NUVASIVE INC
Form 10-K
February 09, 2017

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, 2016

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

(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 and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted 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 and post 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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 $3.0 billion as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2016), 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, 2016 have

been excluded in that such persons may be deemed to be affiliates.

As of February 6, 2017, there were 50,599,338 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 2017 Annual Meeting of Stockholders, which will be filed with the U.S. Securities and Exchange Commission not later than 120 days after December 31, 2016.

NuVasive, Inc.

Annual Report on Form 10-K for the Fiscal Year ended December 31, 2016

Table of Contents

1

Table of Contents

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®, CoRoent®, Creative Spine Technology®, DBR®, Embody®, Embrace®, ExtenSure®, Formagraft®, Gradient Plus®, Halo®, iGA™, ILIF®, InStim®, LessRay®, Leverage®, MAGEC®, MAGEC-EOS™, MAS®, MaXcess®, NeoDisc™, Nerve Avoidance Leader™, NuvaMap™, NuvaLine™, NuvaMap™ O.R., NuVasive®, NVM5®, Osteocel®, Precept®, PRECICE®, PROPEL®, Radian®, Reline™, Speed of Innovation®, SpheRx®, The Better Way Back®, Traverse®, Triad®, VuePoint®, 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. Currently, our

marketed product portfolio is focused on applications for spine fusion surgery, including biologics used to aid in the spinal fusion process. For the year ended December 31, 2016, we generated global revenues of $962.1 million, including sales in over 40 countries.

Table of Contents

Our principal product offering includes a minimally-disruptive surgical platform called Maximum Access Surgery, or MAS. The MAS platform 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, NVM5, and Intraoperative Monitoring, or IOM, services and support; 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. In May 2015, we launched Integrated Global Alignment, or iGA, in which products and computer assisted technology under our MAS platform help achieve more precise spinal alignment. Our biologics products, which are used to aid in the spinal fusion process or bone healing process, include allograft (donated human tissue) and synthetic offerings.

We believe our MAS platform and its related offerings 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. 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 nerve monitoring systems, enables an innovative lateral 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 continue to focus significant research and development efforts to expand 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. During 2016, we acquired businesses and technologies to further expand our product and services offerings and drive growth in our business:

- In February 2016, we acquired Ellipse Technologies, Inc., or Ellipse Technologies, which developed and commercialized 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. Following the acquisition, these product offerings are now sold by our NuVasive Specialized Orthopedics division, or NSO.
- In July 2016, we acquired BNN Holdings Corp., which through its subsidiaries and affiliates, owns and operates Biotronic NeuroNetwork, a patient-centric healthcare organization that provides intraoperative neurophysiological monitoring services to surgeons and healthcare facilities across the U.S. Following the acquisition, we combined the service offerings of Biotronic NeuroNetwork with our existing IOM business, Impulse Monitoring, Inc., under the newly created division NuVasive Clinical Services, or NCS.
- In September 2016, we acquired the LessRay software technology suite, which is designed to be integrated into current surgeon workflow and utilizes an algorithm to drive image registration and help surgeons and hospital staff manage radiation exposure using low-dose image quality enhancement. This technology is expected to become an

integral component of our IOM service and MAS platform.

We expect to continue to pursue business and technology acquisitions targets, strategic partnerships and out of the box thinking 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 imaging and navigation.

Table of Contents

Our corporate headquarters is located in San Diego, California where we occupy approximately 154,000 square feet, including a six-suite state-of-the-art cadaver operating theatre designed to accommodate the training of spine surgeons. Our location in Amsterdam, the Netherlands, serves as our international headquarters. Our NSO division is based in Aliso Viejo, California, and our NCS division has corporate offices in Columbia, Maryland and Ann Arbor, Michigan. 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, we have a manufacturing facility located in West Carrollton, Ohio that produces spinal implants. In furtherance of our initiative to increase the amount of products that we self-manufacture, in 2015 we added an approximately 180,000 square foot manufacturing facility in West Carrollton, Ohio. Throughout 2016, we have worked to build out and equip the new facility in order to expand our internal manufacturing efforts, and initial production is underway.

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 that 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, the Company must continue to protect and defend its 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 an exclusive sales force consisting of a mix of directly-employed sales representatives and exclusive sales agents that 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. We believe that continuing to expand the range of such teams will allow us to increase our market share and drive adoption of our products and procedures.
- Provide Tailored Solutions in Response to Surgeon Needs. Responding quickly to the needs of spine surgeons, which we refer to as “Absolute Responsiveness”, is central to our corporate 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 state-of-the-art 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. Absolute Responsiveness goes beyond product development to include active support in all areas, including clinical research and payer relations. We believe that continuing to remain connected and responsive to the collective voices of the surgeon community will allow us to increase our market share and drive adoption of our procedurally-integrated spine solutions.

Table of Contents

- 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 that we believe will keep us on the forefront of innovation and to pursue opportunities that allow us to expand our presence in emerging geographical opportunities. For example, following our acquisition of Ellipse Technologies, we now 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. In addition, with our acquisition of the LessRay software technology suite, we will be able to help surgeons and hospital staff manage radiation exposure, without compromising intra-operative images or visual accuracy. By acquiring complementary products and executing on domestic and international footprint opportunities, like our acquisition of our exclusive distributor in Brazil, we believe we can leverage our expertise at 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.
- 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 nerve monitoring has increased along with the advancement of technologies and techniques used in IOM. We believe our proprietary NVM5 platform is a differentiator in the market and is unique in its ability to provide information about the directionality and proximity of nerves. Following our acquisition of Biotronic NeuroNetwork, we have expanded the scale of our IOM services business and are driving increased utilization of our NVM5 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 that 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). We believe this large population segment will 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 we believe will 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.

Although we believe that the market for procedurally-integrated spine surgery solutions will 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.

Table of Contents

Surgical Alternatives with Less Tissue Disruption

The benefits of minimally invasive surgery 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 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.

We believe the principal factor contributing to spine surgeons' slow adoption of traditional minimally invasive spine 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 movement 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 nerve monitoring 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 assisting in the bone healing process.

Table of Contents

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, and 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 polyetheretherketone, or PEEK. Our CoRoent family of implants, which are made from PEEK, are available in a variety of shapes and sizes to accommodate specific approach, pathology 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.

Nerve Monitoring

Our nerve monitoring 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 the NVM5 platform, 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. 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 nerve monitoring 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 nerve monitoring systems through an instrument already familiar to the surgeon. The system's proprietary software and easy to use graphical user interface allows the surgeon to make critical decisions in real time enabling safer, faster, and more reproducible procedures with the design for improved patient outcomes.

In addition to our MAS platform, our comprehensive procedural solution includes our biologics products, IOM services, and iGA technology.

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. Our synthetic biologics product offerings include Formagraft (collagen-based synthetic bone substitute), AttraX (synthetic bone graft material delivered in putty form), and Propel DBM (highly moldable demineralized bone matrix putty).

Table of Contents

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 nerve monitoring has increased along with the advancement of technologies and techniques used in IOM. We believe that our proprietary NVM5 platform is a differentiator in the market and is unique in its ability to provide information about the directionality and proximity of nerves. 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 three software solutions, NuvaMap, NuvaLine and NuvaMap O.R., 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 interoperative 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 and our Bendini spinal rod bending system.

Following our acquisition of Ellipse Technologies, we now offer products to treat the unmet clinical needs of children who suffer from early onset scoliosis and patients who suffer from limb length discrepancies.

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 early onset scoliosis 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 spinal rods are highly invasive and associated with significant scarring, long recovery times, high infection rates, post-operative pain and impaired mobility as the child heals from surgery. Surgical adjustments to traditional growing rods are typically made every six to nine months to accommodate the growth of the spine. The MAGEC-EOS system is designed to overcome the limitations of conventional adjustable rod treatments for EOS. By enabling non-invasive adjustments, we believe MAGEC-EOS results in lower rates of complications associated with surgical procedures and repetitive exposure to general anesthesia. Our non-invasive adjustment technology enables physicians to perform more frequent adjustments in an 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 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 ERC. 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.

In addition, we intend to continue development on a wide variety of projects intended to broaden surgical applications for greater procedural integration of our MAS techniques and additional applications of the MAGEC technology. Such applications include tumor, trauma, and deformity, as well as increased fixation options and sagittal alignment products. We also expect to continue expanding our other product and services offerings as we execute on our strategy to offer our customers a procedural solution for spine surgery that distinguishes us from traditional spine implant companies.

Table of Contents

Research and Development

Our research and development efforts are primarily focused on developing further enhancements to our existing products and improving and further integrating 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

We believe a spine market shift towards minimally invasive surgery and increases in international access to healthcare will 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. During 2016, we expanded our geographical footprint as part of our focus on increasing our commercial reach outside the United States. We have continued to expand our available product offerings internationally with our acquisition of Ellipse Technologies. Our international revenue, which excludes Puerto Rico, was $130.4 million or 14% of total revenue for the year ended December 31, 2016.

Sales and Marketing

In the United States, we currently sell our procedurally-integrated solutions through a combination of 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 salesforce.

Surgeon Training and Education

We devote significant resources to training and educating surgeons regarding the safety and reproducibility of our MAS surgical techniques and our complementary 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 the XLIF technique and our other MAS platform products including: our proprietary nerve monitoring systems, MaXcess, biologics, and specialized implants.

Manufacturing and Supply

We rely on third parties for the manufacture of a majority of our products, their components and servicing, and we maintain alternative manufacturing sources for a majority of our finished goods products. We also manufacture certain implants internally at our facility in Dayton, Ohio. 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 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. We believe that these types of manufacturing relationships historically have balanced our capital investment, helped control costs and provided manufacturing capacity necessary to compete with larger volume manufacturers of spine surgery products. As our business has continued to scale, we have determined to increase the amount of products that we self-manufacture. In 2015, we added an approximately 180,000 square foot manufacturing facility in West Carrollton, Ohio, in order to expand our internal manufacturing efforts. Throughout 2016, we have worked to build out and equip the new facility and initial production is underway. As we shift to the manufacturing of more of our products in-house, we will look to maintain adequate raw materials suppliers, sourcing alternatives and adequate supply to support our operations.

Our products are inspected, packaged and labeled, as needed, at either our San Diego headquarters or our Memphis distribution 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.

Table of Contents

We currently rely on several tissue banks as our suppliers of allograft tissue implants, including two 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 one, exclusive supplier for PEEK, which comprises many of our CoRoent partial vertebral body replacement and interbody product lines. We also rely on one, exclusive supplier for our NVM5 neuromonitoring system, and rely on one, exclusive supplier for our neuromonitoring equipment that is used outside of the NV platform.

We, and our third-party manufacturers, are subject to the quality system regulations of the U.S. Food and Drug Administration (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 and Implant Sets

For many of our customers, we provide surgical instrumentation sets, including both implants and instruments, as well as our nerve monitoring 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.

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 loan to or place with 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.

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. We believe that 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, 2016, we had over 820 issued and pending patents, including over 360 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;
- Motion preservation products;
- Magnetic technology for non-invasive distraction of an implanted device, including the MAGEC technology platform; and

Table of Contents

- Digital imaging processing technology that generates high resolution images of the surgical field from low resolution scans, including the LessRay technology platform.

Our issued patents begin 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, 2016, we had over 220 trademark registrations in both domestic and foreign regions.

Competition

Competition within the industry is primarily based on technology, innovation, quality, reputation and customer service. We believe that 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, K2M and others. With respect to our nerve monitoring systems, we compete with Medtronic, and Vyaire Medical (formerly VIASYS Healthcare, a division of Becton, Dickinson and Company). Our IOM services business competes with SpecialtyCare and numerous smaller and regional service providers. 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 recently 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'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. There are numerous risks associated with conducting clinical trials, including 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, H2 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.

Table of Contents

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.

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 (PPACA), 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 PPACA - 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 that 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.

Table of Contents

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 agreed to pay $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. 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. 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 31st of a calendar year for the transfers of value incurred for the prior calendar year. This law, along with 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.

Table of Contents

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.

The Japanese government in recent years 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.

Third-Party Reimbursement

Broadly speaking, payer pushback on spine surgery 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 CMS. 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.

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.

Table of Contents

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.

Particularly in the United States where major healthcare reform provisions are scheduled, third-party payers must 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.

We believe that the overall escalating cost of medical products and services has led to, and will 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, 2016, we had a direct and indirect workforce of over 2,200, including approximately 1,900 shareowners. In addition to our shareowners, we partner with exclusive independent sales agencies and independent distributors who sell our products in the United States and internationally. As of December 31, 2016, there are approximately 280 individuals associated with such sales agencies and distributors. 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 2016.

The public can also obtain any documents that we file with the Commission at http://www.sec.gov. The public may read and copy any materials that we file with the Commission at the Commission's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330.

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.

Table of Contents

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. We believe spine surgeons will 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. 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 lateral procedural offerings;
- lack or perceived lack of differentiation among lateral 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.

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 the conduct of clinical investigations or the collection of existing relevant clinical data; and
- obtain the necessary regulatory clearances or approvals for new products or product enhancements.

Table of Contents

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 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 for obsolete inventory, and our results of operations may suffer.

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 nerve monitoring systems, we compete with Medtronic and Vyaire Medical (formerly VIASYS Healthcare, a division of Becton, Dickinson and Company), each of which have significantly greater resources than we do. Our IOM services business competes with Specialty Care and numerous smaller and regional nerve monitoring 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.

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;
- 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.

Changes to 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. We believe that 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.

Table of Contents

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.

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.

If the quality of our products does not meet the expectations of physicians or patients, then our brand and reputation could suffer and our business could be adversely impacted.

In the course of conducting our business, we must adequately address quality 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 issues, we may not be able to eliminate or mitigate occurrences of these issues and associated liabilities. If the quality of our products does not meet the expectations of physicians or patients, then our brand and reputation could suffer and our business could be adversely impacted.

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, which typically does 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.

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, or joint development agreements that may have an adverse effect on our business.

We may pursue transactions, including acquisitions of complementary businesses, technology licensing arrangements 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 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 or joint development agreement. 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 acquisition-related charges, 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.

Table of Contents

In February 2016, we completed the acquisition of Ellipse Technologies for an upfront payment of $380.0 million and a potential milestone payment of $30.0 million payable in 2017 related to the achievement of specific revenue targets. In July 2016, we acquired BNN Holdings Corp., which through its subsidiaries and affiliates, owns and operates Biotronic NeuroNetwork for a purchase price of $98.0 million. Acquisitions, including the acquisitions of Ellipse Technologies and Biotronic NeuroNetwork, 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 the acquired companies, which may require significant attention of the Company's 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 the 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 the 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. In addition, we may face additional risks related to foreign acquisitions. Foreign acquisitions 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.

Healthcare policy changes, including United States healthcare reform legislation signed in 2010, may have a material adverse effect on us.

In March 2010, the Affordable Care Act was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other things, the Affordable Care Act:

- requires certain medical device manufacturers to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, provided that such tax, after going into effect in 2013, has now been suspended until 2018;
- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- establishes an Independent Payment Advisory Board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Table of Contents

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

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

Our IOM services and support business operated though our subsidiary, NuVasive Clinical Services, exposes us to different risks than our other products and technologies. 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. 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 computer 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.

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 agencies, 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 exclusive 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 spine surgeons they serve. If our sales representatives fail to adequately promote, market and sell our products, or fail to develop lasting relationships with spine surgeons, 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.

Table of Contents

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. 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, purchase of equipment or process enhancements may not be successfully implemented.

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.

We rely on a limited number of third-party suppliers and manufacturers to supply and manufacture a majority of our products, and we may not be able to find replacements or immediately transition to alternative suppliers. Many of our key products are manufactured at single locations, with limited alternate facilities. 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. 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. 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.

Table of Contents

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

We currently manufacture a portion of our products at our manufacturing facility in Dayton, Ohio. In 2015, we added an approximately 180,000 square foot manufacturing facility in West Carrollton, Ohio, in order to expand our internal manufacturing efforts and this new facility commenced limited commercial scale production in the fourth quarter of 2016. As part of our business strategy, we intend 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;
- 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.

These risks may be exacerbated by our limited experience with in-house 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.

22

Table of Contents

We face risks associated with our international business.

During the year ended December 31, 2016, $130.4 million or approximately 14% 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 export control 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 regulatory requirements for obtaining clearances or approvals to market our products;
- 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;
- complex data privacy requirements;
- 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; 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.

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, 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.

23

Table of Contents

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, if our international sales increase, we may enter into a greater number of transactions denominated in non-U.S. dollars, which could expose us 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;
- 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; and
- expend time and resources to receive product approvals and clearances to sell and promote products.

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 Company 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.

Cyber security 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 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.

Table of Contents

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. Although our computer and communications hardware is protected through physical and software safeguards, it is still vulnerable to system malfunction, computer viruses, and cyber-attacks. These events could lead to the unauthorized access of our information technology systems and result in 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 and we could lose trade secrets or other confidential information, the occurrence of which could harm 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. A major earthquake, fire or other disaster (such as a major flood, tsunami, or terrorist attack) affecting our 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 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.

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.

Table of Contents

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.

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 international 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.

Table of Contents

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 subject to a purported securities class action lawsuit, shareholder derivative litigation, and various commercial and product liability 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.

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 enf