NUVASIVE INC
Form 10-K
February 25, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2014

OR

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

Commission file number: 000-50744

NUVASIVE, INC.

(Exact name of registrant as specified in its charter)

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

(858) 909-1800

(Registrant’s telephone number, including area code)

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

| Title of Class: | Name of Exchange on which Registered: |
|---|---|
| Common Stock, par value $0.001 per share | The NASDAQ Stock Market LLC (NASDAQ Global Select Market) |

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act of 1933, as amended. YES þ 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 þ

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 þ 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 þ 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 þ | 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 þ

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $1.6 billion as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2014), 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, 2014 have been excluded in that such persons may be deemed to be affiliates.

As of February 23, 2015, there were 48,147,397 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 registrant's definitive Proxy Statement for the Annual Meeting of Stockholders to be held on May 22, 2015 (the "Proxy Statement"). The Proxy Statement will be filed with the U.S. Securities and Exchange Commission not later than 120 days after December 31, 2014.

NuVasive, Inc.

Annual Report on Form 10-K for the Fiscal Year ended December 31, 2014

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PART I

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements that involve risks, uncertainties, assumptions and other factors which, if they do not materialize or prove correct, could cause our results to differ from historical results or those expressed or implied by such forward-looking statements. Many of the forward-looking statements are located in Part I, Item 1 under the heading "Business" and Part II, Item 7 under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report and the documents incorporated by reference to this Annual Report. In some cases, you can identify these forward-looking statements by words like "may", "will", "should", "could", "expect", "plan", "anticipate", "believes", "estima "predicts", "potential", "intends", or "continues" (or other tenses 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. Accordingly, 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 on Form 10-K refers 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, ILIF, InStim, JJB, Leverage, M5, Magnitude, MAS, MaXcess, NeoDisc, Nerve Avoidance Leader, NuVasive, NVJJB, NVM5, Osteocel, Precept, Radian, SOLAS, Speed of Innovation, SpheRx, The Better Way Back, Traverse, Triad, VuePoint, X-Core, XL-TDR, XLIF and XLP, 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 Form 10-K 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.

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Item 1.Business

Overview

We are the third largest global medical device company in the global spine market, focused on developing minimally-disruptive surgical products and procedurally-integrated solutions for the spine. Our currently-marketed product portfolio is focused on applications for spine fusion surgery (including biologics), a combined market estimated to be approximately $9.0 billion globally in 2015. 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 NVJJB, and Intra-Operative Monitoring (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 surgeons access to the spine to perform restorative and fusion procedures in a minimally-disruptive fashion. Our biologic product line offerings used to aid the spinal fusion process or bone healing process include Osteocel Plus® and Osteocel Pro® allograft (donated human tissue) which are cellular matrix products containing viable mesenchymal stem cells (or MSCs), as well as other allograft offerings, FormaGraft® - a collagen synthetic product, and AttraX® - a synthetic bone graft material that is currently available commercially only in select markets outside of the United States. We also offer IOM services for insight into the nervous system during non-spine (in addition to the offerings noted above). We continue to focus significant research and development efforts to expand our MAS product platform and advance the applications of our unique technology into procedurally-integrated surgical solutions. We have dedicated and continue to dedicate significant resources toward training spine surgeons around the world; both those who are new to our MAS product platform as well as previously MAS-trained surgeons attending advanced courses.

We believe our MAS platform and its related offerings provide(s) 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 and 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. 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. Our MaXcess instruments provide access to the spine in a manner that affords direct visualization and our nerve monitoring systems assist surgeons in the detection and navigation of critical nerves. It has been demonstrated clinically that the 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 also have robust product offerings that we continue to expand for procedures in the cervical spine. Our cervical product offering provides a full set of solutions for cervical fusion surgery, including both allograft and CoRoent® implants, as well as cervical plating and posterior fixation products.

Our corporate headquarters is located in San Diego, California. We lease approximately 208,000 square feet in San Diego. Our headquarters has a six-suite state-of-the-art cadaver operating theatre designed to accommodate the training of spine surgeons. During 2014, we committed to a plan to consolidate its offices located in San Diego, California into one corporate headquarters for efficiency purposes. This project is expected to be completed by March 31, 2015. Our location in Amsterdam, the Netherlands was established in 2014 and now serves as our International Headquarters. We have historically maintained a secondary training facility in Paramus, New Jersey, which we expect to depart in 2015. We are now in the process of committing or re-purposing resources to develop regional training facilities and centers for excellence in strategic locations around the globe. Impulse Monitoring, Inc. (Impulse Monitoring), our IOM services and support arm, is located in Columbia, Maryland. 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 Dayton, Ohio that produces spinal implants.

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Our Strategy

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

Establish our MAS Platform as the Standard of Care. We believe our MAS platform has the potential to become the standard of care for spine surgery as hospitals, providers and spine surgeons alike continue to recognize its many benefits and adopt our products and procedures. We also believe that 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. 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. We intend to accomplish our continued product expansion with an unwavering commitment to our MAS platform and extending our core technology. We believe that these additional products will allow us to increase our market share while at the same time improving patient care. Protecting and defending the intellectual property related to our innovative products is also a core component to this strategy.

Expand the Reach of Our Exclusive Sales Force. We believe that 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 shareowners (our employees) 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 shareowners, 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 while 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 have historically maintained a training facility in Paramus, New Jersey which we expect to depart in 2015. We are in the process of committing or re-purposing resources to develop 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 while and drive adoption of our products and procedures.

Selectively License or Acquire Complementary Spine Products and Technologies and Drive our OUS Presence. In addition to building our company through internal product development 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. By acquiring complementary products and executing on international footprint opportunities, 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 Intra-Operative 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 that our proprietary NVJJB and NVM5 platforms are differentiators in the market and are unique in their ability to provide information about the directionality and proximity of nerves. We intend to continue to advance the utility and adoption of such platforms and, accordingly, further our value to our customer base.

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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.

Hundreds of millions of people around the world suffer from some type of back or neck pain. The prescribed treatment 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 that the market for spine surgery procedures 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 that 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. Health care 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 health care treatments.

Although we believe that the market for spine surgery procedures will continue to grow over the long term, economic, political and regulatory influences are subjecting our industry to significant changes that may slow the spine market's growth rate. These changes include pricing pressure from the continued consolidation of our hospital customers and the expansion of group purchasing organizations, unfavorable third-party payer coverage and reimbursement policies, and new and proposed legislation and regulations designed to contain or reduce the cost of healthcare.

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 complications and decreased patient hospitalization periods. At the same time, patients seek procedures that cause less trauma, allow for faster recovery times and result in more favorable clinical outcomes. Despite the patient and doctor demands, the rate of adoption of surgical alternatives

with less tissue disruption procedures has been relatively slow with respect to the spine. Currently, the majority of spine surgery patients are treated with 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 two main reasons: (i) the limited or lack of direct access to and visibility of the surgical anatomy; and (ii) the associated complex instruments that have been required to perform these procedures. Most traditional "minimally invasive" spine 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 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.

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The NuVasive Solution — Maximum Access Surgery with minimal tissue disruption

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 platform is designed to treat a wide range of spinal pathologies while accommodating a surgeon's preferred surgical technique. We believe our products improve 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 MAS platform combines three product categories: our MaXcess retractors, our specialized implants, 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. Each of these offerings is summarized in a bit more detail below. MaXcess also allows surgeons to use well-established traditional instruments in a minimally-disruptive and less traumatic manner while our biologics offerings complement our MAS\ platform by facilitating bone growth and fusion. We also offer a variety of specialized implants that enable the maximization of disc height restoration and sufficient structural support while conforming to the anatomical requirements of the patient.

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.

MAS — Nerve Monitoring

Our nerve monitoring systems utilize electromyography (EMG), 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 and NVJJB platforms, we give surgeons the option to connect their instruments to a computer system that provides discrete, real-time, surgeon directed and surgeon controlled feedback about the directionality and relative proximity of nerves during surgery. Our systems analyze and then translate complex neurophysiologic data into simple, useful information to assist the surgeon's clinical decision-making process. For example, during a pedicle screw test, in which the integrity of the bone is tested where the implant is placed, if the insertion of a screw results in a breach of the bone, the system is designed so that a red light and corresponding numeric value will be displayed to alert the surgeon that the screw may need to be repositioned to avoid potential nerve impingement or irritation. If no breach of the bone occurs, the system is designed so that a green light and corresponding numeric value will result. The health and integrity of the spinal cord and related nerves can also be assessed using motor evoked potentials (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 systems' proprietary software and easy to use graphical user interface enables the surgeon to make critical decisions in real time resulting in safer, faster, and more

reproducible procedures with the design for improved patient outcomes.

Through our IOM subsidiary, Impulse Monitoring, the data from the various nerve monitoring systems, including our own, can be analyzed in real time by healthcare professionals for additional interpretation of intra-operative information. Adding the value of real time healthcare professional oversight further improves the safety and reproducibility of the vast array of our spine procedures.

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MAS — MaXcess

Our MaXcess system integrates nerve monitoring and specialized implants that provide maximum access to the spine with minimal soft tissue disruption. MaXcess has 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 off-the-shelf “minimally invasive” spine surgical systems. MaXcess’ 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 (TLIFs) and posterior lumbar interbody fusions (PLIFs), the thoracolumbar spine for eXtreme Lateral Interbody Fusion (XLIFs), and the thoracic region for tumors and trauma, as well as in adult degenerative scoliosis procedures.

MAS — Specialized Implants and Fixation Systems

We have many implants and fixation devices designed to be used with our MAS platform. These implants are used for interbody disc height restoration for fusion and stabilization of the spine. Our implants 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 systems 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 MaXcess system to provide stabilization of the spine. These systems enable minimally-disruptive placement of implants and are intended to reduce patient morbidity, at times through a single approach.

The following products and services complement our MAS platform:

Biologics

The global biologics market in spine surgery consists of autograft (autologous human tissue), allograft (donated human tissue), a varied offering of synthetic products, stem cell-based products, and growth factors. We currently offer FormaGraft, a collagen-based synthetic bone substitute, and Osteocel Plus and Osteocel Pro, an allograft cellular matrix designed to mimic the biologic profile of autograft that includes endogenous MSCs and osteoprogenitors to aid in fusion. Additionally, we have developed biologics products such as AttraX, a synthetic bone graft material delivered in putty form, to meet the different needs of these international markets. We have successfully commercialized AttraX in several international countries.

Intra-Operative Monitoring Service

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 NVJJB and NVM5 platforms are differentiators in the market and are unique in their ability to provide information about the directionality and proximity of nerves.

Development Projects

We continue development on a wide variety of projects intended to broaden surgical applications for greater procedural integration of our MAS techniques. Such applications include tumor, trauma, and deformity, and increased fixation options, including motion preservation and sagittal alignment products. We also continue expanding our cervical product portfolio to provide for a comprehensive cervical offering that will include further segmentation of both the fixation and motion preservation segments. In biologics, we continue to pursue advancements in our existing product lines as well as new and innovative biologics offerings. Additionally, we intend to focus on integrated product offerings that focus on sagittal alignment.

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. Our research and development group has extensive experience in developing products to treat spine pathologies and 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 and the subsequent hospitalization and rehabilitation times, and - as a result - reduce overall costs to patients and the healthcare system.

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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 products 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 complementary instruments and our implants to our international customers. During 2014, we opened many offices across the world as part of our focus on increasing our commercial footprint in the regions. Among them was the opening of a new office in Amsterdam, the Netherlands, which now serves as our International Headquarters and is a continued investment in its strategic expansion throughout the European market and also European center of excellence for customer services. Additionally, we have continued to expand our available product offerings internationally. Our geographic expansion efforts will enable us to accelerate our global market share position and change patient's lives, not just in the United States, but around the world. Our international revenue, which excludes Puerto Rico, was $94.6 million or 12% of total revenue for the year ended December 31, 2014.

Sales and Marketing

In the United States, we currently sell our products through a combination of exclusive independent sales agencies and directly-employed sales shareowners. 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 shareowner or an independent sales agency 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 shareowners as well as exclusive distributors and independent sales agents. The split between directly-employed sales shareowners and independent sales agents and distributors in our sales force is approximately equal. There are many reasons that we believe strongly in an exclusive sales force, none more important than having a sales force that is properly educated, trained and incentivized to sell and represent only our portfolio of products.

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 and historically our facility in Paramus, New Jersey, which we expect to depart in 2015. We are in the process of committing or re-purposing resources to develop regional training facilities and centers for excellence in strategic locations around the globe. 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. The number of surgeons trained annually includes first-time surgeons new to our MAS product platform as well as surgeons previously trained on our MAS product platform who are attending advanced training programs. The Society of Lateral Access Surgery (SOLAS), Surgeon Education Committee helps direct the continued evolution of our many procedure-related training classes and materials.

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, at our current scale, these types of manufacturing relationships balance our capital investment, help control costs and provide manufacturing capacity necessary to compete with larger volume manufacturers of spine surgery products. As our business continues to scale, we will continue to evaluate this strategy for selective product lines to drive improving profitability and shareholder returns. We anticipate that we will ultimately internally manufacture greater portions of our products and product components as such opportunities arise and when a transition to such capability would be and efficient and appropriate use of capital that aligns with our overall strategy.

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.

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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 (AATB)).

We rely on one, exclusive supplier of polyetheretherketone (PEEK), which comprises our CoRoent PEEK partial vertebral body replacement and interbody product lines. We also rely on one, exclusive supplier for our NVM5 and NVJJB neuromonitoring systems, 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 FDA's quality system regulations, 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.

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 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, 2014, we had 258 issued U.S. patents, 119 foreign national patents, and 252 pending patent applications, including 188 U.S. applications, 2 international (PCT) application and 62 foreign national applications. 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; and
- Motion preservation products.

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.

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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, 2014, we had 213 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 (Medtronic), DePuy/Synthes, a Johnson & Johnson company, Stryker Spine, Globus Medical, Biomet Spine, and Zimmer 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. (Orthofix), Alphatec Spine (Alphatec), Landauer (LDR), K2M and others. We also face competition from physician owned distributorships (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 (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 tissue 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 (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 twelve 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 process before they are marketed. 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 and donor testing and our compliance with those aspects of the Current Good Tissue Practices regulations that regulate those functions are dependent upon the actions of these independent entities.

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

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

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Continuing FDA Regulation

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

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

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

We are also subject to unannounced device inspections by the FDA and the California Food and Drug Branch, as well as other regulatory agencies overseeing the implementation and adherence of applicable state and federal 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.

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. During the second quarter of 2013, we received a federal administrative subpoena from the Office of the Inspector General of the U.S. Department of Health and Human Services (OIG) in connection with an investigation into possible false or otherwise improper claims submitted to Medicare and Medicaid. The subpoena seeks discovery of documents for the period January 2007 through April 2013. We continue to work with the OIG to understand the scope of the subpoena and to provide the requested documents. Responding to the subpoena requires the Company's management team's attention and results in significant legal expense. Any adverse findings related to this investigation could result in material financial penalties against the Company.

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Health Insurance Portability and Accountability Act: Under the Health Insurance Portability and Accountability Act of 1996, as was amended in 2005 and in 2009 (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 (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 and/or our Puerto Rico subsidiary may be 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, including in-kind transfers of value such as free gifts or meals. The Act also provides penalties for non-compliance. The Centers for Medicare and Medicaid Services, or CMS, issued final regulations and the requirement of the collection of payments to physicians began effective August 2013, with the first annual report due March 2014. 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.

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 registration and allowing the CE conformity marking to be applied to certain of our devices under the European Union Medical Device Directive.

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The Japanese government in recent years made revisions to the Pharmaceutical Affairs Law (PAL) 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 PAL requirements prior to placing products on the market: Pre-market Submission (Todokede); Pre-market Certification (Ninsho); and Pre-market Approval (Shonin). NuVasive intends to market devices in Japan that will be 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 Pharmaceutical Affairs Law. Manufacturers must also obtain a manufacturing or import license from the prefectural government prior to importing medical devices. We will also be pursuing authorizations required by the prefectural government.

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 (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.

However, certain carriers, large and small, may have policies significantly limiting coverage of XLIF, Interlaminar Lumbar Interbody Fusion (ILIF), Osteocel Plus and Osteocel Pro, the PCM motion-preserving Cervical Disc System, 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.

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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.

In addition, there is downward pressure on reimbursement for our IOM service offerings. Significant coding changes for IOM services took effect in 2013 in the way of new Current Procedural Terminology (CPT) codes that have led to reduced reimbursement by private payers for the professional remote oversight component of the service. Medicare patients were also subject to additional coding changes imposed by CMS which may restrict access to care and limit Impulse Monitoring's ability to cover, bill and collect for cases performed.

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, 2014, we had approximately 1,500 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. There are approximately 450 individuals associated with such sales agencies and distributors. None of our shareowners are represented by a labor union, and we believe our shareowner 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 2014.

The public can also obtain any documents that we file with the SEC at http://www.sec.gov. The public may read and copy any materials that we file with the SEC at the SEC'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 SEC 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.

Item 1A.Risk Factors

An investment in our common stock involves a high degree of risk. Risk factors which could cause actual results to differ from our expectations and which 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 occurs, 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.

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Risks Related to Our Business and Industry

To be commercially successful, we must convince spine surgeons that our minimally disruptive surgical products are an attractive alternative to our competitors' products for the treatment of spine disorders.

Acceptance of our products by spine surgeons depends on educating and training spine surgeons as to the distinctive characteristics, perceived benefits, safety and cost-effectiveness of our minimally-disruptive surgical products as compared to our competitors' products. Surgeons may be hesitant to change their medical treatment practices for the following reasons, among others:

- lack of 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;
- limited or lack of availability of coverage and reimbursement within healthcare payment systems;
- increased competition in lateral procedural offerings;
- lack of perceived 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 successful in convincing spine surgeons of the merit of our minimally disruptive surgical products, educating them on the use of our products and maintaining their support in the use of our minimally disruptive surgical products, we will be unable to increase our sales and sustain our growth and profitability. Subsequently, if we fail to adequately and continually promote and market our products to spine surgeons or if spine surgeons adopt competing products into their practice, our sales could significantly decrease which could significantly impact our profitability and cash flow.

Additionally, we compete with companies throughout the world, many of which have developed or plan to develop competing products for use in minimally-disruptive surgical spine procedures. Several of our current and potential competitors have substantially greater financial, technical and marketing resources than we do, and they may succeed in developing products that would render our products obsolete or noncompetitive. In addition, these competitors may have significantly greater operating history and patent portfolios than we do in their respective fields. 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 alternatives available for the same purpose. Because of the significant size of the potential market, we anticipate that companies will continue to dedicate significant resources to developing competing products.

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

We have the objective of staying ahead of the spine market by obsoleting our own products with new technologies. It is important to our business that we continue to build upon our product offering to surgeons and hospitals, and enhance the products we currently offer. 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 the rapidly changing spine market. We cannot assure you that we will be able to successfully acquire, develop, obtain regulatory approval for or market new products or that any of our future products or enhancements will be accepted by the surgeons who use our products or the third-party payers who financially support many of the procedures performed with our products. Additionally, in our quest to obsolete our own products, we must effectively manage our inventory, the demand for new and current products and the regulatory process for new products in order to avoid unintended adverse financial and accounting consequences. Additionally, the research and development of many of our new and improved products is vetted by the health care professionals we maintain relationships with. We rely on these professionals to provide us

with considerable knowledge and experience in this regard. If we are unable to maintain our strong relationships with these professionals and continue to receive their advice and input, the development of our products could suffer, which would have a material adverse effect on our business and results of operations.

Additionally, if we do not effectively manage our strategy of obsoleting our own products by acquiring or developing new products or product enhancements that we can introduce in time to meet market demand or if there is insufficient demand for these products or enhancements, or if we do not manage the product transitions well which would result in margin reducing write-offs for obsolete inventory, our results of operations may suffer.

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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 services depend on the availability of adequate reimbursement from third-party payers. We believe that future third-party reimbursement for health care 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 intraoperative monitoring, both in the United States and internationally. The continuing efforts of governmental authorities, insurance companies, and other payers of health care costs to contain or reduce these costs could lead to patients being unable to obtain approval for payment from these third-party payers. Future legislation, regulation or reimbursement policies of third-party payers may adversely affect the demand for our products and services as healthcare providers (such as hospitals that purchase medical devices and services for treatment of their patients) 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.

Certain third-party payers have stated non-coverage decisions concerning our technologies and services and implementation of such decisions could significantly alter our ability to sell our products.

Additionally, there is downward pressure on reimbursement for the IOM services provided by Impulse Monitoring. Significant coding changes for IOM services took effect in 2013. New Current Procedural Terminology (CPT) codes were introduced in 2013 that have led to reduced reimbursement by private payers for the professional remote oversight component of the service. Medicare patients were also subject to additional coding changes imposed by CMS which may restrict access to care and limit Impulse Monitoring’s ability to cover, bill and collect for cases performed.

As we sell our products internationally, market acceptance may depend, in part, upon the availability of reimbursement within respective healthcare payment systems in the markets we compete in. In international markets, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific product lines. The volatilities in these international reimbursement and healthcare payment systems can have a material effect on our ability to achieve financial guidance and our results of operations.

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 this has attracted numerous new companies and technologies, and encouraged more established companies to intensify competitive pressure. New entrants to our markets include numerous niche companies with singular product focus, as well as companies owned partially by spine surgeons (physician-owned distributorships or PODs). PODs can have significant market knowledge and access to the surgeons who use our products. We believe there will be continued pricing pressure as a result of this increased competition. In addition, we may experience decreasing prices for our products due to pricing pressure experienced by our hospital customers from managed care organizations, insurance providers and other third-party payers and increased market power of our hospital customers as the medical device industry consolidates.

If competitive forces drive down the price we are able to charge for some of our products, and we are not able to counter that pressure as we have historically with the rapid introduction of new offerings, our profit margins will shrink, which will hinder our ability to generate profits and cash flow, and, as a result, to invest in and grow our business, including the investment into new and innovative technologies.

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

In recent years, in response to perceived increases in health care costs, there have been and continue to be proposals by the United States federal government, state governments, regulators and third-party payers to control costs and generally reform the United States health care system. Certain of these proposals could limit the acceptance and availability of our products and could therefore have a material adverse effect on our financial position and results of operations.

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In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010. Certain provisions of the law will not be effective for a number of years and there are many programs and requirements for which the details have not yet been fully established, and it is unclear what the full impacts on us will be from the law. The legislation imposes significant new taxes on medical device makers in the form of a 2.3 percent excise tax on all U.S. medical device sales, which commenced in January 2013. Under the new legislation, the total cost to the medical device industry is expected to be approximately $20 billion over the first 10 years of such tax. We continue to expect the tax will have a material and adverse effect on our business and results of operations. The law also focuses on a number of Medicare provisions aimed at improving quality and decreasing costs. It is uncertain what negative unintended consequences these provisions may have on patient access to new technologies. The Medicare provisions include value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the law includes a reduction in the annual rate of inflation for Medicare payments to hospitals that began in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending. We cannot predict what health care programs and regulations will be ultimately implemented at the United States federal or state level, or the effect any future legislation or regulation may have on us. Any changes that lower reimbursement for our products or reduce medical procedure frequency adversely affect our business and results of operations.

We are in a highly competitive market segment that is subject to rapid change and face competition from large, well-established medical device manufacturers as well as new market entrants.

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. With respect to our nerve monitoring systems and IOM services, we compete with Medtronic and VIASYS Healthcare, a division of CareFusion Corporation, which has announced it is being acquired by Becton Dickinson and Company, each of which have significantly greater resources than we do, as well as numerous 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 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 may develop alternative treatments, products or procedures for the treatment of spine disorders that compete directly or indirectly with our products.

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 relations 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 funds available to engage in legal action; and
- greater financial assets, cash flow, capital markets access and other resources for product research and development, sales and marketing, and litigation.

In addition, the spine industry is becoming increasingly crowded with new market entrants, including PODs. Many of these new competitors focus on a specific product or market segment, making it more difficult for us to expand our

overall market position. If these companies are continually successful, we expect that competition will become even more intense, leading to greater pricing pressure and making it more difficult for us to expand.

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

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 POD 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 prevalence of PODs may reduce our market opportunities and may hamper our ability to grow or maintain revenues. In addition, we have seen increasingly aggressive competitive tactics from PODs focused on attracting customers away from us. To the extent these tactics are successful, our revenues may materially suffer.

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If our acquisitions are unsuccessful, our business may be harmed.

As part of our business strategy, we have acquired, and expect to continue to acquire, companies, technologies, and product lines to maintain our objectives of developing or acquiring innovative technologies and expanding our capabilities, increasing revenues, and widening our footprint. Acquisitions involve numerous risks, including the following:

- 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;
- difficulties in retaining key relationships with shareowners (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. For example, we may not be able to successfully integrate an acquired company's operations, business processes, technologies, products and services, information systems and personnel into our business. Acquisitions may also further strain our existing financial and managerial controls, and divert the Company's management team's attention away from our other business concerns.

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

We sell IOM services that are unique from the sale of our biologics, lumbar, thoracic, cervical and motion preservation products and have applications outside of our core business of spinal surgery. Our IOM services involve neurophysiologists who oversee and interpret neurophysiological data gathered via broadband transmission in real-time being located in the operating room and working in partnership with supervising physicians. Providing this service subjects us to malpractice exposure.

Additionally, our ability to deliver our IOM services could be severely affected if we fail to manage our relationships with the supervising physicians and the hospital customers. Any disruption to our technology infrastructure or the Internet could harm our service operations and our reputation among our customers. Any disruption to our computer systems could adversely impact the performance of our neurophysiologists.

Our Impulse Monitoring business also engages in direct billing of Medicare and commercial payers for IOM service 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. The laws that may affect our ability to operate include: (i) the federal healthcare programs Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying

remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare or Medicaid, (ii) federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which bill federal healthcare programs, and/or (iii) state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, many of which differ from their federal counterparts in significant ways, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above 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. The risk of our being found in violation of these laws is increased by the fact that their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert Management’s attention from the operation of our business.

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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 agencies and directly-employed sales shareowners (employees). Our international sales force is comprised of directly-employed sales shareowners as well as exclusive distributors and independent sales agents. 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, our sales could significantly decrease.

We face significant challenges and risks in managing our geographically dispersed distribution network and retaining the individuals who make up that network. For example, in 2012 and 2013, we experienced an increase in sales representatives leaving us (with year-over-year departures holding flat in 2014). If any additional sales representatives were to leave us, our sales could be adversely affected. 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.

If we are unable to recruit, hire and retain skilled and experienced personnel, our ability to effectively manage and expand our business will be harmed.

Our success largely depends on attracting, motivating and retaining executive talent and other key shareowners. Specifically, our performance depends in part on the continued services of many of our current shareowners including members of management and other key personnel who may terminate their employment at any time. Competition for qualified personnel in our industry is significant. The loss of any of our senior management team could harm our business and the announcement of the loss of one of our key employees could negatively affect our stock price. Our ability to retain our skilled workforce and our success in attracting and hiring new skilled employees will be a critical factor in determining whether we will be successful in the future. We face challenges in hiring, training, managing and retaining employees in certain areas including clinical, technical, sales and marketing. This could delay new product development and commercialization and hinder our marketing and sales efforts, which would adversely impact our competitiveness and financial results.

Sales to customers outside the United States have accounted for a large portion of our revenues, which exposes us to risks inherent in international sales.

As a key component of our business strategy to develop new markets, we intend to continue to expand our international sales, but success cannot be assured. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subject us to extensive U.S. and foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and we are subject to penalties for non-compliance. Other laws and regulations that can significantly affect us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act (FCPA), and anti-boycott laws. 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. 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.

Additionally, 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. Should the U.S. dollar strengthen, our products may become more expensive for our international customers, and as a result, our results of operations and net cash flows from international operations may be adversely affected, especially if international sales continue to grow as a percentage of our total sales. Accordingly, fluctuations in the rate of exchange between the United States dollar and foreign currencies, primarily the pound sterling the euro, the Australian dollar and the yen, could adversely affect our financial results, including our revenues, revenue growth rates, gross margins, income and losses as well as assets and liabilities.

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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 shareowners as well as distributors and independent 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 the 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 revenues 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 growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

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

We rely on third-party suppliers and manufacturers to supply and manufacture a majority of our products. To be successful, our contract manufacturers must be able 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. Among other factors, our anticipated growth could strain the ability of suppliers to deliver an increasingly large supply of products, materials and components. If we are unable to obtain sufficient quantities of high quality components to meet customer demand on a timely basis, we could lose customers, our reputation may be harmed and our business could suffer.

We currently use one or two manufacturers (respectively) for many of our devices, biologics, and components. Our dependence on one or two manufacturers for each such product line involves several risks, including limited control over pricing, availability, quality and delivery schedules. If any one or more of our manufacturers cease to provide us

with sufficient quantities of our components in a timely manner or on terms acceptable to us, cease to manufacture components of acceptable quality or cease to do business in general, we would have to seek alternative sources of manufacturing. We could incur delays while we locate and engage alternative qualified suppliers and we might be unable to engage alternative suppliers on favorable terms. Any such disruption or increased expenses could harm our commercialization efforts and adversely affect our ability to generate revenue. In the event we experience delays, shortages, or stoppages of supply with any supplier, we would be forced to locate a suitable alternative supplier which could take significant time and result in significant expense. Any inability to meet our customers' demands for these products could lead to decreased sales and harm our reputation and result in the loss of customers to our competitors, which could cause the market price of our common stock to decline.

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

In May 2013, we acquired a spine implant manufacturer based in Dayton, Ohio and currently manufacture a portion of our products at this facility. 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 owned manufacturing facilities and those of our third party suppliers, such as:

·defects in product components that we source from third-party suppliers;
·failing to increase production of products to meet demand;