including our revenues, revenue growth rates, gross margins, income and losses as well as assets and liabilities. We enter into forward currency contracts to partially offset the impact from fluctuations of the foreign currency rates on our third party and short-term intercompany receivables and payables between our domestic and international operations. We currently do not hedge future forecasted transactions but will continue to assess whether that strategy is appropriate. At December 31, 2018, the cash balance held by our foreign subsidiaries with currencies other than the United States dollar was approximately $39.3 million and it is our intention to indefinitely reinvest all of current foreign earnings in order to partially support foreign working capital and to expand our existing operations outside the United States. As of December 31, 2018, our account receivable balance held by our foreign subsidiaries with currencies other than the United States dollar was approximately $41.7 million. We have operations in markets in which there is governmental financial instability which could impact funds that flow into the medical reimbursement system. In addition, loss of financial stability within these markets could lead to delays in reimbursement or inability to remit payment due to currency controls. Specifically, we have operations and/or sales in Puerto Rico, Brazil, Argentina and Venezuela. We do not have any material financial exposure to one customer or one country that would significantly hinder our liquidity.

On August 31, 2015, we received a civil investigative demand, or CID, issued by the DOJ pursuant to the federal False Claims Act. The CID requires the delivery of a wide range of documents and information related to an

investigation by the DOJ concerning allegations that we assisted a physician group customer in submitting improper claims for reimbursement and made improper payments to the physician group in violation of the Anti-Kickback Statute. We are cooperating with the DOJ in regards to this matter. No assurance can be given as to the timing or outcome of this investigation, and the probable outcome of this matter cannot be determined.

In May 2018, we settled all outstanding matters with Madsen Medical, Inc. for $27.8 million, which was funded by cash on hand and credit available under our revolving senior credit facility. We no longer have any remaining liability related to this matter. See Note 10 to the Consolidated Financial Statements included in this Annual Report for further discussion.

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We are involved in a number of legal actions and investigations arising out of the normal course of our business as discussed in Note 10 and Note 11 of the Consolidated Financial Statements included in this Annual Report. Due to the inherent uncertainties associated with pending legal actions and investigations, we cannot predict the outcome, and, with respect to certain pending litigation or claims where no liability has been accrued, to make a meaningful estimate of the reasonably possible loss or range of loss that could result from an unfavorable outcome, other than those matters disclosed in this Annual Report. We have no material accruals for pending litigation or claims for which accrual amounts are not disclosed in our Consolidated Financial Statements included in this Annual Report. It is reasonably possible, however, that an unfavorable outcome that exceeds our current accrual estimate, if any, for one or more of the matters described in our Consolidated Financial Statements included in this Annual Report could have a material adverse effect on our liquidity and access to capital resources. Additionally, it is possible that in connection with a legal proceeding we are required to pay fees and expenses of the other party or set aside funds in an escrow or purchase a performance bond, regardless of our assessment of the probability of a loss. These requirements to pay fees and expenses or escrow funding in connection with a legal proceeding could have an adverse impact on our liquidity or impact our access to additional capital resources.

In 2018, we drew $100.0 million from our $500.0 million revolving senior credit facility to be used for working capital, general corporate purposes, and strategic investments and acquisitions, including the acquisition of SafePassage, a privately-held provider of IOM services. We do not carry any outstanding amount under the revolving senior credit facility as of December 31, 2018.

On September 7, 2017, we completed an acquisition of a medical device company that developed interbody implants for spinal fusion using patented porous PEEK technology. In connection with the acquisition we recorded a purchase accounting fair value estimate of $31.4 million for contingent consideration liabilities related to the achievement of certain manufacturing and commercial milestones. We anticipate these milestones will become payable at varying times between 2019 and 2021, but are subject to change based on the achievement of those manufacturing and commercial milestones.

On August 28, 2017, we entered into a 17 year operating lease agreement for the purpose of expanding and restructuring our corporate headquarters in San Diego, California, from approximately 145,000 square feet to approximately 252,000 square feet. The lease and its terms supersede the existing lease agreement with respect to the currently occupied office buildings comprising our corporate headquarters. The renovation and expansion of the corporate headquarters is expected to be completed in three phases over a period of two years. The rental payments associated with the lease will total approximately $164.2 million over the 17 year term of the lease. Rental payments escalate annually at 3% for the term of the lease upon the anniversary of completion of each phase of expansion.

On September 12, 2016, we completed an acquisition of an imaging software and technology platform known as LessRay. In connection with the acquisition, we recorded a purchase accounting fair value estimate of $34.1 million for contingent consideration liabilities related to the achievement of certain regulatory and commercial milestones. In January 2018, we paid $9.0 million of the outstanding contingent consideration liabilities for the achievement of a commercial milestone. In July 2018, we paid $10.0 million of the outstanding contingent consideration liabilities for the achievement of a regulatory approval milestone. We anticipate the remaining sales-based milestones will become payable at varying times between 2022 and 2023.

Cash and cash equivalents were $117.8 million and $72.8 million at December 31, 2018 and December 31, 2017, respectively. Our existing cash and cash equivalents and available liquidity should be sufficient to meet our anticipated cash needs for the next twelve months. We could have varying needs for cash as a result of the achievement of certain acquisition related milestones. We anticipate funding these milestones from cash on hand and operations, however, we have the ability to fund these from our existing revolving senior credit facility if necessary. The increase in liquidity during the year ended December 31, 2018 of $45.0 million was mainly driven by $219.5

million cash inflow from operations, which includes the $27.8 million settlement payment in the Madsen litigation, offset by $101.9 million in cash used for purchases of property and equipment, $62.9 million in cash used for business combinations, strategic investments and intangible assets, and $19.8 million in cash used for payments of contingent consideration. At December 31, 2018, we have cash totaling $2.4 million in restricted accounts which is not available to us to meet any ongoing capital requirements if and when needed. Future litigation or requirements to escrow funds could materially impact our liquidity and our ability to invest in and run our business on an ongoing basis.

Cash Flows

The following table summarizes our Consolidated Statements of Cash Flows:

	Year Ended December 31,			2017 to 2018		2016 to 2017	
(in thousands)	2018	2017	2016	$ Change	% Change	$ Change	% Change
Cash provided by operating activities	$219,183	$176,969	$158,085	$42,214	24 %	$18,884	12 %
Cash used in investing activities	(161,285)	(174,861)	(304,885)	13,576	8 %	130,024	43 %
Cash (used in) provided by financing activities	(14,578)	(87,028)	110,823	72,450	83 %	(197,851)	179 %
Effect of exchange rate changes on cash	(1,283)	2,070	(929)	(3,353)	162 %	2,999	323 %
Increase (decrease) in cash, cash equivalents and restricted cash	$42,037	$(82,850)	$(36,906)	$124,887	151 %	$(45,944)	124 %

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Cash provided by operating activities

Cash provided by operating activities was $219.2 million for the year ended December 31, 2018, compared to $177.0 million for the same period in 2017. The $42.2 million increase in cash provided by operating activities was primarily due to increased operational cash flows in 2018 related to timing of cash receipts and disbursements, offset by $27.8 million in cash paid for the settlement of the Madsen litigation matter in 2018.

Cash provided by operating activities was $177.0 million for the year ended December 31, 2017, compared to $158.1 million for the same period in 2016. The $18.9 million increase in cash provided by operating activities was primarily due to $45.0 million in cash paid for the settlement of the Medtronic litigation matter in 2016, offset with increased operational cash flows in 2016 related to timing of spending and cash receipts. Additionally, we paid $30.0 million in 2017 for contingent consideration related to the acquisition of Ellipse Technologies, of which $11.2 million related to increased fair value adjustments and thus decreased cash flows from operating activities, with the remaining $18.8 million representing the initial purchase price allocation classified in financing activities.

Cash used in investing activities

Cash used in investing activities was $161.3 million in 2018, compared to $174.9 million used in 2017. The $13.6 million decrease in cash used in investing activities was primarily due to an $8.3 million decrease in cash used for purchases of property and equipment and a decrease of $1.7 million in cash used for business combinations, strategic investments and intangible assets in 2018 as compared to 2017.

Cash used in investing activities was $174.9 million in 2017, compared to $304.9 million in 2016. The $130.0 million decrease in cash used in investing activities in 2017 as compared to 2016 is primarily due to the $380.1 million cash payment (net of cash received) to fund the acquisition of Ellipse Technologies and a net $278.1 million cash received related to activities within investment portfolios during the year ended December 31, 2016. The year ended December 31, 2017 includes a decrease of $49.9 million in cash used for business combinations, strategic investments and purchases of intangible assets and an increase of $21.8 million in cash used on purchases of property and equipment associated with our manufacturing initiative and general business as compared to the same period in 2016.

For 2019, we expect capital expenditures to support expansions of our business globally to be in the range of $110.0 million to $120.0 million which is expected to be sourced by the cash generated from operations and the revolving senior credit facility, as described below in the section “Revolving Senior Credit Facility”.

Cash (used in) provided by financing activities

Cash used in financing activities was $14.6 million in 2018, compared to $87.0 million cash used in 2017. The $72.4 million decrease in cash used in financing activities was primarily due to the $63.3 million settlement of the remaining principal on the Senior Convertible Notes due July 2017 during the third quarter of 2017, offset by decreased treasury stock purchases of $8.9 million in 2018 as compared to the same period in 2017.

Our equity incentive plans allow for “net share settlement” of certain equity awards whereby, in lieu of (i) making cash payments in satisfaction of the exercise price owed respective to non-qualified stock option awards, or (ii) open market selling award shares to generate cash proceeds for use in satisfaction of statutory tax obligations respective to an award’s settlement or exercise, we offset the award shares being settled in a respective transaction by the number of shares of our common stock with a value equal to the respective obligation, and, in the case of taxes, making a cash payment to the respective taxing authority on behalf of the shareowner using our cash on hand. The net share settlement is accounted for with the cost of any award shares that are net settled being included in treasury stock and reported as a reduction in total equity at the time of settlement.

During 2019, we estimate at least $20.0 million of such cash tax payments will be made, however the actual remittance can vary significantly depending on our share price at the date of RSU or PRSU release or option exercises or actual volume of such activities. We anticipate using cash generated from operating activities and the credit facility to fund all such payments.

Cash used in financing activities was $87.0 million for the year ended December 31, 2017, compared to $110.8 million cash provided for the same period in 2016. The $197.9 million decrease in cash provided by financing activities was primarily due to the net issuance of the Senior Convertible Notes due 2021 of $634.1 million. The proceeds from the issuance of the Senior Convertible Notes due 2021 were offset by the net $66.3 million purchase of a call spread related to that issuance and approximately $439.5 million in cash to repurchase a portion of the Senior Convertible Notes due 2017 during the year ended December 31, 2016. We used $63.3 million to settle the remaining principal on the Senior Convertible Notes due 2017 during the year ended December 31, 2017.

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Senior Convertible Notes

2.25% Senior Convertible Notes due 2021

In March 2016, we issued $650.0 million principal amount of unsecured senior convertible notes with a stated interest rate of 2.25% and a maturity date of March 15, 2021, which we refer to as the 2021 Notes. The net proceeds from the offering, after deducting initial purchasers' discounts and costs directly related to the offering, were approximately $634.1 million. Interest on the 2021 Notes began accruing upon issuance and is payable semi-annually. The 2021 Notes may be settled in cash, stock, or a combination thereof, solely at our discretion. It is our current intent and policy to settle all conversions through combination settlement, which involves satisfying the principal amount outstanding with cash and any note conversion value over the principal amount in shares of our common stock. The initial conversion rate of the 2021 Notes is 16.7158 shares per $1,000 principal amount, which is equivalent to a conversion price of approximately $59.82 per share, subject to adjustments. Prior to September 15, 2020, holders may convert their 2021 Notes only under the following conditions: (a) during any calendar quarter beginning June 30, 2016, if the reported sale price of our common stock for at least 20 days out of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than 130% of the conversion price on each applicable trading day; (b) during the five business day period in which the trading price of the 2021 Notes falls below 98% of the product of (i) the last reported sale price of our common stock and (ii) the conversion rate on that date; and (c) upon the occurrence of specified corporate events, as defined in the 2021 Notes. From September 15, 2020 and until the close of business on the second scheduled trading day immediately preceding March 15, 2021, holders may convert their 2021 Notes at any time (regardless of the foregoing circumstances). We may not redeem the 2021 Notes prior to March 20, 2019. We may redeem the 2021 Notes, at our option, in whole or in part on or after March 20, 2019 until the close of business on the business day immediately preceding September 15, 2020 if the last reported sale price of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we deliver written notice of a redemption. The redemption price will be equal to 100% of the principal amount of such 2021 Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date. No principal payments are due on the 2021 Notes prior to maturity. Other than restrictions relating to certain fundamental changes and consolidations, mergers or asset sales and customary anti-dilution adjustments, the 2021 Notes do not contain any financial covenants and do not restrict us from paying dividends or issuing or repurchasing any of our other securities. We are unaware of any current events or market conditions that would allow holders to convert the 2021 Notes. The impact of the convertible feature will be dilutive to our earnings per share when our average stock price for the period is greater than the conversion price.

In connection with the offering of the 2021 Notes, we entered into transactions for convertible notes hedge, which we refer to as the 2021 Hedge, and warrants, which we refer to as the 2021 Warrants. The 2021 Hedge was entered into with the initial purchasers of the 2021 Notes and/or their affiliates, which we refer to as the 2021 Counterparties, entitling us to purchase up to 10,865,270 shares of our own common stock at an initial stock price of $59.82 per share, each of which is subject to adjustment. The cost of the 2021 Hedge was $111.2 million. The 2021 Hedge will expire on March 15, 2021. The 2021 Hedge is expected to reduce the potential equity dilution upon conversion of the 2021 Notes if the daily volume-weighted average price per share of our common stock exceeds the strike price of the 2021 Hedge. Our assumed exercise of the 2021 Hedge is considered anti-dilutive since the effect of the inclusion would always be anti-dilutive with respect to the calculation of diluted earnings per share.

In addition, we sold the 2021 Warrants to the 2021 Counterparties to acquire up to 10,865,270 common shares of our stock. The 2021 Warrants will expire on various dates from June 2021 through December 2021 and may be settled in cash or net shares. It is our current intent and policy to settle all conversions in shares of our common stock. We received $44.9 million in cash proceeds from the sale of the 2021 Warrants. The 2021 Warrants could have a dilutive effect on our earnings per share to the extent that the price of our common stock during a given measurement period

exceeds the strike price of the 2021 Warrants, which is $80.00 per share.

Revolving Senior Credit Facility

In April 2017, we entered into an Amended and Restated Credit Agreement (the “2017 Credit Agreement”) for a revolving senior credit facility (the “2017 Facility”), which replaced the previous credit agreement we had entered into in February 2016. The 2017 Credit Agreement provides for secured revolving loans, multicurrency loan options and letters of credit in an aggregate amount of up to $500.0 million. The 2017 Credit Agreement also contains an accordion feature, which allows us to increase the aggregate principal amount of the 2017 Facility provided we remain in compliance with the underlying financial covenants, including but not limited to, compliance with the consolidated interest coverage ratio and certain consolidated leverage ratios. The 2017 Facility matures in April 2022 (subject to an earlier springing maturity date), and includes a sublimit of $100.0 million for multicurrency borrowings, a sublimit of $50.0 million for the issuance of standby letters of credit, and a sublimit of $5.0 million for swingline loans. All of our assets including the assets of our material domestic subsidiaries are pledged as collateral under the 2017 Facility (subject to customary exceptions) pursuant to the term set forth in the Amended and Restated Security and Pledge Agreement (the “2017 Security Agreement”) executed in favor of the administrative agent. Each of our material domestic subsidiaries guarantees the 2017 Facility. In connection with the 2017 Facility, we incurred issuance costs which will be amortized over the term of the 2017 Facility. We did not carry any outstanding revolving loans under the 2017 Facility as of December 31, 2018 and 2017.

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Borrowings under the 2017 Facility bear interest, at our option, at a rate equal to an applicable margin plus: (a) the applicable Eurocurrency Rate (as defined in the 2017 Credit Agreement), or (b) a base rate determined by reference to the highest of (1) the federal funds effective rate plus 0.50%, (2) the Bank of America prime rate, and (3) LIBOR for an interest period of one month plus 1.00%. The margin for the 2017 Facility ranges, based on our consolidated leverage ratio, from 0.00% to 1.00% in the case of base rate loans and from 1.00% to 2.00% in the case of Eurocurrency Rate loans. The 2017 Facility includes an unused line fee ranging, based on our consolidated leverage ratio, from 0.20% to 0.35% per annum on the revolving commitment.

The 2017 Credit Agreement contains affirmative, negative, permitted acquisition and financial covenants, and events of default customary for financings of this type. The financial covenants require us to maintain ratios of consolidated earnings before interest, taxes, depreciation and amortization (EBITDA) in relation to consolidated interest expense and consolidated debt, respectively, as defined in the 2017 Credit Agreement. The 2017 Facility grants the lenders preferred first priority liens and security interests in capital stock, intercompany debt and all of our present and future property and assets including each guarantor. We are currently in compliance with the Credit Agreement covenants.

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Contractual Obligations and Commitments

Contractual obligations and commitments represent future cash commitments and liabilities under agreements with third parties, including our 2021 Notes, operating leases and other contractual obligations.

The following table summarizes our contractual obligations and commitments as of December 31, 2018:

		Payments Due by Period			
(in thousands)	Total	Less Than 1 Year	1 to 3 Years	4 to 5 Years	After 5 Years
Convertible Notes (1)	$686,563	$14,625	$ 671,938	$ —	$ —
Operating leases	175,488	13,750	23,961	21,093	116,684
Capital leases	1,314	534	751	29	—
Other long-term liabilities	43,647	8,610	13,100	11,937	10,000
Total	$907,012	$37,519	$ 709,750	$ 33,059	$ 126,684

(1) Convertible Notes includes the expected coupon interest payments on the outstanding debt. See Note 5 to the Consolidated Financial Statements included in this Annual Report for further discussion of the terms of the convertible notes.

Total contractual obligations and commitments listed in the table above excludes the following liabilities:

- Potential contingent consideration payments pursuant to certain merger, purchase, and product development agreements, other than achieved milestones. See Notes 3 and 6 to the Consolidated Financial Statements included in this Annual Report for further discussion on the contingent consideration obligations and product development agreements, respectively.

The expected timing of payments of the obligations discussed above is estimated based on current information. Timing of payment and actual amounts paid may be different depending on the time of receipt of services or changes to agreed-upon amounts for some obligations.

Off-Balance Sheet Arrangements

As of December 31, 2018, we did not have any off-balance sheet activities.

Item 7A.Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Sensitivity and Risk

Our exposure to interest rate risk at December 31, 2018 is related to our investment portfolio which consists largely of cash equivalents in the form of debt instruments of high quality corporate issuers and the U.S. government and its agencies. Due to the short-term nature of these investments, we have assessed that there is no material exposure to interest rate risk arising from our investments. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. At December 31, 2018, we do not hold any material asset-backed investment securities and in 2018, we did not realize any losses related to asset-backed investment securities. Based upon our overall interest rate exposure as of December 31, 2018, a change of 10 percent in interest rates, assuming the amount of our investment portfolio and overall economic environment remains constant, would not have a material effect on interest income.

The primary objective of our investment activities is to preserve the principal while at the same time maximizing yields without significantly increasing the risk. To achieve this objective, we maintain our portfolio of cash equivalents and investments in instruments that meet high credit quality standards, as specified in our investment

policy. None of our investments are held for trading purposes. Our policy also limits the amount of credit exposure to any one issue, issuer and type of instrument.

As of December 31, 2018, we only held investments in securities of a short-term nature classified as cash equivalents. During the periods presented, we did not hold any investments that were in a significant unrealized loss position and no impairment charges were recorded. Realized gains and losses and interest income related to marketable securities were immaterial during all periods presented.

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Market Price Sensitive Instruments

In order to reduce the potential equity dilution, we entered into the 2021 Hedge in connection with the issuance of the 2021 Notes entitling us to purchase our common stock. Upon conversion of our convertible notes, the 2021 Hedge is expected to reduce the equity dilution if the daily volume-weighted average price per share of our common stock exceeds the strike price of the applicable hedge. We also entered into warrant transactions with the counterparties of the 2021 Hedge entitling them to acquire shares of our common stock. The warrant transactions could have a dilutive effect on our earnings per share to the extent that the price of our common stock during a given measurement period (the quarter or year to date period) exceeds the strike price of the warrants. See Note 5 to the Consolidated Financial Statements included in this Annual Report for further discussion.

Foreign Currency Exchange Risk

A substantial portion of our operations are located in the United States, and the majority of our sales since inception have been made in the United States dollars. Accordingly, we have assessed that we do not have any material net exposure to foreign currency rate fluctuations. However, as our business in markets outside of the United States continues to increase, we will be exposed to foreign currency exchange risk related to our foreign operations. Fluctuations in the rate of exchange between the United States dollar and foreign currencies, primarily the pound sterling the euro, the Australian dollar, the Brazilian real, the Singapore dollar, and the yen, could adversely affect our financial results, including our revenues, revenue growth rates, gross margins, income and losses as well as assets and liabilities. In addition, loss of financial stability within these markets could lead to delays in reimbursement or inability to remit payment due to currency controls. Specifically, we have operations in Puerto Rico, Brazil, Argentina and Venezuela that have financial instability or currency controls. We do not have any material financial exposure to one customer or one country that would significantly hinder our liquidity.

We translate the financial statements of our foreign subsidiaries with functional currencies other than the United States dollar into the United States dollar for consolidation using end-of-period exchange rates for assets and liabilities and average exchange rates during each reporting period for results of operations. Net gains or losses resulting from the translation of foreign financial statements and the effect of exchange rate changes on intercompany receivables and payables of a long-term investment nature are recorded as a separate component of stockholders' equity. These adjustments will affect net income only upon sale or liquidation of the underlying investment in foreign subsidiaries. Exchange rate fluctuations resulting from the translation of the short-term intercompany balances between domestic entities and our foreign subsidiaries are recorded as foreign currency transaction gains or losses and are included in other income (expense) in the Consolidated Statement of Operations. For those short-term intercompany balances, we enter into the foreign currency forward contracts to partially offset the impact from fluctuation of the foreign currency rates. The notional amount of the outstanding foreign currency forward contracts was $26.8 million as of December 31, 2018, which was settled in January 2019. During the year ended December 31, 2018, a gain of $0.5 million was recognized in other income (expense) due to the change in the fair value of the derivative instruments, and the fair value of the hedge contracts we held was $(0.3) million on our Consolidated Balance Sheet as of December 31, 2018. The notional principal amounts provide one measure of the transaction volume outstanding as of period end, but do not represent the amount of our exposure to market loss. The estimates of fair value are based on applicable and commonly used pricing models using prevailing financial market information. The amounts ultimately realized upon settlement of these financial instruments, together with the gains and losses on the underlying exposures, will depend on actual market conditions during the remaining life of the instruments. The financial exposures by exchange rate fluctuations are monitored and managed by us as an integral part of our overall risk management program, which recognizes the unpredictability of financial markets and seeks to reduce potentially adverse effects on our results.

Item 8.Financial Statements and Supplementary Data

The Consolidated Financial Statements and supplementary data required by this item are set forth at the pages indicated in Item 15 of this Annual Report.

Item 9.Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A.Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended (Exchange Act) is recorded, processed, summarized and reported within the timelines specified in the Commission’s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of the Company's disclosure controls and procedures (as defined in SEC Rules 13a — 15(e) and 15d — 15(e) of the Exchange Act) as of December 31, 2018. Based on such evaluation, our management has concluded as of December 31, 2018, the Company's disclosure controls and procedures are effective.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

Management has used the framework set forth in the report entitled Internal Control — Integrated Framework published by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) to evaluate the effectiveness of the Company's internal control over financial reporting. On May 14, 2013, the Committee of Sponsoring Organizations of the Treadway Commission published a 2013 framework and related illustrative documents. We adopted the new framework during 2014. Management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2018, based on those criteria. Ernst & Young LLP, the Company's independent registered public accounting firm, has issued an attestation report on the Company's internal control over financial reporting which is included herein.

Changes in Internal Control over Financial Reporting

We are involved in ongoing evaluations of internal controls. In anticipation of the filing of this Form 10-K, our Chief Executive Officer and Chief Financial Officer, with the assistance of other members of our management, performed an evaluation of any change in internal control over financial reporting that occurred during our last fiscal quarter that has materially affected, or is likely to materially affect, our internal controls over financial reporting. There has been no change to our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of NuVasive, Inc.

Opinion on Internal Control over Financial Reporting

We have audited NuVasive, Inc.'s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, NuVasive, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of NuVasive, Inc. as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income, equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and our report dated February 20, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have

a material effect on the financial statements.

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

/s/ Ernst & Young LLP

San Diego, California

February 20, 2019

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Item 9B.Other Information

None.

PART III

Certain information required by Part III is omitted from this report because the Company will file a definitive proxy statement within 120 days after the end of its fiscal year pursuant to Regulation 14A (the Proxy Statement) for its 2019 annual meeting of stockholders, and certain information included in the Proxy Statement is incorporated herein by reference.

Item 10.Directors, Executive Officers and Corporate Governance

We have adopted a Code of Ethical Business Conduct for all officers, directors and shareowners. The Code of Ethical Business Conduct is available on our website, www.nuvasive.com. We intend to disclose future amendments to, or waivers from, provisions of our Code of Ethical Business Conduct that apply to our Principal Executive Officer, Principal Financial Officer, Principal Accounting Officer, or Controller, or persons performing similar functions, within four business days of such amendment or waiver.

The other information required by this Item 10 will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 11.Executive Compensation

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 12.Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 13.Certain Relationships and Related Transactions, and Director Independence

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 14.Principal Accounting Fees and Services

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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PART IV

Item 15.Exhibits, Financial Statement Schedules

(a) The following documents are filed as a part of this report:
(1) Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets as of December 31, 2018 and 2017

Consolidated Statements of Operations for the years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Comprehensive Income for the years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Equity for the years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules: Schedule II — Valuation Accounts
All other financial statement schedules have been omitted because they are not applicable, not required or the information required by such schedules is shown in the financial statements or the notes thereto.

(3) Exhibits
See Item 15, subsection (b) below.

(b) The following exhibits are filed as part of this report:

Exhibit Number	Description
2.1†	Agreement and Plan of Merger, dated January 4, 2016, by and among the Company, Magneto Acquisition Corporation, a Delaware corporation and wholly-owned subsidiary of the Company, Ellipse Technologies, Inc., and Fortis Advisors LLC, a Delaware limited liability corporation, in its capacity as the equity holders' representative (incorporated by reference to our Current Report on Form 8-K filed with the Commission on February 11, 2016)

2.2	Agreement and Plan of Merger, dated June 6, 2016, by and among the Company, Bionic Acquisition Corporation, a Delaware corporation and wholly-owned subsidiary of the Company, BNN Holdings Corp., and GPP I-BNN, LLC, a Delaware limited liability corporation, in its capacity as the security holders' agent to BNN Holdings Corp. (incorporated by reference to our Current Report on Form 8-K filed with the Commission on July 5, 2016)
3.1	Restated Certificate of Incorporation (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 13, 2004)
3.2	Certificate of Amendment to the Restated Certificate of Incorporation (incorporated by reference to our Current Report on Form 8-K filed with the Commission on September 28, 2011)
3.3	Restated Bylaws (incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 6, 2012)
3.4	Amendment No. 1 to the Restated Bylaws (incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 19, 2014)
3.5	Amendment No. 2 to the Restated Bylaws (incorporated by reference to our Current Report on Form 8-K filed with the SEC on August 1, 2016)
4.1	Specimen Common Stock Certificate (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 16, 2006)
4.2	Certificate of Designations of Series A Participating Preferred Stock filed with the Delaware Secretary of State on June 28, 2011 (incorporated by reference to our Current Report on Form 8-K filed with the Commission on June 29, 2011)

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Exhibit Number	Description
4.3	Indenture, dated March 16, 2016, between the Company and Wilmington Trust, National Association, as Trustee (incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 16, 2016)
4.4	Form of 2.25% Convertible Senior Note due 2021 (incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 16, 2016)
10.1#	2004 Amended and Restated Equity Incentive Plan (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on July 26, 2012)
10.2#	Amendment No. 1 to the 2004 Amended and Restated Equity Incentive Plan (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 3, 2014)
10.3#	Form of Stock Option Award Notice under the 2004 Amended and Restated Equity Incentive Plan (incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 filed with the Commission on April 8, 2004)
10.4#	Form of Option Exercise and Stock Purchase Agreement under the 2004 Amended and Restated Equity Incentive Plan (incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 filed with the Commission on April 8, 2004)
10.5#	Form of Restricted Stock Unit Award Agreement under the 2004 Amended and Restated Equity Incentive Plan (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)

10.6#	Form of Restricted Stock Grant Notice and Restricted Stock Agreement under the 2004 Amended and Restated Equity Incentive Plan (incorporated by reference to Amendment No.1 to our Registration Statement on Form S-1 filed with the Commission on April 8, 2004)
10.7#	2004 Amended and Restated Employee Stock Purchase Plan of NuVasive, Inc. (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on October 30, 2014)
10.8#	Amendment No. 1 to 2004 Amended and Restated Employee Stock Purchase Plan of NuVasive, Inc.
10.9#	2014 Equity Incentive Plan (incorporated by reference to Exhibit A to our Definitive Proxy Statement filed with the Commission on March 27, 2014)
10.10#	Form of Performance Restricted Stock Unit Agreement (with accompanying Form Notice of Grant) under the 2014 Equity Incentive Plan (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 4, 2015)
10.11#	Form of Executive Restricted Stock Unit Agreement (with accompanying Form Notice of Grant) under the 2014 Equity Incentive Plan (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 4, 2015)
10.12#	Form of Performance Cash Award Agreement (with accompanying Form Notice of Grant) under the 2014 Equity Incentive Plan (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 4, 2015)
10.13#	Form of Performance Restricted Stock Unit Agreement (with accompanying Notice of Grant) for grants after February 11, 2016 under the 2014 Equity Incentive Plan (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on February 11, 2016)

10.14#	Form of Executive Restricted Stock Unit Agreement (with accompanying Form Notice of Grant) for grants after February 11, 2016 under the 2014 Equity Incentive Plan (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on February 11, 2016)
10.15#	Form of Performance Cash Award Agreement (with accompanying Form Notice of Grant) for grants after February 11, 2016 under the 2014 Equity Incentive Plan (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on February 11, 2016)
10.16#	Form of Performance Restricted Stock Unit Agreement (with accompanying Notice of Grant) for grants after February 8, 2017 under the 2014 Equity Incentive Plan (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on February 9, 2017)

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Exhibit Number	Description
10.17#	Form of Executive Restricted Stock Unit Agreement (with accompanying Form Notice of Grant) for grants after February 8, 2017 under the 2014 Equity Incentive Plan (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on February 9, 2017)
10.18#	Form of Performance Cash Award Agreement (with accompanying Form Notice of Grant) for grants after February 8, 2017 under the 2014 Equity Incentive Plan (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on February 9, 2017)
10.19#	Form of Performance Restricted Stock Unit Agreement (with accompanying Notice of Grant) for grants on or after April 30, 2018 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the SEC on May 1, 2018)
10.20#	Form of Executive Restricted Stock Unit Agreement (with accompanying Form Notice of Grant) for grants on or after April 30, 2018 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the SEC on May 1, 2018)
10.21#	Form of Performance Cash Award Agreement (with accompanying Form Notice of Grant) for grants on or after April 30, 2018 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the SEC on May 1, 2018)
10.22#	NuVasive, Inc. 2014 Executive Incentive Compensation Plan (incorporated by reference to Exhibit B to our Definitive Proxy Statement filed with the Commission on March 27, 2014)
10.23#	2015 Ellipse Technologies, Inc. Incentive Award Plan (incorporated by reference to our Registration Statement on Form S-8 filed with the Commission on February 11,

	2016)
10.24#	Form of Indemnification Agreement between the Company and its directors and certain executives thereof (incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 19, 2014)
10.25#	NuVasive, Inc. Amended and Restated Executive Severance Plan (incorporated by reference to our Quarterly Report on Form 10-Q filed with the SEC on July, 27, 2017)
10.26#	Form of Change in Control Agreement between the Company and certain executives thereof (incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 19, 2014)
10.27#	NuVasive, Inc. Deferred Compensation Plan (incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 6, 2015)
10.28#	Employment Letter dated October 16, 2018 between the Company and J. Christopher Barry (incorporated by reference to our Current Report on Form 8-K Filed with the SEC on October 19, 2018)
10.29#	Letter Agreement dated May 22, 2015 between the Company and Gregory T. Lucier (incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 26, 2015)
10.30#	Amendment to Employment Letter effective October 16, 2018 between the Company and Gregory T. Lucier (incorporated by reference to our Current Report on Form 8-K Filed with the SEC on October 19, 2018)
10.31#	General Consulting and Services Agreement effective October 16, 2018 between the Company and Gregory T. Lucier (incorporated by reference to our Current Report on Form 8-K Filed with the SEC on October 19, 2018)
10.32#	

	Assignment and Novation Agreement effective November 12, 2018 by and among Gregory T. Lucier, River Road Capital Partners, LLC and the Company
10.33#	Amendment No. 1 to Proprietary Information, Inventions Assignment and Restrictive Covenant Agreement effective October 16, 2018 between the Company and Gregory T. Lucier (incorporated by reference to our Current Report on Form 8-K Filed with the SEC on October 19, 2018)
10.34#	Employment Letter dated October 17, 2018 between the Company and Matthew Link (incorporated by reference to our Current Report on Form 8-K Filed with the SEC on October 19, 2018)
10.35#	Notice of Grant of Performance Cash Award and Award Agreement granted to Matthew Link on December 3, 2018

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Exhibit Number	Description
10.36#	Notice of Grant of Share Purchase Matching Performance Restricted Stock Units and Award Agreement granted to Gregory T. Lucier on May 22, 2015 (incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 26, 2015)
10.37#	Notice of Grant of "Inducement" Performance Restricted Stock Units and Award Agreement granted to Gregory T. Lucier on May 22, 2015 (incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 26, 2015)
10.38#	Separation Agreement and General Release dated December 29, 2018 between the Company and Pete Leddy (incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 3, 2019)
10.39#	General Consulting and Services Agreement dated December 29, 2018 between the Company and Pete Leddy (incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 3, 2019)
10.40#	Amendment No. 1 to Propriety Information, Inventions Assignment and Restrictive Covenant Agreement dated December 29, 2018 between the Company and Pete Leddy (incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 3, 2019)
10.41#	Non-Employee Director Cash Compensation Plan (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 3, 2014)
10.42	Lease for Sorrento Summit, dated as of August 28, 2017, by and between HCPI/Sorrento, LLC and the Company (incorporated by reference to our Current Report on Form 8-K filed with the SEC on August 29, 2017)

10.43	Amended and Restated Credit Agreement, dated April 25, 2017, by and among the Company, as the Borrower, certain material subsidiaries of the Company, as guarantors, Bank of America, N.A. and each of those additional Lenders party thereto (incorporated by reference to our Current Report on Form 8-K filed with the SEC on April 25, 2017)
10.44	Amended and Restated Security and Pledge Agreement, dated April 25, 2017, by and among the Company and certain material subsidiaries of the Company in favor of Bank of America, N.A. (incorporated by reference to our Current Report on Form 8-K filed with the SEC on April 25, 2017)
10.45	Confirmation for base call option transaction, dated March 10, 2016, by and between the Company and Bank of America, N.A. (incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 16, 2016)
10.46	Confirmation for additional call option transaction, dated March 11, 2016, by and between the Company and Bank of America, N.A. (incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 16, 2016)
10.47	Confirmation for base call option transaction, dated March 10, 2016, by and between the Company and Goldman, Sachs & Co. (incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 16, 2016)
10.48	Confirmation for additional call option transaction, dated March 11, 2016, by and between the Company and Goldman, Sachs & Co. (incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 16, 2016)
10.49	Confirmation for base warrant transaction, dated March 10, 2016, by and between the Company and Bank of America, N.A. (incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 16, 2016)
10.50	

	Confirmation for additional warrant transaction, dated March 11, 2016, by and between the Company and Bank of America, N.A. (incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 16, 2016)
10.51	Confirmation for base warrant transaction, dated March 10, 2016, by and between the Company and Goldman, Sachs & Co. (incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 16, 2016)
10.52	Confirmation for additional warrant transaction, dated March 11, 2016, by and between the Company and Goldman, Sachs & Co. (incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 16, 2016)

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Exhibit Number	Description
10.53†	Settlement and Patent License Agreement dated July 13, 2016 between the Company and Medtronic plc together with its wholly owned subsidiaries Medtronic Sofamor Danek USA, Inc., Warsaw Orthopedic, Inc., Medtronic Puerto Rico Operations Co., and Medtronic Sofamor Danek Deggendorf GmbH (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on October 26, 2016)
21.1	List of subsidiaries of the Company
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
32.1*	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Calculation Linkbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document

101.PRE	XBRL Taxonomy Presentation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document

† Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with an asterisk. We have filed separately with the Commission an unredacted copy of the exhibit.
# Indicates management contract or compensatory plan.
* These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of NuVasive, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 16.Form 10-K Summary

The Company has elected not to provide a summary.

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SIGNATURES

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

NUVASIVE, INC.

Date: February 20, 2019

By: /s/ J. Christopher Barry
J. Christopher Barry
Chief Executive Officer
(Principal Executive Officer)

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POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints J. Christopher Barry and Rajesh J. Asarpota, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes may do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ J. Christopher Barry J. Christopher Barry	Chief Executive Officer (Principal Executive Officer)	February 20, 2019
/s/ Rajesh J. Asarpota Rajesh J. Asarpota	Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 20, 2019
/s/ Vickie L. Capps Vickie L. Capps	Director	February 20, 2019
/s/ John A. DeFord John A. DeFord	Director	February 20, 2019
/s/ Robert F. Friel Robert F. Friel	Director	February 20, 2019
/s/ R. Scott Huennekens R. Scott Huennekens	Director	February 20, 2019
/s/ Gregory T. Lucier Gregory T. Lucier	Director	February 20, 2019
/s/ Leslie V. Norwalk, Esq. Leslie V. Norwalk, Esq.	Director	February 20, 2019
/s/ Michael D. O'Halleran Michael D. O'Halleran	Director	February 20, 2019
/s/ Donald J. Rosenberg Donald J. Rosenberg	Director	February 20, 2019
/s/ Daniel J. Wolterman Daniel J. Wolterman	Director	February 20, 2019

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NUVASIVE, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of NuVasive, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of NuVasive, Inc. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income, equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 20, 2019 expressed an unqualified opinion thereon.

Adoption of ASU No. 2014-09

As discussed in Note 1 to the consolidated financial statements, the Company changed its method for recognizing revenue as a result of the adoption of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), and the amendments in ASUs 2015-14, 2016-08, 2016-10 and 2016-12 effective January 1, 2018.

Adoption of ASU No. 2016-16

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for intra-entity transfers of assets other than inventory in 2017 due to the adoption of ASU No. 2016-16, Intra-Entity Transfers of Assets Other Than Inventory.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in

the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2000.

San Diego, California

February 20, 2019

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NUVASIVE, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except par value and shares)

	December 31, 2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$117,840	$72,803
Restricted cash and investments	—	3,901
Accounts receivable, net of allowances of $16,171 and $13,026, respectively	196,487	200,220
Inventory, net	273,244	247,138
Prepaid income taxes	16,905	17,209
Prepaid expenses and other current assets	13,733	18,792
Total current assets	618,209	560,063
Property and equipment, net	238,841	215,326
Intangible assets, net	252,048	280,774
Goodwill	561,366	536,926
Deferred tax assets	5,263	6,440
Restricted cash and investments	2,395	1,494
Other assets	29,737	39,117
Total assets	$1,707,859	$1,640,140
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$105,877	$75,767
Contingent consideration liabilities	7,560	18,952
Accrued payroll and related expenses	59,960	55,618
Litigation liabilities	1,415	8,150
Income tax liabilities	4,648	2,908
Total current liabilities	179,460	161,395
Long-term senior convertible notes	602,526	582,920
Deferred and income tax liabilities, non-current	4,964	18,870
Other long-term liabilities	86,384	77,539
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, none outstanding	—	—
Common stock, $0.001 par value; 120,000,000 shares authorized at December 31, 2018 and December 31, 2017, 56,648,077 and 56,164,060 issued and outstanding at December 31, 2018 and December 31, 2017, respectively	61	60
Additional paid-in capital	1,397,829	1,363,549
Accumulated other comprehensive loss	(8,628)	(6,933)
Retained earnings	17,241	4,762
Treasury stock at cost; 5,116,496 shares and 5,001,886 shares at December 31, 2018 and December 31, 2017, respectively	(571,978)	(565,867)
Total NuVasive, Inc. stockholders' equity	834,525	795,571

Non-controlling interests	—	3,845
Total equity	834,525	799,416
Total liabilities and equity	$1,707,859	$1,640,140

See accompanying notes to Consolidated Financial Statements.

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NUVASIVE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	Year Ended December 31,		
	2018	2017	2016
Revenue			
Product revenue	$986,458	$938,981	$893,544
Service revenue	115,256	87,704	68,588
Total revenue	1,101,714	1,026,685	962,132
Cost of revenue (excluding below amortization of intangible assets)			
Cost of products sold	234,509	207,307	195,605
Cost of services	76,650	61,134	44,500
Total cost of revenue	311,159	268,441	240,105
Gross profit	790,555	758,244	722,027
Operating expenses:			
Sales, marketing and administrative	575,836	539,507	533,600
Research and development	61,695	50,425	47,999
Amortization of intangible assets	50,670	48,039	42,001
Purchase of in-process research and development	8,913	—	—
Litigation liability loss (gain)	27,800	4,500	(43,310)
Business transition costs	11,473	4,287	18,138
Total operating expenses	736,387	646,758	598,428
Interest and other expense, net:			
Interest income	586	440	1,091
Interest expense	(37,857)	(38,021)	(40,520)
Loss on repurchases of convertible notes	—	—	(19,085)
Other income (expense), net	(8,174)	(1,542)	(305)
Total interest and other expense, net	(45,445)	(39,123)	(58,819)
Income before income taxes	8,723	72,363	64,780
Income tax benefit (expense)	3,756	7,492	(29,309)
Consolidated net income	$12,479	$79,855	$35,471
Add back net loss attributable to non-controlling interests	$—	$(1,743)	$(1,721)
Net income attributable to NuVasive, Inc.	$12,479	$81,598	$37,192
Net income per share attributable to NuVasive, Inc.:			
Basic	$0.24	$1.60	$0.74
Diluted	$0.24	$1.48	$0.69
Weighted average shares outstanding:			
Basic	51,382	50,874	50,077
Diluted	52,355	55,193	54,102

See accompanying notes to Consolidated Financial Statements.

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NUVASIVE, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Consolidated net income	$12,479	$79,855	$35,471
Other comprehensive (loss) income:			
Unrealized (loss) gain on marketable securities, net of tax	—	(1)	330
Translation adjustments, net of tax	(1,695)	3,699	1,151
Other comprehensive (loss) income:	(1,695)	3,698	1,481
Total consolidated comprehensive income	10,784	83,553	36,952
Net loss attributable to non-controlling interests	—	1,743	1,721
Comprehensive income attributable to NuVasive, Inc.	$10,784	$85,296	$38,673

See accompanying notes to Consolidated Financial Statements.

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NUVASIVE, INC.

CONSOLIDATED STATEMENTS OF EQUITY

(in thousands)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive		Treasury Stock		Total NuVasive, Inc. Stockholders'	Non-Controlling	Total
	Shares	Amount	Capital	Loss	Accumulated Deficit	Shares	Amount	Equity	Interests	Equity
Balance at December 31, 2015	52,616	53	989,387	(12,112)	(104,006)	(3,316)	(161,788)	711,534	7,309	718,843
Adjustment for full retrospective adoption of accounting standard	—	—	—	—	1,625	—	—	1,625	—	1,625
Issuance of common stock under employee and director stock option and purchase plans	2,480	2	60,720	—	—	(1,443)	(76,079)	(15,357)	—	(15,357)
Stock-based compensation expense	—	—	24,981	—	—	—	—	24,981	—	24,981
Tax benefits related to convertible note repurchase	—	—	13,374	—	—	—	—	13,374	—	13,374
Issuance of common stock in connection with royalty milestone achievement	88	—	5,761	—	—	—	—	5,761	—	5,761
Issuance of common stock through conversion of notes payable	1	—	—	—	—	—	—	—	—	—

Sale of warrants	—	—	44,850	—	—	—	—	44,850	—	44,850
Convertible note hedge	—	—	(111,150)	—	—	—	—	(111,150)	—	(111,150)
Equity component of convertible note issuance	—	—	84,784	—	—	—	—	84,784	—	84,784
Equity component of convertible note repurchase	—	—	(100,524)	—	—	—	—	(100,524)	—	(100,524)
Debt issuance costs attributable to convertible feature	—	—	(1,931)	—	—	—	—	(1,931)	—	(1,931)
Securities registration fees	—	—	(14)	—	—	—	—	(14)	—	(14)
Net income attributable to NuVasive, Inc.	—	—	—	—	37,192	—	—	37,192	—	37,192
Net loss attributable to non-controlling interests	—	—	—	—	—	—	—	—	(1,721)	(1,721)
Other comprehensive income	—	—	—	1,481	—	—	—	1,481	—	1,481
Balance at December 31, 2016	55,185	$55	$1,010,238	$(10,631)	$(65,189)	(4,759)	$(237,867)	$696,606	$5,588	$702,194

See accompanying notes to Consolidated Financial Statements.

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NUVASIVE, INC.

CONSOLIDATED STATEMENTS OF EQUITY – (Continued)

(in thousands)

		Accumulated	Total
	Additional	Other	