NUVASIVE INC
Form 10-K
February 25, 2011

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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, 2010

OR

o **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 o

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 o 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 o

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 o

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. o

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $1.4 billion as of the last business day of the registrant s most recently completed second fiscal quarter (i.e. June 30, 2010), 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 18, 2011, there were 39,627,071 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 25, 2011.

NuVasive, Inc.

Form 10-K for the Fiscal Year ended December 31, 2010

EX-101 LABELS LINKBASE DOCUMENT
EX-101 PRESENTATION LINKBASE DOCUMENT
EX-101 DEFINITION LINKBASE DOCUMENT

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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 simila 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 procedures for the spine. Our currently-marketed product portfolio is focused on applications for spine fusion surgery, including biologics, a combined market estimated to exceed $7.7 billion globally in 2011. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS®, as well as a growing offering of biologics, cervical and motion preservation products. Our spine surgery product line offerings, which include products for the thoracolumbar spine, the cervical spine, and a set of motion preservation product offerings still under development, are primarily used to enable access to the spine and to perform restorative and fusion procedures in a minimally disruptive fashion. Our biologic product line offerings include allograft (donated human tissue), FormaGraft®, a collagen synthetic product used to aid the fusion process, and Osteocel Plus®, an allograft cellular matrix containing viable mesenchymal stem cells, or MSCs, to aid in spinal fusion. We focus significant research and development efforts to expand our MAS product platform, advance the applications of our unique technology to additional procedures and develop motion preserving products such as our total disc replacement products. We dedicate significant resources toward training spine surgeons on our unique technology and products. Currently, we are training over 500 surgeons annually, which includes surgeons new to our MAS product platform as well as surgeons previously trained on our MAS product platform who are attending advanced training programs.

Our MAS platform combines four categories of our product offerings:

NV M5 and NV JJB our proprietary software-driven nerve monitoring systems;

MaXcess® a unique split-blade design retraction system providing enhanced surgical access to the spine;

Biologics includes our FormaGraft and Osteocel Plus line of products; and

Specialized implants includes our SpheRX® and Armada™ pedicle screw systems, CoRoent® suite of implants, and several fixation systems.

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We believe our MAS platform provides a unique and comprehensive solution for safe and reproducible minimally disruptive surgical treatment of spine disorders by enabling surgeons to access the spine in a manner that affords direct visualization and avoidance of critical nerves. The fundamental difference between our MAS platform and what has been previously named MIS, or minimally invasive surgery, is the ability to customize safe and reproducible access to the spine while allowing surgeons to continue to use instruments that are familiar to them. Simply stated, the MAS platform does not force surgeons to reinvent approaches that add complexity and undermine safety, ease and efficacy. An important ongoing objective has been to maintain a leading position in access and nerve avoidance, as well as being the pioneer and ongoing leader in lateral surgery. Our MAS platform, with the unique advantages provided by our nerve monitoring systems, enables an innovative lateral procedure known as eXtreme Lateral Interbody Fusion, or XLIF®, in which surgeons access the spine for a fusion procedure from the side of the patient s body, rather than from the front or back. Our MaXcess instruments provide access to the spine in a manner that affords direct visualization and our nerve monitoring systems allow surgeons to avoid critical nerves. We believe that the procedures facilitated by our MAS platform decrease trauma and blood loss, and lead to faster overall patient recovery times compared to open spine surgery.

In recent years, we have significantly expanded our product offering relating to procedures in the cervical spine as well as in the area of biologics. Our cervical product offering now provides a full set of solutions for cervical fusion surgery, including both allograft and CoRoent implants, as well as cervical plating and posterior fixation products. In 2009, we acquired Cervitech®, Inc., a company focused on gaining regulatory approval of the PCM® cervical disc system, a motion preserving total disc replacement device. This strategic acquisition allows us the potential to accelerate our entry into the growing mechanical cervical disc replacement market. In the first quarter of 2010, we submitted a premarket approval (PMA) application for U.S. Food and Drug Administration (FDA) approval for the PCM cervical disc system. Approval, if obtained, would further strengthen our cervical product offering and should enable us to continue our trend of increasing our market share. Our biologic offering includes FormaGraft, a collagen synthetic bone substitute, and Osteocel Plus, an allograft cellular matrix designed to mimic the biologic profile of autograft that includes endogenous mesenchymal stem cells (MSCs) and osteoprogenitors, both of which are used to aid in spinal fusion. In 2009, we invested in Progentix Orthobiology, B.V., a company organized under the laws of the Netherlands that is developing a synthetic bone graft material to aid in the healing and generation of human bone. As part of the investment transaction, we became the exclusive distributor for certain Progentix biologic products. We are currently in the process of seeking regulatory clearance for AttraX™, a synthetic bone graft material being developed by Progentix delivered in putty form.

Our corporate headquarters are located in San Diego, California. We lease approximately 208,000 square feet in San Diego. Our headquarters has a six-suite state-of-the-art cadaver operating theatre designed to accommodate the training of spine surgeons. In 2010 we opened a secondary training facility in Paramus, New Jersey with a five-suite operating theatre for surgeon training. Our primary distribution and warehousing operations are located in our facility in Memphis, Tennessee. Our business requires overnight delivery of products and surgical instruments for almost all surgeries involving our products. Because of its location and proximity to overnight third-party transporters, our Memphis facility has greatly enhanced our ability to meet demanding delivery schedules and provide a greater level of customer service.

Recent Product Introductions

In the last few 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 moved us closer to entry into the growing motion preservation market. We have also acquired complementary and strategic assets and technology, particularly in the area of biologics. Our newly-launched and acquired products are highlighted by the following products:

Implants our implant products, which include among other implants, the CoRoent family of products and our SpheRx and Armada pedicle screw systems, have historically focused on the lumbar spine; with our recent and planned product introductions, such as VuePoint® OCT and Thoracic XLIF, we will increasingly address the cervical and thoracic spine as well.

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NV M5 is, along with its predecessors, the enabling technology for the XLIF procedure, and utilizes proprietary technology and software hunting algorithms to locate and avoid critical nerves during access for and completion of spine surgery. NV M5 s name refers to five monitoring modalities, covering the entire spine, available in this enhanced version of our technology, which include: (i) stimulated electromyography (EMG); (ii) free run EMG; (iii) motor evoked potentials (MEPs); (iv) somatosensory evoked potentials (SSEPs); and (v) navigated guidance.

Biologics in 2008 we expanded our biologics offering by acquiring the Osteocel technology, an allograft cellular matrix designed to mimic the biologic profile of autograft that includes endogenous MSCs and osteoprogenitors to aid in fusion. Additionally, in early 2009 we made an investment in Progentix Orthobiology, B.V., a private company working to develop a novel synthetic bone graft material with a unique nano surface structure that allows for superior protein attachment. This investment includes options and obligations to buy Progentix Orthobiology, B.V. over time as development and commercial milestones are achieved.

Our Strategy

Our objective is to become a leading provider of creative medical products that provide comprehensive solutions for the surgical treatment of spine disorders. We are pursuing the following business strategies in order to achieve this objective:

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 their benefits and adopt our products. We also believe that our MAS platform has the potential to dramatically improve the clinical results of spine surgery. We dedicate significant resources to educating spine surgeons and their patients on the clinical benefits of our products, and we intend to capitalize on the demand for minimally disruptive surgical alternatives.

Continue to Develop and Introduce New Creative Products. One of our core competencies is our ability to develop and commercialize creative spine surgery products. In the past several years, we have introduced a continuous flow of new products and product enhancements. We have several additional products currently under development that should expand our presence in fusion surgery as well as provide an entry into the motion preservation market segment. We intend to accomplish this with an unwavering commitment to our MAS platform and building on our core technology. We believe that these additional products will allow us to increase our market share while improving patient care. Protecting and defending the intellectual property related to our innovative products is a core component to this strategy.

Expand the Reach of Our Exclusive Sales Force. We believe that having a sales force dedicated to selling only our spine surgery products is critical to achieving continued growth across product lines, greater market penetration and increased sales. Our global sales force is managed by three Executive Vice Presidents managing the following territories: Asia Pacific, EMEA (Europe, Middle East and Africa) and the Americas. In the United States, we have an exclusive sales force that is managed by our Executive Vice President of the Americas who manages five Area Vice Presidents, responsible for a geographic region of the country. Each Area Vice President manages the directly-employed and exclusive independent sales agents engaged in that territory. Outside of the United States, each Executive Vice President manages directly-employed sales agents, independent sales agents and exclusive distributors within their respective territory.

Provide Tailored Solutions in Response to Surgeon Needs. Responding quickly to the needs of spine surgeons, which we refer to as Absolute Responsiveness®, is central to our corporate culture, critical to our success and, we believe, differentiates us from our competition. We solicit information and feedback from our surgeon customers and clinical advisors regarding the utility of, and potential improvements, to our products. For example, we have an on-site machine shop to allow us to rapidly manufacture product prototypes and two state-of-the-art cadaver operating theatres (one on the East Coast and one on the West Coast) to provide clinical training and validate new ideas through prototype testing. Absolute Responsiveness goes beyond product development to include active support in clinical research and payer relations. For

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example, to ensure that patients have access to optimal spine care, we offer support to spine surgeons in their efforts to educate payers on the proven clinical benefits of 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 costs.

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 conduit, 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, is degenerative conditions of the facet joints and intervertebral disc space. These conditions can result in instability and pressure on the nerve roots as they exit the spinal column, causing back pain or radiating pain in the arms or legs.

In the United States, over 5 million people suffer from some type of chronic back 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 most cases, non-operative treatment options are effective; however, some patients require spine fusion surgery. iData Research has estimated that over 600,000 spine fusion procedures are performed annually in the United States, and the vast majority are done using traditional open surgical techniques from either a front or back approach. These traditional open surgical approaches require a large incision in the patient s abdomen or back in order to enable the surgeon to access and see the spine and surrounding area. These open procedures are invasive, lengthy and complex, and typically result in significant blood loss, extensive dissection of tissue and lengthy patient hospitalization and rehabilitation.

Back pain is one of the leading causes of healthcare expenditures in the United States, with a direct cost of more than $50 billion annually for diagnosis, treatment and rehabilitation. The U.S. market for lumbar and cervical spine fusion, the focus of our business, was estimated to be approximately $5.0 billion in 2010 and is estimated to remain at approximately that level in 2011.

We believe that the implant market for spine surgery procedures will continue to grow over the long term because of the following market dynamics:

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

Increasing Demand for Motion-preserving Treatments. Motion-preserving treatments potentially offer more effective earlier intervention in the degenerative disease process for many patients.

Favorable Demographics. The population segment most likely to experience back pain is expected to increase as a result of aging baby boomers, people born between 1946 and 1965. We believe this population segment will increasingly demand a quicker return to activities of daily living following surgery than prior generations.

Increased Use of Implants. The use of implants has evolved into the standard of care in spine surgery. Over the past five years, there has been a significant increase in the percentage of spine fusion surgeries using implants and we estimate that over 85% of all spine fusion surgeries now involve implants.

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Surgical Alternatives with Less Tissue Disruption

The benefits of minimally invasive surgery procedures in other areas of orthopedics have significantly contributed to the strong and growing demand for surgical alternatives with less tissue disruption of the spine. Surgeons and hospitals seek spine procedures that result in fewer operative complications and decreased hospitalization. At the same time, patients seek procedures that cause less trauma, allow for faster recovery times and more positive clinical outcomes. Despite these benefits, the rate of adoption of surgical alternatives with less tissue disruption procedures has been relatively slow with respect to the spine.

We believe the two principal factors contributing to spine surgeons slow adoption of traditional minimally invasive spine alternatives are: (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 (MAS)

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

Our MAS platform combines four product categories: our nerve monitoring systems, MaXcess, biologics and specialized implants. Our nerve monitoring systems enable surgeons to detect and navigate around nerves while MaXcess affords direct customized access to the spine for implant delivery. MaXcess also allows surgeons to use well-established traditional instruments in a minimally disruptive and less traumatic manner while our biologics offering complements our MAS platform by facilitating fusion. We also offer a variety of specialized implants that enable the maximization of disc height restoration and sufficient structural support while conforming to the anatomical requirements of the patient.

Our products facilitate minimally disruptive applications of the following spine surgery procedures, among others:

Lumbar fusion procedures in which the surgeon approaches the spine through the patient s back or abdomen;

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, or EMG, proprietary software hunting algorithms and graphical user interfaces to provide surgeons with an enhanced 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. We connect the instruments that surgeons use to a computer system that provides real time, surgeon directed

and surgeon controlled feedback during surgery. Our systems analyze and then translate complex neurophysiologic data into simple, useful information to assist the surgeon s clinical decision-making process. For example, during a pedicle screw test, in which the integrity of the bone where the implant is placed is tested, if the insertion of a screw results in a breach of the bone, a red light and corresponding numeric value will result so that the surgeon may reposition the screw to avoid potential nerve impingement or irritation. If no breach of the bone occurs, a green light and corresponding numeric value will result.

Surgeons can dynamically link familiar surgical instruments to our nerve monitoring systems, thus creating an interactive set of instruments that enable the safe navigation through the body s nerve anatomy. The connection is

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accomplished using a clip that is attached to the instrument, effectively providing the benefits of our nerve monitoring systems through an instrument already familiar to the surgeon. The systems proprietary software and easy to use graphical user interface enables the surgeon to make critical decisions in real time resulting in safer and faster procedures with the potential for improved patient outcomes. With recent additions, the health and integrity of the spinal cord can also be assessed using motor evoked potentials (MEPs) and somatosensory evoked potentials (SSEPs). Both methods of intraoperative monitoring involve applying stimulation and recording the response that must travel along the motor or sensory paths of the spinal cord. The data developed using our nerve monitoring systems can now be sent to health care professionals for additional interpretation of intraoperative information via networking capabilities and software that allows real-time assessment from remote locations.

MAS MaXcess

Our patented MaXcess system consists of instrumentation 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 build the surgical exposure in the shape and size specific to the surgical requirements rather than the fixed tube design of traditional minimally invasive spine surgical systems. MaXcess split blade design also provides expanded 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 significantly smaller incision. 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.

Over the years, several improvements to our MaXcess systems have been made, including incorporating nerve avoidance technology and improving the blade systems. Further, our MaXcess products are used in the cervical spine for posterior application, the lumbar spine for decompression, transforaminal interbody fusion, or TLIF, and have been used in the thoracic region as the lateral approach has broadened from the lumbar to the thoracic region as well as into 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 the anatomical requirements of the patient and the particular fusion procedure. Our implants are designed for insertion into the smallest possible space while maximizing surface area contact for fusion. Our fixation systems have been uniquely designed to be delivered through our MaXcess system to provide stabilization of the spine. These systems enable minimally disruptive placement of implants and are intended to reduce patient morbidity, often through a single approach.

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

MAS Biologics

As part of our MAS offering, we have expanded our product offerings in the last few years to include products in the biologics market. The global biologics market in spine surgery has grown to approximately $1.7 billion and consists of autograft (autologous human tissue), allograft (donated human tissue), a varied offering of synthetic products, stem cell-based products, and growth factors. We made our initial entry into this market in 2007 by acquiring rights to

FormaGraft, a collagen-based synthetic bone substitute. We expanded this offering in 2008 by acquiring Osteocel, an allograft cellular matrix designed to mimic the biologic profile of autograft that includes endogenous MCSs and osteoprogenitors to aid in fusion. Additionally, in early 2009, we made an investment in Progentix Orthobiology, B.V., a private company working to develop a novel synthetic bone graft material. We are currently in the process of seeking regulatory clearance for AttraX, a synthetic bone graft material being developed by Progentix delivered in putty form.

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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 physiological range of motion compared with fusion. Commercialization of these devices, including PCM, NeoDisc®, and XL TDR, will require premarket approval rather than 510(k) clearance. In the cervical spine, the PCM investigational device, a total disc replacement device designed to preserve motion, was submitted for FDA approval in the first quarter of 2010. Approval of PCM, if obtained, should further strengthen our cervical product offering and should enable us to continue our trend of increasing our market share. Also in the cervical spine, patient enrollment in the FDA-approved clinical trial of the NeoDisc total disc replacement device in the United States is complete.

Our lumbar motion preservation development efforts include XL TDR, a mechanical total disc replacement implanted through the XLIF approach. Enrollment in a FDA-approved XL TDR clinical trial in the United States was initiated in 2009 and will continue throughout 2011.

In addition to the motion preservation platforms previously mentioned, we continue development on a wide variety of projects intended to broaden surgical applications such as with tumor, trauma, and deformity, and increase fixation options for greater vertical integration of our MAS techniques. We also continue expanding our cervical product portfolio to provide for a comprehensive cervical offering that will include further segmentation of both the fixation and motion preservation markets.

Research and Development

Our research and development efforts are primarily focused on developing further enhancements to our existing products, launching new product categories, as well as developing our total disc replacement products. As of December 31, 2010, our research and development staff consists of 142 shareowners (employees), which includes 64 shareowners in regulatory and quality assurance. 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 hospitalization and rehabilitation times and, as a result, reduce costs.

Sales and Marketing

In the United States, we currently sell our products through a combination of exclusive independent sales agencies and direct sales representatives employed by us. Importantly, both our direct sales representatives as well as our independent sales agencies are exclusive and sell only NuVasive spine surgery products. Each member of our U.S. sales force is responsible for a defined territory, with our independent sales representatives acting as our sole representative in their respective territories. The determination of whether to engage a directly-employed shareowner or exclusive distributor is made on a territory by territory basis, with a focus on the candidate who brings the best skills and experience. Currently, the split between directly-employed and independent sales agents in our sales force is roughly equal. Our international sales force is comprised of directly-employed exclusive 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.

Our global sales force is managed by three Executive Vice Presidents managing the following territories: Asia Pacific, EMEA (Europe, Middle East and Africa) and the Americas. In the United States, our Executive Vice President of the Americas manages five Area Vice Presidents. Each Area Vice President is responsible for a portion of the United

States and manages the directly-employed and exclusive independent sales agents engaged in that territory. Outside of the United States, each Executive Vice President manages directly-employed sales agents, independent sales agents and exclusive independent distributors in their respective territory.

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Surgeon Training and Education

NuVasive devotes significant resources to training and educating surgeons regarding the safety and reproducibility of our surgical techniques and our complimentary instruments and implants. We maintain state-of-the-art cadaver operating rooms and training facilities at our corporate headquarters and our facility in Paramus, New Jersey to help promote adoption of our products. Currently, we are training over 500 surgeons annually in the XLIF technique and our other MAS platform products including: our proprietary nerve monitoring systems, MaXcess, Biologics, and specialized implants. NuVasive has also helped to establish SOLAS®, the Society of Lateral Access Surgery, a group of spine surgeons dedicated to the development and expanded application of lateral spine surgery techniques that offer significant patient benefits and improved clinical outcomes through peer-to-peer communication, clinical education efforts, and ongoing research. 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.

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

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

We currently rely on Tissue Banks International, Inc., Community Tissue Services and AlloSource, Inc. as our only suppliers of allograft tissue implants. AlloSource is also our sole supplier of Osteocel Plus, which is processed from allograft. Like our relationships with our device manufacturing suppliers, we subject our tissue processing suppliers to the same quality criteria in terms of selection, qualification, and verification of processed tissue quality upon receipt of goods, as well as hold them accountable to compliance with FDA regulation, state requirements, as well as voluntary industry standards such as the American Association of Tissue Banks, or AATB.

Invibio, Inc. is our exclusive supplier of polyetheretherketone (PEEK), which comprises our PEEK partial vertebral body product called CoRoent. We also have an exclusive supply arrangement with Sparton Medical Corporation (Sparton) pursuant to which Sparton is our exclusive supplier of our NV M5 and NV JJB neuromonitoring systems.

We acquired PCM, a motion preserving total disc replacement device, through our acquisition of Cervitech, Inc. (Cervitech). Our supply of the product comes from Waldemar Link GmbH & Co. KG, a company that was affiliated with Cervitech prior to the acquisition, and Sandvik Medical Solutions Limited.

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 European Compliance. Our facility and the facilities of our third-party manufacturers are subject to periodic unannounced inspections by regulatory authorities, and may undergo compliance inspections conducted by the FDA and corresponding state agencies.

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Loaned Instrument Sets

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

Intellectual Property

We rely on a combination of patent, trademark, copyright, trade secret and other intellectual property laws, nondisclosure agreements and other measures to protect our intellectual property rights. We believe that in order to have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. We require our shareowners, consultants and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationships with us. We also require our shareowners, consultants and advisors who we expect to work on our products to agree to disclose and assign to us all inventions conceived during the work day, using our property or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary.

Patents

As of December 31, 2010, we had 81 issued U.S. patents, 48 foreign national patents, and 299 pending patent applications, including 191 U.S. applications, 6 international (PCT) applications and 81 foreign national applications. Our issued and pending patents cover, among other things:

MAS surgical access and spine systems;

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

Implants and related instrumentation and targeting systems;

Biologics, including Osteocel Plus and Formagraft; and

Motion preservation products.

Our issued patents begin to expire in 2018. We do not believe that the expiration of any single patent is likely to significantly affect our intellectual property position.

We have undertaken to protect our neurophysiology platform, including our proprietary nerve monitoring systems, through a comprehensive strategy covering various important aspects of our neurophysiology-enabled instrumentation, including, screw test, software hunting algorithms, navigated guidance, surgical access and related methodology. Our neurophysiology patent portfolio includes 15 issued U.S. patents, 48 U.S. patent applications (including 45 U.S. utility patent applications, 2 U.S. provisional applications, and 1 U.S. design application), 12 issued foreign national patents, 2 international (PCT) patent applications, and 25 foreign national applications on these

systems and related instrumentation.

We have also undertaken to protect our XLIF surgical technique franchise, including methodology, implants, and systems used during XLIF procedures. Our XLIF patent portfolio includes 11 issued U.S. patents, 58 U.S. utility patent applications, 7 U.S. provisional patent applications, 1 international (PCT) patent application, and 17 foreign national patent applications covering various additional aspects of XLIF methodology, implants, and systems.

Our biologics intellectual property portfolio includes 5 U.S. patent applications, 2 foreign applications, and 1 International Application (PCT) owned outright by NuVasive. It also includes 4 U.S. patents and 4 foreign patents exclusively licensed from Osiris Therapeutics.

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We acquired a substantial intellectual property portfolio as part of our purchase of Cervitech, Inc. This portfolio currently includes 10 issued U.S. patents, 17 U.S. applications, 142 issued foreign national patents, 1 international (PCT) application, and 86 foreign national applications, directed towards the PCM cervical disc system and related technologies.

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

Trademarks

As of December 31, 2010, we had 129 trademark registrations, both domestic and foreign, including the following U.S. trademarks: Absolute Responsiveness, Acuity, Affix, Armada, CerPass, CoRoent, Creative Spine Technology, DBR, Embrace, ExtenSure, FormaGraft, Gradient Plus, Halo, InStim, Leverage, M5, MAS, MaXcess, NeoDisc, Nerve Avoidance Leader, NeuroVision, NuVasive, Osteocel Plus, PCM, SmartPlate, SOLAS, SpheRx, The Better Way Back, Triad, VuePoint, XL TDR, XLIF and XLP. We also had 26 trademark applications pending, both domestic and foreign, including the following trademarks: AttraX, Back Pact, Better Back Alliance, Bendini, Billion Dollar Start-Up, Brigade, Brigade Strong, Cheetah Gives Back Foundation, Corex, Corpomotion, ILIF, JJB, Magnitude, Microlif, MicroXlif, NV JJB, NV M5, Radian, Speed of Innovation, The Lateral Gold Standard, Traverse, and X-Core.

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 in each of our current and future product categories.

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 dedicate significant resources to developing competing products. Below are our primary competitors grouped by our product categories.

Our nerve monitoring systems compete with the traditional nerve monitoring systems offered by Medtronic Sofamor Danek (Medtronic), Cadwell, and VIASYS Healthcare, a division of CareFusion. We believe our systems compete 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 with automated, real-time information. Medtronic s NIM-Eclipse neuromonitoring system, acquired from Axon, while surgeon directed, requires manual interpretation for neuromonitoring. Several companies offer products that compete with our MaXcess system, SpheRx pedicle screw system and implants, including competitive offerings by DePuy Spine, Inc. (Depuy), a Johnson & Johnson company, Medtronic and Stryker Spine.

Competition is intense in the fusion product market. We believe that our most significant competitors are Medtronic, DePuy, Stryker Spine and Synthes, Inc., each of which has substantially greater sales and financial resources than we do. Medtronic, in particular, has a broad classic fusion product line. We believe our differentiation in the market is an innovative portfolio of products elegantly delivered through our MaXcess system, as well as through our XLIF approach, complemented by additional innovative and pull-though products along the entirety of

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the spine. However, with the introduction of competing lateral techniques, such as Medtronic s DLIF, we face more competition in the market.

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

While our acquisition of Osteocel and our investment in Progentix Orthobiology, B.V. provide us with additional products to compete in the biologics market, competition is increasing. In addition to our larger competitors, which are investing in their biologics platforms, we face competition from smaller orthobiologics companies such as Orthovita, Inc., Orthofix International N.V. (Blackstone Medical, Inc.) (Orthofix), Alphatec Spine, Inc. (Alphatec), Nutech Medical, Inc., the Musculoskelatal Transplant Foundation (MTF) and Osteotech, Inc.

We also face competition from a significant number of smaller companies with more limited product offerings and geographic reach than our larger competitors. These companies, who represent intense competition in specified markets, include Globus Medical, Inc., Zimmer Spine, Orthofix, Biomet EBI/Spine, Alphatec, and others.

Government Regulation

Our products are medical devices and tissues 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 wish 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.

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

Premarket Approval (PMA) Pathway

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

Human Cell, Tissue, and Cellular and Tissue Based Products

Our allograft implant products 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. 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.

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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 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 have gained IDE approval from the FDA to begin a clinical trial relating to NeoDisc, our embroidery cervical disc replacement device, and have completed patient enrollment for this trial. We filed with the FDA for IDEs on the mechanical lateral TDR (XL TDR), and were granted an IDE in 2008. Our clinical trials must be conducted in accordance with FDA regulations and other federal regulations concerning human subject protection and privacy and must be publicly registered. The results of our clinical trials may not be sufficient to obtain approval of our product. There are numerous risks associated with conducting such a clinical trial, including the high costs and uncertain outcomes. For a complete discussion of these risks, please see the Risk Factors section of this Annual Report.

Pervasive and Continuing FDA Regulation

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

quality system regulation, which requires manufacturers to follow design, testing, process control, and other quality assurance procedures;

labeling regulations, which prohibit the promotion of products for unapproved or off-label uses and impose other restrictions on labeling; and

medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

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

fines, injunctions, and civil penalties;

recall or seizure of our products;

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.

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Healthcare Regulation and Commercial Compliance

The healthcare industry is highly regulated and changes in laws and regulations can be significant. Changes in the law or new interpretation of existing laws can have a material effect on our permissible activities, the relative costs associated with doing business and the amount of reimbursement by government and other third-party payers. The federal government and all states in which we currently operate regulate various aspects of our business. Failure to comply with these laws could adversely affect our ability to receive reimbursement for our services and subject us and our officers and agents to civil and criminal penalties.

Anti-kickback Statute: We are subject to the federal anti-kickback statute which, among other things, prohibits the knowing and willful solicitation, offer, payment or receipt of any remuneration, direct or indirect, in cash or in kind, in return for or to induce the referral of patients for items or services covered by Medicare, Medicaid and certain other governmental health programs. Under Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or PPACA, knowledge of the anti-kickback statute or the specific intent to violate the law is not required. Violation of the anti-kickback statute may result in civil or criminal penalties and exclusion from the 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 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, which would adversely affect our financial condition and results of operations. We strive to ensure that we meet applicable requirements of the False Claims Act. However, 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 not a Covered Entity, except to the extent we provide neuromonitoring services, and is not a Business Associate to Covered Entities. 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 HIPAA standards, there is no guarantee that the government will not disagree. 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. Any of the foregoing actions could result in

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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. 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, in the federal sentencing guidelines, that health care companies 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 health care companies to have a formal compliance program in place in order to do business within the state. For years, NuVasive has maintained a compliance program structured to meet the requirements of the federal sentencing guidelines for an effective compliance program and the model compliance programs promulgated by HHS over the years and includes, but is not limited to, a Code of Ethical Business Conduct, designation of a compliance officer, 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, 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 (MHLW) 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

We expect that sales volumes and prices of our products will continue to be largely dependent on the availability of reimbursement from third-party payers, such as governmental programs, for example, Medicare and

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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 the Centers for Medicare and Medicaid Services, or CMS. XLIF is included in the nomenclature for hospital codes as an additional descriptor under existing 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, such as 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 over the past two years, 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, all major insurance companies provide reimbursement for XLIF procedures, including Aetna, CIGNA, Humana, Health Care Service Corporation, and United Healthcare, each of whom has reversed their prior policy of non-coverage. Certain smaller regional carriers, however, have policies against coverage of XLIF. We will continue to provide the appropriate resources to patients, surgeons, hospitals, and insurers in order to ensure optimum patient care and clarity regarding XLIF 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. For a complete 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 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, third-party payers carefully review, and increasingly challenge, the prices charged for procedures and medical products as well as any technology that they, in their own judgment, consider experimental or investigational. In addition, an increasing percentage of insured individuals are receiving their medical care through managed care programs, which monitor and often require pre-approval of the services that a member will receive. Many managed care programs are paying their providers on a capitated basis, which puts the providers at financial risk for the services provided to their patients by paying them a predetermined payment per member per month. The percentage of individuals covered by managed care programs is expected to grow in the United States over the next decade.

We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. There can be no assurance that third-party reimbursement and coverage will be available or adequate, or that future legislation, regulation, or reimbursement policies of third-party payers will not adversely affect the demand for our products or our ability to sell these products 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 complete

discussion of these risks, please see the Risk Factors section of this Annual Report.

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Shareowners (our employees)

We refer to our employees as shareowners. As of December 31, 2010, we had 789 shareowners, of which 78 were employed in research and development, 64 in regulatory and quality assurance, 331 in general and administrative and operations and 316 in sales and marketing (including 61 international 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. In addition, there are approximately 300 individuals that are a part of the sales, marketing and administrative staffs 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 Cheetah Gives Back Foundation

NuVasive Cheetah Gives Back Foundation™ is a non-profit organization that has common management with the Company. NuVasive Cheetah Gives Back Foundation is committed to providing innovative medical devices, surgical support, and necessary funds to those in need of life-saving spine surgery around the world and encouraging creativity through the support of the San Diego performing arts community. We are not required to make contributions to NuVasive Cheetah Gives Back Foundation, except for amounts pledged. No amounts were pledged as of December 31, 2010.

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 2010.

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.

Risks Related to Our Business and Industry

Changes to third party reimbursement policies and practices can negatively impact our ability to sell our products at prices necessary to expand our operations and increase profitability.

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, both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third-party payers may adversely affect the demand for our existing products or our products currently under development and limit our ability to sell our products on a profitable basis.

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To the extent 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.

There can be no assurance that third-party payers reimbursement policies and practices will not adversely affect our ability to sell our products profitably.

Non-coverage decisions concerning our technologies by third-party payers may negatively impact our ability to sell our complete product portfolio, expand our operations and increase profitability.

Sales of our products will depend on the availability of adequate reimbursement from third-party payers. Healthcare providers, such as hospitals that purchase medical devices 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. Likewise, spine surgeons rely primarily on third-party reimbursement for the surgical fees they earn. Spine surgeons are unlikely to use our products 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 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. Additional payers may also state that our technologies are not covered. The inability to successfully market our technologies due to lack of reimbursement coverage may adversely impact our ability to acquire new physician clients, increase market penetration with existing clients, or retain existing clients across NuVasive product lines and, therefore, may adversely impact our ability to sell our complete product portfolio, expand our operations and increase profitability.

Pricing pressure from our competitors may impact our ability to sell our products at prices necessary to expand our operations, invest in innovative technologies and increase profitability.

The market for spine surgery products is large and growing at a significant rate. 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. 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, we compete with Medtronic Sofamor Danek, Inc., a wholly owned subsidiary of Medtronic, Inc., and VIASYS Healthcare, a division of CareFusion, 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 Sofamor Danek, Inc., DePuy Spine, Inc., a

Johnson & Johnson company, and Synthes, Inc. 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.

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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 U.S. Food and Drug Administration, or FDA, and other regulatory approvals or clearances for products and product enhancements;
- more expansive portfolios of intellectual property rights; and
- greater financial 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 companies owned at least partially by spine surgeons. Many of these new competitors focus on a specific product or market segment, making it more difficult for us to expand our overall market position. If these companies 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.

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 payers who financially support many of the procedures performed with our products. Additionally, in our quest to obsolete our products, we must effectively manage our inventory, the demand for new and current product and the regulatory process for new products in order to avoid unintended financial and accounting consequences.

If we do not effectively manage our strategy of obsoleting our 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 writeoffs for obsolete inventory, our results of operations may suffer.

If clinical trials of our current or future product candidates do not produce results necessary to support regulatory approval in the United States, we will be unable to commercialize these products.

Several investigational devices in our development pipeline, including our NeoDisc cervical disc replacement device, PCM and lateral TDR (XL TDR), will require a PMA from the FDA. A PMA application must be submitted if the

device cannot be cleared through the less rigorous 510(k) process. A PMA application must be supported by extensive data including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA s satisfaction the safety and effectiveness of the device for its intended use.

As a result, to receive regulatory approval for NeoDisc, PCM, XL TDR or other devices requiring PMA approval, we must conduct, at our own expense, adequate and well controlled clinical trials to demonstrate efficacy and safety in humans. Clinical testing is expensive, takes many years and has an uncertain outcome. Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results, and we may

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decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. Our failure to adequately demonstrate the efficacy and safety of any of our devices would prevent receipt of regulatory approval and, ultimately, the commercialization of that device.

Our NeoDisc, PCM, and XL TDR devices are currently the subject of an Investigational Device Exemption clinical study. There is no assurance that these devices will be approved for sale in the United States by the FDA. The clinical study may prove that the device does not provide the intended benefit or that there are unintended negative side effects of the device that make it unsafe or not effective. In addition, the NeoDisc device includes embroidery technology, which has not been thoroughly studied for use as permanent implants in the spine. Any failure or delay in obtaining regulatory approval for these devices will hamper our ability to commercialize the device in the United States.

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, 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 assumption of certain known and unknown liabilities of the acquired companies; and
- difficulties in retaining key relationships with shareowners (employees), customers, partners and suppliers of the acquired company.

Any of these factors could have a negative impact on our business, results of operations or financing position. Our investment in Progentix Orthobiology B.V., a private company working to develop a synthetic bone graft material, includes options and obligations to buy Progentix Orthobiology B.V. over time as development milestones are achieved. If the Progentix products are not commercially successful or unable to meet expected commercial success, but certain development milestones are achieved, we may be obligated to purchase Progentix Orthobiology B.V. at a price greater than the economic value we can derive from the acquisition of that company.

Further, past and potential acquisitions entail risks, uncertainties and potential disruptions to our business, especially where we have little experience as a company developing or marketing a particular product or technology (as is the case with the Progentix products). 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.

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.

We currently use one or two manufacturers for each 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

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in a timely manner or on terms acceptable to us, or cease to manufacture components of acceptable quality, 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.

Invibio, Inc. (Invibio) is our exclusive supplier of polyetheretherketone (PEEK), which comprises our PEEK partial vertebral body product called CoRoent. We have a supply agreement with Invibio, pursuant to which we have agreed to purchase our entire supply of polyetheretherketone for our current product lines from Invibio. We also have an exclusive supply arrangement with Sparton Medical Corporation (Sparton) pursuant to which Sparton is our exclusive supplier of our proprietary neuromonitoring systems. In the event we experience delays, shortages, or stoppages of supply with either 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.

Maxigen Biotech, Inc., or MBI, is our sole supplier of our FormaGraft product. We may require that MBI significantly expand its manufacturing capacity to meet our potential forecasted needs, and no assurance can be given that MBI will be able to meet our requirements. If we experience difficulties in dealing with MBI, we may not be able to secure an adequate source of supply of FormaGraft, which could adversely affect our operational results.

We acquired PCM, a motion preserving total disc replacement device, through our acquisition of Cervitech, Inc. (Cervitech). Our supply of the product comes from two sources: Waldemar Link GmbH & Co. KG, a company that was affiliated with Cervitech prior to the acquisition, and Sandvik Medical Solutions Limited. Upon approval of the PCM product by the FDA, we plan on using Sandvik Medical Solutions Limited as our sole supplier of PCM. At such time, we will determine whether to establish alternate suppliers and there is no assurance that we will be able to establish a new supplier which could adversely affect our operational results.

Further, Tissue Banks International, Inc., AlloSource, Inc. and Community Tissue Services collectively supply us with all of our allograft implants. The processing of human tissue into allograft implants is very labor intensive and it is therefore difficult to maintain a steady supply stream. AlloSource is also our exclusive supplier of Osteocel Plus, which is processed from allograft. Allograft, which is donated human tissue, is a supply-constrained material and there is ongoing risk that there will be insufficient supply to produce the necessary quantity of Osteocel Plus and our other allograft products. In addition, due to seasonal changes in mortality rates, some scarce tissues used for our allograft products are at times in particularly short supply. Allograft also carries with it the possibility of disease transmission, which could result in negative patient outcomes and negative publicity for us. We cannot be certain that our supply of allograft from Tissue Banks International, Inc. and AlloSource, Inc. will be available at current levels or will be sufficient to meet our needs. If we are no longer able to obtain allograft from these sources in amounts sufficient to meet our needs, we may not be able to locate and engage replacement sources of allograft on commercially reasonable terms, if at all. Any interruption of our business caused by the need to locate additional sources of allograft could reduce our revenues.

We are dependent on the services of Alexis V. Lukianov and Keith C. Valentine, and the loss of either of them could harm our business.

Our continued success depends in part upon the continued service of Alexis V. Lukianov, our Chairman and Chief Executive Officer, and Keith C. Valentine, our President and Chief Operating Officer, who are critical to the overall management of NuVasive as well as to the development of our technology, our culture and our strategic direction. We have entered into employment arrangements with Messrs. Lukianov and Valentine, but neither of these agreements guarantees the service of the individual for a specified period of time. The loss of either Messr. Lukianov or Valentine

could have a material adverse effect on our business, results of operations and financial condition. We have not obtained and do not expect to obtain any key-person life insurance policies.

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

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

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

expand our clinical development resources to manage and execute increasingly global, larger and more complex clinical trials;

expand our sales and marketing resources for international expansion and to launch products targeted for international markets; and

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.

We currently expect that our operating expenses will continue to increase as we continue to expand into international markets. We have only limited experience in expanding into international markets as well as marketing and operating our products and services in such markets. Certain international markets, such as Japan, take a lot of time and resources to receive product approvals and clearances to sell and promote products. After we receive the appropriate approvals and clearances, international markets may be slower than domestic markets in adopting our products and are expected to yield lower profit margins when compared to our domestic operations.

Additionally, our international endeavors may involve significant risks and uncertainties, including distraction of management from domestic operations, insufficient revenue to offset 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.

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.

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.

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. We are currently in the process of seeking regulatory clearance for AttraX, a synthetic bone graft material being developed by Progentix delivered in putty form,

through the 510(k) process. 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, premarket approval. The FDA may not agree with any of our decisions regarding whether new clearances or approvals are necessary.

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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 constitutes 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 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 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.

We obtained clearance to offer almost all of our products that require FDA clearance or approval through the FDA s 510(k) clearance process. The FDA s 510(k) clearance process is less rigorous than the PMA process and requires less supporting clinical data. As a result, we currently lack the breadth of published long-term clinical data supporting the safety of our products and the benefits they offer that might have been generated in connection with the PMA process. 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 costly product liability litigation.

If we or our suppliers fail to comply with the FDA s quality system regulations, the manufacture of our products could be delayed and we may be subject to an enforcement action by the FDA.

We and our suppliers are required to comply with the FDA s quality system regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA enforces the quality system regulation through inspections. If we or one of our suppliers fail a quality system regulations inspection or if any corrective action plan is not sufficient, the manufacture of our products could be delayed. We underwent FDA inspections regarding our allograft implant business and FDA inspections regarding our medical device activities. In connection with these inspections as well as prior inspections, the FDA 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 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

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suppliers 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.

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 $478.2 million in 2010. We anticipate continued growth and have provided guidance related to such growth for 2011. Our ability to achieve the anticipated growth will depend upon, among other things, the success of our growth strategies, which we cannot assure you will be successful. In addition, we may have more difficulty maintaining our prior rate of growth of revenues or recent earnings. 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 which may cause our selling, general and administrative expenses to increase as a percentage of revenue. Because these expenses are generally fixed, particularly in the short-to-medium term, operating results may be adversely impacted if we do not achieve our anticipated growth.

The financial crisis and general slowdown of the economy may adversely affect our liquidity and the liquidity of our customers.

At December 31, 2010, we had $92.6 million in cash and cash equivalents and $137.1 million in investments in marketable securities. We have historically invested these amounts in U.S. treasuries and government agencies, corporate debt, money market funds, commercial paper and municipal bonds meeting certain criteria. 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 the current financial crisis. 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 current financial crisis and the condition of the economy, our ability to collect on our outstanding invoices and our collection cycles may be adversely affected.

We may not be able to refinance our Senior Convertible Notes.

Our $230 million Senior Convertible Notes outstanding at December 31, 2010 are due March 2013 and will need to be refinanced before then. Capital markets, including the debt markets, have seen periods of time when liquidity was just not available. Most recently, when the economic crisis hit in 2008 there was an extended period of time when the capital markets were illiquid and debt refinancings could not get done. There can be no guarantee that our financial performance will justify and enable, or that capital markets will be favorable, to allow for a refinancing of this debt. If a refinancing were prevented or impossible it would have a material adverse impact on our ability to fund, or grow, our existing operations.

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Upon the achievement of certain milestones related to our acquisitions, we may be required to make payments which may affect our liquidity and our financial results.

In connection with our recent acquisitions, we may be obligated to make payments in the future upon the achievement of certain milestones. We currently have $33.0 million in outstanding potential milestone obligations under our agreement with the shareholders of Cervitech and may be required to make milestone payments upon the completion of certain milestones and purchase the remaining sixty (60) percent of Progentix Orthobiology B.V. for an aggregate amount up to $61.0 million (effective January 14, 2011, this amount is reduced to $56.0 million). The likelihood of those milestones being achieved and the timing of such payments are uncertain and are subject to change over time. If we are required to make those payments, particularly at a time when we are experiencing financial difficulty, our liquidity, financial results and financial condition may be adversely affected.

Risks Related to Our Intellectual Property and Potential Litigation

We are currently involved in several patent litigation actions, including an action involving Medtronic, and, if we do not prevail in this action against Medtronic, we could be liable for past damages and might be prevented from making, using, selling, offering to sell, importing or exporting certain of our products.

On August 18, 2008, Medtronic Sofamor Danek USA, Inc. and its related entities (Medtronic) filed suit against NuVasive in the United States 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. Medtronic is a large, publicly-traded corporation with significantly greater financial resources than us.

As further examples of intellectual property risks we face in this industry, on April 20, 2010, we filed a lawsuit against Orthofix, Inc. and its related entities (Orthofix) and Musculoskeletal Transplant Foundation for infringement of a patent licensed as part of our purchase of Osteocel Plus®. In December 2010, the parties entered into a license agreement covering the subject product marketed by Orthofix, Trinity Evolution®, and the lawsuit was settled by the parties. Similarly, on October 5, 2010, we initiated a patent infringement lawsuit against Globus Medical, Inc. (Globus) to protect our investment in our XLIF procedure and MaXcess retractor system. The lawsuit against Globus is in its early stages, and the outcome of this litigation is difficult to predict.

Intellectual property litigation is expensive, complex and lengthy and its outcome is difficult to predict. We may also be subject to negative publicity due to the 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 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, and 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 attorney s fees and costs, which may be substantial.

An unfavorable outcome for us in this patent 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 defense and any damages resulting from the litigation may materially adversely affect our business and financial results. The 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.

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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 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), such as was done by Medtronic on two of our U.S. patents related to aspects of our XLIF surgical technique. We asserted these patents against Medtronic as part of our ongoing patent litigation. Patent reexamination was granted by the U.S. Patent Office in each case. If the U.S. Patent Office 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. 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.

In addition, there are numerous proposed changes to the patent laws and rules of the U.S. Patent and Trademark Office which, if enacted, may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. Moreover, Congress is considering several significant changes to the U.S. patent laws, including, among other things, changing from a first to invent to a first inventor to file system, limiting where a patentee may file a patent suit, requiring the apportionment of patent damages, and creating a post-grant opposition process to challenge patents after they have issued.

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.

In addition, certain product categories, including pedicle screws, have been the subject of significant patent litigation in recent years. Since we sell pedicle screws and recently introduced our SpheRx and Armada pedicle screw systems, any related litigation could harm our business.

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 patents and proprietary

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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.

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

A judgment in our ongoing trademark dispute regarding the NeuroVision brand name was handed down by the U.S. District Court for the Central District of California. An unfavorable jury verdict was delivered against us in our use of the NeuroVision name. The verdict, which we plan to immediately appeal, awarded damages to the plaintiff of $60 million. We sought emergency relief and on February 3, 2011, the Ninth Circuit Court of Appeals stayed enforcement of the injunction. During pendency of the appeal, we may be required to post a supersedeas bond or escrow funds to secure the amount of the judgment. This could result in a material reduction in the liquidity required to run or grow our business. While this case relates solely to the use of the NeuroVision brand name and does not involve our proprietary neuromonitoring technology underlying the NeuroVision system or future products, it may require us to rebrand and re-market the NeuroVision brand name. This could result in a significant impact on our marketing costs and other related financial costs. There is a chance that the acceptance of a new brand name will be lengthy and may not be well received by our customers. The appeals process could be expensive, complex and lengthy and its outcome is difficult to predict. We may also be subject to negative publicity due to this trademark litigation. The litigation required during the appeals process may significantly divert the attention of our technical and management personnel. We are unable to predict the outcome of our appeal. In the event that we are unsuccessful in our appeal, we could be required to pay significant damages which are not covered under any of our insurance plans. In the event this outcome occurred, our business, liquidity, financial condition or results of operations would be materially adversely affected.

If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage.

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for spine surgery procedures. Spine surgery involves significant risk of serious complications, including bleeding, nerve injury, paralysis and even death. In addition, we sell allograft products, derived from cadaver bones, which pose the potential risk of biological contamination. If any such contamination is found to exist, sales of allograft products could decline and our reputation would be harmed.

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.

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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. As a result, we are subject to periodic inspection by the FDA for compliance with the FDA s Quality System Regulation, or QSR, requirements, which require manufacturers of medical devices 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 similar requirements, this could delay product production and lead to fines, difficulties in obtaining regulatory clearances, recalls or other consequences, which in turn could have a material adverse effect on our financial condition and results of operations or prospects.

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 approvals by the FDA can be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval

Pursuant to FDA regulations, we c