

NUVASIVE INC
Form 10-K
February 25, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 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	(I.R.S. Employer
incorporation or organization)	Identification No.)

7475 Lusk Boulevard,	92121
San Diego, California	(Zip Code)

(Address of principal executive offices)

(858) 909-1800

(Registrant's telephone number, including area code)

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act of 1933, as amended. YES NO

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$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”, “estimates”, “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: