NUVASIVE INC
Form 10-K
February 27, 2012
Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2011

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**
(Address of principal executive offices)	*(Zip Code)*

Registrant s telephone number, including area code:

(858) 909-1800

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

Title of Each Class:	Name of Each Exchange on which Registered:
Common Stock, par value $0.001 per share	**The NASDAQ 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 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 $1.3 billion as of the last business day of the registrant s most recently completed second fiscal quarter (i.e. June 30, 2011), 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 have been excluded in that such persons may be deemed to be affiliates.

As of February 17, 2012, there were 42,653,363 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 the registrant s definitive Proxy Statement for the Annual Meeting of Stockholders to be held on May 24, 2012.

Table of Contents

NuVasive, Inc.

Form 10-K for the Fiscal Year ended December 31, 2011

Table of Contents

PART I

This Annual Report on Form 10-K, particularly in Item 1. Business and Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations, and the documents incorporated by reference, include forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including, but not limited to, statements regarding our future financial position, business strategy and plans and objectives of management for future operations. When used in this Annual Report, the words believe, may, could, will, estimate, continue, anticipate, intend, expect, and similar expressions are intended to identify forward-looking sta

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to certain risks and uncertainties that could cause our actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this report, and in particular, the risks discussed under the heading Risk Factors and those discussed in other documents we file with the Securities and Exchange Commission. Except as required by law, we do not intend to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report and in the documents incorporated in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, readers are cautioned not to place undue reliance on such forward-looking statements.

Item 1. ***Business.***

Overview

We are a medical device company focused on developing minimally disruptive surgical products and procedures for the spine. Our currently-marketed product portfolio is focused on applications for spine fusion surgery, including biologics, a combined market estimated to exceed $8.0 billion globally in 2012. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS®, as well as an offering of biologics, cervical, motion preservation products, and Intra-Operative Monitoring (IOM) services. Our spine surgery product line offerings, which include products for the thoracolumbar spine, the cervical spine, and a set of motion preservation product offerings still under development, are primarily used to enable access to the spine and to perform restorative and fusion procedures in a minimally disruptive fashion. Our biologic product line offerings include allograft, (donated human tissue) Triad®, and Osteocel Plus®, an allograft cellular matrix containing viable mesenchymal stem cells, or MSCs, FormaGraft®, a collagen synthetic product used to aid the fusion process, and AttraX®, a synthetic bone graft material, which is still in the process of U.S. regulatory clearance, to aid in spinal fusion. Our recently acquired subsidiary, Impulse Monitoring, Inc. (Impulse Monitoring) provides IOM services for insight into the nervous system during spine and other surgeries. 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 dedicate significant resources toward training spine surgeons on our unique technology and products. We continue to train surgeons who are new to our MAS product platform as well as surgeons previously trained on our MAS product platform who are attending advanced training programs.

We believe our MAS platform provides a unique and comprehensive solution for safe and reproducible minimally disruptive surgical treatment of spine disorders by enabling surgeons to access the spine in a manner

Table of Contents

that affords direct visualization and avoidance of critical nerves. The fundamental difference between our MAS platform and what has been previously called MIS, or minimally invasive surgery, 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. Simply stated, the MAS platform does not force surgeons to reinvent approaches that add complexity and undermine safety, ease and efficacy. For our Company, an important ongoing objective has been to maintain a leading position in access and nerve avoidance, as well as to pioneer and remain the ongoing leader in lateral 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 allow surgeons to avoid 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.

In recent years, we have significantly expanded our product offering relating to procedures in the cervical spine as well as in the area of biologics. Our cervical product offering now 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. In the first quarter of 2010, we submitted a premarket approval (PMA) application to the U.S. Food and Drug Administration (the FDA) for approval of the PCM® cervical disc system, a motion preserving total disc replacement device. Approval, if obtained, would further strengthen our cervical product offering and should enable us to continue our trend of increasing our market share. Our biologic offering includes FormaGraft, a collagen synthetic bone substitute, and Osteocel Plus, an allograft cellular matrix designed to mimic the biologic profile of autograft that includes endogenous MSCs and osteoprogenitors, both of which are used to aid in spinal fusion. In addition, we are currently in the process of seeking U.S. regulatory clearance for AttraX™, a synthetic bone graft material delivered in putty form, to aid in the healing and generation of human bone. Our nerve monitoring offering includes the NVM5 and NVJJB products based on our proprietary software-driven nerve monitoring systems. In October 2011, to establish our initial footprint in the services business, we acquired Impulse Monitoring, a company dedicated to providing IOM services.

Our corporate headquarters are 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. In 2010 we opened a secondary training facility in Paramus, New Jersey with a five-suite operating theatre for surgeon training. Our IOM business, Impulse Monitoring, is headquartered in Columbia, Maryland. Our primary distribution and warehousing operations are located in our facility in Memphis, Tennessee. Our business requires rapid delivery of products and surgical instruments for almost all surgeries involving our products. Because of its location and proximity to overnight third-party transporters, our Memphis facility has greatly enhanced our ability to meet demanding delivery schedules and provide a greater level of customer service.

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 spine surgeons continue to recognize its benefits and adopt our products. 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 and their patients on the clinical benefits of our products, and we intend to capitalize on the growing demand for minimally disruptive surgical procedures.

Table of Contents

Continue to Develop and Introduce New Innovative Products. One of our core competencies is our ability to 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 several additional products currently under development that should expand our presence in fusion surgery as well as provide an entry into the motion preservation market segment. We intend to accomplish our continued product expansion with an unwavering commitment to our MAS platform and building on 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 spine surgery 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 exclusive distributors within their respective territory.

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 two state-of-the-art cadaver operating theatres (in San Diego, California and Paramus, New Jersey) to provide clinical training and validate new ideas through prototype testing. Absolute Responsiveness goes beyond product development to include active support in clinical research and payer relations. For example, to ensure that patients have access to optimal spine care, we offer support to spine surgeons in their efforts to educate payers on the proven clinical benefits of fusion surgery for well selected patients.

Selectively License or Acquire Complementary Spine Products and Technologies. 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. By acquiring complementary products, we believe we can leverage our expertise at bringing new products to market that are intended to improve patient outcomes, simplify techniques, reduce hospitalization and rehabilitation times and, as a result, reduce overall costs to the healthcare system.

Provide Intra-Operative Monitoring Capabilities. Monitoring the health of the nervous system during spinal surgery has been a key component of NuVasive s strategy of product differentiation since early in the company s 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. With our October 2011 acquisition of Impulse Monitoring, we believe we can further leverage our platform of nerve monitoring and uniquely meet the demands of our surgeon and hospital customers by offering best in class products and IOM services.

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 (used herein to define 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

Table of Contents

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.

In the United States, millions of people suffer from some type of chronic 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 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 implant market for spine surgery procedures will continue to grow over the long term because of the following market dynamics:

Demand for Surgical Alternatives with Less Tissue Disruption. As with other surgical markets, we anticipate that the broader acceptance of surgical treatments with less tissue disruption and patient trauma will result in increased demand.

Increasing Demand for Motion-preserving Treatments. Motion preservation may be advantageous when compared to traditional treatments because preserving motion has the potential to avoid acceleration of the natural degeneration of the spine and thereby may become a more attractive earlier intervention option for patients in the degenerative disease process.

Favorable 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 population segment will increasingly demand a quicker return to activities of daily living following surgery than prior generations.

Increased Use of Implants. The use of implants has evolved into the standard of care in spine surgery. There continues to be an increase in the percentage of spine fusion surgeries using implants and we estimate that over 85% of all spine fusion surgeries now involve implants.

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 hospitalization. At the same time, patients seek procedures that cause less trauma, allow for faster recovery times and more positive clinical outcomes. Despite these benefits, the rate of adoption of surgical alternatives with less tissue disruption procedures has been relatively slow with respect to the spine.

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 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.

Table of Contents

The NuVasive Solution Maximum Access Surgery with minimal tissue disruption

Our MAS platform allows surgeons to perform a wide range of minimally disruptive procedures, while overcoming the shortcomings of traditional minimally invasive spine surgical techniques. We believe our products improve clinical results and have both the potential to expand the number of minimally disruptive procedures performed and become the standard of care in spine fusion and non-fusion surgery.

Our MAS platform combines four product categories: our nerve monitoring systems, MaXcess, biologics and specialized implants. Our nerve monitoring systems enable surgeons to detect and navigate around nerves while MaXcess affords direct customized access to the spine for implant delivery. MaXcess also allows surgeons to use well-established traditional instruments in a minimally disruptive and less traumatic manner while our biologics offering complements our MAS platform by facilitating 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;
- Decompression, which is removal of a portion of bone or disc from over or under the nerve root to relieve pinching of the nerve; and
- Procedures designed to correct and/or stabilize the spine while simultaneously maintaining motion.

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 where the implant is placed is tested, if the insertion of a screw results in a breach of the bone, a red light and corresponding numeric value will result so that the surgeon may reposition the screw to avoid potential nerve impingement or irritation. If no breach of the bone occurs, a green light and corresponding numeric value will result.

Surgeons can connect their instruments to our nerve monitoring systems, thus creating an interactive set of instruments that enable the safe navigation through the body s nerve anatomy. 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 and faster procedures with the potential for improved patient outcomes. With recent additions, 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 methods of IOM involve applying stimulation and recording the response that must travel along the motor or sensory paths of the spinal cord.

Table of Contents

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.

MAS MaXcess

Our MaXcess system consists of instrumentation, integrated 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 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 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. Our MaXcess products are used in the cervical spine for posterior application, the lumbar spine for both decompressions and transforaminal lumbar interbody fusions (TLIFs), the thoracic region, as the lateral approach has broadened from the lumbar to the thoracic region, as well as in adult degenerative scoliosis procedures.

MAS Specialized Implants

We have a number of implants 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 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, often through a single approach.

We have also made significant progress in the last few years on our research and development initiatives related to motion preservation, including our PCM and mechanical lateral total disc replacement (XL TDR®) products. The status of our regulatory applications with the FDA related to our motion preservation products is discussed below under the heading Development Projects.

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, an allograft cellular matrix designed to mimic the biologic profile of autograft that includes endogenous MCSs and osteoprogenitors to aid in fusion. We are also in the process of seeking U.S. regulatory clearance for AttraX, a synthetic bone graft material delivered in putty form.

Intra-Operative Monitoring Service

Monitoring the health of the nervous system during spinal surgery has been a key component of NuVasive s strategy of product differentiation since early in the company s development. Over time surgeon and hospital

Table of Contents

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. With our October 2011 acquisition of Impulse Monitoring, we believe we can further leverage our platform of nerve monitoring and uniquely meet the demands of our surgeon and hospital customers by offering best in class products and IOM services.

Development Projects

We are developing proprietary total disc replacement devices for lateral lumbar spine applications and separately for cervical spine applications. These devices are intended to allow surgeons to address a patient s pain and dysfunction while maintaining a more natural physiological range of motion compared with fusion. Commercialization of these devices, including PCM and XL TDR, will require premarket approval rather than 510(k) clearance. In the cervical spine, the PCM investigational device, a total disc replacement device designed to preserve motion, was submitted for FDA approval in the first quarter of 2010. If obtained, approval of PCM should further strengthen our cervical product offering and should enable us to continue our trend of gaining market share.

Our lumbar motion preservation development efforts include XL TDR, a mechanical total disc replacement implanted through the XLIF approach. Enrollment in a FDA-approved XL TDR clinical trial in the United States was initiated in 2009 and will continue throughout 2012.

In addition to the motion preservation platforms previously mentioned, we continue development on a wide variety of projects intended to broaden surgical applications such as with tumor, trauma, and deformity, and increase fixation options for greater vertical integration of our MAS techniques. 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 markets.

We are no longer pursuing regulatory approval to commercialize NeoDisc®, our embroidery cervical disc replacement device, in the U.S.

Research and Development

Our research and development efforts are primarily focused on developing further enhancements to our existing products, launching new product categories, as well as developing our total disc replacement products. 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 that are intended to improve patient outcomes, simplify techniques, reduce patient trauma and the subsequent hospitalization and rehabilitation times and, as a result, reduce costs to the healthcare system. In addition to this work, NuVasive is the sole financial supporter of the Society of Lateral Access Surgeons (SOLAS®), a group of spine surgeons dedicated to the development and expanded application of lateral spine surgery techniques, to collect and assess data to affirm economic and clinical value.

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 U.S. 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 exclusive distributor is made on a territory by territory basis, with a focus on the candidate who brings the best skills and experience. Domestically, the split between directly-employed sales shareowners and independent sales agents in our sales force is roughly equal. Our international sales force is comprised of directly-employed sales shareowners as well

Table of Contents

as exclusive distributors and independent sales agents. 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 surgical techniques and our complimentary instruments and implants. We maintain state-of-the-art cadaver operating rooms and training facilities to help promote adoption of our products at our corporate headquarters in San Diego, California and our facility in Paramus, New Jersey. We continue to train surgeons in 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. As its sole financial supporter, we have also helped to establish SOLAS, a group of spine surgeons dedicated to the development and expanded application of lateral spine surgery techniques that offer significant patient benefits and improved clinical outcomes through peer-to-peer communication, clinical education efforts, and ongoing research.

Manufacturing and Supply

We rely on third parties for the manufacture of our products, their components and servicing. We currently maintain alternative manufacturing sources for a majority of our finished goods products. We have and are in the process of identifying and qualifying additional suppliers, on a per product basis, for our highest volume products to maintain consistent supply to our customers. Our outsourcing strategy is targeted at companies that meet FDA, International Organization for Standardization, or ISO, and quality standards supported by internal policies and procedures. Supplier performance is maintained and managed through a supplier qualification and corrective action program intended to ensure that all product requirements are met or exceeded. We believe at our current scale these manufacturing relationships minimize our capital investment, help control costs, and allow us to compete with larger volume manufacturers of spine surgery products.

Following the receipt of products or product components from our third-party manufacturers, we conduct inspection, packaging and labeling, as needed, at either our San Diego headquarters or our Memphis distribution facility. Under our existing contracts, we reserve the exclusive right to inspect and assure conformance of each product and product component to our specifications. In the future, we may consider manufacturing certain products or product components internally, if and when demand or quality requirements make it economic or appropriate to do so.

We currently rely on several tissue banks as our suppliers of allograft tissue implants. We rely on one source to supply us with Osteocel Plus, which is processed from allograft. 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 regulation, state requirements, as well as voluntary industry standards such as the American Association of Tissue Banks, or AATB.

We rely on one exclusive supplier of polyetheretherketone (PEEK), which comprises our CoRoent PEEK partial vertebral body replacement and interbody product lines. We have an exclusive supply arrangement to supply our NVM5 and NVJJB neuromonitoring systems, and an exclusive supply arrangement to supply our neuromonitoring equipment outside of the NV platform. We rely on a limited number of suppliers for our motion preserving total disc replacement device PCM.

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

Table of Contents

regulations promulgated by 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 Compliance. Our facility 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 and corresponding state agencies.

Surgical Instrument Sets

We seek to deliver surgical instrument sets, including our nerve monitoring systems, on a just in time basis to fulfill our customer obligations to meet surgery schedules. We do not receive separate economic value specific to the surgical instrument sets from the surgeons or hospitals that utilize them. In most cases, once the surgery is finished, the surgical instrument sets are returned to us and we prepare them for shipment to meet future surgeries. This strategy is designed to minimize backlogs, increase asset turns and maximize cash flow. Our pool of surgical equipment that we loan to or place with hospitals continues to increase as we expand our distribution channels and increase market penetration of our products. These surgical instrument sets are important to the growth of our business and we anticipate additional investments in our loaner assets.

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 during the work day, 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, 2011, we had 110 issued U.S. patents, 58 foreign national patents, and 318 pending patent applications, including 252 U.S. applications, 7 international (PCT) applications and 59 foreign national applications. Our issued and pending patents cover, among other things:

- MAS surgical access and spine systems;
- Neurophysiology enabled instrumentation and methodology, including pedicle screw test systems, software hunting algorithms, navigated guidance, and surgical access systems;
- Implants and related instrumentation and targeting systems;
- Biologics, including Osteocel Plus and Formagraft; 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.

We have undertaken to protect our neurophysiology platform, including our proprietary nerve monitoring systems, through a comprehensive strategy covering various important aspects of our neurophysiology-enabled instrumentation, including, screw test, software hunting algorithms, navigated guidance, surgical access and related methodology. We have also undertaken to protect our XLIF surgical technique franchise,

including methodology, implants, and systems used during XLIF procedures.

Table of Contents

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 take 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, 2011, we had 195 trademark registrations, both domestic and foreign, including the following U.S. trademarks: $ Billion Start-Up, Absolute Responsiveness, Acuity, Affix, Armada, Attrax, Back Pact, Bendini, Better Back Alliance, Brigade, CerPass, CoRoent, Corpomotion, Creative Spine Technology, DBR, Embody, Embrace, ExtenSure, FormaGraft, Gradient Plus, Halo, InStim, I-PAS, Leverage, M5, MAS, MaXcess, NeoDisc, Nerve Avoidance Leader, NeuroVision, NuVasive, NVJJB, Osteocel, PCM, SmartPlate, SOLAS, SpheRx, The Better Way Back, Traverse, Triad, VuePoint, X-Core, XL TDR, XLIF and XLP. We also had 13 trademark applications pending, both domestic and foreign, including the following trademarks: EasyScreen, H2, Helix, ILIF, Radian, NVJJB, Osteocel, SOLAS, Speed of Innovation, Traverse, and Precept.

Included in the count above are two registered trademarks for NeuroVision which, in 2010, as a result of a jury verdict delivered against us, the U.S. District Court for the Central District of California ordered, among other things, cancellation of these two registered trademarks. We continue to believe that the verdict and judgment delivered against us in this case are not supported by the facts or by applicable law and have filed an appeal.

Competition

We are aware of a number of major medical device companies that have developed or plan to develop products for use in surgical alternatives with less tissue disruption to compete with us.

Our currently marketed products are, and any future products we commercialize will be, subject to intense competition. 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 reputations 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 size of the potential market, we anticipate that companies will continue to dedicate significant resources to developing competing products. Below are our primary competitors grouped by our product categories.

Our nerve monitoring products compete with the traditional nerve monitoring systems offered by Medtronic Sofamor Danek (Medtronic), Natus, Cadwell Laboratories, and VIASYS Healthcare, a division of CareFusion Corporation. We believe our technology competes favorably with these systems on ease of use for the spine surgeon, with the added advantage that our nerve monitoring systems were designed to support surgeon directed, surgeon controlled applications delivering automated, real-time feedback about the directionality and relative proximity of nerves. Medtronic s NIM-Eclipse neuromonitoring system, acquired from Axon, while surgeon directed, requires manual interpretation for neuromonitoring. Our IOM service offering competes with regional IOM companies as well as in-house hospital services.

Table of Contents

Several companies offer products that compete with our MaXcess system, SpheRx pedicle screw system and implants, including competitive offerings by DePuy Spine, Inc. (Depuy), a Johnson & Johnson company, Medtronic and Stryker Spine.

Competition is intense in the fusion product market. We believe that our most significant competitors are Medtronic, DePuy, Stryker Spine and Synthes, Inc. (who has entered into a definitive agreement to be acquired by Johnson & Johnson), each of which has substantially greater sales and financial resources than we do. Medtronic, in particular, has a broad classic fusion product line. We believe our differentiation in the market is an innovative portfolio of products elegantly delivered through our MaXcess system, as well as through our XLIF approach, complemented by additional innovative and pull-though products along the entirety of the spine. However, with the introduction of competing lateral techniques, such as Medtronic s DLIF, we face more competition in the market.

Competition in the motion preservation segment is increasing, with Medtronic, DePuy, Stryker Spine and Synthes, Inc. all investing in this rapidly growing market. In the cervical total disc replacement (TDR) segment, our PCM device, which was submitted for FDA approval in the first quarter of 2010, if approved, will face competition from several products that received FDA approval in 2007 including Medtronic s Prestige and Bryan TDRs as well as Synthes, Inc. s ProDisc-C TDR.

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 specified markets, include Globus Medical, Inc., Zimmer Spine, Orthofix International N.V. (Orthofix), Biomet EBI/Spine, Alphatec Spine, Inc. (Alphatec), K2M, Inc. and others.

Competition in the biologics market is increasing as well. In addition to our larger competitors, which are investing in their biologics platforms, we face competition from smaller orthobiologics companies such as Orthofix, Alphatec, Nutech Medical, Inc., and the Musculoskelatal Transplant Foundation.

Government Regulation

Our products are medical devices and tissue subject to extensive regulation by the FDA and other regulatory bodies. FDA regulations govern, among other things, the following activities that we or our partners perform and will continue to perform:

- product design and development;
- product testing;
- product manufacturing;
- product labeling;
- product storage;
- premarket clearance or approval;
- advertising and promotion; and
- product sales and distribution.

FDA s Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device we develop to commercially distribute in the United States will require either prior 510(k) clearance or prior premarket approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk are placed in either class I or II, which requires the manufacturer to submit to the FDA a premarket notification requesting permission for

Table of Contents

commercial distribution. This process is known as 510(k) clearance. Some low risk devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device are placed in class III, requiring premarket approval.

510(k) Clearance Pathway

To obtain 510(k) clearance, a premarket notification must be submitted demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of premarket approval applications. The FDA s 510(k) clearance pathway usually takes from three to twelve months from the date the application is completed, but it can take significantly longer.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require premarket approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer s determination. If the FDA disagrees with a manufacturer s determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. If the FDA requires us to seek 510(k) clearance or premarket approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties. We have made and plan to continue to make additional product enhancements that we believe do not require new 510(k) clearances.

Premarket Approval (PMA) Pathway

A PMA application must be submitted if the device cannot be cleared through the 510(k) process. A PMA application must be supported by extensive data including, but not limited to, technical information, preclinical data, clinical trial data, manufacturing data and labeling to demonstrate, to the FDA s satisfaction, the safety and efficacy of the device for its intended use. Once a complete PMA application is submitted, the FDA begins an in-depth review which generally takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. New PMAs or PMA supplements are required for significant modifications to the manufacturing process, labeling or design of a device that is approved through the PMA process. A PMA supplement often requires submission of the same type of information as an original PMA application, except that a supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

Human Cell, Tissue, and Cellular and Tissue Based Products

Our allograft implant products, Triad, H2 and ExtenSure, and our Osteocel Plus products are regulated by the FDA as Human Cell, Tissue, and Cellular and Tissue Based Products. FDA regulations do not currently require products regulated as minimally manipulated human tissue-based products to be 510(k) cleared or PMA approved before they are marketed. We are, however, required to register our establishment, list these products with the FDA and comply with Current Good Tissue Practices for Human Cell, Tissue, and Cellular and Tissue Based Product Establishments. The FDA periodically inspects tissue processors to determine compliance with these requirements. Violations of applicable regulations noted by the FDA during facility inspections could adversely affect the continued marketing of our products. We believe we comply with all aspects of the Current Good Tissue Practices, although there can be no assurance that we will comply, or will comply on a timely basis,

Table of Contents

in the future. 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 U.S. federal law pursuant to the National Organ Transplant Act, or NOTA, a criminal statute which prohibits the purchase and sale of human organs used in human transplantation, including bone and related tissue, for valuable consideration. 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 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.

Clinical Trials

A clinical trial is almost always required to support a PMA application and is sometimes required for a 510(k) premarket notification. These trials generally require approval of a submitted application for an investigational device exemption Investigational Device Exemption (IDE) to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to evaluate the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the responsible institutional review boards. Future clinical trials of our motion preservation designs will likely require that we obtain IDEs from the FDA prior to commencing clinical trials. We filed with the FDA for an IDE on the XL TDR, and were granted an IDE in 2008. Our clinical trials must be conducted in accordance with FDA regulations and other federal regulations concerning human subject protection and privacy and must be publicly registered. The results of our clinical trials may not be sufficient to obtain approval of our product. There are numerous risks associated with conducting such a clinical trial, including the high costs and uncertain outcomes. For a complete discussion of these risks, please see the Risk Factors section of this Annual Report.

Pervasive and Continuing FDA Regulation

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

- quality system regulation, which requires manufacturers to follow design, testing, process control, and other quality assurance procedures;
- labeling regulations, which prohibit the promotion of products for unapproved or off-label uses and impose other restrictions on labeling; and
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- fines, injunctions, and civil penalties;

recall or seizure of our products;

Table of Contents

operating restrictions, partial suspension or total shutdown of production;

refusing our request for 510(k) clearance or premarket approval of new products;

withdrawing 510(k) clearance or premarket approvals that are already granted; and

criminal prosecution.

We are 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 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. 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. The federal government and all states in which we currently operate regulate various aspects of our business. Failure to comply with these laws could adversely affect our ability to receive reimbursement for our services and subject us and our officers and agents to civil and criminal penalties.

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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or PPACA, knowledge of the anti-kickback statute or the specific intent to violate the law is not required. 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.