NUVASIVE INC
Form 10-K
February 27, 2013
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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, 2012
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 $1.1 billion as of the last business day of the registrant's most recently completed second fiscal quarter (i.e. June 30, 2012), 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 15, 2013, there were 44,032,705 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 23, 2013.

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NuVasive, Inc.
Form 10-K for the Fiscal Year ended December 31, 2012

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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 expre intended to identify forward-looking statements.

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 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 exceed $8.2 billion globally in 2013. 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 reproducible outcomes for the surgeon and the patient. The platform includes a proprietary software-driven nerve detection and avoidance systems, NVM5 and NVJJB, and Intra-Operative Monitoring (IOM) support; MaXcess®, a unique and integrated split-blade retractor system; and a wide variety of specialized implants. When the three elements of MAS are used together, they may significantly reduce surgery time and return patients to activities of daily living much faster than conventional approaches. The individual components of our MAS platform, and many of our products, can also be used in open or traditional spine surgery and may independently offer patient benefits to various surgical approaches dealing with a wide variety of pathologies. Our spine surgery product line offerings, which include products for the thoracolumbar and the cervical spine, 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), FormaGraft®, a collagen synthetic product, Osteocel Plus®, an allograft cellular matrix containing viable mesenchymal stem cells, or MSCs, and AttraX®, a synthetic bone graft material, which is still in the process of U.S. regulatory clearance, all used to aid the spinal fusion process. Our 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 courses.

We believe our MAS platform, and its related offerings, provides 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 direct visualization and detection 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. Accordingly, the MAS platform does not force surgeons to reinvent or learn new approaches that add complexity and undermine safety, ease and 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 less invasive spine surgery. Our MAS platform, with the unique advantages provided by our nerve monitoring

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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 may 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 and services offerings relating to procedures in the cervical spine as well as in the area of intraoperative monitoring. 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 fourth quarter of 2012, we received U.S. Food and Drug Administration (the FDA) approv

al of the PCM® device, a motion preserving total disc replacement device, which further strengthens our cervical product offering and enables us to continue our trend of increasing our market share. Our nerve monitoring offering includes both the NVM5 and NVJJB products based on our proprietary software-driven nerve monitoring systems and our IOM services business, Impulse Monitoring.

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. We also maintain 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 is facilitated by 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 enhances 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.
- 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 several additional products 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 improve 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.
- 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 all areas, including clinical research

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and payer relations. For example, to ensure that patients have access to optimal spine care, we offer education 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 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. 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 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 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 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 fusion or conservative 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.

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 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.

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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.

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 MAS platform is designed to treat a wide range of spinal pathologies while accommodating a surgeon's preferred surgical technique and is not limited to a single approach. We believe our products improve clinical results and have both the potential to expand the number of minimally disruptive procedures performed and 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 nerve monitoring systems, MaXcess 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 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 result so that the surgeon may reposition the screw 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.

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. 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, more reproducible 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.

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

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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 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 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 and anterior retraction, the lumbar spine for decompressions, transforaminal lumbar interbody fusions (TLIFs) and posterior lumbar interbody fusions (PLIFs), and the thoracic region, as the MAS 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, possibly 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, an allograft cellular matrix designed to mimic the biologic profile of autograft that includes endogenous MSCs 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, which we have successfully commercialized 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. 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 will require premarket approval rather than 510(k) clearance. In the cervical spine, the PCM device was approved by the FDA in the fourth quarter of 2012.

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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 a premarket approval will be required before commercialization may occur in the U.S.

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 procedural 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. In biologics, we continue to pursue advancements in our existing product lines as well as new and innovative biologics offerings.

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 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 Surgery (SOLAS®), a group of spine surgeons dedicated to studying the clinical effectiveness of lateral spine surgery techniques, and to collecting and assessing data to determine 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 independent sales agencies 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 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 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 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. The SOLAS Surgeon Education Committee helps direct the continued evolution of our XLIF-related training classes and materials.

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 identified or 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 types of manufacturing relationships minimize our capital investment, help control costs, and allow us to compete with larger volume manufacturers of spine surgery products. As our business continues to scale, we will continue to

evaluate this strategy on selective product lines to drive improving profitability and shareholder returns. In the future, we may consider manufacturing certain products or product components internally, if and when demand or quality requirements make it economical or otherwise appropriate to do so.

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

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contracts, we reserve the exclusive right to inspect and assure conformance of each product and product component to our specifications.

We currently rely on several tissue banks as our suppliers of allograft tissue implants. We have two tissue banks that 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 regulations, state requirements, as well as voluntary industry standards such as those put forward by 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 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 Conformity. 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, state or international regulatory agencies.

Surgical Instrument and Implant Sets

For many of our customers, we seek to deliver surgical instrumentation sets, including both implants and instruments, as well as 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 many cases, once the surgery is finished, the surgical instrument sets are returned to us and we prepare them for shipment to meet future surgeries.

A wide selection of implants are also delivered to our customers on a just in time basis to enable them to choose the best shape and size implant for each of their patients.

We complement this model with field-based assets. This hybrid strategy is designed to improve customer service, 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 instrumentation and implant 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 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, 2012, we had 178 issued U.S. patents, 95 foreign national patents, and 342 pending patent applications, including 241 U.S. applications, 4 international (PCT) applications and 97 foreign national applications. Our issued and pending patents cover, among other things:

- MAS surgical access instrumentation and methodology, including our XLIF procedure and aspects thereof;

- Neurophysiology enabled instrumentation and methodology, including pedicle screw test systems, software hunting algorithms, navigated guidance, and surgical access systems;

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- 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.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Patent litigation can involve complex factual and legal questions and its outcome is uncertain. Our success will depend in part on our not infringing patents issued to others, including our competitors and potential competitors. As the number of entrants into our market increases, the possibility of future patent infringement claims against us grows. While we make extensive efforts to ensure that our products do not infringe other parties' patents and proprietary rights, our products and methods may be covered by patents held by our competitors. There are numerous risks associated with our intellectual property. For a complete discussion of these risks, please see the "Risk Factors" section of this Annual Report.

Trademarks

As of December 31, 2012, we had 201 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, ILIF, InStim, I-PAS, JJB, Leverage, M5, MAS, MaXcess, NeoDisc, Nerve Avoidance Leader, NeuroVision, NuVasive, NVJJB, Osteocel, PCM, Radian, SOLAS, Speed of innovation, SpheRx, The Better Way Back, Traverse, Triad, VuePoint, X-Core, XL TDR, XLIF and XLP. We also had 11 trademark applications pending, both domestic and foreign, including the following trademarks: $1 Billion Start-Up, Archon, Helix, IOS Integrated Operative Solutions, Leaders in Lateral, MicroLIF, and Precept.

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. Our IOM service offering competes with regional IOM companies as well as in-house hospital services.

Several companies offer products that compete with our MaXcess platform, including our XLIF and other MAS procedures, our pedicle screw systems and implants, including competitive offerings by DePuy/Synthes, a Johnson & Johnson company, Medtronic, Globus Medical and Stryker Spine. In recent years, the lateral spine surgery market has seen many new competitive product launches by both large and small spine companies.

Competition is intense in the spine fusion product market. We believe that our most significant competitors are Medtronic, DePuy/Synthes, a Johnson & Johnson company, and Stryker Spine, 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 a continually upgraded and innovative portfolio of products elegantly delivered through our MaXcess system 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 and DePuy/Synthes investing in this rapidly growing market. In the cervical total disc replacement (TDR) segment, our PCM device will face competition from several products

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that received FDA approval in 2007 including Medtronic's Prestige and Bryan TDRs, as well as Synthes' ProDisc-C TDR and more recently approved products from smaller competitors.

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, Zimmer Spine, Orthofix International N.V. (Orthofix), Biomet EBI/Spine, Lanx, Alphatec Spine (Alphatec), K2M 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, 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 seek to 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 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.

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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, 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," as defined in the NOTA. 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 device, 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.

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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 occur.

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;
- 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 the 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.

Federal False Claims Act: The Federal False Claims Act and, in particular, the False Claims Act's "qui tam" or "whistleblower" provisions allow a private individual to bring actions in the name of the government alleging that a defendant has made false claims for payment from federal funds. In addition, various states are considering enacting or have enacted laws modeled after the Federal False Claims Act, penalizing false claims against state funds. If an action is brought against us, even if it is dismissed with no judgment or settlement, we may incur substantial legal fees and other costs relating to an investigation. Actions brought under the False Claims Act may result in significant fines and legal fees and distract our management's attention,

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which would adversely affect our financial condition and results of operations. The costs of defending claims under the False Claims Act, as well as sanctions imposed under the Act, could significantly affect our business, financial condition and results of operations.

Health Insurance Portability and Accountability Act: Under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as was amended in 2005 and in 2009, a covered entity is required to adhere to certain requirements regarding the use, disclosure and security of protected health information, or PHI. In the past, HIPAA has generally affected us indirectly, as NuVasive is generally neither a Covered Entity nor a Business Associate to Covered Entities, except that our provision of IOM services through various subsidiaries may create a Business Associate relationship and/or our Puerto Rico subsidiary may be a Covered Entity. Notwithstanding, in those cases where patient data is received, NuVasive is committed to maintaining the security and privacy of PHI. The potential for enforcement action against us is now greater, as the U.S. Department of Health and Human Services (HHS) can take action directly against Business Associates. Thus, while we believe we are and will be in compliance with all required HIPAA standards, there is no guarantee that the government will agree. Enforcement actions can be costly and interrupt regular operations of our business. Nonetheless, these new requirements affect only a small portion of our business. We believe the ongoing costs and impacts of assuring compliance with the HIPAA privacy and security rules are not material to our business.

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

Physician Payments Sunshine Act of 2009, or Sunshine Act: The Sunshine Act was enacted into law in 2010 and requires public disclosure to the federal government of payments to physicians, including in-kind transfers of value such as free gifts or meals. These requirements all provide for penalties for non-compliance. The Centers for Medicare and Medicaid Services, or CMS, has recently issued final regulations and the requirement of the collection of payments to physicians begins effective August 2013, with the first annual report due March 2014. This new law, along with individual state reporting requirements, such as in Massachusetts and Vermont, increases the possibility that a healthcare company may run afoul of one or more of the requirements.

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

Foreign Government Regulation

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

shorter than that required for FDA approval, and the requirements may differ.

The European Union, which consists of 27 countries in Europe, has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a “Notified Body.” This third-party assessment consists of an audit of the manufacturer’s quality system and technical review of the manufacturer’s product. We have now successfully passed several Notified Body audits since our original certification in 2001,

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

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

Third-Party Reimbursement

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

We expect that sales volumes and prices of our products and services will continue to be largely dependent on the availability of reimbursement from third-party payers, such as governmental programs, for example, Medicare and Medicaid, private insurance plans and managed care programs. Reimbursement is contingent on established coding for a given procedure, coverage of the codes by the third-party payers, and adequate payment for the resources used. Physician coding for procedures is established by the American Medical Association, or AMA. For coding related to spine surgery, the North American Spine Society, or NASS, is the primary liaison to AMA. In July of 2006, NASS established the proper physician coding for the XLIF procedure by declaring it to be encompassed in existing codes that describe an anterolateral approach to the spine. This position was confirmed in a formal statement by NASS in January 2010. Hospital coding is established by CMS. XLIF is included in the nomenclature for hospital codes as an additional descriptor under long standing codes. All physician and hospital coding is subject to change which could impact reimbursement and physician practice behavior.

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

However, certain carriers, large and small, may, have policies significantly limiting coverage of XLIF, Interlaminar Lumbar Interbody Fusion (ILIF), Osteocel Plus, PCM or other procedures or products we sell. We will continue to provide the appropriate resources to patients, surgeons, hospitals, and insurers in order to ensure optimum patient care and clarity regarding reimbursement and work to remove any and all non-coverage policies. National and regional coverage policy decisions are subject to unforeseeable change and have the potential to impact physician behavior and reimbursement for physician services. For a discussion of these risks, please see the “Risk Factors” section of this Annual Report.

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

In international markets, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific product lines. There can be no assurance that our products will be accepted by third-party payers, that reimbursement will be available or, if available, that the third-party payers’

reimbursement policies will not adversely affect our ability to sell our products profitably.

Particularly in the United States where major healthcare reform provisions are scheduled, third-party payers must demonstrate they can improve quality and reduce costs and thus we see an increase in pre-approval/prior authorizations and non-coverage policies citing higher levels of evidence requirements for medical therapies and technologies. In addition, insured individuals are facing increased premiums and higher out of pocket costs for medical coverage which can lead a patient to delay medical treatment. An increasing number of insured individuals receive their medical care through managed care programs, which monitor and often

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require pre-approval of the services that a member will receive. The percentage of individuals covered by managed care programs is expected to grow in the United States over the next decade.

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

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

Shareowners (our employees)

We refer to our employees as shareowners. As of December 31, 2012, we had 1,173 shareowners. In addition to our shareowners, we partner with exclusive independent sales agencies and independent distributors who sell our products in the United States and internationally. There are approximately 449 individuals associated with the exclusive independent sales agencies and independent distributors with whom we partner. None of our shareowners are represented by a labor union, and we believe our shareowner relations are good.

NuVasive Spine Foundation

The NuVasive Spine Foundation, formerly known as Cheetah Gives Back, is a non-profit organization that has common management with us. The NuVasive Spine Foundation is committed to providing life-changing spine surgery to individuals around the world who have limited access to medical treatment and to developing sustainable spine care programs and advancing spine surgery technology by providing surgeons to train and educate other surgeons in disadvantaged communities.

We are not required to make contributions to The NuVasive Spine Foundation, except for any amounts pledged. No amounts were pledged by us as of December 31, 2012.

Corporate Information

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

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to those reports, electronically with the Securities and Exchange Commission (the Commission). We make these reports available free of charge on our website under the investor relations page as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Commission. All such reports were made available in this fashion during 2012.

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

Item 1A. Risk Factors

Risk factors which could cause actual results to differ from our expectations and which could negatively impact our financial condition and results of operations are discussed below and elsewhere in this report. If any of the following risks actually occurs, our business, financial condition, results of operations and our future growth prospects could be materially and adversely affected. Under these circumstances, the trading price of our common stock could decline, and you may lose all or part of your investment. Further, additional risks not currently known to us or that we currently believe are immaterial also may impair our business, operations, liquidity and stock price materially and adversely.

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Risks Related to Our Business and Industry

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

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

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

If we are not successful in convincing spine surgeons of the merit of our minimally disruptive surgical products, educating them on the use of our products and maintaining their support in the use of our minimally disruptive products, we will be unable to increase our sales and sustain our growth or profitability. Subsequently, if we fail to adequately and continually promote and market our products to these spine surgeons or if a spine surgeon adopts a competitor's products into their practice, our sales could significantly decrease which could significantly impact our profitability and cash flow.

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

We have the objective of staying ahead of the spine market by obsoleting our own products with new products and enhancements. It is important to our business that we continue to build upon our product offering to surgeons and hospitals, and enhance the products we currently offer. As such, our success will depend in part on our ability to acquire, develop and introduce new products and enhancements to our existing products to keep pace with the rapidly changing spine market. We cannot assure you that we will be able to successfully acquire, develop, obtain regulatory approval for or market new products or that any of our future products or enhancements will be accepted by the surgeons who use our products or the third-party payers who financially support many of the procedures performed with our products. Additionally, in our quest to obsolete our own products, we must effectively manage our inventory, the demand for new and current products and the regulatory process for new products in order to avoid unintended adverse financial and accounting consequences.

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

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

We believe that future reimbursement may be subject to changes in policies and practices, such as more restrictive criteria to qualify for surgery or reduction in payment amount to hospitals and surgeons for approved surgery and intraoperative monitoring, both in the United States and in international markets. Sales of our products and services will depend on the availability of adequate reimbursement from third-party payers. Future legislation, regulation or reimbursement policies of third-party payers may adversely affect the demand for our products and services as healthcare providers, such as hospitals that purchase medical devices and services for treatment of their patients, generally rely on third-party payers to reimburse all or part of the costs and fees associated with the procedures performed with these devices and services. Likewise, spine surgeons, neurophysiologists and their supervising physicians rely primarily on third-party reimbursement for the surgical or monitoring fees they earn. Spine surgeons are unlikely

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to use our products and services if they do not receive reimbursement adequate to cover the cost of their involvement in the surgical procedures.

Certain third-party payers have stated non-coverage decisions concerning our technologies and services and implementation of such policies could significantly alter our ability to sell our products. For example, several smaller regional third-party payers, such as Blue Cross Blue Shield of Florida and Medica of Minnesota, continue to have reimbursement policies that label XLIF® surgeries as experimental.

As we sell our products internationally, market acceptance may depend, in part, upon the availability of reimbursement within prevailing healthcare payment systems. In international markets, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific product lines.

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

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

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

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

The market for spine surgery products and procedures is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. With respect to our nerve monitoring systems and IOM services, we compete with Medtronic and VIASYS Healthcare, a division of CareFusion Corporation, both of which have significantly greater resources than we do, as well as numerous regional nerve monitoring companies. With respect to MaXcess®, our minimally disruptive surgical system, our largest competitors are Medtronic, DePuy, Synthes, Stryker Spine, and Globus Medical. We compete with many of the same companies with respect to our other products. We also compete with numerous smaller companies with respect to our implant products, many of whom have a significant regional market presence. At any time, these companies may develop alternative treatments, products or procedures for the treatment of spine disorders that compete directly or indirectly with our products.

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

- significantly greater name recognition;
- established relations with a greater number of spine surgeons, hospitals, other healthcare providers and third-party payers;
- larger and more well established distribution networks with significant international presence;
- products supported by long-term clinical data;
- greater experience in obtaining and maintaining FDA and other regulatory approvals or clearances for products and product enhancements;
- more expansive portfolios of intellectual property rights and greater funds available to engage in legal action; and
- greater financial, cash flow, capital markets access and other resources for product research and development, sales and marketing and litigation.

In addition, the spine industry is becoming increasingly crowded with new market entrants, including physician-owned distributorships (PODs). Many of these new competitors focus on a specific product or market segment, making it more difficult

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

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

In 2012, we saw increased surgeon participation in PODs and the loss of a few large customer accounts. PODs are medical device distributors that are owned, directly or indirectly, by physicians. These physicians derive a portion of their revenue from selling or arranging for the sale of medical devices for use in procedures they perform on their own patients at hospitals that agree to purchase from or through the POD, or that otherwise furnish ordering physicians with income that is based directly or indirectly on those orders of medical devices. We do not sell or distribute any of our products to PODs. However, the increasing prevalence of PODs may reduce our market opportunities and may hamper our ability to grow or maintain revenues. In addition, we have seen increasingly aggressive competitive tactics focused on attracting customers away from us. To the extent these tactics are successful, our revenues may materially suffer.

Our financial performance may be adversely affected by medical device tax provisions in the healthcare reform laws.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA). On December 5, 2012, the Internal Revenue Service issued final regulations, based on the PPACA, imposing an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States beginning in 2013. The tax is applied to revenues regardless of a Company's level of pre-tax income or profits. As such, for smaller and medium size companies like ourselves, the tax's revenue-basis means that it can consume a substantial portion of any pre-tax income we generate on a GAAP basis. Under the law's provisions, the Congressional Research Service predicts that the total cost to the medical device industry may be up to $20 billion over the next ten years. The financial impact of this tax on our business is unclear though this significant increase in the tax burden on our company could have a material, negative impact on our results of operations and, consequently, our cash flows. In addition, as a result of this tax, we will have less cash available to reinvest in our business which could affect our ability to develop innovative new product offerings or support our global expansion efforts.

Other elements of this legislation, such as comparative effectiveness research, an independent payment advisory board, payment system reforms, including shared savings pilots, and other provisions, could meaningfully change the way health care is developed and delivered, and may materially impact numerous aspects of our business.

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

As part of our business strategy, we have acquired companies, technologies, and product lines to maintain our objectives of developing or acquiring innovative technologies. Acquisitions involve numerous risks, including the following:

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

Any of these factors could have a negative impact on our business, results of operations or financing position. Further, past and potential acquisitions entail risks, uncertainties and potential disruptions to our business, especially where we have limited experience as a company developing or marketing a particular product or technology. For example, we

may not be able to successfully integrate an acquired company's operations, business processes, technologies, products and services, information systems and personnel into our business. Acquisitions may also further strain our existing financial and managerial controls, and divert management's attention away from our other business concerns.

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Our IOM business exposes us to risks inherent with the sale of services, to which we were not previously exposed as a medical device company.

With the acquisition of Impulse Monitoring in October 2011, we are now selling IOM services that are unique from the sale of our biologics, lumbar, thoracic, cervical and motion preservation products and have applications outside of our core business of spinal surgery. Our IOM services involve neurophysiologists located in the operating room, working in partnership with supervising physicians who oversee and interpret neurophysiological data gathered via broadband transmission in real-time. Providing this service subjects us to malpractice exposure.

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

Impulse Monitoring also engages in direct billing of Medicare and commercial payers for IOM service which brings with it additional risks associated with proper billing practice regulations, HIPAA compliance, corporate practice of medicine laws, and new collections risk associated with third-party payers.

Due to the breadth of many healthcare laws and regulations, we could be subject to healthcare fraud regulation and enforcement by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include: (i) the federal healthcare programs Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare or Medicaid, (ii) federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers, and/or (iii) state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, many of which differ from their federal counterparts in significant ways, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

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

In the United States, we sell our products through a combination of exclusive independent sales agencies and directly-employed sales shareowners (employees). Our international sales force is comprised of directly-employed sales shareowners as well as exclusive distributors and independent sales agents. We expect these sales representatives to develop long-lasting relationships with the spine surgeons they serve. If our sales representatives fail to adequately promote, market and sell our products, our sales could significantly decrease.

We face significant challenges and risks in managing our geographically dispersed distribution network and retaining the individuals who make up that network. For example, in 2012, we experienced an increase in sales representatives leaving us. If any additional sales representatives were to leave us, our sales could be adversely affected. If sales representatives were to depart and be retained by one of our competitors, we may be unable to prevent them from helping competitors solicit business from our existing customers, which could further adversely affect our sales. Because of the intense competition for their services, we may be unable to recruit or retain sales representatives to work with us. Failure to hire or retain qualified sales representatives would prevent us from expanding our business and generating sales.

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

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

- manage the complexities associated with a larger, faster growing and more geographically diverse organization;

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- expand our clinical development resources to manage and execute increasingly global, larger and more complex clinical trials;
- expand our sales and marketing presence in international markets generally to avoid revenue concentration in a small number of markets that would subject us to the risk of business disruption as a result of economic or political problems in concentrated locations;
- upgrade our internal business processes and capabilities (e.g., information technology platform and systems, product distribution and tracking) to create the scalability and properly handle the transaction volumes that our growing geographically diverse organization demands; and
- expend time and resources to receive product approvals and clearances to sell and promote products.

We expect that our operating expenses will continue to increase as we continue to expand into international markets. International markets may be slower than domestic markets in adopting our products and are expected, in many instances, to yield lower profit margins when compared to our domestic operations. We have only limited experience in expanding into international markets as well as marketing and operating our products and services in such markets. Additionally, our international endeavors may involve significant risks and uncertainties, including distraction of management from domestic operations, insufficient revenue to offset the expenses associated with our international strategy, and unidentified issues not discovered in our due diligence. Because expansion into international markets is inherently risky, no assurance can be given that such strategies and initiatives will be successful and will not materially adversely affect our financial condition and operating results. Even if our international expansion is successful, our expenses may increase at a greater pace than our revenues and our operating results could be harmed.

A significant portion of our foreign subsidiaries' operating expenses are incurred in foreign currencies. If the U.S. dollar weakens, our consolidated operating expenses would increase. Should the U.S. dollar strengthen, our products may become more expensive for our international customers, and as a result, our results of operations and net cash flows from international operations may be adversely affected, especially if international sales continue to grow as a percentage of our total sales.

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

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

As a key component of our business strategy to develop new markets, we intend to continue to expand our international sales, but success cannot be assured. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subject us to extensive U.S. and foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly affect us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act (FCPA), and anti-boycott laws. Any failure to comply with applicable legal and regulatory obligations in the United States or abroad could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities. Any reduction in international sales, or our failure to further develop our international markets, could have a material adverse effect on our business, results of operations and financial condition.

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

We rely on third-party suppliers and manufacturers to supply and manufacture our products. To be successful, our contract manufacturers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable cost and on a timely basis. Our anticipated growth could strain the ability of suppliers to deliver an increasingly large supply of products, materials and components. If we are unable to obtain sufficient quantities of high quality components to

meet customer demand on a timely basis, we could lose customers, our reputation may be harmed and our business could suffer.

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

Risks Related to Our Intellectual Property and Litigation

We are currently involved in patent litigation involving Medtronic, and, if we do not prevail in the litigation and/or on our appeal of the Medtronic verdict in phase one of the litigation, we could be liable for substantial damages and might be prevented from making, using, selling, offering to sell, importing or exporting certain of our products.

On August 18, 2008, Medtronic filed suit against us in the U.S. District Court for the Southern District of California, alleging that certain of our products infringe, or contribute to the infringement of, U.S. patents owned by Medtronic. Trial in the first phase of the case began in August 2011 and in September 2011 a jury delivered an unfavorable verdict against us with respect to three Medtronic patents and a favorable verdict with respect to one of our patents. The jury awarded monetary damages of approximately $0.7 million to us which includes back royalty payments. Additionally, the jury awarded monetary damages of approximately $101.2 million to Medtronic which includes lost profits and back royalties. The District Court still needs to determine the amount of any ongoing royalties before we can properly appeal the unfavorable verdict to the Federal Circuit Court of Appeals. During pendency of our appeal, we have been required to secure the amount of the judgment, plus prejudgment interest, which could result in a material reduction in the liquidity required to run or grow our business. Should we lose our appeal or should the District Court ultimately award a much higher ongoing royalty rate, our ability to generate profits and cash flow, and, as a result, to invest in and grow our business, including the investment into new and innovative technologies may suffer.

In addition, in August 2012, Medtronic filed additional patent claims against us in the United States District Court for the Northern District of Indiana alleging that various of our spinal implants (including its CoRoent® XL family of spinal implants) infringe U.S. Patent No. 8,021,430, and that our Osteocel® Plus bone graft product infringes U.S. Patent No. 5,676,146 C2. Medtronic subsequently amended its complaint in the Northern District of Indiana alleging that our XLIF® procedure and use of MaXcess IV retractor during the XLIF procedure infringe methodology claims of U.S. Patent No. 8,251,997. The lawsuit has since been transferred to the Southern District of California. We deny infringing any valid claims of these additional patents and intend to defend the lawsuit vigorously. However, should we lose this suit, our ability to invest in and grow our business may suffer.

We are currently involved in a trademark litigation action involving the NeuroVision brand name and, if we do not prevail, we could be liable for substantial damages.

In September 2009, Neurovision Medical Products, Inc. (NMP) filed suit against us in the U.S. District Court for the Central District of California alleging trademark infringement and unfair competition. NMP sought cancellation of our “NeuroVision” trademark registrations, injunctive relief and damages based on NMP's common law use of the “Neurovision” mark. After trial of the matter, in October 2010 an unfavorable jury verdict was delivered against us relating to our use of the NeuroVision trade name. In January 2011, the District Court ordered a judgment be entered in the case in the amount of $60.0 million plus attorney fees and costs, and granted a permanent injunction prohibiting our use of the NeuroVision name for marketing purposes. We promptly appealed the verdict to the Ninth Circuit Court of Appeals and in January 2011, the Circuit Court stayed enforcement of the injunction. In June 2011, we entered into an escrow arrangement and transferred $62.5 million of cash and investments into a restricted escrow account to secure the judgment. In September 2012, the Circuit Court reversed and vacated the District Court's judgment against

us, and also reversed and vacated the injunction and the award of attorney fees and costs. The Circuit Court remanded the case for a new trial and instructed the District Court to assign the case to a different judge. In December 2012, the full $62.5 million was released from escrow and returned to us. A retrial on the matter is currently scheduled to begin in front of a new judge in the District Court on June 4, 2013.

This litigation process has been expensive, complex and lengthy and its outcome is difficult to predict. We may also be subject to additional negative publicity due to this trademark litigation. This litigation may significantly divert the attention of our technical and management personnel. In the event that we are unsuccessful in our defense, we could be required to pay significant

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damages which are not covered under any of our insurance plans. In the event this outcome occurs, our business, liquidity, financial condition and results of operations would be materially adversely affected.

We are currently involved in several additional litigation actions which could cause us to incur significant legal expenses and/or prevent us from making, using, selling, offering to sell, importing or exporting certain of our products.

In addition to our ongoing patent litigation with Medtronic and trademark litigation with NMP, in October 2010, we initiated a patent infringement lawsuit against Globus Medical, Inc. (Globus) to protect our investment in our XLIF procedure and MaXcess retractor system. We also initiated a patent infringement lawsuit against Cadwell Laboratories, Inc. to protect our investment in our neuromonitoring platform. The outcome of these litigation efforts is difficult to predict, and in certain cases, we have entered into a contingent fee arrangement which grants our legal counsel the ability to share in the monetary recovery, if any, resulting from prosecution of the lawsuit.

Intellectual property litigation is expensive, complex and lengthy and its outcome is difficult to predict. A court could enter orders that temporarily, preliminarily or permanently enjoin us or our customers from modeling, using, selling, offering to sell or importing our current or future products, or could enter an order mandating that we undertake certain remedial activities. We may also be subject to negative publicity due to litigation. Pending or future patent litigation against us or any strategic partners or licensees may force us or any strategic partners or licensees to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third-party's intellectual property, unless we develop alternative non-infringing technology or that party grants us or any strategic partners or licensees rights to use its intellectual property, and may significantly divert the attention of our technical and management personnel. In the event that our right to market any of our products is successfully challenged, or if we fail to obtain a required license or are unable to design around a patent, our business, financial condition or results of operations could be materially adversely affected. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all, and any licenses may require substantial royalties or other payments by us. Even if any strategic partners, licensees or we were able to obtain rights to the third-party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Furthermore, if we are found to infringe patent claims of a third-party, we may, among other things, be required to pay damages, including up to treble damages and attorneys' fees and costs, which may be substantial.

An unfavorable outcome for us in patent or other intellectual property litigation could significantly harm our business if such outcome makes us unable to commercialize some of our current or potential products or cease some of our business operations. In addition, costs of prosecution of claims and defense, and any damages resulting from litigation may materially adversely affect our business and financial results. Litigation may also harm our relationships with existing customers and subject us to negative publicity, each of which could harm our business and financial results.

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

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our pending U.S. and foreign patent applications may not issue as patents at all or not in a form that will be advantageous to us or may issue and be subsequently successfully challenged by others and invalidated. In addition, our pending patent applications include claims to material aspects of our products and procedures that are not currently protected by issued patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Competitors may be able to design around our patents or develop products which provide outcomes which are comparable to ours. Moreover, competitors may challenge our issued patents through the reexamination process (domestically) and/or opposition proceedings (internationally), as was done by both Medtronic and Globus in our ongoing litigation matters. Reexamination has been granted by the U.S. Patent Office with regard to each of the patents asserted in both litigation matters. Each of

those reexam proceedings is pending, and if the U.S. Patent Office ultimately cancels or narrows the claims in these patents, it could prevent or hinder us from being able to enforce them against competitors.

Although we have taken steps to protect our intellectual property and proprietary technology, including entering into confidentiality agreements and intellectual property assignment agreements with our officers, shareowners, consultants and advisors, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. To the extent that our shareowners, consultants, or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

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In addition, recently enacted changes to the U.S. patent laws, together with proposed changes to the rules of the U.S. Patent Office to comport with the newly enacted laws may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. Of significance in the newly enacted patent laws, the United States has shifted from a “first to invent” to a “first inventor to file” system, which goes into effect on March 16, 2013. Consequently, the pool of prior art available to inhibit or limit our ability to obtain issued patents on the technology utilized in our products is expected to expand and the grace period for filing a patent application will be reduced in some ways. It will be possible for a situation to arise in which a competitor is able to obtain patent rights to technology which we invented first. Furthermore, the newly enacted patent laws provide for post grant review of issued patents and expanded reexamination proceedings that may provide our competitors with additional opportunities to challenge the validity of our issued patents.

In the event a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time consuming. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against a challenge.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. It is not unusual for parties to exchange letters surrounding allegations of intellectual property infringement and licensing arrangements. Patent litigation can involve complex factual and legal questions and its outcome is uncertain. Any claim relating to infringement of patents that is successfully asserted against us may require us to pay substantial damages, including treble damages in some cases. Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Our success will also depend in part on our not infringing patents issued to others, including our competitors and potential competitors. If our products are found to infringe the patents of others, our development, manufacture and sale of such potential products could be severely restricted or prohibited. In addition, our competitors may independently develop technologies similar to ours. Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to adequately protect our intellectual property rights.

As the number of entrants into our market increases, the possibility of a patent infringement claim against us grows. While we make an effort to ensure that our products do not infringe other parties' rights, our products and methods may be covered by patents held by our competitors. In addition, our competitors may assert that future products we may market infringe their patents.

A patent infringement suit brought against us or any of our strategic partners or licensees may force us or such strategic partners or licensees to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third-party's intellectual property, unless that party grants us or our strategic partners or licensees rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all, and any licenses may require substantial royalties or other payments by us. Even if our strategic partners, licensees or we were able to obtain rights to the third-party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

Risks Related to our Legal and Regulatory Environment

We are subject to rigorous governmental regulations regarding the development, manufacture, and sale of our products and we may incur significant expenses to comply with these regulations and develop products that are compatible with these regulations. In addition, failure to comply with these regulations could subject us to substantial sanctions which could adversely affect our business, results of operations and financial condition.

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

We are required to register with the FDA as a device manufacturer and tissue bank. As a result, we are subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation (QSR) and Good Tissue Practices requirements, which require manufacturers of medical devices and tissue banks to adhere to certain regulations, including testing, quality control and documentation procedures. Our compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. In the European Community, we are required to maintain certain ISO certifications in order to sell our products, and are subject to periodic inspections by notified bodies to obtain and maintain these certifications. If we or our suppliers fail to adhere to QSR, ISO or other applicable regulations and standards, this could

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delay product production and lead to fines, difficulties in obtaining regulatory clearances and approvals, recalls or other consequences, which in turn could have a material adverse effect on our financial condition, results of operations, or prospects.

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

Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although physicians are permitted to use medical devices for indications other than those cleared or approved by the FDA based on their medical judgment, we are prohibited from promoting products for such off-label uses. We market our products and provide promotional materials and training programs to physicians regarding the use of our products. Although we believe our marketing, promotional materials and training programs for physicians do not constitute promotion of unapproved uses of our products, if it is determined that our marketing, promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure and criminal penalty.

Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, the SEC has promulgated rules regarding disclosure of the presence in a company's products of certain metals, known as “conflict minerals,” which are metals mined from the Democratic Republic of the Congo and adjoining countries, as well as procedures regarding a manufacturer's efforts to identify the sourcing of those minerals from this region. Complying with these rules will require investigative efforts, which will cause us to incur associated costs, and could adversely affect the sourcing, supply, and pricing of materials used in our products, or result in process or manufacturing modifications, all of which could adversely affect our results of operations.

Whenever the United States or another foreign governmental authority concludes that we are not in compliance with applicable laws or regulations, such governmental authority can impose fines, delay or suspend regulatory clearances, institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil penalties against us or our officers or employees, and can recommend criminal prosecution to the Department of Justice (DOJ). Moreover, governmental authorities can ban or request the recall, repair, replacement or refund of the cost of any device or product we manufacture or distribute. Any of the foregoing actions could result in decreased sales as a result of negative publicity and product liability claims, and could have a material adverse effect on our financial condition, results of operations and prospects. In addition to the sanctions for noncompliance described above, commencement of an enforcement proceeding, inspection or investigation could divert substantial management attention from the operation of our business and have an adverse effect on our business, results of operations and financial condition.

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

We currently market our products internationally and intend to expand our international marketing. International jurisdictions require separate regulatory approvals and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing, and

the time required to obtain approval may differ from country to country and from that required to obtain FDA clearance or approval.

Clearance or approval by the FDA does not ensure approval or certification by regulatory authorities in other countries or jurisdictions, and approval or certification by one foreign regulatory authority does not ensure approval or certification by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval or certification process may include all of the risks associated with obtaining FDA clearance or approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals or certifications and may not receive necessary approvals to commercialize our products in any market. If we fail to receive necessary approvals or certifications to commercialize our products in foreign jurisdictions on a timely basis, or at all, our business, results of operations and financial condition could be adversely affected.

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

Our medical devices are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device, particularly from the FDA, can be costly and time consuming, and there can be no assurance that such clearances or approvals will be granted on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved PMA. If clinical trials of our current or future product candidates do not produce results necessary to support regulatory approval, we will be unable to commercialize these products, including our lateral TDR (XL TDR) devices.

The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. Additionally, any modification to a 510(k)-cleared device that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, requires a new 510(k) clearance or, possibly, a PMA. The FDA may not agree with any of our decisions regarding whether new clearances or approvals are necessary.

Our failure to comply with such regulations could lead to the imposition of injunctions, suspensions or loss of regulatory approvals, product recalls, termination of distribution, or product seizures. In the most egregious cases, criminal sanctions or closure of our manufacturing facilities are possible.

Pursuant to FDA regulations, we can only market our products for cleared or approved uses. If the FDA determines that our promotional materials or training constitute promotion of an unapproved use, it could request that we modify our training or promotional materials, or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities. Additionally, surgeons use several of our products for unapproved uses. While surgeons are permitted by the FDA to use our products for unapproved uses, there is a heightened risk of an enforcement action against us by a governmental enforcement authority when surgeons engage in that practice.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we market and sell our products in foreign countries, we may be subject to rigorous regulation in the future. In such circumstances, we would rely significantly on our foreign subsidiaries and independent sales agencies to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

The safety of our products is not yet supported by long-term clinical data and our products may therefore prove to be less safe and effective than initially thought which could subject us to product liability claims.

We obtained clearance to offer almost all of our medical device products that require FDA clearance through the FDA's 510(k) premarket notification clearance process. The FDA's 510(k) process, much like other foreign premarket regulatory review processes to which our devices are subject, seldom requires clinical data. As a result, we currently lack the breadth of published long-term clinical data supporting the safety and effectiveness of our products, devices and tissue that might have been generated in connection with a U.S. PMA-like application. For these reasons, spine surgeons may be slow to adopt our products; we may not have comparative data that our competitors have or are generating and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes. Such results would reduce demand for our products, affect our ability to have sustainable reimbursement for our products from third-party payers, significantly reduce our ability to achieve expected revenues and could prevent us from sustaining or increasing profitability. Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to significant legal liability and harm to our business reputation. The spine medical device market has been particularly prone to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices and products for spine surgery

procedures.

A product liability or other damages claim, product recall or product misuse, regardless of the ultimate outcome, could require us to spend significant time and money in litigation or to pay significant damages or costs and could seriously harm our business. Currently, we maintain product liability insurance in the amount of $10 million. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, if our product liability insurance proves to be inadequate to pay a damage award, we may have to pay the excess out of our cash reserves which may harm our financial condition. If longer-term patient results and experience indicate that our products or any component cause tissue damage, motor impairment or other adverse effects, we could be subject to significant liability. Finally, even a meritless or unsuccessful product liability claim could harm our reputation in the industry, lead to significant legal fees and could result in the diversion of management's attention from managing our business. A product liability or other

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damages claim, product recall, or product misuse involving any of our products could also materially and adversely damage our reputation and affect our ability to attract and retain customers, irrespective of whether or not the claim or recall was meritorious.

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

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

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

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

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

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

Any claims relating to our making improper payments or providing improper gifts or benefits to physicians or other potential violations of laws or regulations governing interactions between us and healthcare professionals and our involvement in federal healthcare programs could be time consuming and costly.

Our relationship with healthcare professionals, such as physicians, hospitals and those that may market our products (e.g., distributors, etc.), are subject to scrutiny under various state and federal laws, rules and regulations (e.g., anti-kickback statute, self-referral/Stark laws, false claims, etc.), often referred to collectively as healthcare fraud and abuse laws. These laws are broad in scope and are subject to evolving interpretation, which could require us to incur substantial costs to monitor compliance or to alter our practices if they are found not to be in compliance. Violations of these laws may be punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in governmental healthcare programs. Despite implementation of a comprehensive global healthcare compliance program, we cannot provide assurance that any of the healthcare fraud and abuse laws will not change or be interpreted in the future in a manner which restricts or adversely affects our business activities or relationships with healthcare professionals nor can we make any assurances that authorities will not challenge or investigate our current or future activities under these laws.

In recent years, both the United States and foreign government regulators have increased regulation, enforcement, inspections and governmental investigations of the medical device industry, including increased United States government oversight and enforcement of the FCPA. Despite implementation of a comprehensive global healthcare compliance program, we may be subject to more regulation, enforcement, inspections and investigations by governmental authorities in the future. Whenever the United

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States or another foreign governmental authority concludes that we are not in compliance with applicable laws or regulations, such governmental authority can impose fines, delay or suspend regulatory clearances, institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, exclude or debar us from federal healthcare programs, impose compliance obligations, enjoin future violations and assess civil penalties against us or our officers or employees, and can recommend criminal prosecution to the DOJ. Any of the foregoing actions could result in decreased sales as a result of negative publicity, and could have a material adverse effect on our financial condition, results of operations and prospects.

Although physicians are permitted to use medical devices for indications other than those cleared or approved by the FDA based on their medical judgment, we are prohibited from promoting products for such off-label uses. We market our products and provide promotional materials and training programs to physicians regarding the use of our products. Although we believe our marketing, promotional materials and training programs for physicians do not constitute promotion of unapproved uses of our products, if it is determined that our marketing, promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure and criminal penalty.

In addition to the sanctions for noncompliance described above, commencement of an enforcement proceeding, inspection or investigation could divert substantial management attention from the operation of our business, as well as could result in a material adverse effect on the market price of our common stock and on our business, results of operations and financial condition. For example, in November 2012, Orthofix's subsidiary, Blackstone Medical, settled with the DOJ for $30 Million relating to the alleged payment of kickbacks to surgeons to induce them to use their products and Synthes, Inc., in 2010, settled with the DOJ and the Office of Inspector General (OIG) for $22 million relating to allegations that it illegally tested bone cement on patients.

Additionally, we must comply with a variety of other laws, such as the (i) HIPAA and the HITECH Act which protects the privacy of individually identifiable healthcare information; (ii) the Physician Payment Sunshine Act which requires medical device companies to begin reporting all compensation, gifts and benefits provided to certain healthcare professionals in 2013; and (iii) the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections.

We are subject to risks associated with our non-U.S. operations.

The FCPA and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. The FCPA also imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of “off books” slush funds from which such improper payments can be made. Because of the predominance of government-sponsored healthcare systems around the world, many of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws. Our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction and result in a material adverse effect on our business, results of operations and financial condition. We also could suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures, including further changes or enhancements to our procedures, policies and controls, as well as potential personnel changes and disciplinary actions.

Furthermore, we are subject to the export controls and economic embargo rules and regulations of the United States, including, but not limited to, the Export Administration Regulations and trade sanctions against embargoed countries, which are administered by the Office of Foreign Assets Control within the Department of the Treasury, as well as the laws and regulations administered by the Department of Commerce. These regulations limit our ability to market, sell, distribute or otherwise transfer our products or technology to prohibited countries or persons. A determination that we have failed to comply, whether knowingly or inadvertently, may result in substantial penalties, including fines and enforcement actions and civil and/or criminal sanctions, the disgorgement of profits and the imposition of a court-appointed monitor, as well as the denial of export privileges, and may have an adverse effect on our reputation.

These and other factors may have a material adverse effect on our international operations or on our business, results of operations and financial condition generally.

Risks Related to Our Financial Results and Need for Financing

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

We have experienced rapid growth since our inception, and have increased our revenues from $38.4 million in 2004, the year of our initial public offering, to approximately $620.3 million in 2012. Our ability to achieve future growth will depend upon,

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

The current adverse global economic conditions may adversely affect our liquidity and the liquidity of our customers.

As of December 31, 2012, we had approximately $346.1 million in cash, cash equivalents and investments in marketable securities. In May 2012, we entered into an escrow arrangement in connection with the Medtronic litigation and have transferred $113.3 million of cash into a restricted escrow account to secure the amount of judgment, plus prejudgment interest, during the pendency of our appeal of the judgment. In addition, as of December 31, 2012, we had approximately $74.3 million remaining under our 2.25% Senior Convertible Notes due in March 2013 (the 2013 Notes). Our escrow arrangement and the payment of the 2013 Notes will result in a significant reduction in the liquidity available to run or grow our business.

We have historically invested our cash primarily in U.S. government sponsored entities and U.S. treasuries, corporate debt, and money market funds. Certain of these investments are subject to general credit, liquidity and other market risks. The general condition of the financial markets and the economy has exacerbated those risks and may affect the value of our current investments and restrict our ability to access the capital markets or even our own funds.

The liquidity of our customers and suppliers may also be affected by adverse global economic conditions. If our suppliers experience credit or liquidity problems, important sources of raw materials or manufactured goods may be affected. If our customers' liquidity and creditworthiness is negatively impacted by the condition of the economy, our ability to collect on our outstanding invoices and our collection cycles may be adversely affected.

The sale of our 2.75% Senior Convertible Notes due 2017 significantly increased our amount of long-term debt, and our financial condition and results of operations could be adversely affected if we do not efficiently manage our liabilities.

In June 2011, we issued $402.5 million aggregate principal amount of our 2.75% Senior Convertible Notes due in 2017 (the 2017 Notes). In addition, as of December 31, 2012, we had approximately $74.3 million remaining under our 2013 Notes. As a result of the sale of the 2017 Notes and the 2013 Notes, we have a substantially greater amount of long-term debt then we have maintained in the past. Our maintenance of such increased level of debt could adversely affect our financial condition and results of operations.

In addition, there are a large number of shares of common stock reserved for issuance upon the potential conversion of our 2017 Notes and our Series A Preferred Stock that may be available for future sale and the sale of these shares may depress the market price of our common stock.

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

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

The market price of our common stock has been and may continue to be subject to wide fluctuations. For example, the closing price for our stock on the last day of the past four quarters was: $15.46 on December 31, 2012, $22.91 on September 30, 2012, $25.36 on June 30, 2012 and $16.84 on March 31, 2012. Fluctuation in the stock price may occur due to many factors, including:

- general market conditions and other factors related to the economy or otherwise, including factors unrelated to our operating performance or the operating performance of our competitors. These conditions might include people’s expectations, favorable or unfavorable, as to the likely unit growth of the spine sector;
- negative stock market reactions to the results of litigation;
- negative publicity regarding spine surgeon’s practices or outcomes, whether warranted or not, that cast the sector in a negative light;

- the introduction of new products or product enhancements by us or our competitors;

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- changes in the availability of third-party reimbursement in the United States or other countries;
- disputes or other developments with respect to intellectual property rights or other potential legal actions;
- our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis;
- quarterly variations in our or our competitor's results of operations;
- sales of large blocks of our common stock, including sales by our executive officers and directors;
- announcements of technological or medical innovations for the treatment of spine pathology;
- changes in governmental regulations or in the status of our regulatory approvals, clearances or applications;
- the acquisition or divestiture of businesses, products, assets or technology;
- litigation, including intellectual property litigation and any associated negative verdicts or ruling;
- announcements of actions by the FDA or other regulatory agencies; and
- changes in earnings estimates or recommendations by us or by securities analysts.

Market price fluctuations may negatively affect the ability of investors to sell our shares at consistent prices.

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

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

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

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

We do not intend to pay cash dividends.

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

Item 1B. Unresolved Staff Comments

None.

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Item 2. Properties

As of December 31, 2012, we operated the following facilities:

Description of Use	Square Footage	Location	Lease Term
Corporate office and training facilities (1)	145,225	San Diego, CA	From 2008 to 2023
Corporate office facilities	62,367	San Diego, CA	From 2012 to 2013
Fulfillment and warehouse operations	100,000	Memphis, TN	Owned
Office and training facilities	63,761	Paramus, NJ	From 2010 to 2020
Office facilities	10,579	Columbia, MD	From 2006 to 2017
Office facilities	2,073	Puerto Rico	From 2011 to 2014
Office facilities	2,462	UK	From 2008 to 2013
Office facilities	4,378	Japan	From 2009 to 2015
Office facilities	4,456	Singapore	From 2011 to 2014
Office facilities	8,588	Australia	From 2009 to 2015
Office facilities and warehouse	7,383	Germany	From 2009 to 2015
Office facilities	902	Italy	From 2012 to 2013
Office facilities	1,851	Malaysia	From 2011 to 2014

(1) Our corporate headquarters.

Item 3. Legal Proceedings.

Medtronic Sofamor Danek USA, Inc. Litigation

As reported by us previously, Medtronic Sofamor Danek USA, Inc. and its related entities (Medtronic), on August 18, 2008, filed a patent infringement lawsuit against NuVasive in the United States District Court for the Southern District of California, alleging that certain of NuVasive's products or methods, including the XLIF® procedure, infringe, or contribute to the infringement of, twelve U.S. patents. Three of the patents were later withdrawn by Medtronic leaving the following nine patents in the lawsuit: Nos. 5,860,973; 5,772,661; 6,936,051; 6,936,050; 6,916,320; 6,945,933; 6,969,390; 6,428,542; 6,592,586 assigned or licensed to Medtronic (Medtronic Patents). Medtronic is seeking monetary damages and a court injunction against future infringement by NuVasive. NuVasive answered the complaint, denying the allegations.

Additionally, NuVasive made counterclaims against Medtronic seeking the following relief: (i) Medtronic being permanently enjoined from charging that NuVasive has infringed or is infringing the Medtronic Patents; (ii) a declaration that the Medtronic Patents are invalid; (iii) a declaration that the 5,860,973 and 5,772,661 patents are unenforceable due to inequitable conduct; and (iv) costs and reasonable attorneys' fees.

NuVasive filed an amended counterclaim on September 4, 2009, alleging that NuVasive's U.S. Patent Nos. 7,207,949; 7,582,058; and 7,470,236 are infringed by Medtronic's NIM-Eclipse System and accessories and Quadrant products, and DLIF (Direct Lateral Interbody Fusion) surgical technique. Medtronic, on June 23, 2009, filed a request for inter partes reexamination with the Patent Office on NuVasive's U.S. Patent No. 7,207,949. On October 14, 2009, Medtronic filed a request for inter partes reexamination on NuVasive's U.S. Patent No. 7,582,058. The Patent Office granted both requests and issued rejections of the claims. Both reexaminations are pending.

Given the number of patents asserted in the litigation, the parties agreed to proceed on a limited number of patents. The District Court determined to proceed only with patents that are not the subject of active reexamination proceedings. As a result, the first phase of the case included three Medtronic patents and one NuVasive patent. Trial on the first phase of the case began in August 2011 and on September 20, 2011, a jury from the District Court, delivered an unfavorable verdict against NuVasive with respect to three Medtronic patents and a favorable verdict with respect to the one NuVasive patent. The jury awarded monetary damages of approximately $101.2 million to Medtronic, which includes lost profits and back royalties. Medtronic's subsequent motion for a permanent injunction was denied by the District Court on January 26, 2012. The District Court entered judgment on March 2, 2012, and both parties appealed the verdict. Medtronic subsequently filed a motion to dismiss its own appeal and NuVasive's

cross-appeal with the Federal Circuit Court of Appeals. On August 2, 2012, the Federal Circuit issued a ruling stating that ongoing royalty rates must be determined by the District Court prior to the appeal going forward. As a result, the appeal in the Federal

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Circuit is temporarily dismissed while the post-verdict royalty rate is resolved by the District Court. On March 19, 2012, the District Court issued an order granting prejudgment interest, but has not provided a date for determining the post-verdict royalty rate, and no hearings are scheduled at this time. The Company entered into an escrow arrangement on April 27, 2012 and in May 2012, transferred $113.3 million of cash into a restricted escrow account to secure the amount of judgment, plus prejudgment interest, during pendency of the appeal. These funds are included in restricted cash and investments on the Company's December 31, 2012 consolidated balance sheet.

In accordance with the authoritative guidance on the evaluation of loss contingencies, during the third quarter of 2011, the Company recorded an accrual for the $101.2 million verdict. In addition, the Company is currently accruing ongoing royalties on sales subsequent to the verdict at the royalty rates stated in the judgment, as well as post-judgment interest. With respect to the prejudgment interest award, the Company, based on its own assessment as well as that of outside counsel, believes a reversal of the prejudgment interest award on appeal is probable, and therefore, in accordance with the authoritative guidance on the evaluation of loss contingencies, the Company has not recorded an accrual for this amount, which is estimated to approximate $13 million. Additional damages, including interest and potential ongoing royalties may still be awarded, and at December 31, 2012, the Company cannot estimate a range of additional potential loss.

The second phase of the case pending in the Southern District of California currently involves one Medtronic Patent (6,916,320), and claim construction is expected to commence during the first half of 2013. On August 17, 2012, Medtronic filed additional patent claims in the U.S. District Court for the Northern District of Indiana alleging that various NuVasive spinal implants (including its CoRoent® XL family of spinal implants) infringe U.S. Patent No. 8,021,430, and that NuVasive's Osteocel® Plus bone graft product infringes U.S. Patent No. 5,676,146 C2. On August 28, 2012, Medtronic amended its complaint in the Northern District of Indiana alleging that NuVasive's XLIF® procedure and use of MaXcess IV retractor during the XLIF procedure infringe methodology claims of U.S. Patent No. 8,251,997.

NuVasive denies infringing any valid claims of these additional patents and on September 4, 2012, NuVasive moved to motion to extend the time to respond to the complaint and transfer the Indiana case to the Southern District of California. The Indiana District Court granted NuVasive's motion to extend the time to respond and transferred the case to the Southern District of California. At December 31, 2012, the probable outcome of this litigation cannot be determined, nor can the Company estimate a range of potential loss. Accordingly, in accordance with the authoritative guidance on the evaluation of loss contingencies, the Company has not recorded an accrual related to this litigation.

Trademark Infringement Litigation

In September 2009, NMP filed suit against NuVasive in the U.S. District Court for the Central District of California (Case No. 2:09-cv-06988-R-JEM) alleging trademark infringement and unfair competition. NMP sought cancellation of NuVasive's “NeuroVision” trademark registrations, injunctive relief and damages based on NMP's common law use of the “Neurovision” mark. On November 23, 2009, the Company denied the allegations in NMP's complaint. After trial of the matter, on October 25, 2010 an unfavorable jury verdict was delivered against the Company relating to its use of the “NeuroVision” trade name. The verdict awarded damages to NMP of $60.0 million. On January 3, 2011, the District Court ordered a judgment be entered in the case in the amount of $60.0 million, and granted a permanent injunction prohibiting the Company's use of the “NeuroVision” name for marketing purposes. The Company sought emergency relief, and on February 3, 2011, the Ninth Circuit Court of Appeals stayed enforcement of the injunction, and consolidated this issue with our appeal of the verdict filed on May 6, 2011. During pendency of the appeal, the Company was required to escrow funds to secure the amount of the judgment, plus interest, attorneys' fees and costs. Accordingly, on June 16, 2011, the Company entered into an escrow arrangement and transferred $62.5 million of cash and investments into a restricted escrow account. On September 10, 2012, the Court of Appeals reversed and vacated the District Court judgment and ordered the case back to the District Court for a new trial before a different judge. On October 5, 2012, the case was reassigned to a new District Court judge and proceedings are scheduled to commence in the District Court in June 2013. NMP's right to appeal the Court of Appeals reversal and vacation of the judgment expired on December 10, 2012 and NMP stipulated to the release of the $62.5 million from the restricted escrow account. As a result, the full $62.5 million was released from escrow and returned to NuVasive. At December 31, 2012, the probable outcome of this litigation cannot be determined, nor can the Company estimate a

range of potential loss. Accordingly, in accordance with the authoritative guidance on the evaluation of loss contingencies, the Company has not recorded an accrual related to this litigation.

Item 4. Mine Safety Disclosures.
Not applicable.

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PART II

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

Common Stock Market Price

Our common stock is traded on the NASDAQ Global Select Market under the symbol "NUVA." The following table presents the high and low per share sale prices of our common stock during the periods indicated, as reported on NASDAQ.

	High	Low
2011:		
First Quarter	$30.43	$24.37
Second Quarter	34.91	24.91
Third Quarter	34.64	17.05
Fourth Quarter	18.22	11.02
2012:		
First Quarter	$17.89	$11.25
Second Quarter	25.37	15.36
Third Quarter	25.99	19.44
Fourth Quarter	23.81	12.35

We had approximately 124 stockholders of record as of January 31, 2013. We believe that the number of beneficial owners is substantially greater than the number of record holders because a large portion of our common stock is held of record through brokerage firms in "street name."

Recent Sales of Unregistered Securities

During the fourth quarter of 2012, we did not issue any securities that were not registered under the Securities Act of 1933, as amended (the Securities Act).

Dividend Policy

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

Equity Compensation Plan Information

The following table provides certain information with respect to all of our compensation plans in effect as of December 31, 2012:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Option, Warrants and Rights (a)		Weighted Average Exercise Price of Outstanding Options Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)	
Equity Compensation Plans approved by stockholders	8,826,202	(1)	$30.44	2,247,003	(2)
Equity Compensation Plans not approved by stockholders	—		—	—	
Total	8,826,202		$30.44	2,247,003	

(1) Consists of shares subject to outstanding options and restricted stock units under our 1998 Stock Option/Stock Issuance Plan and our 2004 Equity Incentive Plan.

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(2) Consists of shares available for future issuance under our 2004 Equity Incentive Plan and 2004 Employee Stock Purchase Plan. As of December 31, 2012, an aggregate of 689,883 shares of common stock were available for issuance under the 2004 Equity Incentive Plan and 1,557,120 shares of common stock were available for issuance under the 2004 Employee Stock Purchase Plan. The 2004 Equity Incentive Plan contains a provision for an automatic increase in the number of shares available for grant each January until and including January 1, 2014, subject to certain limitations, by a number of shares equal to the least of: (1) 4% of the number of shares of our common stock issued and outstanding on the immediately preceding December 31, (2) 4,000,000 shares, or (3) a number of shares set by our Board. The 2004 Employee Stock Purchase Plan contains a provision for an automatic increase in the number of shares available for grant each January until and including January 1, 2014, subject to certain limitations, by a number of shares equal to the least of: (1) 1% of the number of shares of our common stock outstanding on that date, (2) 600,000 shares, or (3) a lesser number of shares determined by our Board.

PERFORMANCE GRAPH

The following graph compares the cumulative total stockholder return data on our common stock with the cumulative return of (i) The NASDAQ Stock Market Composite Index, and (ii) NASDAQ Medical Equipment Index over the five year period ending December 31, 2012. The graph assumes that $100 was invested on December 31, 2007 in our common stock and in each of the comparative indices. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

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

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
AMONG NUVASIVE, INC.,
THE NASDAQ COMPOSITE INDEX
AND THE NASDAQ MEDICAL EQUIPMENT INDEX

*$100 invested on 12/31/07 in stock or index, including reinvestment of dividends.

Item 6. Selected Financial Data.

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

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	Year Ended December 31,				
	2012(1)(2)	2011(1)(2)	2010(1)	2009(1)	2008
	(In thousands, except per share amounts)				
Statement of Operations Data:					
Total revenues	$620,255	$540,506	$478,237	$370,340	$250,082
Gross profit	466,846	428,395	393,098	309,230	211,074
Consolidated net income (loss)	2,442	(71,021)	76,533	4,437	(27,528)
Net income (loss) attributable to NuVasive, Inc.	3,144	(69,849)	78,285	5,808	(27,528)
Net income (loss) per share attributable to NuVasive, Inc.:					
Basic	$0.07	$(1.73)	$1.99	$0.16	$(0.77)
Diluted	$0.07	$(1.73)	$1.85	$0.15	$(0.77)
	December 31,				
	2012(1)(2)	2011(1)(2)	2010(1)	2009(1)	2008
	(In thousands)				
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$346,116	$342,223	$229,690	$204,660	$223,361
Working capital	349,474	384,457	262,795	262,355	256,491
Total assets	1,163,785	1,123,562	802,029	652,820	487,406
Senior Convertible Notes, net of current portion	332,404	394,019	230,000	230,000	230,000
Litigation liability	101,200	—	—	—	—
Other long-term liabilities	18,328	17,413	16,821	58,222	24,288
Noncontrolling interests	10,003	10,705	11,877	13,629	—
Total stockholders' equity	537,575	494,045	434,355	296,222	187,631

(1) Consolidated statement of operations and balance sheet data for the years ended December 31, 2012, 2011, 2010 and 2009 includes the results of Progentix Orthobiology, B.V., a variable interest entity which is consolidated pursuant to existing guidance issued by the Financial Accounting Standards Board (FASB).

(2) Consolidated statement of operations and balance sheet data for the years ended December 31, 2012 and 2011 include Impulse Monitoring from October 7, 2011, the date of acquisition.

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

Forward-Looking Statements May Prove Inaccurate

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the consolidated financial statements and the notes to those statements included in this report. This discussion and analysis may contain forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, such as those set forth under heading "Risk Factors," and elsewhere in this report.

Overview

We are a medical device company 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 exceed $8.2 billion globally in 2013. 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 reproducible outcomes for the surgeon. The platform includes a proprietary software-driven nerve detection and avoidance systems, NVM5 and NVJJB, and Intra-Operative Monitoring (IOM) support; MaXcess®, a unique and integrated split-blade retractor system; and a

wide variety of specialized implants. When the three elements of MAS are used together, they may significantly reduce surgery time and return patients to activities of daily living much faster than conventional approaches. The

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individual components of our MAS platform, and many of our products, can also be used in open or traditional spine surgery and may independently offer patient benefits to various surgical approaches dealing with a wide variety of pathologies. Our spine surgery product line offerings, which include products for the thoracolumbar and the cervical spine 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), FormaGraft®, a collagen synthetic product, Osteocel Plus®, an allograft cellular matrix containing viable mesenchymal stem cells, or MSCs, and AttraX®, a synthetic bone graft material, which is still in the process of U.S. regulatory clearance, all used to aid the spinal fusion process. Our 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 courses.

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.

At various times in the past, certain insurance providers have adopted policies of not providing reimbursement for the XLIF procedure. We have worked with our surgeon customers and the North American Spine Society (NASS) who, in turn, have worked with these insurance providers to supply the information, explanation and clinical data they require to categorize the XLIF procedure as a procedure entitled to reimbursement under their policies. At present, the majority of insurance companies provide reimbursement for XLIF procedures.

However, certain carriers, large and small, may have policies significantly limiting coverage of XLIF, Interlaminar Lumbar Interbody Fusion (ILIF), Osteocel Plus, the PCM® device, or other procedures or products we sell. We cannot offer definitive time frames or final outcomes regarding reversal of the limiting-coverage policies, as the process is dictated by the third-party insurance providers. To date, we have not experienced significant lack of payment for our procedures based on these policies.

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

In recent years, we have significantly expanded our product offerings relating to procedures in the cervical spine as well as in the area of nerve monitoring. Our cervical product offerings now provide a full set of solutions for cervical fusion surgery, including both allograft tissue and CoRoent® implants, as well as cervical plating and posterior fixation products. In the fourth quarter of 2012, we received U.S. Food and Drug Administration (FDA) approval of the PCM device, a motion preserving total disc replacement device, which further strengthens our cervical product offerings and enables us to continue our trend of increasing our market share. Our nerve monitoring offerings include both the NVM5 and NVJJB products based on our proprietary software-driven nerve monitoring systems and our IOM services business, Impulse Monitoring.

Revenues. To date, the majority of our revenues are derived from the sale of disposables and implants and we expect this trend to continue for the foreseeable future. We loan our proprietary software-driven nerve monitoring systems and surgical instrument sets at no cost to surgeons and hospitals that purchase disposables and implants for use in individual procedures. In addition, we place our proprietary software-driven nerve monitoring systems, MaXcess® and other MAS or cervical surgical instrument sets with hospitals for an extended period at no up-front cost to them. Our implants and disposables are currently sold and shipped from our primary distribution and warehousing operations facility located in Memphis, Tennessee. We generally recognize revenue for disposables or implants used upon receiving acknowledgement of a purchase order from the hospital indicating product use or implantation. In addition,

we sell an immaterial number of MAS instrument sets, MaXcess devices, and our proprietary software-driven nerve monitoring systems. To date, we have derived less than 5% of our total revenues from these sales.

We expect monitoring service revenue from IOM services to remain consistent with the current year. Monitoring service revenue consists of hospital based revenues and net patient service revenues and is recorded in the period the service is provided. Hospital based revenues are recorded based upon contracted billing rates. Net patient services are billed to various payers, including Medicare, commercial insurance companies, other directly billed managed healthcare plans, employers, and individuals. We report revenues based on the amount expected to be collected.

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Sales and Marketing. Through 2012, substantially all of our operations are located in the United States and substantially all of our sales have been generated in the United States. We sell our products in the United States through a sales force comprised of exclusive independent sales agencies and directly-employed sales shareowners; both selling only NuVasive products. Our sales force provides a delivery and consultative service to our surgeon and hospital customers and is compensated based on sales and product placements in their territories. Sales force commissions are reflected in our statement of operations in the sales, marketing and administrative expense line. We expect to continue to expand our distribution channels. We are continuing our expansion of international sales efforts with the focus on European, Asian and Latin American markets. Our international sales force is comprised of directly-employed sales shareowners as well as exclusive distributors and independent sales agents.

Critical Accounting Policies

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

We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition. We follow the provisions of the Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition, which sets forth guidelines for the timing of revenue recognition based upon factors such as passage of title, installation, payment and customer acceptance. We recognize revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured. Specifically, revenue from the sale of implants and disposables is recognized upon acknowledgement of a purchase order from the hospital indicating product use or implantation or upon shipment to third-party customers who immediately accept title. Revenue from the sale of our instrument sets is recognized upon receipt of a purchase order and the subsequent shipment to customers who immediately accept title.

Monitoring service revenue consists of hospital based revenues and net patient service revenues and is recorded in the period the service is provided. Hospital based revenues are recorded based upon contracted billing rates. Net patient services are billed to various payers, including Medicare, commercial insurance companies, other directly billed managed healthcare plans, employers, and individuals. We report revenues from contracted payers, including Medicare, certain insurance companies and certain managed healthcare plans, based on the contractual rate, or in the case of Medicare, the published fee schedules. We report revenues from non-contracted payers, including certain insurance companies and individuals, based on the amount expected to be collected. The difference between the amount billed and the amount expected to be collected from non-contracted payers is recorded as a contractual allowance to arrive at net revenues. The expected revenues from non-contracted payers are based on the historical collection experience of each payer or payer group, as appropriate. In each reporting period, we review our historical collection experience for non-contracted payers and adjust our expected revenues for current and subsequent periods accordingly.

Allowance for Doubtful Accounts and Sales Return Reserve. We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. The allowance for doubtful accounts is reviewed quarterly and is estimated based on the aging of account balances, collection history and known trends with current customers and in the economy in general. As a result of this review, the allowance is adjusted on a specific identification basis. An increase to the allowance for doubtful accounts results in a corresponding charge to sales, marketing and administrative expense. If the historical data used to calculate the allowance provided for doubtful accounts does not reflect the Company’s future ability to collect outstanding receivables or if the financial

condition of customers were to deteriorate, resulting in impairment of their ability to make payments, an increase in the provision for doubtful accounts may be required. We maintain a relatively large customer base that mitigates the risk of concentration with any one particular customer. However, if the overall condition of the healthcare industry were to deteriorate, or if the historical data used to calculate the allowance provided for doubtful accounts does not accurately reflect our customer's future failure to pay outstanding receivables, significant additional allowances could be required.

In addition, we establish a reserve for estimated sales returns that is recorded as a reduction to revenue. This reserve is maintained to account for future return of products sold in the current period. This reserve is reviewed quarterly and is estimated based on an analysis of our historical experience related to product returns.

Excess and Obsolete Inventory. We provide an inventory reserve for estimated obsolescence and excess inventory based upon historical turnover and assumptions about future demand for our products and market conditions. Our allograft products

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have shelf lives ranging from two to five years and are subject to demand fluctuations based on the availability and demand for alternative products. Our inventory, which consists primarily of disposables and specialized implants, is at risk of obsolescence following the introduction and development of new or enhanced products. Our estimates and assumptions for excess and obsolete inventory are reviewed and updated on a quarterly basis. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our revenue forecasts. Increases in the reserve for excess and obsolete inventory result in a corresponding charge to cost of goods sold.

A stated goal of our business is to focus on continual product innovation and to obsolete our own products. While we believe this provides a competitive edge, it also results in the risk that our products and related capital instruments will become obsolete prior to sale or to the end of their anticipated useful lives. If we introduce new products or next-generation products, we may be required to dispose of existing inventory prior to the end of its estimated useful life and/or write off the value or accelerate the depreciation of the capital instruments.

Financial Instruments and Fair Value. Inputs to valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. These two types of inputs have created the following fair-value hierarchy:

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

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

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

This hierarchy requires us to minimize the use of unobservable inputs and to use observable market data, if available, when determining fair value. We recognize transfers between levels of this hierarchy based on the fair values of the respective financial instruments at the end of the reporting period in which the transfer occurred. Changes in fair value are recognized in earnings each period for financial instruments that are carried at fair value.

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

As more fully discussed in Notes 1 and 4 to the consolidated financial statements included in this Annual Report, in June 2011, in connection with the offering of the 2017 Notes, we entered into convertible note hedge transactions, and recorded an embedded conversion derivative liability and derivative asset. The fair values of these derivatives were determined using an option pricing model based on unobservable inputs and were classified within Level 3. The significant inputs to the model included our stock price, risk free interest rate, bond yield, credit rating, and expected volatility of our stock price. On September 28, 2011, upon obtaining stockholder approval to increase the number of authorized shares of our common stock, in accordance with authoritative literature, the derivative asset and liability were marked to fair value and reclassified to stockholders' equity.

Certain contingent consideration liabilities are classified within Level 3 of the fair value hierarchy because they use unobservable inputs. For those liabilities, fair value is determined using a probability-weighted discounted cash flow model, the significant inputs which are not observable in the market.

Property and Equipment. Property and equipment is carried at cost less accumulated depreciation. Depreciation is computed using the straight-line method based on estimated useful lives. Effective January 1, 2011, we changed the estimated useful lives of certain surgical instrument sets that we loan to or place with hospitals from three to four years. If we introduce new products or next-generation products, we may be required to dispose of surgical instrument sets prior to the end of their estimated useful life and/or write off the value or accelerate the depreciation of the these assets. Maintenance and repairs on all property and equipment are expensed as incurred.

Valuation of Goodwill and Intangible Assets. Our goodwill represents the excess of the cost over the fair value of net assets acquired from our business combinations. Our intangible assets are comprised primarily of acquired technology, in-process research and development, customer relationships, manufacturing know-how, licensed technology, supply agreements, and trade names and trademarks. We make significant judgments in relation to the valuation of goodwill and intangible assets resulting from business combinations and asset acquisitions.

The determination of the value of goodwill and intangible assets arising from business combinations and asset acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the fair value of the net tangible and intangible assets acquired, including in-process research and development (IPR&D). Goodwill and IPR&D are not amortized. The value and useful lives assigned to other acquired intangible assets impact future amortization.

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Authoritative guidance requires that goodwill and intangible assets with indefinite lives be assessed for impairment using fair value measurement techniques on an annual basis or more frequently if facts and circumstance warrant such a review. For purposes of assessing the impairment of goodwill, we estimate the value of our primary reporting unit using our market capitalization as the best evidence of fair value. For other reporting units, we estimate the fair value using the income approach valuation methodology based on discounted cash flows. If the carrying amount of a reporting unit exceeds its fair value, then a goodwill impairment test is performed to measure the amount of the impairment loss, if any. During the years ended December 31, 2011 and 2010, we did not record any impairment charges related to goodwill. During the fourth quarter of 2012, we updated our discounted cash flow valuation model for Impulse Monitoring and based on Management's current estimates of revenues and expenses, related cash flows and the discount rate used in the model, the estimated fair value of Impulse Monitoring's reporting unit was less than its carrying value. Management's estimates of revenues and related cash flows reflect the impacts of the significant coding changes for IOM services which take effect in 2013 and are expected to result in reduced reimbursement for IOM services. In accordance with the authoritative guidance, we recorded an impairment charge to Impulse Monitoring's goodwill of $8.3 million.

Additionally, during the years ended December 31, 2012 and 2011, we recorded an impairment charge of $1.4 million and $17.6 million, respectively, related to the in-process research and development recorded for the PCM® device acquired from Cervitech in 2009. The primary factor contributing to these impairment charges was the reduction in management’s estimates of revenue for this device, and the related decreases to the estimated cash flows due to updated views of the competitive and regulatory landscape in the cervical market. The PCM device received U.S. Food and Drug Administration (FDA) approval in late 2012.

We evaluate our intangible assets with finite lives for indications of impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Intangible assets consist of purchased technology, trademarks and trade names, customer relationships and agreements, manufacturing know-how and other intangibles and are amortized on a straight-line basis over their estimated useful lives of two to 17 years. Factors that could trigger an impairment review include significant under-performance relative to expected historical or projected future operating results, significant changes in the manner of our use of the acquired assets or the strategy for our overall business or significant negative industry or economic trends. If this evaluation indicates that the value of the intangible asset may be impaired, we make an assessment of the recoverability of the net carrying value of the asset over its remaining useful life. If this assessment indicates that the intangible asset is not recoverable, based on the estimated undiscounted future cash flows of the technology over the remaining amortization period, we reduce the net carrying value of the related intangible asset to fair value and may adjust the remaining amortization period. During the year ended December 31, 2011, we recorded an impairment charge of $0.6 million related to developed technology acquired from Cervitech in 2009. The primary factor contributing to this impairment charge was the reduction in management’s revenue estimate and the related decrease to the estimated cash flows for this device. Significant management judgment is required in the forecasts of future operating results that are used in the discounted cash flow valuation models. It is possible that plans may change and estimates used may prove to be inaccurate. If our actual results, or the plans and estimates used in future impairment analyses, are lower than the original estimates used to assess the recoverability of these assets, we could incur additional impairment charges.

Valuation of Stock-Based Compensation. The estimated fair value of stock-based awards exchanged for shareowner (employee) and non-employee director services are expensed over the requisite service period. Option awards issued to non-employees (excluding non-employee directors) are recorded at their fair value as determined in accordance with authoritative guidance, and are periodically revalued as the options vest and are recognized as expense over the related service period.

For purposes of calculating stock-based compensation, we estimate the fair value of stock options and shares issued under the Employee Stock Purchase Plan using a Black-Scholes option-pricing model. The determination of the fair value of stock-based payment awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected volatility is based on the historical volatility of our common stock over the most recent period commensurate with the estimated expected term of the stock options. The expected life of the stock options is based on historical and other

economic data trended into the future. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected terms of our stock options. The dividend yield assumption is based on our history and expectation of no dividend payouts. The fair value of restricted stock units granted is based on the market price of our common stock on the date of grant.

In February 2012, the Compensation Committee of the Board of Directors (the Compensation Committee) granted Performance-Based Restricted Stock Units (PRSUs) to certain senior Company executives. We recognize the stock-based compensation expense related to PRSUs granted based on the probability of achieving the specified performance criteria, as defined in the PRSU agreements. Expense is recognized using the graded vesting attribution method over the remaining recognition period based on these probabilities. Due to the nature of the performance goals, assessing the probability of achieving those goals is a highly subjective process that requires judgment.

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If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there is a difference between the assumptions used in determining stock-based compensation expense and the actual factors which become known over time, specifically with respect to anticipated forfeitures, we may change the input factors used in determining stock-based compensation costs for future grants. These changes, if any, may materially impact our results of operations in the period such changes are made.

Accounting for Income Taxes. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and the valuation allowance recorded against our net deferred tax assets. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting. During the fourth quarter of 2010, we concluded that it was more likely than not that we would be able to realize the benefit of our domestic deferred tax assets in the future. We based this conclusion on historical and projected operating performance, as well as our expectation that our operations will generate sufficient taxable income in future periods to realize the tax benefits associated with the deferred tax assets. As a result, we released the valuation allowance on our domestic deferred tax assets.

As a result of the litigation award accrual totaling $101.2 million recorded in the third quarter of 2011, we evaluated the need for a valuation allowance on our deferred tax assets by reviewing all available positive and negative evidence. Based on our review, we concluded that it was more likely than not that we would be able to realize the benefit of our U.S. federal deferred tax assets and our deferred tax assets for all states except California in the future. This conclusion was primarily based on historical and projected operating performance, as well as our expectation that our operations will generate sufficient taxable income in future periods to realize the tax benefits associated with the federal deferred tax assets well within the statutory carryover periods. Accordingly, we did not establish a valuation allowance on our federal or non-California state deferred tax assets as of December 31, 2012 or 2011.

Based on this same evidence and consideration of the state of California’s past and current suspension of the use of net operating loss carryforwards, the state of California’s statutory carryover periods and our apportionment election beginning in 2011, we concluded that it is more likely than not that we will not be able to utilize our California deferred tax assets. Therefore, we established a full valuation allowance on our California deferred tax assets as of December 31, 2011. Accordingly, the income tax benefit reported for the year ended December 31, 2011, includes income tax expense totaling $4.8 million in connection with the establishment of this valuation allowance. A full valuation allowance on our California deferred tax assets continues to exist as of December 31, 2012.

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

Legal Proceedings. We are involved in a number of legal actions involving both product liability and intellectual property disputes. The outcomes of these legal actions are not within our complete control and may not be known for prolonged periods of time. In some actions, the claimants seek damages as well as other relief, including injunctions barring the sale of products that are the subject of the lawsuit, that could require significant expenditures or result in lost revenues. In accordance with authoritative guidance, we disclose information regarding each material claim where the likelihood of a loss contingency is probable or reasonably possible. An estimated loss contingency is accrued in our financial statements if it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. If a loss is reasonably possible and can be reasonably estimated, the estimated loss or range of loss is disclosed in the notes to the consolidated financial statements. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded. Our significant legal proceedings are discussed in Note 11 to the consolidated financial statements included in this Annual Report. While it is not possible to predict the outcome for the matters discussed in Note 11 to the consolidated financial statements, we believe it is possible that costs

associated with them could have a material adverse impact on our consolidated earnings, financial position or cash flows.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. See our consolidated financial statements and notes thereto included in this report, which contain accounting policies and other disclosures required by GAAP.

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Results of Operations
Revenue

	Year Ended December 31,			2011 to 2012		2010 to 2011	
	2012	2011	2010	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Spine Surgery Products	$471,186	$430,970	$387,797				
Biologics	110,179	99,759	90,152				
Monitoring Service	38,890	9,777	288				
Total revenue	$620,255	$540,506	$478,237	$79,749	15 %	$62,269	13 %

Our Spine Surgery Product line offerings, which include products for the thoracolumbar spine, the cervical spine, and a set of motion preservation product offerings, 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), FormaGraft, a collagen synthetic product, Osteocel Plus, an allograft cellular matrix containing viable mesenchymal stem cells, or MSCs, and AttraX, a synthetic bone graft material, all used to aid the spinal fusion process. Our Monitoring Service line offering includes hospital-based revenues and net patient service revenues related to IOM services performed.

The continued adoption of minimally invasive procedures for spine has led to the continued expansion of our innovative lateral procedure known as 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. In addition, increased market acceptance in our international markets contributed to the increase in revenues noted for the periods presented. We expect continued adoption of our XLIF procedure and deeper penetration into existing accounts and our newer international markets as our sales force executes on the strategy of selling the full mix of our products. However, recent changes in market dynamics, the public and private insurance markets and ongoing policy and legislative changes in the United States have created less predictability in the lumbar portion of the spine market and have substantially reduced the overall spine market's procedural growth rate. Accordingly, we believe that our growth in revenue in 2013 will come primarily from market share gains related to the market shift toward less invasive spinal surgery, both domestically and internationally.

Our total revenues increased $79.7 million in 2012 compared to 2011 and $62.3 million in 2011 compared to 2010, representing total revenue growth of 15% and 13%, respectively.

Revenue from our Spine Surgery Products increased $40.2 million, or 9%, in 2012 compared to 2011 and $43.2 million, or 11%, in 2011 compared to 2010. These increases resulted from increases in volume of approximately 11% and 12% for the years ended December 31, 2012 and 2011 respectively, compared to the prior periods, offset by small unfavorable changes in price of approximately 1% and 2%, respectively, for the same periods.

Revenue from Biologics increased $10.4 million, or 10%, in 2012 compared to 2011 and $9.6 million, or 11%, in 2011 compared to 2010. These increases resulted from increases in volume of approximately 11% and 12% for the years ended December 31, 2012 and 2011, respectively, compared to the prior periods, offset by small unfavorable changes in price of approximately 1% for the same periods.

Revenue from Monitoring Services increased $29.1 million in 2012 compared to 2011, and $9.5 million from $0.3 million in 2011 compared to 2010. These increases resulted from the acquisition of Impulse Monitoring in October of 2011.

Cost of Goods Sold, excluding amortization of purchased technology

	Year Ended December 31,			2011 to 2012		2010 to 2011	
	2012	2011	2010	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Cost of Goods Sold	$153,409	$112,111	$85,139	$41,298	37 %	$26,972	32 %
% of total revenue	25 %	21 %	18 %				

Cost of goods sold consists of costs of purchased goods, inventory-related costs and royalty expense, as well as the cost of providing IOM service, which includes personnel and physician oversight costs.

Cost of goods sold as a percentage of revenue increased in 2012 over 2011 primarily related to higher costs as a percentage of revenue with monitoring service revenues of approximately 2% and estimated royalty expense accruals associated with the

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judgment in the Medtronic litigation of approximately 1%. Cost of goods sold as a percentage of revenue increased slightly in 2011 over 2010, primarily related to an increase in excess and obsolete inventory reserves of approximately 1%, higher costs as a percentage of revenue with monitoring service revenues of approximately 1% and estimated royalty expense accruals associated with the 2011 judgment in the Medtronic litigation of approximately 1%.

For 2013, we expect cost of goods sold, as a percentage of revenue, to increase compared to 2012, primarily as a result of the impact of the medical device excise tax. We are currently accruing royalties related to the Medtronic litigation at the rates stated in the judgment; however, ongoing royalty rates have not yet been determined. Accordingly, any increase to those rates will have a negative impact on cost of goods sold.

Operating Expenses

Sales, Marketing and Administrative

	Year Ended December 31,			2011 to 2012		2010 to 2011	
	2012	2011	2010	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Sales, Marketing and Administrative	$372,416	$349,052	$314,675	$23,364	7 %	$34,377	11 %
% of total revenue	60 %	65 %	66 %				

Sales, marketing and administrative expenses consist primarily of compensation, commission and training costs for shareowners engaged in sales, marketing and customer support functions; distributor commissions; depreciation expense for surgical instrument sets; shipping costs; surgeon training costs; shareowner (employee) related expenses for our administrative functions; and third-party professional service fees.

As a percentage of revenue, sales, marketing and administrative expenses decreased in 2012 compared to 2011, primarily as a result of the addition of Impulse Monitoring, which has a lower sales, marketing and administrative expense profile than the rest of NuVasive, as well as lower stock-based compensation expense and lower legal expenses incurred in connection with the Medtronic litigation. As a percentage of revenue, sales, marketing and administrative expenses decreased in 2011 compared to 2010, principally as a result of increased operating leverage in our expenses, as well as lower legal expenses incurred on non-Medtronic related litigation, relative to the 13% growth in revenue in 2011 compared to 2010.

Costs that tend to vary based on revenue, which include commissions, depreciation expense for loaned surgical instrument sets, worldwide sales force headcount, distribution and customer support headcount, and shipping, increased $22.2 million in 2012 compared to 2011. This increase is less than our increased revenue growth in 2012 compared to the prior year due to the addition of Impulse Monitoring. Excluding the impact resulting from a change in an accounting estimate related to the useful life of certain surgical instrument sets in 2011, costs that tend to vary based on revenue increased $18.1 million in 2011 compared 2010.

Effective January 1, 2011, we changed the useful life of certain surgical instrument sets from three to four years. This change, which was accounted for as a change in accounting estimate, resulted in approximately $1.2 million and $5.9 million less depreciation expense for the years ended December 31, 2012 and 2011 than would have been recorded had the useful life of these assets not been extended.

Compensation and other shareowner related expenses for our marketing and administrative support functions increased $8.3 million in 2012 compared to 2011. This increase is primarily the result of additions to our headcount and an increase in performance-based compensation. Compensation and other shareowner related expenses for our marketing and administrative support functions increased $11.9 million in 2011 compared to 2010. This increase is primarily the result of additions to our headcount.

We continue to make significant investments in our Japanese operations. This investment, along with increased depreciation expense associated with certain system software investments, represented increases of $4.0 million and $1.3 million in 2012 and 2011, respectively, compared to the prior year.

Stock-based compensation decreased $5.5 million in 2012 as compared to 2011, primarily related to a decrease in the weighted average grant date fair value of 2012 grants compared to 2011 grants, as well as the timing of annual grants in the current year as compared to the prior year. The decrease in the weighted average grant date fair value is

primarily attributed to the decrease in our average stock price for 2012 compared to 2011. Stock-based compensation increased $4.6 million in 2011 compared to 2010, primarily related to an increase in stock-based awards granted to shareowners associated with the continued increase in headcount.

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In addition, legal expenses incurred in connection with the Medtronic litigation decreased $4.6 million in 2012 as compared to 2011. Legal expenses decreased $0.8 million in 2011 as compared to 2010, primarily due to increased expenses incurred in connection with the Medtronic litigation during 2011, which were more than offset by decreased expenses incurred in connection with the defense of the NeuroVision trademark infringement litigation during 2010. On a long-term basis, we expect total sales, marketing and administrative costs, as a percentage of revenue, to continue to decrease moderately.

Research and Development

	Year Ended December 31,			2011 to 2012		2010 to 2011	
	2012	2011	2010	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Research and Development	$35,296	$38,408	$40,926	$(3,112)	(8)%	$(2,518)	(6)%
% of total revenue	6%	7%	9%				

Research and development expense consists primarily of product research and development, clinical trial and study costs, regulatory and clinical functions, and shareowner related expenses.

In the last several years, we have introduced numerous new products and product enhancements that have significantly expanded our MAS platform, enhanced the applications of the XLIF procedure, expanded our offering of cervical products, and continued to invest to further enable our entry into the growing motion preservation market. We have also acquired complementary and strategic assets and technology, particularly in the area of biologics. We are developing proprietary total disc replacement devices for spine applications, which are currently in different phases of clinical trials and related studies. We anticipate continuing to incur costs associated with patient follow-up and advancing the products through the regulatory process related to these clinical trials and studies through at least 2013. Expenses incurred in connection with clinical trials and various studies decreased approximately $2.4 million in 2012 compared to 2011, primarily due to reduced costs as a result of the completion of enrollment in a clinical trial and the completion of certain biologics-related studies. Expenses incurred in connection with clinical trials and study related activities decreased $2.7 million in 2011 compared to 2010.

Compensation and other shareowner related expenses, including performance-based compensation, decreased $0.5 million in 2012 compared to 2011, and primarily relates to compensation-related savings, including a shift of expenses out of shareowner compensation and into outside consulting expenses. Compensation and other shareowner related expenses, including performance-based compensation, increased $1.1 million in 2011 compared to 2010, which includes expenses totaling $0.3 million recorded in the year ended December 31, 2011 resulting from the correction of an immaterial error related to the accrual of payroll expenses. This increase is primarily due to increased compensation and other shareowner related expenses resulting from additions to our headcount to support our product development and enhancement efforts, offset by a decrease in performance-based compensation.

For the foreseeable future, as a percentage of revenue, we expect total research and development costs to remain consistent with 2012 in support of our ongoing development and 510k product approval efforts.

Amortization of Intangible Assets

	Year Ended December 31,			2011 to 2012		2010 to 2011	
	2012	2011	2010	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Amortization of Intangible Assets	$12,430	$6,609	$5,407	$5,821	88%	$1,202	22%
% of total revenue	2%	1%	1%				

Amortization of intangible assets relates to the amortization of finite-lived intangible assets acquired. Amortization expense increased $5.8 million and $1.2 million in 2012 and 2011, respectively, as compared to prior years, primarily due to the acquisition of Impulse Monitoring in October 2011 and intangible assets acquired during 2012 and 2011, compared to the prior years.

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We expect expenses recorded in connection with the amortization of intangible assets to continue to increase in absolute dollars for the foreseeable future as amortization of acquired in-process research and development commences once acquired research and development projects reach technological feasibility, including additional expense resulting from the recent approval of the PCM device.

Impairment of Goodwill and Intangible Assets

	Year Ended December 31,			2011 to 2012		2010 to 2011	
	2012	2011	2010	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Impairment of Goodwill and Intangible Assets	$9,700	$18,167	$—	$(8,467)	(47)%	$18,167	—
% of total revenue	2%	3%	—%				

During the fourth quarter of 2012, we recorded $8.3 million of impairment charges related to Impulse Monitoring's goodwill. Additionally, during the fourth quarter of 2012 and 2011, we recorded $1.4 million and $18.2 million, respectively, of impairment charges related to intangible assets acquired from Cervitech in 2009.

Litigation Award

	Year Ended December 31,			2011 to 2012		2010 to 2011	
	2012	2011	2010	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Litigation Award	$—	$101,200	$—	$(101,200)	(100)%	$101,200	100%
% of total revenue	—%	19%	—%				

Litigation award expenses represent the monetary damages awarded to Medtronic during September 2011.

Interest and Other Expense, Net

	Year Ended December 31,			2011 to 2012		2010 to 2011	
	2012	2011	2010	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Interest income	$915	$832	$760				
Interest expense	(27,710)	(17,933)	(6,672)				
Other income (expense), net	1,047	2,078	(264)				
Total interest and other expense, net	$(25,748)	$(15,023)	$(6,176)	$(10,725)	71%	$(8,847)	143%
% of total revenue	(4)%	(3)%	(1)%				

Interest and other expense, net, consists principally of interest expense incurred on our outstanding $476.8 million Senior Convertible Notes, offset by income earned on marketable securities and other income (expense) items. Interest expense increased $9.8 million and $11.3 million in 2012 and 2011, respectively, as compared to prior years, as a result of the additional cash and non-cash interest expense associated with the 2017 Notes offering which closed in June 2011, slightly offset by reduced interest incurred from the repurchase of the 2013 Notes during 2011.

Other income, net decreased $1.0 million and increased $2.3 million in 2012 and 2011, respectively, as compared to prior years, primarily as a result of the $2.4 million net non-cash gain recorded during 2011 related to the changes in the fair values of the derivative asset and liability recorded in connection with the 2017 Notes offering, slightly offset by a foreign currency gain of $0.9 million in 2012 and a foreign currency loss of $0.7 million in 2011.

Interest and other expense, net, as a percentage of revenues, is expected to remain at current levels in 2013.

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Income Tax Expense (Benefit)

	Year Ended December 31,			2011 to 2012		2010 to 2011	
	2012	2011	2010	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Income Tax Expense (Benefit)	$8,814	$(29,043)	$(50,619)	$37,857	(130)%	$21,576	(43)%
Effective income tax (Benefit) rate	78%	(29)%	(195)%				

The effective income tax expense rate for 2012 was 78% compared to an effective tax benefit rate of 29% in 2011. The effective tax rate for 2012 reflects the impact of the non-deductible goodwill impairment charge of $8.3 million. Excluding the impact of the non-deductible goodwill impairment charge, the effective tax rate for 2012 would have differed from the U.S. federal statutory rate of 35% due primarily to state income taxes, net of federal benefit, and non-deductible stock award compensation.

In January 2013, the American Taxpayer Relief Act of 2012 was signed into law in the U.S. This legislation includes the temporary extension of several expired business tax incentives retroactively to calendar year 2012 and prospectively through calendar year 2013. Among the expired tax provisions was the research and development tax credit. The effects of the change in the tax law will be recognized in our first quarter of 2013, the quarter during which the law was enacted. Had the legislation been enacted during 2012, our income tax expense would have been reduced by approximately $1.0 million for the year ended December 31, 2012.

The 29% effective tax benefit rate for 2011 reflects the impact of the significant charges related to the litigation award and asset impairment. As a result of the litigation award accrual totaling $101.2 million recorded in 2011, we evaluated the need for a valuation allowance on our deferred tax assets by reviewing all available positive and negative evidence. Based on our review, we concluded that it was more likely than not that we would be able to realize the benefit of our U. S. federal deferred tax assets and our deferred tax assets for all states except California in the future. This conclusion was primarily based on historical and projected operating performance, as well as our expectation that our operations will generate sufficient taxable income in future periods to realize the tax benefits associated with the federal deferred tax assets well within the statutory carryover periods. Accordingly, we did not establish a valuation allowance on our federal or non-California state deferred tax assets as of December 31, 2011. Based on this same evidence and consideration of the state of California’s past and current suspension of the use of net operating loss carryforwards, the state of California’s statutory carryover periods and our apportionment election beginning in 2011, we concluded that it is more likely than not that we will not be able to utilize our California deferred tax assets. Therefore, we established a full valuation allowance on our California deferred tax assets as of December 31, 2011. Accordingly, the income tax benefit reported for 2011 includes income tax expense totaling $4.8 million in connection with the establishment of this valuation allowance. A full valuation allowance on our California deferred tax assets continues to exist at December 31, 2012.

In addition, certain future tax deductions were no longer going to be realized as a result of the repurchase of $155.7 million of our 2013 Notes in 2011. Accordingly, the income tax benefit for 2011 includes a charge totaling $1.8 million, representing the write off of deferred tax assets associated with these future deductions.

Excluding the impact of the establishment of the $4.8 million valuation allowance on our California deferred tax assets, the effective income tax rate for 2011 would have differed from the U.S. federal statutory rate of 35% due primarily to state income taxes, net of federal benefit, and non-deductible stock award compensation.

The 195% income tax benefit for 2010 includes federal, state and foreign income tax expense, offset by the reversal of a valuation allowance totaling $55.7 million. We generated pre-tax book income in both 2010 and 2009. As a result of this positive earnings trend, three years of cumulative profits and projected future taxable income, we determined that it was more likely than not that our domestic deferred tax assets would be realized and, accordingly, we reversed a valuation allowance totaling approximately $72.7 million that was recorded against these deferred tax assets ($17.0 million of the reversal resulted in a benefit recorded to additional paid in capital). Excluding the impact of this reversal of the valuation allowance, the effective income tax rate for 2010 would have differed from the U.S. federal

statutory rate of 35% due to state income taxes, net of federal benefit, and non-deductible stock award compensation in 2010.

We are subject to audits by federal, state, local, and foreign tax authorities. We believe that adequate provisions have been made for any adjustments that may result from tax examinations. However, the outcome of tax audits cannot be predicted with certainty. Should any issues addressed in our tax audits be resolved in a manner not consistent with management's expectations,

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we could be required to adjust our provision for income taxes in the period such resolution occurs. We will continue to assess the likelihood of realization of our tax credits and other net deferred tax assets. If future events occur that do not make the realization of such assets more likely than not, a valuation allowance will be established against all or a portion of the net deferred tax assets.

We expect our effective income tax rate to exceed the U.S. federal and state statutory income tax rates primarily due to non-deductible expenses, state income taxes, net of federal benefit, and certain foreign losses expected to be incurred for which no benefit can be recorded.

Stock-Based Compensation

The compensation expense that has been included in the statement of operations for all stock-based compensation arrangements was as follows:

	Year Ended December 31,			2011 to 2012		2010 to 2011	
	2012	2011	2010	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Stock-Based Compensation							
Sales, Marketing & Administrative	$24,096	$29,583	$24,945				
Research & Development	2,138	2,487	3,280				
Cost of Goods Sold	78	—	—				
Total Stock-Based Compensation	$26,312	$32,070	$28,225	$(5,758)	(18)%	$3,845	14 %
% of total revenue	4 %	6 %	6 %				

Stock-based compensation related to stock awards is recognized and amortized on an accelerated basis in accordance with authoritative guidance. The decrease in stock-based compensation of approximately $5.8 million in 2012 as compared to 2011 primarily related to a decrease in the weighted average grant date fair value of 2012 grants compared to 2011 grants, as well as timing of annual grants in the current year as compared to the prior year. The decrease in the weighted average grant date fair value is primarily attributed to the decrease in our average stock price for 2012 compared to 2011. The increase in stock-based compensation of approximately $3.8 million in 2011 as compared to 2010 can be primarily attributed to an increase in the number of awards due to increased headcount year over year.

As of December 31, 2012, there was approximately $3.0 million, $15.4 million, and $1.7 million of unrecognized compensation expense for stock options, RSUs and PRSUs, respectively, which is expected to be recognized over a weighted-average period of approximately 1.2 years, 1.9 years and 1.5 years, respectively. In addition, as of December 31, 2012, there was $2.0 million of unrecognized compensation expense for shares expected to be issued under the Employee Stock Purchase Plan which is expected to be recognized through October 2014.

Business Combinations and Asset Acquisitions

Acquisition of Impulse Monitoring, Inc. In October 2011, we completed the purchase of all of the outstanding shares of Impulse Monitoring for an initial payment of approximately $79.7 million consisting of cash totaling approximately $40.5 million and the issuance of 2,336,200 shares of NuVasive common stock to certain stockholders of Impulse Monitoring. Impulse Monitoring, a company headquartered in Maryland, is a leading provider of outsourced IOM services to hospitals and became a wholly owned subsidiary of the Company upon completion of the acquisition. During the first quarter of 2012, we made an additional cash payment of approximately $1.2 million related to a working capital adjustment, resulting in a total purchase price of approximately $80.9 million. Of the total purchase price of $80.9 million, $57.7 million was allocated to goodwill based on management’s valuation of the fair value of the assets acquired and liabilities assumed on the date of acquisition. During the fourth quarter of 2012, we updated our discounted cash flow valuation model for Impulse Monitoring and based on Management's current estimates of

revenues and expenses, related cash flows and the discount rate used in the model, the estimated fair value of Impulse Monitoring's reporting unit was less than its carrying value. Management's estimates of revenues and related cash flows reflect the impacts of the significant coding changes for IOM services which take effect in 2013 and are expected to result in reduced reimbursement for IOM services. In accordance with the authoritative guidance, we recorded an impairment charge to Impulse Monitoring's goodwill of $8.3 million.

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Investment in Progentix Orthobiology, B.V. On January 13, 2009, we completed the purchase of forty percent (40%) of the capital stock of Progentix Orthobiology, B.V., a company organized under the laws of the Netherlands (Progentix), from existing shareholders (the Progentix Shareholders) pursuant to a Preferred Stock Purchase Agreement. NuVasive, Progentix and the Progentix Shareholders also entered into an Option Purchase Agreement dated January 13, 2009 (the Option Agreement), whereby (i) the Progentix Shareholders had two separate rights, upon the achievement of pre-defined development milestones by Progentix or sales milestones by us, to cause us to purchase the remaining sixty percent (60%) of capital stock of Progentix (Remaining Shares) at pre-defined prices (the Put Options), and (ii) we have the right, upon the occurrence of pre-defined events, to purchase the remaining sixty percent (60%) of capital stock of Progentix (the Call Option). We also entered into a Distribution Agreement with Progentix dated January 13, 2009, whereby Progentix appointed us as its exclusive distributor for certain Progentix products.

In accordance with authoritative guidance issued by the FASB, we determined that Progentix is a variable interest entity and that we are the primary beneficiary. Accordingly, the financial position and results of operations of Progentix have been included in the consolidated financial statements from the date of the initial investment. The equity interests in Progentix not owned by us are reported as noncontrolling interests on our consolidated balance sheet. Losses incurred by Progentix are charged to us and to the noncontrolling interest holders based on their ownership percentage. The Remaining Shares and the Option Agreement that was entered into between us, Progentix and the Progentix Shareholders are not considered to be freestanding financial instruments as defined by authoritative guidance. Therefore the Remaining Shares and the Option Agreement are accounted for as a combined unit in the consolidated financial statements as a redeemable noncontrolling interest that was initially recorded at fair value and classified as mezzanine equity.

On December 30, 2009, we entered into an amendment (the Amendment) to the Option Agreement and the Distribution Agreement with Progentix and the Progentix Shareholders in connection with the execution of an exclusive supply agreement between us and Ceremed, Inc. The Amendment, among other things, extended by five months the period of time allotted for the achievement of each of the milestones required to trigger the Put Options, reduced the transfer price paid to Progentix by us for the supply of product, and also reduced by up to $14.0 million the purchase price to be paid by us upon execution of either of the Put Options or the Call Option. As the Remaining Shares and the Option Agreement are accounted for as a combined unit in the consolidated financial statements, the Amendment resulted in the retirement of the noncontrolling equity interests originally recorded in January 2009, and in accordance with authoritative guidance, the noncontrolling equity interests were recorded at fair value as of December 30, 2009, the date of the Amendment. The fair value of the equity interests issued on December 30, 2009 approximated the carrying value of the noncontrolling equity interests on that date.

These transactions and their impact to our consolidated statement of financial position and results of operations are fully described in Note 2 to the consolidated financial statements included in this Annual Report.

Liquidity, Cash Flows and Capital Resources

Liquidity and Capital Resources

Our principal sources of liquidity are our existing cash, cash equivalents and marketable securities, cash generated from operations and proceeds from our convertible debt financings issued in March 2008 and June 2011.

In March 2008, we issued $230.0 million principal amount of 2.25% Senior Convertible Notes due 2013 (the 2013 Notes). The net proceeds from the offering, after deducting the initial purchasers' discounts and costs directly related to the offering, were approximately $208.4 million. We pay 2.25% interest per annum on the principal amount of the 2013 Notes, payable semi-annually in arrears in cash on March 15 and September 15 of each year. At December 31, 2012, approximately $74.3 million of the 2013 Notes remain outstanding. Any 2013 Notes not converted prior to March 15, 2013, the maturity date, will be paid in cash.

In June 2011, we issued $402.5 million principal amount of the 2.75% Convertible Senior Notes due 2017 (the 2017 Notes). The net proceeds from the offering, after deducting initial purchasers' discounts and costs directly related to the offering, were approximately $359.2 million. We pay 2.75% interest per annum on the principal amount of the 2017 Notes. The 2017 Notes mature on July 1, 2017 and may be settled in cash, stock, or a combination thereof, solely at our election. Interest on the 2017 Notes began accruing in June 2010 and is payable semi-annually on January 1 and

July 1 of each year.

In connection with the Medtronic litigation, a jury from the U.S. District Court, Southern District of California delivered an unfavorable verdict to us and awarded monetary damages of approximately $101.2 million to Medtronic. In May 2012, in accordance with an escrow arrangement, we transferred $113.3 million of cash into a restricted escrow account to secure the amount of the judgment, plus prejudgment interest, during pendency of our appeal of the judgment. These funds are included in restricted cash and investments in our December 31, 2012 consolidated balance sheet.

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Cash, cash equivalents and marketable securities was $346.1 million and $342.2 million at December 31, 2012 and 2011, respectively. We believe that our existing cash, cash equivalents and short-term marketable securities will be sufficient to meet our anticipated cash needs for the next 12 months. Our future capital requirements will depend on many factors including our rate of revenue growth, the timing and extent of spending to support development efforts, the expansion of sales, marketing and administrative activities, the timing of introductions of new products and enhancements to existing products, the continuing market acceptance of our products, the expenditures associated with possible future acquisitions or other business combination transactions, and the outcome of current and future litigation. At December 31, 2012, we have cash and investments totaling $119.0 million in restricted accounts which are not available to us to meet any ongoing capital requirements if and when needed. This could negatively impact our liquidity and our ability to invest in and run our business on an ongoing basis.

We expect that cash provided by operating activities may fluctuate in future periods as a result of a number of factors, including fluctuations in our operating results and working capital requirements. We have historically invested our cash primarily in U.S. treasuries and government agencies, corporate debt, and money market funds. Certain of these investments are subject to general credit, liquidity and other market risks. The general condition of the financial markets and the economy has exacerbated those risks and may affect the value of our current investments and restrict our ability to access the capital markets or even our own funds.

Cash Flows

The following table summarizes, for the periods indicated, selected items in our consolidated statements of cash flows (in thousands):

	Year Ended December 31,			2011 to 2012	2010 to 2011
	2012	2011	2010	$ Change	$ Change
Cash provided by operating activities	$130,082	$62,965	$65,827	$67,117	$(2,862)
Cash used in investing activities	(147,894)	(201,724)	(45,795)	53,830	(155,929)
Cash (used in) provided by financing activities	(22,556)	209,879	7,082	(232,435)	202,797
Effect of exchange rate changes on cash	175	(225)	70	400	(295)
(Decrease) increase in cash and cash equivalents	$(40,193)	$70,895	$27,184	$(111,088)	$43,711

Cash flows from operating activities

Cash provided by operating activities was $130.1 million in 2012, compared to $63.0 million in 2011. The $67.1 million increase in cash provided by operating activities in 2012 as compared to 2011 is due to an increase in net income, adjusted for noncash items, a decrease in amounts paid for other current assets, including a refund of $11.2 million relating to an overpayment at December 31, 2011, increased collections on outstanding accounts receivable and other working capital management initiatives related to accounts payable, inventories and accrued liabilities. Cash provided by operating activities was $63.0 million in 2011, compared to $65.8 million in 2010. The $2.9 million decrease in cash provided by operating activities in 2011 as compared to 2010 is primarily due to an increase in amounts paid for other current assets, including an overpayment of $11.2 million, which was refunded in January 2012, and increased payments related to accounts payable and accrued liabilities, offset by improved collections from accounts receivable.

Cash flows used in investing activities

Cash used in investing activities was $147.9 million in 2012, compared to $201.7 million in 2011. The $53.8 million decrease in cash used in investing activities in 2012 as compared to 2011 is primarily due to a decrease in cash paid for business and asset acquisitions, a decrease in purchases of property, plant and equipment, and a decrease in investment activity in marketable securities and restricted investments. Cash used in investing activities was $201.7 million in 2011, compared to $45.8 million in 2010. The $155.9 million increase in cash used in investing activities in 2011 as compared to 2010 is primarily due to an increase in our net purchases of marketable securities of $102.3

million, an increase in cash used related to the acquisition of Impulse Monitoring of $35.4 million, net of cash acquired, and increased purchases of surgical instrument sets which are deployed to support our increasing revenue volume.

Cash flows from financing activities

Cash used in financing activities was $22.6 million in 2012, compared to cash provided in financing activities of $209.9 million in 2011. The $232.4 million decrease in cash provided by financing activities in 2012 as compared to 2011 is primarily

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due to net proceeds totaling approximately $205.0 million from the convertible debt financing activity which occurred in 2011, and an increase in 2012 in cash paid for contingent consideration of $29.7 million. Cash provided by financing activities was $209.9 million in 2011, compared to $7.1 million in 2010. The $202.8 million increase in cash provided by financing activities in 2011 as compared to 2010 is primarily due to net proceeds totaling approximately $359.2 million from the issuance of 2017 Notes on June 28, 2011, offset by the repurchase of $154.2 million of our outstanding 2013 Notes.

Contractual Obligations and Commitments

Contractual obligations and commitments represent future cash commitments and liabilities under agreements with third parties, including our 2013 Notes and 2017 Notes (collectively, the Senior Convertible Notes), operating leases and other contractual obligations. The following summarizes our long-term contractual obligations and commitments as of December 31, 2012 (in thousands):

		Payments Due by Period			
	Total	Less Than 1 Year	1 to 3 Years	4 to 5 Years	After 5 Years
Senior Convertible Notes(1)	$526,909	$85,714	$22,137	$419,058	$—
Operating leases	82,536	10,748	15,724	15,415	40,649
Capital leases	1,049	590	459	—	—
Royalty obligations	600	120	240	240	—
Clinical advisory agreements	329	69	130	130	—
Supply agreements	17,500	8,900	8,600	—	—
Total	$628,923	$106,141	$47,290	$434,843	$40,649

(1) See Note 6 to the consolidated financial statements included in this Annual Report for further discussion of the terms of the Senior Convertible Notes.

The following obligations and commitments are not included in the table above:

In connection with the investment in Progentix, we are contingently obligated to make additional payments of up to $24.0 million.

In connection with several purchase and product development agreements, we are contingently obligated to make additional payments up to $17.1 million primarily upon the achievement of specified milestones.

We have not included an amount related to uncertain tax benefits or liabilities in the table above because we cannot make a reasonably reliable estimate regarding the timing of settlements with taxing authorities, if any. As of December 31, 2012, the liability included in the consolidated balance sheets related to tax uncertainties is immaterial.

The expected timing of payments of the obligations discussed above is estimated based on current information. Timing of payment and actual amounts paid may be different depending on the time of receipt of services or changes to agreed-upon amounts for some obligations. Amounts disclosed as contingent or milestone-based obligations depend on the achievement of the milestones or the occurrence of the contingent events and can vary significantly.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet activities.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity and Risk. Our exposure to interest rate risk at December 31, 2012 is related to our investment portfolio which consists largely of debt instruments of high quality corporate issuers and the U.S. government and its agencies. Due to the short-term nature of these investments, we have assessed that there is no material exposure to interest rate risk arising from our investments. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. At December 31, 2012, we do not hold any material asset-backed investment securities and in 2012, we did not realize any losses related to asset-backed investment securities. Based upon our overall interest rate exposure as of December 31, 2012, a change of 10 percent in interest rates, assuming the amount of our investment portfolio remains constant, would not have a material effect on interest expense. Further, this analysis does not consider the effect of the change in the level of the overall

economic activity that could exist in such an environment.

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Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. The primary objective of our investment activities is to preserve the principal while at the same time maximizing yields without significantly increasing the risk. To achieve this objective, we maintain our portfolio of cash equivalents and investments in instruments that meet high credit quality standards, as specified in our investment policy. None of our investments are held for trading purposes. Our policy also limits the amount of credit exposure to any one issue, issuer and type of instrument.

The following table presents the carrying value and related weighted-average rate of return for our investment portfolio as of December 31, 2012 (dollars in thousands):

	Carrying Value	Weighted Average Rate of Return	
Money market funds	$89,101	0.1	%
Certificates of deposit	998	0.4	%
Corporate notes	42,447	0.3	%
Commercial paper	9,997	0.2	%
U.S. government treasury securities	56,472	0.2	%
Securities of government-sponsored entities	198,326	0.2	%
Total interest bearing instruments	$397,341		

As of December 31, 2012, the stated maturities of our available for sale securities are $202.2 million within one year and $106.0 million from one to two years. These investments are recorded on the balance sheet at fair market value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income.

Market Price Sensitive Instruments. In order to reduce the potential equity dilution, we entered into convertible note hedge transactions (the Hedges) in connection with the issuance of the Senior Convertible Notes entitling us to purchase our common stock. Upon conversion of our Senior Convertible Notes, the Hedges are expected to reduce the equity dilution if the daily volume-weighted average price per share of our common stock exceeds the strike price of the Hedges. We also entered into warrant transactions with the counterparties of the Hedges entitling them to acquire shares of our common stock. The warrant transactions could have a dilutive effect on our earnings per share to the extent that the price of our common stock during a given measurement period (the quarter or year to date period) at maturity of the warrants exceeds the strike price of the warrants. These transactions are more fully discussed in Note 6 to the consolidated financial statements.

Foreign Currency Exchange Risk. We have operated mainly in the United States of America, and the majority of our sales since inception have been made in U.S. dollars. Accordingly, we have assessed that we do not have any material exposure to foreign currency rate fluctuations. However, as our business in markets outside of the United States continues to increase, we will be exposed to foreign currency exchange risk related to our foreign operations. Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies, primarily the euro, the australian dollar and the yen, could adversely affect our financial results.

Exchange rate fluctuations resulting from the translation of the short-term intercompany balances between NuVasive, Inc., our U.S. entity, and our foreign subsidiaries, are recorded as foreign currency transaction gains or losses and are included in other income (expense) in the consolidated statement of operations.

We do not currently engage in hedging activities with respect to our foreign currency exchange risk.

Item 8. Financial Statements and Supplementary Data.

The consolidated financial statements and supplementary data required by this item are set forth at the pages indicated in Item 15.

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

None

Item9A. Controls and Procedures

Disclosure Controls and Procedures. We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended (Exchange Act) is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and

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procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of the Company's disclosure controls and procedures (as such term is defined in SEC Rules 13a — 15(e) and 15d — 15(e)) as of December 31, 2012. Based on such evaluation, our management has concluded as of December 31, 2012, the Company's disclosure controls and procedures are effective.

Management's Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Management has used the framework set forth in the report entitled Internal Control — Integrated Framework published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of the Company's internal control over financial reporting. Management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2012. Ernst & Young LLP, the Company's independent registered public accounting firm, has issued an attestation report on the Company's internal control over financial reporting which is included herein.

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

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
NuVasive, Inc.

We have audited NuVasive, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). NuVasive, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, NuVasive, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of NuVasive, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012 of NuVasive, Inc. and our report dated February 26, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP
San Diego, California
February 26, 2013

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Item 9B. Other Information
None.
PART III
Certain information required by Part III is omitted from this report because the Company will file a definitive proxy statement within 120 days after the end of its fiscal year pursuant to Regulation 14A (the Proxy Statement) for its annual meeting of stockholders to be held on May 23, 2013, and certain information included in the Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.
We have adopted a Code of Conduct and Ethics for all officers, directors and shareowners. The Code of Conduct and Ethics is available on our website, www.nuvasive.com, and in our filings with the Securities and Exchange Commission. We intend to disclose future amendments to, or waivers from, provisions of our Code of Conduct and Ethics that apply to our Principal Executive Officer, Principal Financial Officer, Principal Accounting Officer, or Controller, or persons performing similar functions, within four business days of such amendment or waiver.
The other information required by this Item 10 will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 11. Executive Compensation.
The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.
The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.
The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 14. Principal Accountant Fees and Services.
The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.
PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as a part of this report:
(1) Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets as of December 31, 2012 and 2011
Consolidated Statements of Operations for the years ended December 31, 2012, 2011 and 2010
Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2012, 2011 and 2010
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2012, 2011 and 2010
Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010
Notes to Consolidated Financial Statements
(2) Financial Statement Schedules: Schedule II — Valuation Accounts
All other financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

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(3) Exhibits. See subsection (b) below.
(b) Exhibits. The following exhibits are filed as part of this report:

Exhibit Number	Description
3.1	Restated Certificate of Incorporation (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 13, 2004)
3.2	Certificate of Amendment to the Restated Certificate of Incorporation (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 1, 2012)
3.3	Restated Bylaws (incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 6, 2012)
4.1	Indenture, dated March 7, 2008, between the NuVasive Inc. and U.S. Bank National Association, as Trustee (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
4.2	Form of 2.25% Convertible Senior Note due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
4.3	Registration Rights Agreement, dated March 7, 2007, among NuVasive, Inc. and Goldman, Sachs & Co., and J.P. Morgan Securities Inc., related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
4.4	Specimen Common Stock Certificate (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 16, 2006)
10.1#	2004 Amended and Restated Equity Incentive Plan (incorporated by reference to Quarterly Report on Form 10-Q filed with the Commission on July 26, 2012)
10.2#	Form of Stock Option Award Notice under our 2004 Equity Incentive Plan (incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on April 8, 2004)
10.3#	Form of Option Exercise and Stock Purchase Agreement under our 2004 Equity Incentive Plan (incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on April 8, 2004).
10.4#	Form of Restricted Stock Unit Award Agreement under our 2004 Equity Incentive Plan (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10. 5#	2004 Employee Stock Purchase Plan (incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on April 8, 2004)
10.6#	Amendment No. 1 to the 2004 Employee Stock Purchase Plan (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on November 7, 2008)

10.7#	Amendment No. 2 to the 2004 Employee Stock Purchase Plan (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on February 25, 2011)
10.8#	Amendment No. 3 to the 2004 Employee Stock Purchase Plan (filed herewith)
10.9#	Executive Employment Agreement, dated as of January 2, 2011, by and between NuVasive, Inc. and Alexis V. Lukianov (incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 2, 2011)

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10.10#	Form of Compensation Letter Agreement dated March 4, 2011 between NuVasive, Inc. and each of the following: Keith C. Valentine, Patrick Miles, Jason M. Hannon, Michael J. Lambert, Jeffrey P. Rydin, Tyler P. Lipschultz and Craig E. Hunsaker (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 6, 2011)
10.11#	Letter Agreement by and between NuVasive, Inc. and Jeffrey P. Rydin, dated October 5, 2012 (incorporated by reference to our Current Report on Form 8-K filed with the Commission on October 9, 2012)
10.12#	Employment Agreement by and between NuVasive, Inc. and Matthew Link, dated January 2, 2013 (filed herewith)
10.13#	Employment Agreement by and between NuVasive, Inc. and Russell Powers, dated October 4, 2012 (filed herewith)
10.14	Form of Indemnification Agreement between NuVasive, Inc. and each of our directors and officers (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)
10.15#	Non-Employee Director Cash Compensation (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 5, 2011)
10.16	Lease Agreement for Sorrento Summit, entered into as of November 6, 2007, between the Company and HCPI/Sorrento, LLC. (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on November 8, 2007)
10.17	Purchase Agreement, dated March 3, 2008, among NuVasive, Inc. and Goldman, Sachs & Co., and J.P. Morgan Securities Inc., related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.18	