

NUVASIVE INC  
Form 10-K  
February 25, 2011

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**Form 10-K**

(Mark One)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the fiscal year ended December 31, 2010**
- OR**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the transition period from        to**

**Commission file number: 000-50744**

**NUVASIVE, INC.**

*(Exact name of registrant as specified in its charter)*

**Delaware**

*(State or other jurisdiction of incorporation or organization)*

**33-0768598**

*(I.R.S. Employer Identification No.)*

**7475 Lusk Boulevard,  
San Diego, California**

*(Address of principal executive offices)*

**92121**

*(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  NO

Edgar Filing: NUVASIVE INC - Form 10-K

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

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

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

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

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

Large accelerated  
filer

Accelerated filer

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

Smaller reporting  
company

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$1.4 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**

**PART I**

<u>Item 1.</u>	<u>Business</u>	1
<u>Item 1A.</u>	<u>Risk Factors</u>	17
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	31
<u>Item 2.</u>	<u>Properties</u>	31
<u>Item 3.</u>	<u>Legal Proceedings</u>	32
<u>Item 4.</u>	<u>(Removed and Reserved)</u>	33

**PART II**

<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	33
<u>Item 6.</u>	<u>Selected Financial Data</u>	35
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	36
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	48
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	50
<u>Item 9.</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	50
<u>Item 9A.</u>	<u>Controls and Procedures</u>	50
<u>Item 9B.</u>	<u>Other Information</u>	52

**PART III**

<u>Item 10.</u>	<u>Directors and Executive Officers and Corporate Governance</u>	52
<u>Item 11.</u>	<u>Executive Compensation</u>	52
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	52
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	52
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	52

**PART IV**

<u>Item 15.</u>	<u>Exhibits, Financial Statements and Schedules</u>	52
-----------------	---	----

**SIGNATURES**

<u>Index to Consolidated Financial Statements</u>	59
---	----

<u>EX-10.13</u>	61
-----------------	----

EX-10.28

EX-10.29

EX-10.30

EX-10.31

EX-21.1

EX-23.1

EX-31.1

EX-31.2

EX-32.1

EX-32.2

EX-101 INSTANCE DOCUMENT

EX-101 SCHEMA DOCUMENT

EX-101 CALCULATION LINKBASE DOCUMENT

[EX-101 LABELS LINKBASE DOCUMENT](#)

[EX-101 PRESENTATION LINKBASE DOCUMENT](#)

[EX-101 DEFINITION LINKBASE DOCUMENT](#)

---

**Table of Contents**

**PART I**

*This Annual Report on Form 10-K, particularly in Item 1. Business and Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, and the documents incorporated by reference, include forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including, but not limited to, statements regarding our future financial position, business strategy and plans and objectives of management for future operations. When used in this Annual Report, the words believe, may, could, will, estimate, continue, anticipate, intend, expect, and similar are 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<sup>®</sup>, 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<sup>®</sup>, a collagen synthetic product used to aid the fusion process, and Osteocel Plus<sup>®</sup>, 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 SpheR® and Armada™ pedicle screw systems, CoRoent® suite of implants, and several fixation systems.

## **Table of Contents**

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.

## **Table of Contents**

*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<sup>®</sup>, 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

## **Table of Contents**

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.

**Table of Contents**

**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

## **Table of Contents**

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.

## **Table of Contents**

### **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.

## **Table of Contents**

### **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<sup>®</sup>, 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.

## **Table of Contents**

### **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.

## **Table of Contents**

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-through products along the entirety of

## **Table of Contents**

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 Musculoskeletal 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.

## **Table of Contents**

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.

**Table of Contents**

***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.

**Table of Contents**

***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

## **Table of Contents**

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

**Table of Contents**

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.

## **Table of Contents**

### **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<sup>tm</sup> 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](http://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.

## **Table of Contents**

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.

## **Table of Contents**

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

## **Table of Contents**

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

## **Table of Contents**

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.

**Table of Contents**

***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.

## **Table of Contents**

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

**Table of Contents**

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.

## **Table of Contents**

***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.

**Table of Contents**

***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

## **Table of Contents**

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.

**Table of Contents**

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

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 decreased sales as a result of negative publicity and product liability

**Table of Contents**

claims, and could have a material adverse effect on our financial condition, results of operations and prospects. In addition to the sanctions for noncompliance described above, commencement of an enforcement proceeding, inspection or investigation could divert substantial management attention from the operation of our business and have an adverse effect on our business, results of operations and financial condition.

***Any claims relating to our making improper payments or providing improper gifts or benefits to physicians or other potential violations of laws or regulations governing interactions between us and health care professionals, could be time consuming and costly.***

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

In recent years, both the United States and foreign government regulators have increased regulation, enforcement, inspections and governmental investigations of the medical device industry, including increased United States government oversight and enforcement of the Foreign Corrupt Practices Act. Despite implementation of a comprehensive global compliance program, we may be subject to more regulation, enforcement, inspections and investigations by governmental authorities in the future. 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. Any of the foregoing actions could result in decreased sales as a result of negative publicity and product liability claims, and could have a material adverse effect on our financial condition, results of operations and prospects.

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

In addition to the sanctions for noncompliance described above, commencement of an enforcement proceeding, inspection or investigation could divert substantial management attention from the operation of our business, as well as could result in a material adverse effect on the market price of our common stock and on our business, results of operations and financial condition. For example, Synthes, Inc., in 2010, settled with the Office of Inspector General (OIG) for \$22 million relating to allegations that it illegally tested bone cement on patients and Guidant Corporation/Boston Scientific, in 2009, settled with the OIG for \$22 million relating to alleged improper payments made to physicians for certain post-market surveys.

Additionally, we must comply with a variety of other laws, such as the (i) Healthcare Insurance Portability and Accountability Act of 1996, or HIPAA, which protects the privacy of individually identifiable healthcare information; (ii) ) The Physician Payment Sunshine Act which requires medical device companies to begin reporting all compensation, gifts and benefits provided to certain health care professional in 2013; and (iii) the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections.

**Table of Contents**

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

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

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

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

The market price of our common stock is likely to be volatile and may fluctuate substantially. For example, the closing price for our stock on the last day of the past four quarters was: \$45.20 on March 31, 2010; \$35.46 on June 30, 2010; \$35.14 on September 30, 2010; and \$25.65 on December 31, 2010. Fluctuation in the stock price may occur due to many factors, including:

general market conditions and other factors (such as the effect the financial crisis is having on stock markets as a whole), including factors unrelated to our operating performance or the operating performance of our competitors. These conditions might include people's expectations, favorable or unfavorable, as to the likely unit growth of the spine sector;

negative publicity regarding spine surgeon's practices or outcomes, whether warranted or not, that shed the sector in a negative light;

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

changes in the availability of third-party reimbursement in the United States or other countries;

disputes or other developments with respect to intellectual property rights or other potential legal actions;

our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis;

quarterly variations in our or our competitor's results of operations;

sales of large blocks of our common stock, including sales by our executive officers and directors;

announcements of technological or medical innovations for the treatment of spine pathology;

changes in governmental regulations or in the status of our regulatory approvals, clearances or applications;

the acquisition or divestiture of businesses, products, assets or technology;

litigation, including intellectual property litigation;



announcements of actions by the FDA or other regulatory agencies; and

changes in earnings estimates or recommendations by us or by securities analysts.

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

**Table of Contents**

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

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

authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, with rights senior to those of the common stock;

provide for a classified board of directors, with each director serving a staggered three-year term;

prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent;

prohibit our stockholders from making certain changes to our certificate of incorporation or bylaws except with 66 2/3% stockholder approval; and

require advance written notice of stockholder proposals and director nominations.

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

***We do not intend to pay cash dividends.***

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

**Item 1B. *Unresolved Staff Comments***

None.

**Item 2. *Properties.***

As of December 31, 2010, we operated the following facilities:

<b>Description of Use</b>	<b>Square Footage</b>	<b>Location</b>	<b>Lease Term</b>
Corporate office and training facilities(1)	145,225	San Diego, CA	From 2008 through 2023
Corporate office facilities	62,367	San Diego, CA	From 2004 through 2012

Edgar Filing: NUVASIVE INC - Form 10-K

Fulfillment and warehouse operations	100,000	Memphis, TN	Owned
Office and training facilities	63,761	Paramus, NJ	From 2010 through 2020
Office facilities	600	Puerto Rico	From 2009 through 2011
Office facilities	2,462	United Kingdom	From 2008 through 2013
Office facilities	2,700	Germany	From 2009 through 2014
Fulfillment and warehouse operations	4,683	Germany	From 2010 through 2015
Office facilities	1,119	Singapore	From 2009 through 2011
Office facilities	3,712	Australia	From 2009 through 2013
Office facilities	210	Japan	From 2009 through 2011

(1) Our corporate headquarters.

**Table of Contents****Item 3. *Legal Proceedings.*****Medtronic Sofamor Danek USA, Inc. Litigation**

As reported by us previously, Medtronic Sofamor Danek USA, Inc. and its related entities (Medtronic), on August 18, 2008, filed a patent infringement lawsuit against NuVasive in the United States District Court for the Southern District of California, alleging that certain of NuVasive's products or methods, including the XLIF® procedure, infringe, or contribute to the infringement of, twelve U.S. patents. Three of the patents were later withdrawn by Medtronic leaving the following nine patents in the lawsuit: Nos. 5,860,973; 5,772,661; 6,936,051; 6,936,050; 6,916,320; 6,945,933; 6,969,390; 6,428,542; 6,592,586 assigned or licensed to Medtronic (Medtronic Patents). Medtronic is seeking unspecified monetary damages and a court injunction against future infringement by NuVasive. NuVasive has answered the complaint denying the allegations, and filed counterclaims seeking dismissal of Medtronic's complaint and a declaration that NuVasive has not infringed and currently does not infringe any valid claim of the Medtronic Patents. Additionally, NuVasive has made counterclaims against Medtronic seeking the following relief: (i) Medtronic being permanently enjoined from charging that NuVasive has infringed or is infringing the Medtronic Patents; (ii) a declaration that the Medtronic Patents are invalid; (iii) a declaration that the 5,860,973 and 5,772,661 patents are unenforceable due to inequitable conduct; and (iv) costs and reasonable attorneys' fees.

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

Given the number of patents asserted in the litigation, the parties agreed to proceed on a limited number of patents. The court determined to proceed only with patents that are not the subject of active reexamination proceedings. As a result, the initial phase of the case includes three Medtronic patents and one NuVasive patent. Trial on the initial phase of the case is scheduled to begin May 10, 2011. A full schedule for the second phase of the lawsuit has not yet been set by the Court.

**Trademark Infringement Litigation**

In September 2009, Neurovision Medical Products, Inc. (NMP) filed suit against NuVasive in the U.S. District Court for the Central District of California (Case No. 2:09-cv-06988-R-JEM) alleging trademark infringement and unfair competition. NMP sought cancellation of NuVasive's NeuroVision trademark registrations, injunctive relief and damages based on NMP's common law use of the Neurovision mark. On November 23, 2009, NuVasive denied the allegations in NMP's complaint. After trial of the matter, on October 25, 2010 an unfavorable jury verdict was delivered against NuVasive relating to our use of the NeuroVision trade name. The verdict awarded damages to NMP of \$60 million. On January 3, 2011, the Court ordered a judgment be entered in the case in the amount of \$60 million, and granted a permanent injunction prohibiting our use of the NeuroVision name for marketing purposes. We sought emergency relief, and on February 3, 2011, the Ninth Circuit Court of Appeals stayed enforcement of the injunction. We intend to timely appeal the judgment and permanent 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, plus interest, attorneys' fees and costs. However, any payment of damages will be delayed while the appeals process runs its course, which could take up to two years. We continue to believe that the verdict is not supported by the facts or by applicable law. Based on our own assessment, as well as that of outside counsel, we believe that the trial court committed a number of prejudicial legal errors and that these errors were significant, making the possibility of reversal of the judgment on

appeal and/or a new trial probable. Accordingly, at December 31, 2010, in accordance with the authoritative guidance on the evaluation of contingencies, we have not recorded an accrual related to this litigation. We may be required to record an expense related to this damage award in the future.

**Table of Contents****Item 4. *Removed and Reserved.*****PART II****Item 5. *Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*****Common Stock Market Price**

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

	<b>High</b>	<b>Low</b>
<b>2009:</b>		
First Quarter	\$ 39.95	\$ 24.17
Second Quarter	45.06	28.39
Third Quarter	45.01	38.25
Fourth Quarter	44.08	27.45
<b>2010:</b>		
First Quarter	\$ 46.83	\$ 26.92
Second Quarter	46.10	35.03
Third Quarter	36.78	29.13
Fourth Quarter	37.87	22.11

We had approximately 145 stockholders of record as of January 31, 2011. We believe that the number of beneficial owners is substantially greater than the number of record holders because a large portion of our common stock is held of record through brokerage firms in street name.

**Recent Sales of Unregistered Securities**

During the fiscal year ended December 31, 2010, we did not issue any securities that were not registered under the Securities Act of 1933.

**Dividend Policy**

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

**Table of Contents**

**PERFORMANCE GRAPH**

The following graph compares the cumulative total stockholder return data on our common stock with the cumulative return of (i) The NASDAQ Stock Market Composite Index, and (ii) NASDAQ Medical Equipment Index over the five year period ending December 31, 2010. The graph assumes that \$100 was invested on December 31, 2005 in our common stock and in each of the comparative indices. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

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

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

\* \$100 invested on 12/31/05 in stock or index, including reinvestment of dividends.

**Table of Contents****Item 6. Selected Financial Data.**

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

	<b>Year Ended December 31,</b>				
	<b>2010</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
	<b>(In thousands, except per share amounts)</b>				
<b>Statement of Operations Data:</b>					
Total revenues	\$ 478,237	\$ 370,340	\$ 250,082	\$ 154,290	\$ 98,091
Gross profit	393,098	309,230	211,074	130,522	81,954
Consolidated net income (loss) (1)	76,533	4,437	(27,528)	(11,265)	(47,910)
Net income (loss) attributable to NuVasive, Inc.	78,285	5,808	(27,528)	(11,265)	(47,910)
Net income (loss) per share attributable to NuVasive, Inc.:					
Basic	\$ 1.99	\$ 0.16	\$ (0.77)	\$ (0.32)	\$ (1.47)
Diluted	\$ 1.85	\$ 0.15	\$ (0.77)	\$ (0.32)	\$ (1.47)

	<b>December 31,</b>				
	<b>2010</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
	<b>(In thousands)</b>				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and marketable securities	\$ 229,690	\$ 204,660	\$ 223,361	\$ 89,698	\$ 117,402
Working capital	262,795	262,355	256,491	118,188	136,236
Total assets	802,029	652,820	487,406	225,687	196,184
Senior convertible notes	230,000	230,000	230,000		
Other long-term liabilities	16,821	58,222	24,288	1,119	1,399
Noncontrolling interests	11,877	13,629			
Total stockholders' equity	434,355	296,222	187,631	196,578	176,303

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



**Table of Contents**

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

**Forward-Looking Statements May Prove Inaccurate**

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

**Overview**

We are a medical device company focused on developing minimally disruptive surgical products and 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<sup>®</sup>, 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<sup>®</sup>, a collagen synthetic product used to aid the fusion process, and Osteocel<sup>®</sup> Plus<sup>™</sup>, 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, with the unique advantages provided by our nerve monitoring systems, enables an innovative lateral procedure known as eXtreme Lateral Interbody Fusion, or XLIF<sup>®</sup>, in which surgeons access the spine for a fusion procedure from the side of the patient's body, rather than from the front or back. Our MaXcess instruments provide access to the spine in a manner that affords direct visualization and our nerve monitoring systems allow surgeons to avoid critical nerves.

At various times 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 the North American Spine Society (NASS) who, in turn, have worked with these insurance providers to supply the information, explanation and clinical data they require to categorize the XLIF procedure as a procedure entitled to reimbursement under their policies. At present, 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. NuVasive cannot offer definitive time frames or final outcomes regarding reversal of the non-coverage policies, as the process is dictated by the third-party insurance providers. To date, we have not experienced significant lack of payment for our procedures based on these policies.

In 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<sup>®</sup> implants, as well as cervical plating and posterior fixation products. In 2009, we acquired Cervitech<sup>®</sup> Inc., a company focused on gaining regulatory approval of the PCM<sup>®</sup> 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 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.

## **Table of Contents**

In 2009, we purchased forty percent (40%) of the capital stock of Progentix Orthobiology, B.V. (Progentix), a company organized under the laws of the Netherlands, from existing shareholders for \$10.0 million in cash (the Initial Investment). Progentix has as its objective the development and exploitation of knowledge and technology in the field of synthetic bone graft materials to aid in the healing and generation of human bone.

We have an active product development pipeline focused on expanding our current fusion product platform as well as products designed to preserve spinal motion.

*Revenues.* The majority of our revenues are derived from the sale of disposables and implants and we expect this trend to continue for the foreseeable future. We loan our proprietary software-driven nerve monitoring systems and surgical instrument sets at no cost to surgeons and hospitals that purchase disposables and implants for use in individual procedures. In addition, we place our proprietary software-driven nerve monitoring systems, MaXcess® and other MAS or cervical surgical instrument sets with hospitals for an extended period at no up-front cost to them. Our implants and disposables are currently sold and shipped from our primary distribution and warehousing operations facility located in Memphis, Tennessee. We recognize revenue for disposables or implants used upon receiving acknowledgement of a purchase order from the hospital indicating product use or implantation. In addition, we sell an immaterial number of MAS instrument sets, MaXcess devices, and our proprietary software-driven nerve monitoring systems. To date, we have derived less than 5% of our total revenues from these sales.

*Sales and Marketing.* Through 2010, substantially all of our operations are located in the United States and substantially all of our sales have been generated in the United States. We sell our products in the United States through a sales force comprised of exclusive independent sales agents and our own directly-employed sales professionals; both selling only NuVasive spine surgery products. Our sales force provides a delivery and consultative service to our surgeon and hospital customers and is compensated based on sales and product placements in their territories. Sales force commissions are reflected in our statement of operations in the sales, marketing and administrative expense line. We expect to continue to expand our distribution channel. Beginning late in 2007 and continuing today, we are continuing our expansion of international sales efforts with the focus on European, Asian and Latin American markets. Our international sales force is comprised of directly-employed exclusive shareowners as well as exclusive distributors and independent sales agents.

## **Critical Accounting Policies**

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

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

*Revenue Recognition.* We follow the provisions of the Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*, which sets forth guidelines for the timing of revenue recognition based upon factors such as passage of title, installation, payment and customer acceptance. We recognize revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products

and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured. Specifically, revenue from the sale of implants and disposables is recognized upon acknowledgement of a purchase order from the hospital indicating product use or implantation or upon shipment to third party customers who immediately accept title. Revenue from the sale of our instrument sets is recognized upon receipt of a purchase order and the subsequent shipment to customers who immediately accept title.

**Table of Contents**

*Allowance for Doubtful Accounts and Sales Return Reserve.* We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. The allowance for doubtful accounts is reviewed quarterly and is estimated based on the aging of account balances, collection history and known trends with current customers and in the economy in general. As a result of this review, the allowance is adjusted on a specific identification basis. An increase to the allowance for doubtful accounts results in a corresponding charge to sales, marketing and administrative expense. We maintain a relatively large customer base that mitigates the risk of concentration with any one particular customer. However, if the overall condition of the healthcare industry were to deteriorate, or if the historical data used to calculate the allowance provided for doubtful accounts does not accurately reflect our customer's future failure to pay outstanding receivables, significant additional allowances could be required.

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

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

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

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

*Valuation of Stock-Based Compensation.* The estimated fair value of share-based awards exchanged for shareowner (employee) and non-employee director services are expensed over the requisite service period. Option awards issued

to non-employees (excluding non-employee directors) are recorded at their fair value as determined in accordance with authoritative guidance, and are periodically revalued as the options vest and are recognized as expense over the related service period.

For purposes of calculating stock-based compensation, we estimate the fair value of stock options and shares issued under the Employee Stock Purchase Plan using a Black-Scholes option-pricing model. The determination of

## **Table of Contents**

the fair value of share-based payment awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected volatility is based on the historical volatility of our common stock over the most recent period commensurate with the estimated expected term of the stock options. The expected life of the stock options is based on historical and other economic data trended into the future. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected terms of our stock options. The dividend yield assumption is based on our history and expectation of no dividend payouts.

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

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

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

Authoritative guidance requires that goodwill and intangible assets with indefinite lives be assessed for impairment using fair value measurement techniques on an annual basis or more frequently if facts and circumstance warrant such a review. For purposes of assessing the impairment of goodwill and intangible assets with indefinite lives, the Company estimates the value of the reporting unit using its market capitalization as the best evidence of fair value. If the carrying amount of a reporting unit exceeds its fair value, then a goodwill impairment test is performed to measure the amount of the impairment loss, if any. We performed our annual test of goodwill during the fourth quarter of 2010, and have determined there has been no impairment of goodwill or intangible assets with indefinite lives through December 31, 2010.

We evaluate our intangible assets with finite lives for indications of impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Intangible assets consist of purchased technology, trademarks and trade names, customer relationships and agreements, manufacturing know-how and other intangibles and are amortized on a straight-line basis over their estimated useful lives of two to 20 years. Factors that could trigger an impairment review include significant under-performance relative to expected historical or projected future operating results, significant changes in the manner of our use of the acquired assets or the strategy for our overall business or significant negative industry or economic trends. If this evaluation indicates that the value of the intangible asset may be impaired, we make an assessment of the recoverability of the net carrying value of the asset over its remaining useful life. If this assessment indicates that the intangible asset is not recoverable, based on the estimated undiscounted future cash flows of the technology over the remaining amortization period, we reduce the net carrying value of the related intangible asset to fair value and may adjust the remaining amortization period. Any such impairment charge could be significant and could have a material adverse effect on our reported financial results. We have not recognized any impairment charges on our intangible assets through December 31, 2010.

*Legal Proceedings.* We are involved in a number of legal actions involving both product liability and intellectual property disputes. The outcomes of these legal actions are not within our complete control and may not be known for prolonged periods of time. In some actions, the claimants seek damages as well as other relief, including injunctions barring the sale of products that are the subject of the lawsuit, that could require significant expenditures or result in lost revenues. In accordance with authoritative guidance, we record a liability in our



**Table of Contents**

consolidated financial statements for these actions when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is possible, but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed in the notes to the consolidated financial statements. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded. Our significant legal proceedings are discussed in Note 12 to the consolidated financial statements included in this Annual Report. While it is not possible to predict the outcome for the matters discussed in Note 12 to the consolidated financial statements, we believe it is possible that costs associated with them could have a material adverse impact on our consolidated earnings, financial position or cash flows.

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

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

**Results of Operations***Revenue*

	Year Ended December 31,			2009 to 2010		2008 to 2009	
	2010	2009	2008	\$ Change	% Change	\$ Change	% Change
	(Dollars in thousands)						
Spine Surgery Products	\$ 388,252	\$ 308,934	\$ 221,356				
Biologics	89,985	61,406	28,726				
Total revenue	\$ 478,237	\$ 370,340	\$ 250,082	\$ 107,897	29%	\$ 120,258	48%

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.

The continued adoption of minimally invasive procedures for spine has led to the continued expansion of our 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. The execution of our strategy of expanding our product offering for the lumbar region and addressing broader indications further up the spine in the thoracic and cervical regions has contributed to strong revenue growth. In addition, increased market

acceptance in our international markets contributed to the increase in revenues noted for the periods presented. We expect the continued adoption of our XLIF procedure and deeper penetration into existing accounts and our newer international markets as our sales force executes on the strategy of selling the full mix of our products; however, recent changes in payer and hospital behavior in the United States have created less predictability in the lumbar portion of the spine market and impacted the overall spine market's growth rate. Accordingly, we believe that our growth in revenue in 2011 will primarily come from increased sales of our cervical offerings, our biologics product line and in our international businesses.

Our total revenues increased \$107.9 million in 2010 compared to 2009 and \$120.3 million in 2009 compared to 2008, representing total revenue growth of 29% and 48%, respectively. Revenue from our Spine Surgery Products increased \$79.3 million, or 26%, in 2010 compared to 2009 and \$87.6 million, or 40%, in 2009 compared to 2008. Revenue from Biologics increased \$28.6 million, or 47%, in 2010 compared to 2009 and \$32.7 million, or 114%, in



Costs that tend to vary based on revenue increased \$37.7 million and \$38.5 million in 2010 and 2009, respectively, compared to the prior years. The increases are consistent with our increased revenue growth of approximately 29% in 2010 as compared to 2009 and 48% in 2009 as compared to 2008.

Compensation and other shareowner related expenses for our marketing and administrative support functions increased \$5.1 million in 2010 compared to 2009 as increased compensation and other shareowner related expenses resulting from additions to our headcount were more than offset by a decrease in performance-based compensation. Compensation and other shareowner related expenses for our marketing and administrative support functions increased \$18.3 million for 2009 compared to 2008 as a result of our overall growth and headcount additions in our marketing and administrative support functions. Stock- based compensation increased \$5.4 million and \$1.7 million in 2010 and 2009, respectively, compared to prior years primarily related to an increase in stock-based awards granted to shareowners associated with the continued increase in headcount. These increases in expenses were also offset by decreases in costs for 2009 compared to 2008 related to charges totaling \$2.6 million incurred for non-capitalizable expenses related to the implementation of our new ERP system which was completed in 2008.

**Table of Contents**

In addition to the items discussed above, legal expenses increased \$6.3 million in 2010 as compared to 2009 resulting primarily from increased non-Medtronic related litigation and legal activity including recently announced offensive actions to protect our intellectual property and defense costs incurred in connection with the NeuroVision trademark infringement litigation. Legal expenses increased \$4.4 million in 2009 as compared to 2008 primarily from expenses incurred in connection with the Medtronic intellectual property suit that was filed against us in 2008 with which we have now taken an offensive posture. These increased expenses were partially offset by the recovery of an international receivable in the amount of \$1.5 million in 2010 which had previously been reserved for in 2009.

During the first quarter of 2009, we adopted the Financial Accounting Standard Board's (FASB) revised authoritative guidance for business combinations, which requires that acquisition related costs be expensed in the period in which the costs are incurred. This differs from previous accounting treatment in that the acquisition related expenses were included as part of the purchase price of the acquired company. We incurred expenses of approximately \$2.4 million in acquisition related costs in connection with our investment in Progentix and acquisition of Cervitech in 2009.

In connection with the relocation of our corporate headquarters in 2008, we recorded a charge of approximately \$4.8 million to sales, marketing, and administrative expenses for lease termination costs and other related items. During 2009, due to continued growth, we decided to reoccupy the former corporate headquarters facility. Accordingly, in 2009, the remaining liability related to lease termination costs of \$2.0 million was reversed and recorded as a reduction of sales, marketing, and administrative expenses.

On a long-term basis, as a percentage of revenue, we expect total sales, marketing and administrative costs to continue to decrease moderately over time.

*Research and Development*

	Year Ended December 31,			2009 to 2010		2008 to 2009	
	2010	2009	2008	\$ Change	% Change	\$ Change	% Change
	(Dollars in thousands)						
Research and Development	\$ 43,479	\$ 37,581	\$ 25,943	\$ 5,898	16%	\$ 11,638	45%
% of total revenue	9%	10%	10%				

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

In the last several years, we have introduced numerous new products and product enhancements that have significantly expanded our MAS platform, enhanced the applications of the XLIF procedure, expanded our offering of cervical products, and moved closer to entering into the growing motion preservation market. We have also acquired complementary and strategic assets and technology, particularly in the area of biologics. We are developing proprietary total disc replacement devices for lateral lumbar spine applications and separately for cervical spine applications, which are currently in different phases of clinical trials and related studies. We anticipate continuing to incur costs related to such clinical trials and studies through at least 2011.

Compensation and other shareowner related expenses increased \$1.7 million for 2010 as increased compensation and other shareowner related expenses resulting from additions to the Company's headcount were partially offset by a decrease in performance-based compensation for 2010 as compared to 2009. Compensation and other shareowner related expenses increased \$5.1 million for 2009, including an increase in stock-based compensation of \$1.1 million,

primarily due to increased headcount to support our product development and enhancement efforts, as compared to 2008. In addition, expenses related to ongoing clinical trial and study related activities designed to demonstrate the value of our emerging and existing technologies increased \$2.4 million and \$0.4 million for 2010 and 2009, respectively, compared to the prior years. In addition, expenses increased \$2.0 million in 2010 as compared to 2009 as a result of expenses incurred in connection with a supply agreement related to the bone graft product being developed by Progentix and an additional technology acquisition. In 2009, other research related expenses increased \$3.6 million as compared to 2008, including \$2.4 million in research expenses related to our investment in Progentix.

For the foreseeable future, as a percentage of revenue, we expect total research and development costs to remain around 9% in support of our ongoing development and planned clinical trial and study related activities.

**Table of Contents***Amortization of Intangible Assets*

	Year Ended December 31,			2009 to 2010		2008 to 2009	
	2010	2009	2008	\$ Change	% Change	\$ Change	% Change
				(Dollars in thousands)			
Amortization of Intangible Assets	\$ 5,407	\$ 5,335	\$ 2,989	\$ 72	1%	\$ 2,346	79%
% of total revenue	1%	1%	1%				

Amortization of intangible assets relates to amortization of finite-lived intangible assets acquired. Amortization expense remained relatively constant in 2010 as compared to 2009, however the increase in amortization expense in 2009 compared to 2008 is due to the increased acquisition activity undertaken in 2008 and 2009.

We expect expenses recorded in connection with the amortization of intangible assets to continue to increase in absolute dollars for the foreseeable future as amortization of acquired in-process research and development commences once acquired research and development projects reach technological feasibility.

*In-Process Research and Development*

	Year Ended December 31,			2009 to 2010		2008 to 2009	
	2010	2009	2008	\$ Change	% Change	\$ Change	% Change
				(Dollars in thousands)			
In-Process Research and Development	\$	\$	\$ 20,876	\$	%	\$ (20,876)	(100)%
% of total revenue	%	%	8%				

During 2008, we recorded in-process research and development (IPR&D) charges of \$20.9 million related to the acquisitions of pedicle screw technology and Osteocel Plus. As of the date of the acquisitions, the projects associated with the IPR&D efforts had not yet reached technological feasibility and the in-process research and development had no alternative future uses. Accordingly, the amounts were charged to expense on the acquisition dates in accordance with the authoritative guidance in effect on the dates of acquisition.

During the first quarter of 2009, we adopted the FASB's revised authoritative guidance for business combinations, which is applied prospectively for all new business acquisitions entered into after January 1, 2009 and provides that IPR&D acquired is no longer charged to expense on the acquisition date, but rather recorded as an asset on the balance sheet. Amounts recorded as IPR&D beginning after January 1, 2009, will begin being amortized upon first sales of the product over the estimated useful life of the technology. As of December 31, 2010, we have approximately \$46.0 million on our balance sheet related to IPR&D in conjunction with our investment in Progentix and acquisition of Cervitech as regulatory approval has not yet been obtained. In accordance with authoritative guidance, as the technology has not yet been proven, the amortization of the acquired IPR&D has not begun. In the first quarter of 2010, we submitted a PMA application for U.S. Food and Drug Administration (FDA) approval for the PCM cervical disc system acquired from Cervitech, which represents approximately \$34.8 million of the \$46.0 million total capitalized IPR&D. In addition, we are currently in the process of seeking regulatory clearance for Attrax, a product being developed by Progentix, which represents the remaining \$11.2 million of the \$46.0 million total capitalized IPR&D.





**Table of Contents**

2008 is due primarily to (i) an increase in interest expense of \$1.3 million in 2009 as compared to 2008 related to the convertible debt offering due to having a full year of interest expense in the 2009 period as compared to only a partial year during the 2008 period and (ii) a decrease in interest income of \$4.1 million in 2009 as compared to 2008 due to both lower interest rates and lower average balances in marketable securities in 2009 as compared to 2008.

**Income Tax (Benefit) Expense**

	Year Ended December 31,			2009 to 2010		2008 to 2009	
	2010	2009	2008	\$ Change	% Change	\$ Change	% Change
	(Dollars in thousands)						
Income Tax (Benefit) Expense	\$ (50,619)	\$ 1,732	\$	\$ (52,351)	(3023)%	\$ 1,732	%
Effective income tax (benefit) rate	(195)%	28%	%				

The effective income tax benefit rate for 2010 was approximately 195% compared to an effective income tax rate of 28% for 2009. The income tax benefit for 2010 includes federal, state and foreign income tax expense, offset by the reversal of a valuation allowance totaling \$55.7 million. We generated pre-tax book income in both 2010 and 2009. As a result of this positive earnings trend, three years of cumulative profits and projected future taxable income, we determined that it was more likely than not that our domestic deferred tax assets would be realized and, accordingly, we reversed a valuation allowance totaling approximately \$72.7 million that was recorded against these deferred tax assets (\$17.0 million of the reversal resulted in a benefit recorded to additional paid in capital). Excluding the impact of this reversal of the valuation allowance, the effective income tax rate for 2010 would have differed from the U.S. federal statutory rate of 35% due to state income taxes, net of federal benefit, and non-deductible stock award compensation in 2010. The effective tax rate for 2009 was approximately 28%, which differed from the U.S. federal statutory rate of 35% due primarily to state income taxes, net of federal benefit, and non-deductible stock award compensation in 2009. The effective income tax rate for 2008 was nil as the Company was in a net operating loss position and maintained a full valuation allowance on deferred tax assets.

We are subject to audits by federal, state, local, and foreign tax authorities. We believe that adequate provisions have been made for any adjustments that may result from tax examinations. However, the outcome of tax audits cannot be predicted with certainty. Should any issues addressed in our tax audits be resolved in a manner not consistent with management's expectations, we could be required to adjust our provision for income taxes in the period such resolution occurs. We will continue to assess the likelihood of realization of our tax credits and other net deferred tax assets. If future events occur that do not make the realization of such assets more likely than not, a valuation allowance will be established against all or a portion of the net deferred tax assets.

We expect our effective income tax rate to exceed the U.S. federal and state statutory income tax rates primarily due to non-deductible expenses and foreign losses expected to be incurred by Progentix.

**Stock-Based Compensation**

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

Year Ended December 31,	2009 to 2010	2008 to 2009
-------------------------	--------------	--------------

	<b>2010</b>	<b>2009</b>	<b>2008</b>	<b>\$</b>	<b>%</b>	<b>\$</b>	<b>%</b>
				<b>Change</b>	<b>Change</b>	<b>Change</b>	<b>Change</b>
				<b>(Dollars in thousands)</b>			
Stock-Based Compensation							
Sales, Marketing & Administrative	\$ 24,945	\$ 19,549	\$ 17,837				
Research & Development	3,280	4,244	3,110				
Total Stock-Based Compensation	\$ 28,225	\$ 23,793	\$ 20,947	\$ 4,432	19%	\$ 2,846	14%
% of total revenue	6%	6%	8%				

Stock-based compensation related to stock awards is recognized and amortized on an accelerated basis in accordance with authoritative guidance. The increase in stock-based compensation of approximately \$4.4 million in 2010 as compared to 2009 and \$2.8 million in 2009 as compared 2008, can be primarily attributed to an increase in the number of awards due to increased headcount year over year for all years presented. In addition, during 2009, we

**Table of Contents**

began granting restricted stock units (RSUs) which tend to have higher associated stock-based compensation expense as they are valued at the full market price on the day of grant.

As of December 31, 2010, there was \$11.5 million and \$9.9 million of unrecognized compensation expense for stock options and RSUs, respectively, which is expected to be recognized over a weighted-average period of approximately 1.6 years and 2.9 years, respectively. In addition, as of December 31, 2010, there was \$3.3 million of unrecognized compensation expense for shares expected to be issued under the Employee Stock Purchase Plan which is expected to be recognized through October 2012.

***Business Combinations and Asset Acquisitions***

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

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

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

*Acquisition of Cervitech® Inc.* In May 2009, we purchased Cervitech® Inc., (Cervitech), a New Jersey based company focused on clinical approval of the PCM® cervical disc system, a motion preserving total disc replacement device, for a purchase price of approximately \$79.0 million, consisting of cash totaling approximately \$25.0 million and the

issuance of 638,261 shares of NuVasive common stock to certain stockholders of Cervitech and \$29.7 million of contingent consideration due upon FDA approval of the PCM device. Of the total purchase price of \$79.0 million, \$34.8 million and \$54.5 million was allocated to in-process research and development and goodwill, respectively, based on management's valuation of the fair value of the assets acquired and liabilities assumed on the date of acquisition. This strategic acquisition allows us the potential to accelerate our entry into the growing mechanical cervical disc replacement market. We submitted a PMA for FDA approval in the first quarter of 2010. Approval, if obtained, should further strengthen our cervical product offering and will enable us to continue our trend of increasing our market share.

**Table of Contents**

*Acquisition of Osteocel® Biologics Business.* In July 2008, we completed the acquisition of certain assets of Osiris Therapeutics, Inc. (the Osteocel Biologics Business Acquisition). The transaction provides us with an allograft cellular matrix that is designed to mimic the biologic profile of autograft, as well as rights to acquire the next generation cultured version of the product. Osteocel Plus is a unique bone matrix product that contains viable mesenchymal stem cells, or MSCs, to aid in spinal fusion and provides the three beneficial properties similar to autograft: osteoconduction (provides a scaffold for bone growth), osteoinduction (bone formation stimulation) and osteogenesis (bone production). Osteocel Plus is designed to allow surgeons to offer the benefits of these properties to patients without the discomfort and potential complications of autograft harvesting, in addition to eliminating the time spent on a secondary surgical procedure. Osteocel Plus is produced for use in spinal applications through a proprietary processing method that preserves the endogenous cells. The acquisition is consistent with our objective of developing or acquiring innovative technologies. Of the total purchase price of \$85.0 million, \$35.0 million was paid to Osiris at closing (the Initial Purchase Price) and additional payments totaling \$50.0 million were made in cash and through the issuance of shares of our common stock through 2009. Of the total purchase price, \$16.7 million was allocated to in-process research and development, and recorded in expense in 2008, as the associated projects had not yet reached technological feasibility and had no alternative future uses.

*Acquisition of Pedicle Screw Technology.* In March 2008, we completed a buy-out of royalty obligations on SpheRx® pedicle screw and related technology products and acquired new pedicle screw intellectual property totaling \$6.3 million. Of the total purchase price, \$2.1 million, representing the present value of the expected future cash flows associated with the terminated royalty obligations, was allocated to intangible assets to be amortized on a straight-line basis over a seven-year period. The remaining \$4.2 million was allocated to in-process research and development, and recorded as expense in 2008, as the associated projects had not yet reached technological feasibility and had no alternative future uses.

These transactions and their impact to our consolidated statement of financial position and results of operations are fully described in Notes 2 and 3 to the consolidated financial statements included in this Annual Report.

**Liquidity, Cash Flows and Capital Resources*****Liquidity and Capital Resources***

Since our inception in 1997, we have incurred significant losses and as of December 31, 2010, we had an accumulated deficit of approximately \$111.4 million. Through 2008, our operations were funded primarily with proceeds from the sale of our equity securities, which at December 31, 2008, totaled \$284.5 million since inception, including \$210.1 million sold in the public markets. Since 2009, our operations have been funded primarily with our convertible debt proceeds issued in March 2008 as well as the positive cash flow generated from operations.

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

Cash, cash equivalents and marketable securities was \$229.7 million and \$204.7 million at December 31, 2010 and at December 31, 2009, respectively. We believe that our existing cash, cash equivalents and short-term marketable securities will be sufficient to meet our anticipated cash needs for at least the next 12 months. Our future capital requirements will depend on many factors including our rate of revenue growth, the timing and extent of spending to support development efforts, the expansion of sales, marketing and administrative activities, the timing of introductions of new products and enhancements to existing products, the continuing market acceptance of our

products and the expenditures associated with possible future acquisitions or other business combination transactions.

We expect that cash provided by operating activities may fluctuate in future periods as a result of a number of factors, including fluctuations in our operating results and working capital requirements. In addition, as more fully discussed in Note 12 to the consolidated financial statements included in this Annual Report, we may be required to post a supersedeas bond or escrow fund to secure the recent \$60.0 million judgment against us in connection with the NeuroVision trademark infringement litigation. Including attorney's fees and interest during the appeals period, this \$60.0 million could reach approximately \$63.0 million. Our anticipated cash needs for the coming twelve month period have contemplated this potential requirement.

**Table of Contents****Cash Flows**

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

	Year Ended December 31,			2009 to	2008 to 2009
	2010	2009	2008	2010 \$ Change	\$ Change
Cash provided by (used in) operating activities	\$ 65,827	\$ 46,419	\$ (5,002)	\$ 19,408	\$ 51,421
Cash used in investing activities	(45,795)	(127,903)	(144,615)	82,108	16,712
Cash provided by financing activities	7,082	14,458	220,020	(7,376)	(205,562)
Effect of exchange rate changes on cash	70	121		(51)	121
Increase (decrease) in cash and cash equivalents	\$ 27,184	\$ (66,905)	\$ 70,403	\$ 94,089	\$ (137,308)

**Cash flows from operating activities**

Cash provided by operating activities was \$65.8 million in 2010, compared to \$46.4 million in 2009. The \$19.4 million increase in cash provided by operating activities in 2010 as compared to 2009 is primarily due to improvement in our profitability profile and an increase in non-cash expenses of depreciation, amortization and stock-based compensation. These increases were partially offset by the non-cash benefit resulting from the reversal of the valuation allowance on our domestic deferred tax assets. Cash provided by operating activities increased \$51.4 million in 2009 as compared with 2008 primarily due to improved operating results in 2009 as compared to 2008, as well as improved collections from accounts receivable.

**Cash flows used in investing activities**

Cash used in investing activities was \$45.8 million in 2010, compared to \$127.9 million in 2009. The \$82.1 million decrease in cash used in investing activities in 2010 as compared to 2009 is primarily due to a decrease in cash used for acquisitions and investments in 2010 compared to 2009 as the acquisition of Cervitech, Inc. and our investment in Progentix were completed in 2009 with no comparable investments in 2010, and a net decrease in our investing activities. These decreases in spending were offset by increased purchases of surgical instrument sets, which are deployed to support our increasing revenue volume, and increased expenditures in infrastructure related to the addition of our New York facility and expansion of our Memphis facility. Cash used in investing activities decreased \$16.7 million in 2009 as compared with 2008 primarily due to decreases in our investment activities and capital asset purchases, slightly offset by an increase in cash used to fund acquisitions and investments.

**Cash flows from financing activities**

Cash provided by financing activities was \$7.1 million in 2010, compared to \$14.5 million in 2009. The \$7.4 million decrease in cash provided by financing activities in 2010 as compared to 2009 is primarily due to an increase in cash used for long-term other assets (primarily cash used as collateral for letters of credit), partially offset by an increase in proceeds from the issuance of common stock. Cash provided by financing activities decreased \$205.6 million in 2009 as compared to 2008 primarily due to the receipt of net proceeds of \$208.4 million in March 2008 from the issuance of our Senior Convertible Notes, which financing was not replicated or needed in 2009.

**Contractual Obligations and Commitments**

Contractual obligations and commitments represent future cash commitments and liabilities under agreements with third parties, including our Senior Convertible Notes, operating leases and other contractual obligations. The



**Table of Contents**

following summarizes our long-term contractual obligations and commitments as of December 31, 2010 (*in thousands*):

	<b>Total</b>	<b>Payments Due by Period</b>			
		<b>Less Than 1 Year</b>	<b>1 to 3 Years</b>	<b>4 to 5 Years</b>	<b>After 5 Years</b>
Senior Convertible Notes(1)	\$ 241,385	\$ 5,175	\$ 236,210	\$	\$
Operating leases	95,857	8,935	17,017	14,337	55,568
Royalty obligations	830	160	320	320	30
Clinical advisory agreements	938	238	355	345	
Supply agreements	31,500	7,500	15,500	8,500	
<b>Total</b>	<b>\$ 370,510</b>	<b>\$ 22,008</b>	<b>\$ 269,402</b>	<b>\$ 23,502</b>	<b>\$ 55,598</b>

(1) See Note 7 to the consolidated financial statements included in this Annual Report for further discussion of the terms of the Senior Convertible Notes.

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

In connection with the 2005 acquisition of RSB Spine LLC, we are contingently obligated to make additional consideration payments over a period of 12 years based upon sales of the products derived from Smart Plate®, Gradient CLP™ and related technology.

In connection with the investment in Progentix, we are contingently obligated to make additional payments of up to \$61 million based upon the achievement of specified milestones (effective January 14, 2011, this amount is reduced to \$56 million).

In connection with the acquisition of Cervitech, we are contingently obligated to make an additional payment up to \$33 million upon FDA approval of the PCM device. The milestone payment may be made in cash or a combination of cash and up to half in NuVasive common stock, at our discretion.

In connection with several purchase agreements, we are contingently obligated to make additional payments up to \$6.4 million primarily upon the achievement of specified milestones.

We have not included an amount related to uncertain tax benefits or liabilities in the table above because we cannot make a reasonably reliable estimate regarding the timing of settlements with taxing authorities, if any. As of December 31, 2010, the liability included in the consolidated balance sheets related to tax uncertainties is immaterial.

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

**Off-Balance Sheet Arrangements**

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

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

*Interest Rate Sensitivity and Risk.* Our exposure to interest rate risk at December 31, 2010 is related to our investment portfolio which consists largely of debt instruments of high quality corporate issuers and the U.S. government and its agencies. Due to the short-term nature of these investments, we have assessed that there is no material exposure to interest rate risk arising from our investments. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates. At December 31, 2010, we do not hold any material asset-backed investment securities and in 2010, we did not realize any losses related to asset-backed investment securities. Based upon our overall interest rate exposure as of December 31, 2010, a change of 10 percent in interest rates, assuming the amount of our investment portfolio remains constant, would not have a

**Table of Contents**

material effect on interest expense. Further, this analysis does not consider the effect of the change in the level of the overall economic activity that could exist in such an environment.

We have operated mainly in the United States of America, and the majority of our sales since inception have been made in U.S. dollars. Accordingly, we have assessed that we do not have any material exposure to foreign currency rate fluctuations.

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

The following table presents the carrying value and related weighted-average rate of return for our investment portfolio as of December 31, 2010 (dollars in thousands):

	<b>Carrying Value</b>	<b>Weighted Average Rate of Return</b>
Money market funds	\$ 46,144	%
Certificates of deposit	1,394	0.5%
Corporate notes	15,193	0.7%
U.S. government treasury securities	20,584	0.1%
Securities of government-sponsored entities	99,922	0.4%
Total interest bearing instruments	\$ 183,237	

As of December 31, 2010, the stated maturities of our investments are \$86.5 million within one year and \$50.6 million from one to two years. These investments are recorded on the balance sheet at fair market value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income.

*Market Price Sensitive Instruments.* In order to reduce the potential equity dilution, we entered into convertible note hedge transactions (the Hedge) entitling us to purchase up to 5.1 million shares of our common stock at an initial stock price of \$44.74 per share, each of which is subject to adjustment. Upon conversion of our Senior Convertible Notes, the Hedge is expected to reduce the equity dilution if the daily volume-weighted average price per share of our common stock exceeds the strike price of the Hedge. We also entered into warrant transactions with the counterparties of the Hedge entitling them to acquire up to 5.1 million shares of our common stock, subject to adjustment, at an initial strike price of \$49.13 per share, subject to adjustment. The warrant transactions could have a dilutive effect on our earnings per share to the extent that the price of our common stock during a given measurement period (the quarter or year to date period) at maturity of the warrants exceeds the strike price of the warrants.

**Table of Contents**

**Item 8. *Financial Statements and Supplementary Data.***

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

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

None

**Item 9A. *Controls and Procedures***

*Disclosure Controls and Procedures.* We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended (Exchange Act) is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of the Company's disclosure controls and procedures (as such term is defined in SEC Rules 13a-15(e) and 15d-15(e)) as of December 31, 2010. Based on such evaluation, our management has concluded as of December 31, 2010, the Company's disclosure controls and procedures are effective.

*Management's Report on Internal Control over Financial Reporting.* Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

Management has used the framework set forth in the report entitled *Internal Control - Integrated Framework* published by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission to evaluate the effectiveness of the Company's internal control over financial reporting. Management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2010. Ernst & Young LLP, the Company's independent registered public accounting firm, has issued an attestation report on the Company's internal control over financial reporting which is included herein.

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



**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of  
NuVasive, Inc.

We have audited NuVasive, Inc.'s internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). NuVasive, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, NuVasive, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of NuVasive, Inc. as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010 of NuVasive, Inc. and our report dated February 25, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California  
February 25, 2011



**Table of Contents**

**Item 9B. *Other Information.***

*None.*

**PART III**

Certain information required by Part III is omitted from this report because the Company will file a definitive proxy statement within 120 days after the end of its fiscal year pursuant to Regulation 14A (the Proxy Statement ) for its annual meeting of stockholders to be held on May 25, 2011, and certain information included in the Proxy Statement is incorporated herein by reference.

**Item 10. *Directors and Executive Officers and Corporate Governance.***

We have adopted a Code of Conduct and Ethics for all officers, directors and shareowners. The Code of Conduct and Ethics is available on our website, [www.nuvasive.com](http://www.nuvasive.com), and in our filings with the Securities and Exchange Commission. We intend to disclose future amendments to, or waivers from, provisions of our Code of Conduct and Ethics that apply to our Principal Executive Officer, Principal Financial Officer, Principal Accounting Officer, or Controller, or persons performing similar functions, within four business days of such amendment or waiver.

The other information required by this Item 10 will be set forth in the Proxy Statement and is incorporated in this report by reference.

**Item 11. *Executive Compensation.***

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

**Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.***

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

**Item 13. *Certain Relationships and Related Transactions, and Director Independence.***

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

**Item 14. *Principal Accountant Fees and Services.***

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

**PART IV**

**Item 15. *Exhibits and Financial Statement Schedules.***

(a) The following documents are filed as a part of this report:

(1) Report of Independent Registered Public Accounting Firm



Consolidated Balance Sheets as of December 31, 2010 and 2009

Consolidated Statements of Operations for the years ended December 31, 2010, 2009 and 2008

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2010, 2009 and 2008

**Table of Contents**

Consolidated Statements of Cash Flows for the years ended December 31, 2010, 2009 and 2008

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules: Schedule II Valuation Accounts

All other financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits. See subsection (b) below.

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

<b>Exhibit Number</b>	<b>Description</b>
2.1	Asset Purchase Agreement, dated May 8, 2008, by and between the Company and Osiris Therapeutics, Inc. (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the Commission) on August 8, 2008)
2.2	Amendment to Asset Purchase Agreement, dated September 30, 2008, by and between the Company and Osiris Therapeutics, Inc. (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on November 7, 2008)
2.3	Amendment No. 2 to Asset Purchase Agreement, dated March 25, 2009, between the Company and Osiris Therapeutics, Inc. (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 8, 2009)
2.4	Share Purchase Agreement, by and among NuVasive, Inc. and the stockholders of Cervitech, Inc., as listed therein, dated April 22, 2009 (incorporated by reference to our Registration Statement on Form S-3 (File No. 333-159098) filed with the Commission on May 8, 2009)
3.1	Restated Certificate of Incorporation (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 13, 2004)
3.2	Restated Bylaws (incorporated by reference to our Current Report on Form 8-K filed with the Commission on December 15, 2008)
4.1	Second Amended and Restated Investors Rights Agreement, dated July 11, 2002, by and among NuVasive, Inc. and the other parties named therein (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)
4.2	Amendment No. 1 to Second Amended and Restated Investors Rights Agreement, dated June 19, 2003, by and among NuVasive, Inc. and the other parties named therein (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)
4.3	Amendment No. 2 to Second Amended and Restated Investors Rights Agreement, dated February 5, 2004, by and among NuVasive, Inc. and the other parties named therein (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)
4.4	Registration Rights Agreement, dated as of August 4, 2005, between NuVasive, Inc. and Pearsalls Limited (incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 10, 2005)
4.5	Registration Rights Agreement Termination Agreement, dated as of September 26, 2006, between NuVasive, Inc. and Pearsalls Limited (incorporated by reference to our Current Report on Form 8-K filed with the Commission on September 29, 2006)
4.6	Indenture, dated March 7, 2008, between the NuVasive Inc. and U.S. Bank National Association, as Trustee (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on

Edgar Filing: NUVASIVE INC - Form 10-K

- May 9, 2008)
- 4.7 Form of 2.25% Convertible Senior Note due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
- 4.8 Registration Rights Agreement, dated March 7, 2007, among NuVasive, Inc. and Goldman, Sachs & Co., and J.P. Morgan Securities Inc., related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
- 4.9 Specimen Common Stock Certificate (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 16, 2006)
- 10.1# 1998 Stock Option/Stock Issuance Plan (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
10.2#	Form of Notice of Grant of Stock Option under our 1998 Stock Option/Stock Issuance Plan (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)
10.3#	Form of Stock Option Agreement under our 1998 Stock Option/Stock Issuance Plan, and form of addendum thereto (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)
10.4#	Form of Stock Purchase Agreement under our 1998 Stock Option/Stock Issuance Plan (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)
10.5#	Form of Stock Issuance Agreement under our 1998 Stock Option/Stock Issuance Plan (incorporated by reference to Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on May 11, 2004)
10.6#	Form of Stock Issuance Agreement under our 1998 Stock Option/Stock Issuance Plan, dated April 21, 2004, and May 4, 2004 (incorporated by reference to Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on May 11, 2004)
10.7#	2004 Equity Incentive Plan, as amended (incorporated by reference to Appendix A to our Definitive Proxy Statement) filed with the Commission on April 11, 2007)
10.8#	Form of Stock Option Award Notice under our 2004 Equity Incentive Plan (incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on April 8, 2004)
10.9#	Form of Option Exercise and Stock Purchase Agreement under our 2004 Equity Incentive Plan (incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on April 8, 2004).
10.10#	Form of Restricted Stock Unit Award Agreement under our 2004 Equity Incentive Plan (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.11#	2004 Employee Stock Purchase Plan (incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on April 8, 2004)
10.12#	Amendment No. 1 to 2004 Employee Stock Purchase Plan (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on November 7, 2008)
10.13#	Amendment No. 2 to 2004 Employee Stock Purchase Plan (filed herewith)
10.14#	Executive Employment Agreement, dated as of January 2, 2011, by and between NuVasive, Inc. and Alexis V. Lukianov (incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 6, 2011)
10.15#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Keith C. Valentine (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 8, 2008)
10.16#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Patrick Miles (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 8, 2008)
10.17#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Jeffrey P. Rydin (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 8, 2008)
10.18#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Jason M. Hannon (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 2, 2009)
10.19#	

Edgar Filing: NUVASIVE INC - Form 10-K

- Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Keith C. Valentine (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 2, 2009)
- 10.20# Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Patrick Miles (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 2, 2009)
- 10.21# Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Jeffrey P. Rydin (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 2, 2009)

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
10.22#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Jason M. Hannon (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 2, 2009)
10.23#	Compensation Letter Agreement, dated November 4, 2009, between NuVasive, Inc. and Pat Miles (incorporate by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.24#	Compensation Letter Agreement, dated November 4, 2009, between NuVasive, Inc. and Jeff Rydin (incorporate by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.25#	Compensation Letter Agreement, dated December 28, 2009, between NuVasive, Inc. and Jason Hannon (incorporate by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.26#	Offer Letter Agreement, dated October 19, 2009, between NuVasive, Inc. and Michael Lambert (incorporate by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.27#	Compensation Letter Agreement, dated February 24, 2010, between NuVasive, Inc. and Michael Lambert (incorporate by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.28#	Compensation Letter Agreement, dated February 3, 2009, between NuVasive, Inc. and Tyler P. Lipschultz (filed herewith)
10.29#	Amendment to Compensation Letter Agreement, dated January 3, 2011, between NuVasive, Inc. and Tyler P. Lipschultz (filed herewith)
10.30#	Compensation Letter Agreement, dated August 3, 2009, between NuVasive, Inc. and Craig E. Hunsaker (filed herewith)
10.31#	Amendment to Compensation Letter Agreement, dated January 3, 2011, between NuVasive, Inc. and Craig E. Hunsaker (filed herewith)
10.32#	Form of Indemnification Agreement between NuVasive, Inc. and each of our directors and officers (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)
10.33	Sublease, dated October 12, 2004, by and between NuVasive, Inc. and Gateway, Inc. (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on November 15, 2004)
10.34#	Summary of 2009 annual salaries and annual stock grants for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers (incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 8, 2009)
10.35#	Summary of 2010 annual salaries and to our Chief Executive Officer, our Chief Financial Officer and our other named executive officers (incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 8, 2010)
10.36#	Summary of 2011 annual salaries and annual stock grants for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers (incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 6, 2011)
10.37	Customer Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on August 8, 2007)
10.38	IBM Global Services Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on August 8, 2007)

Edgar Filing: NUVASIVE INC - Form 10-K

- 10.39 Lease Agreement for Sorrento Summit, entered into as of November 6, 2007, between the Company and HCPI/Sorrento, LLC. (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on November 8, 2007)
- 10.40 Purchase Agreement, dated March 3, 2008, among NuVasive, Inc. and Goldman, Sachs & Co., and J.P. Morgan Securities Inc., related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
- 10.41 Confirmation of Call Option Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
10.42	Confirmation of Call Option Transaction, dated March 3, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.43	Confirmation of Warrant Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.44	Confirmation of Warrant Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.45	Amendment to the Confirmation of Call Option Transaction, dated March 11, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.46	Amendment to the Confirmation of Call Option Transaction, dated March 11, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.47	Amendment to the Confirmation of Warrant Transaction, dated March 11, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.48	Amendment to the Confirmation of Warrant Transaction, dated March 11, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.49	Form of Voting Agreement, dated May 8, 2008, by and among each of Peter Friedli, Venturetec, Inc., U.S. Venture 05, Inc., Joyce, Ltd. and C Randal Mills, Ph.D, and the Company (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 8, 2008)
10.50	Preferred Stock Purchase Agreement, dated January 13, 2009, among the Company, Progentix Orthobiology, B.V. and the sellers listed on Schedule A thereto (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.51	Option Purchase Agreement, dated January 13, 2009, among the Company, Progentix Orthobiology, B.V. and the sellers listed on Schedule A thereto (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.52	Exclusive Distribution Agreement, dated January 13, 2009, between the Company and Progentix Orthobiology, B.V. (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 8, 2009)
21.1	List of subsidiaries of NuVasive, Inc.
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
32.1*	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350
32.2*	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350
101**	XBRL Instance Document
101**	XBRL Taxonomy Extension Schema Document
101**	XBRL Taxonomy Calculation Linkbase Document



- 101\*\* XBRL Taxonomy Label Linkbase Document
- 101\*\* XBRL Taxonomy Presentation Linkbase Document
- 101\*\* XBRL Taxonomy Definition Linkbase Document

Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with an asterisk. We have filed separately with the Commission an unredacted copy of the exhibit.

# Indicates management contract or compensatory plan.

\* These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934

**Table of Contents**

and are not to be incorporated by reference into any filing of NuVasive, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

\*\* Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these interactive data files are deemed not filed and otherwise are not subject to liability.

**Table of Contents**

**SUPPLEMENTAL INFORMATION**

Copies of the Registrant's Proxy Statement for the Annual Meeting of Stockholders to be held on May 25, 2011, and copies of the form of proxy to be used for such Annual Meeting, will be furnished to the SEC prior to the time they are distributed to the Registrant's Stockholders.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**NUVASIVE, INC.**

Date: February 25, 2011

By:  
/s/ Alexis V. Lukianov  
Alexis V. Lukianov  
Chairman and Chief Executive Officer  
(Principal Executive Officer)

Date: February 25, 2011

By:  
/s/ Michael J. Lambert  
Michael J. Lambert  
Executive Vice President and  
Chief Financial Officer  
(Principal Financial Officer)

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Alexis V. Lukianov and Michael Lambert, jointly and severally, his or her attorneys-in -fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in -fact, or his or her substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Alexis V. Lukianov Alexis V. Lukianov	Chairman and Chief Executive Officer (Principal Executive Officer)	February 25, 2011
/s/ Michael J. Lambert Michael J. Lambert	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 25, 2011
/s/ Jack R. Blair	Director	February 25, 2011

Jack R. Blair		
/s/ Peter C. Farrell	Director	February 25, 2011
Peter C. Farrell		
/s/ Robert J. Hunt	Director	February 25, 2011
Robert J. Hunt		

**Table of Contents**

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Lesley H. Howe Lesley H. Howe	Director	February 25, 2011
/s/ Eileen M. More Eileen M. More	Director	February 25, 2011
/s/ Richard W. Treharne Richard W. Treharne	Director	February 25, 2011

**NUVASIVE, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

<u>Report of Independent Registered Public Accounting Firm</u>	62
<u>Consolidated Balance Sheets as of December 31, 2010 and 2009</u>	63
<u>Consolidated Statements of Operations for the years ended December 31, 2010, 2009 and 2008</u>	64
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2010, 2009 and 2008</u>	65
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2010, 2009 and 2008</u>	66
<u>Notes to Consolidated Financial Statements</u>	67

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of  
NuVasive, Inc.

We have audited the accompanying consolidated balance sheets of NuVasive, Inc. as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of NuVasive, Inc. at December 31, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 1 to the consolidated financial statements, NuVasive, Inc. changed its method of accounting for business combinations with the adoption of the guidance originally issued in Financial Accounting Standards Board (FASB) Statement No. 141(R), *Business Combinations* (codified in FASB ASC Topic 805, *Business Combinations*), effective January 1, 2009.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), NuVasive, Inc.'s internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 25, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California  
February 25, 2011



**Table of Contents****NUVASIVE, INC.****CONSOLIDATED BALANCE SHEETS****(In thousands, except par value)**

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 92,597	\$ 65,413
Short-term marketable securities	86,458	99,279
Accounts receivable, net of allowances of \$2,573 and \$4,163, respectively	76,632	58,462
Inventory	107,577	90,191
Deferred tax assets	4,425	
Prepaid expenses and other current assets	4,082	3,757
Total current assets	371,771	317,102
Property and equipment, net	102,165	82,602
Long-term marketable securities	50,635	39,968
Intangible assets, net	107,121	103,338
Goodwill	103,070	101,938
Deferred tax assets, non-current	52,033	612
Other assets	15,234	7,260
Total assets	\$ 802,029	\$ 652,820
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 58,995	\$ 35,636
Accrued payroll and related expenses	17,266	19,111
Acquisition-related liabilities	32,715	
Total current liabilities	108,976	54,747
Senior convertible notes	230,000	230,000
Long-term acquisition-related liabilities	326	30,694
Deferred tax liabilities	3,685	16,756
Other long-term liabilities	12,810	10,772
Commitments and contingencies		
Noncontrolling interests	11,877	13,629
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized, none outstanding		
Common stock, \$0.001 par value; 70,000 shares authorized, 39,528 and 38,774 issued and outstanding at December 31, 2010 and 2009, respectively	40	39
Additional paid-in capital	545,114	485,757
Accumulated other comprehensive income	616	126
Accumulated deficit	(111,415)	(189,700)
Total stockholders' equity	434,355	296,222

Total liabilities and stockholders' equity	\$ 802,029	\$ 652,820
--	------------	------------

See accompanying notes to consolidated financial statements.

**Table of Contents****NUVASIVE, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS****(In thousands, except per share amounts)**

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Revenue	\$ 478,237	\$ 370,340	\$ 250,082
Cost of goods sold (excluding amortization of purchased technology)	85,139	61,110	39,008
Gross profit	393,098	309,230	211,074
Operating expenses:			
Sales, marketing and administrative	312,122	254,997	189,126
Research and development	43,479	37,581	25,943
Amortization of intangible assets	5,407	5,335	2,989
In-process research and development			20,876
Total operating expenses	361,008	297,913	238,934
Interest and other (expense) income, net:			
Interest income	760	1,507	5,599
Interest expense	(6,672)	(7,116)	(5,571)
Other (expense) income, net	(264)	461	304
Total interest and other (expense) income, net	(6,176)	(5,148)	332
Income (loss) before income taxes	25,914	6,169	(27,528)
Income tax (benefit) expense	(50,619)	1,732	
Consolidated net income (loss)	\$ 76,533	\$ 4,437	\$ (27,528)
Net loss attributable to noncontrolling interests	\$ (1,752)	\$ (1,371)	\$
Net income (loss) attributable to NuVasive, Inc.	\$ 78,285	\$ 5,808	\$ (27,528)
Net income (loss) per share attributable to NuVasive, Inc.:			
Basic	\$ 1.99	\$ 0.16	\$ (0.77)
Diluted	\$ 1.85	\$ 0.15	\$ (0.77)
Weighted average shares outstanding:			
Basic	39,251	37,426	35,807
Diluted	45,514	38,751	35,807

See accompanying notes to consolidated financial statements.



Table of Contents

## NUVASIVE, INC.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount				
<b>Balance at December 31, 2007</b>	35,330	\$ 35	\$ 364,469	\$ 54	\$ (167,980)	\$ 196,578
Issuance of common stock under employee and director stock option and purchase plans	980	1	11,849			11,850
Convertible Note hedge, net of warrants			(13,972)			(13,972)
Stock-based compensation expense			20,947			20,947
Comprehensive loss:						
Unrealized gain on marketable securities, net				519		519
Foreign currency translation				(763)		(763)
Net loss attributable to NuVasive, Inc.					(27,528)	(27,528)
Comprehensive loss attributable to NuVasive, Inc.						(27,772)
<b>Balance at December 31, 2008</b>	36,310	36	383,293	(190)	(195,508)	187,631
Issuance of common stock under employee and director stock option and purchase plans	824	1	12,555			12,556
Issuance of common stock in connection with acquisitions	1,640	2	64,214			64,216
Stock-based compensation expense			23,793			23,793
Tax benefits related to stock-based compensation awards			1,902			1,902
Comprehensive income:						
Unrealized loss on marketable securities, net				(494)		(494)
Foreign currency translation				810		810
Net income attributable to NuVasive, Inc.					5,808	5,808
Comprehensive income attributable to NuVasive, Inc.						6,124

Edgar Filing: NUVASIVE INC - Form 10-K

<b>Balance at December 31, 2009</b>	38,774	39	485,757	126	(189,700)	296,222
Issuance of common stock under employee and director stock option and purchase plans	754	1	14,830			14,831
Stock-based compensation expense			28,225			28,225
Reversal of valuation allowance related to original issue discount, net			16,116			16,116
Tax benefits related to stock-based compensation awards			186			186
Comprehensive income: Unrealized loss on marketable securities, net				(6)		(6)
Foreign currency translation				496		496
Net income attributable to NuVasive, Inc.					78,285	78,285
Comprehensive income attributable to NuVasive, Inc.						78,775
<b>Balance at December 31, 2010</b>	39,528	\$ 40	\$ 545,114	\$ 616	\$ (111,415)	\$ 434,355

See accompanying notes to consolidated financial statements.

**Table of Contents****NUVASIVE, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****(In thousands)**

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
<b>Operating activities:</b>			
Consolidated net income (loss)	\$ 76,533	\$ 4,437	\$ (27,528)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	36,737	29,841	23,105
Deferred income tax benefit	(53,664)		
In-process research and development			20,876
Stock-based compensation	28,225	23,793	20,947
Lease abandonment (reversal)		(1,997)	4,403
Allowance for doubtful accounts and sales return reserve, net of write-offs	(995)	2,211	1,026
Allowance for excess and obsolete inventory	1,607	2,297	(836)
Other non-cash adjustments	6,299	3,359	179
Changes in operating assets and liabilities, net of effects from acquisitions:			
Accounts receivable	(16,411)	(8,582)	(25,152)
Inventory	(18,664)	(23,133)	(32,451)
Prepaid expenses and other current assets	(3,559)	760	274
Accounts payable and accrued liabilities	11,596	5,932	5,098
Accrued payroll and related expenses	(1,877)	7,501	5,057
Net cash provided by (used in) operating activities	65,827	46,419	(5,002)
<b>Investing activities:</b>			
Cash paid for acquisitions and investments	(973)	(46,055)	(41,256)
Purchases of property and equipment	(45,846)	(32,878)	(39,795)
Purchases of marketable securities	(203,415)	(157,278)	(159,186)
Sales of marketable securities	204,439	108,308	95,926
Other assets			(304)
Net cash used in investing activities	(45,795)	(127,903)	(144,615)
<b>Financing activities:</b>			
Payments of long-term liabilities			(300)
Issuance of convertible debt, net of costs			222,442
Purchase of convertible note hedges			(45,758)
Sale of warrants			31,786
Tax benefits related to stock-based compensation awards	186	1,902	
Issuance of common stock	14,831	12,556	11,850
Other assets	(7,935)		
Net cash provided by financing activities	7,082	14,458	220,020
Effect of exchange rate changes on cash	70	121	

Edgar Filing: NUVASIVE INC - Form 10-K

Increase (decrease) in cash and cash equivalents	27,184	(66,905)	70,403
Cash and cash equivalents at beginning of year	65,413	132,318	61,915
Cash and cash equivalents at end of year	\$ 92,597	\$ 65,413	\$ 132,318
<b>Supplemental disclosure of non-cash transactions:</b>			
Landlord paid tenant improvements	\$	\$	\$ 7,309
Issuance of common stock in connection with acquisitions	\$	\$ 64,216	\$
<b>Supplemental cash flow information:</b>			
Interest paid	\$ 5,175	\$ 5,175	\$ 2,703
Income taxes paid	\$ 1,133	\$ 798	\$ 227

See accompanying notes to consolidated financial statements.



**Table of Contents**

**NUVASIVE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Significant Accounting Policies**

*Description of Business.* NuVasive, Inc. (the Company or NuVasive) was incorporated in Delaware on July 21, 1997. The Company is focused on developing minimally disruptive surgical products and procedures for the spine. The Company began commercializing its products in 2001. Its currently-marketed product portfolio is focused on applications for spine fusion surgery. Its principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS<sup>®</sup>, as well as a growing offering of biologics, cervical, and motion preservation products. In the spine surgery market, the Company's currently-marketed products are primarily used to enable access to the spine and to perform restorative and fusion procedures in a minimally disruptive fashion. The Company also focuses significant research and development efforts on expanding its MAS product platform, advancing the applications of their unique technology to additional procedures, and developing motion preservation products. The Company dedicates significant resources toward training spine surgeons on its unique technology and products.

The Company's primary business model is to loan its MAS systems to surgeons and hospitals who purchase disposables and implants for use in individual procedures. In addition, for larger customers, the Company's proprietary nerve monitoring systems, MaXcess<sup>®</sup> and surgical instrument sets are placed with hospitals for an extended period at no up-front cost to them. The Company also offers a range of bone allograft in patented saline packaging, disposables and spine implants, which include its branded CoRoent<sup>®</sup> products and fixation devices such as rods, plates and screws. Implants and disposables are shipped from the Company's inventories. The Company sells an immaterial quantity of MAS instrument sets, MaXcess and nerve monitoring systems to hospitals.

*Basis of Presentation and Principles of Consolidation.* The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. In addition, the consolidated financial statements as of December 31, 2010 and 2009 and for the years then ended include the accounts of a variable interest entity, Progentix Orthobiology, B.V. (Progentix), which is consolidated pursuant to existing guidance issued by the Financial Accounting Standards Board (FASB). All significant intercompany balances and transactions have been eliminated in consolidation.

*Use of Estimates.* To prepare financial statements in conformity with generally accepted accounting principles accepted in the United States of America, management must make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

*Concentration of Credit Risk and Significant Customers.* Financial instruments, which potentially subject the Company to concentrations of credit risk, consist primarily of cash and cash equivalents, short-term and long-term marketable securities and accounts receivable. The Company limits its exposure to credit loss by placing its cash and investments with high credit quality financial institutions. Additionally, the Company has established guidelines regarding diversification of its investments and their maturities, which are designed to maintain principal and maximize liquidity. No single customer represented greater than ten percent of sales for any of the years presented.

*Fair Value of Financial Instruments.* The Company's financial instruments consist principally of cash and cash equivalents, short-term and long-term marketable securities, accounts receivable, accounts payable, accrued expenses and Senior Convertible Notes. The carrying amounts of financial instruments such as cash equivalents, accounts receivable, accounts payable and accrued expenses approximate the related fair values due to the short-term maturities of these instruments. Marketable securities consist of available-for-sale securities that are reported at fair value with

the related unrealized gains and losses included in accumulated other comprehensive income (loss), a component of stockholders' equity. The estimated fair value of the Senior Convertible Notes is determined by using available market information as of December 31, 2010.

*Cash and Cash Equivalents.* The Company considers all highly liquid investments that are readily convertible into cash and have an original maturity of three months or less at the time of purchase to be cash equivalents.

**Table of Contents**

**NUVASIVE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Marketable Securities.* The Company defines marketable securities as income yielding securities that can be readily converted into cash. Marketable securities include U.S. Treasury and agency obligations, certificates of deposit (CDs) issued by domestic banks, and corporate notes and bonds.

*Accounts Receivable and Related Valuation Accounts.* Accounts receivable in the accompanying consolidated balance sheets are presented net of allowances for doubtful accounts and sales returns.

The Company performs credit evaluations of its customers' financial condition and, generally, requires no collateral from its customers. The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for specific receivables if and when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices as well as a review of the overall quality and age of those invoices not specifically reviewed. In determining the provision for invoices not specifically reviewed, the Company analyzes historical collection experience and current economic trends. If the historical data used to calculate the allowance provided for doubtful accounts does not reflect the Company's future ability to collect outstanding receivables or if the financial condition of customers were to deteriorate, resulting in impairment of their ability to make payments, an increase in the provision for doubtful accounts may be required.

In addition, the Company establishes a reserve for estimated sales return that is recorded as a reduction to revenue. This reserve is maintained to account for the future return of products sold in the current period. Product returns were not material for the years ended December 31, 2010, 2009 and 2008.

*Inventory.* Inventory consists primarily of purchased finished goods, which includes specialized implants and disposables, and is stated at the lower of cost or market determined by a weighted average cost method. The Company reviews the components of its inventory on a periodic basis for excess, obsolete or impaired inventory, and records a reserve for the identified items. At December 31, 2010 and 2009, the balance of the allowance for excess and obsolete inventory is \$6.7 million and \$5.1 million, respectively.

*Goodwill and Intangible Assets.* Goodwill represents the excess of the aggregate purchase price over the fair value of the tangible and identifiable intangible assets acquired by the Company. The goodwill recorded as a result of the business combinations in the years presented is not deductible for tax purposes. Goodwill and indefinite lived intangible assets, which consists of in-process research and development acquired, are not amortized. The Company assesses goodwill and indefinite lived intangible assets for impairment using fair value measurement techniques on an annual basis or more frequently if facts and circumstance warrant such a review. For purposes of assessing the impairment of goodwill, the Company estimates the value of the reporting units using its market capitalization as the best evidence of fair value. If the carrying amount of a reporting unit exceeds its fair value, then a goodwill impairment test is performed to measure the amount of the impairment loss, if any. During the years ended December 31, 2010, 2009 and 2008, the Company did not record any impairment charges related to goodwill.

Intangible assets are initially measured at their fair value, determined either by the fair value of the consideration exchanged for the intangible asset, or the estimated discounted cash flows expected to be generated from the intangible asset. Intangible assets with a finite life, such as acquired technology, manufacturing know-how, licensed technology, supply agreements and certain trade names and trademarks, are amortized on a straight-line basis over their estimated useful life, ranging from two to twenty years. Intangible assets with a finite life are tested for impairment whenever events or circumstances indicate that the carrying amount may not be recoverable.

In determining the useful lives of intangible assets, the Company considers the expected use of the assets and the effects of obsolescence, demand, competition, anticipated technological advances, changes in surgical techniques, market influences and other economic factors. For technology based intangible assets, the Company considers the expected life cycles of products which incorporate the corresponding technology. Trademarks and trade names that are related to products are assigned lives consistent with the period in which the products bearing each brand are expected to be sold.

**Table of Contents**

**NUVASIVE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Property, Plant and Equipment.* Property and equipment are carried at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, ranging from three to twenty years. Maintenance and repairs are expensed as incurred. The Company reviews property, plant and equipment for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated future undiscounted cash flows relating to the asset are less than its carrying amount. An impairment loss is measured as the amount by which the carrying amount of an asset exceeds its fair value.

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

*Research and Development.* Research and development costs are expensed as incurred.

*Product Shipment Costs.* Amounts billed to customers for shipping and handling of products are reflected in revenues and are not significant for any period presented. Product shipment costs are included in sales, marketing and administrative expense in the accompanying consolidated statements of operations and were \$16.6 million, \$11.9 million, and \$9.3 million for the years ended December 31, 2010, 2009, and 2008, respectively.

*Income Taxes.* A deferred tax asset or liability is determined based on the difference between the financial statement and tax basis of assets and liabilities as measured by the enacted tax rates which will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

*Net Income (Loss) Per Share.* The Company computes basic net income (loss) per share using the weighted-average number of common shares outstanding during the period. Diluted net income (loss) assumes the conversion, exercise or issuance of all potential common stock equivalents, unless the effect of inclusion would be anti-dilutive. For purposes of this calculation, common stock equivalents include the Company's stock options, unvested restricted stock units, warrants and the shares to be issued upon the conversion of the Senior Convertible Notes. No common stock equivalents were included in the diluted net income (loss) calculation for the year ended December 31, 2008 because the inclusion of such shares would have had an anti-dilutive effect. No shares related to the assumed conversion of the Senior Convertible Notes were included in the net income (loss) calculation for the years ended December 31, 2009 and 2008 because the inclusion of such shares would have had an anti-dilutive effect. The shares to be issued upon exercise of all outstanding warrants were excluded from the diluted net income (loss) calculation for all years presented because the inclusion of such shares would have had an anti-dilutive effect.

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table sets forth the computation of basic and diluted earnings per share (*in thousands, except share data*):

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Numerator:			
Net income (loss) attributable to NuVasive, Inc.	\$ 78,285	\$ 5,808	\$ (27,528)
Income impact of assumed conversion of Senior Convertible Notes outstanding	5,969		
Net income (loss) available to NuVasive, Inc.'s common stockholders	\$ 84,254	\$ 5,808	\$ (27,528)
Denominator for basic and diluted net income (loss) per share:			
Weighted average common shares outstanding for basic	39,251	37,426	35,807
Dilutive potential common stock outstanding:			
Stock options and ESPP	944	1,280	
Restricted stock units	178	45	
Dilutive effect of assumed conversion of Senior Convertible Notes outstanding	5,141		
Weighted average common shares outstanding for diluted	45,514	38,751	35,807
Basic net income (loss) per share attributable to NuVasive, Inc.	\$ 1.99	\$ 0.16	\$ (0.77)
Diluted net income (loss) per share attributable to NuVasive, Inc.	\$ 1.85	\$ 0.15	\$ (0.77)

The following outstanding common stock equivalents were not included in the calculation of net income (loss) per diluted share because their effects were anti-dilutive (*in thousands*):

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Weighted Stock Options and RSUs	4,100	3,123	1,678
Warrants	5,141	5,141	5,141
Senior Convertible Notes		5,141	5,141
Total	9,241	13,405	11,960

*Comprehensive Income (Loss).* Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Comprehensive income (loss) includes unrealized gains or losses on the Company's marketable securities and foreign currency translation adjustments. The Company has disclosed comprehensive income (loss) as a component of stockholders' equity.

The components of Accumulated other comprehensive income, net of tax, is as follows (*in thousands*):

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Translation adjustments, net of tax	\$ 606	\$ 110
Unrealized gains on marketable securities, net of tax	10	16
Total accumulated other comprehensive income (loss)	\$ 616	\$ 126

Comprehensive income (loss) consists of the following (*in thousands*):

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Consolidated net income (loss)	\$ 76,533	\$ 4,437	\$ (27,528)
Other comprehensive income (loss):			
Unrealized (loss) gain on marketable securities, net of tax	(6)	(494)	519
Translation adjustments, net of tax	496	810	(763)
Total consolidated comprehensive income (loss)	77,023	4,753	(27,772)
Plus: Net loss attributable to noncontrolling interests	1,752	1,371	
Comprehensive income (loss) attributable to NuVasive, Inc.	\$ 78,775	\$ 6,124	\$ (27,772)

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Business Combinations.* In accordance with authoritative guidance for business combinations, goodwill and other long-term liabilities on the December 31, 2009 consolidated balance sheet have been retrospectively adjusted to reflect the finalization of the purchase price allocation for assets and liabilities acquired from Cervitech<sup>®</sup>, Inc. (Cervitech) in May 2009 (Note 2).

***Recently Adopted Accounting Standards.***

Effective January 1, 2009, the Company implemented the FASB's revised authoritative guidance for business combinations. This revised guidance requires an acquiring company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date. In addition, an acquiring company is required to capitalize in-process research and development and either amortize it over the life of the product upon commercialization, or write it off if the project is abandoned or impaired. Previously, post-acquisition adjustments related to business combination deferred tax asset valuation allowances and liabilities for uncertain tax positions were generally required to be recorded as an increase or decrease to Goodwill. The revised guidance does not permit this accounting and, generally, requires any such changes to be recorded in current period income tax expense. Thus, all changes to valuation allowances and liabilities for uncertain tax positions established in acquisition accounting, regardless of the guidance used to initially account for the business combination, will be recognized in current period income tax expense. Additionally, this guidance requires that contingent purchase consideration be remeasured to estimated fair value at each reporting period with the change in fair value recorded in the results of operations. The adoption of the revised guidance will have an impact on the Company's consolidated financial statements, but the nature and magnitude of the specific effects will depend upon the nature, terms and size of the acquisitions consummated after the effective date of January 1, 2009. The impact of the adoption of this guidance in 2009 resulted in the capitalization of in-process research and development totaling \$46.0 million that would have been expensed under the previous guidance.

Effective January 1, 2010, the Company adopted a newly issued accounting standard which provides guidance for the consolidation of variable interest entities and requires an enterprise to determine whether its variable interest or interests give it a controlling financial interest in a variable interest entity. This amended consolidation guidance for variable interest entities replaces the existing quantitative approach for identifying which enterprise should consolidate a variable interest entity, which was based on which enterprise is exposed to a majority of the risks and rewards, with a qualitative approach, based on which enterprise has both (1) the power to direct the economically significant activities of the entity and (2) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to the variable interest entity. The adoption of this standard did not have an impact on the Company's consolidated results of operations or financial position. Determination about whether an enterprise should consolidate a variable interest entity is required to be evaluated continuously as changes to existing relationships or future transactions may result in the Company consolidating or deconsolidating current or future business arrangements.

Effective January 1, 2010, the Company adopted the FASB's updated guidance related to fair value measurements and disclosures, which requires a reporting entity to disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and to describe the reasons for the transfers. In addition, in the reconciliation for fair value measurements using significant unobservable inputs, or Level 3, a reporting entity should disclose separately information related to purchases, sales, issuances, and settlements information to be included in the rollforward of activity. The updated guidance also requires that an entity provide fair value measurement disclosures for each class of assets and liabilities and disclosures about the valuation techniques and inputs used to measure fair



value for both recurring and non-recurring fair value measurements for Level 2 and Level 3 fair value measurements. The guidance is effective for interim or annual financial reporting periods beginning after December 15, 2009, except for the disclosures about purchases, sales, issuances and settlements in the rollforward activity in Level 3 fair value measurements, which are effective for fiscal years beginning after December 15, 2010 and for interim periods within those fiscal years. Therefore, the Company has

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

not yet adopted the guidance with respect to the rollforward activity in Level 3 fair value measurements. The Company has updated its disclosures to comply with the updated guidance, however, adoption of the updated guidance did not have an impact on the Company's consolidated results of operations or financial position.

*Reclassifications.* Certain reclassifications have been made to the prior year consolidated financial statements to conform to the current year presentation.

**2. Business Combinations*****Cervitech® Inc. Acquisition***

On May 8, 2009 (the Closing Date), the Company completed the purchase of all of the outstanding shares of Cervitech, a Delaware corporation, for an initial payment of approximately \$49.0 million consisting of cash totaling approximately \$25.0 million and the issuance of 638,261 shares of NuVasive common stock to certain stockholders of Cervitech. Cervitech, a New Jersey based company, is focused on the clinical approval of the PCM® cervical disc system, a motion preserving total disc replacement device in the United States. This acquisition allows NuVasive the potential to accelerate its entry into the growing mechanical cervical disc replacement market. In addition to the initial payment, the Company may be obligated to make an additional milestone payment of \$33.0 million if the U.S. Food and Drug Administration (FDA) issues an approval order allowing the commercialization of Cervitech's PCM device in the United States with an intended use for treatment of degenerative disc disease. The milestone payment may be made in cash or a combination of cash and up to half in NuVasive common stock, at the Company's discretion. The fair value of the contingent consideration at the Closing Date was determined to be \$29.7 million using a probability-weighted discounted cash flow model with the key assumptions being the interest rate, the timing of expected approval and the probability assigned to the milestone being achieved.

In 2009, the assets and liabilities of Cervitech were recorded at their respective acquisition date estimated fair values, and identifiable intangible assets were recorded at fair value. The preliminary allocation of the estimated purchase price was based on management's preliminary valuation of the fair value of tangible assets, intangible assets and in-process research and development acquired and liabilities assumed as of the Closing Date and such estimates were subject to revision. During May 2010, the Company finalized the purchase accounting adjustments to account for facts related to deferred tax assets and liabilities acquired that existed at the Closing Date. Accordingly, the Company reduced the amount of Goodwill recorded on the acquisition of Cervitech by \$0.9 million retrospectively to the Closing Date as follows (*in thousands*):

	<b>Initial Estimate of Fair Value</b>	<b>Purchase Price Adjustments</b>	<b>Final Fair Value</b>
Goodwill	\$ 55,443	\$ (945)	\$ 54,498
Deferred income tax liabilities, net	\$ 13,560	\$ 945	\$ 12,615

The final allocation of the purchase price is as follows (*in thousands*):

	<b>Fair Value</b>	<b>Estimated Useful Life</b>
Total current assets	\$ 1,233	
Property, plant and equipment	59	
Developed technology	700	14 years
Non-compete agreement	100	2 years
Trade name	700	10 years
In-process research and development	34,800	
Goodwill	54,498	
Current liabilities	(483)	
Deferred income tax liabilities, net	(12,615)	
Total estimated purchase price allocation	\$ 78,992	

Table of Contents

## NUVASIVE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Of the total \$79.0 million purchase price, \$34.8 million and \$54.5 million was allocated to in-process research and development (IPR&D) and goodwill, respectively, based on management's valuation of the fair value of the assets acquired and liabilities assumed on the date of acquisition. The IPR&D, which has been capitalized as an indefinite-lived asset, relates to the future commercialization of Cervitech's PCM device in the United States with an intended use for treatment of degenerative disc disease. The projected cash flows utilized in management's valuation of the fair value of the IPR&D acquired were based on key assumptions such as estimates of revenues and operating profits related to the IPR&D considering its stage of development; the time and resources needed to complete the development and approval of the related product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product such as obtaining marketing approval from the FDA and other regulatory agencies; and risks related to the viability of and potential alternative treatments in any future target markets. The Company submitted a premarket approval (PMA) application for FDA approval for the PCM device in the first quarter of 2010, for which an approval date is not predictable. At December 31, 2010, the remaining cost to reach FDA approval for this device is estimated at approximately \$0.9 million to \$1.3 million, depending on when FDA approval is received.

Goodwill totaling \$54.5 million represents the excess of the purchase price over the fair value of tangible and identifiable intangible assets acquired and is due primarily to increased market penetration from future products and customers and synergies expected from combining the PCM device with the Company's existing development of motion preservation systems. This acquisition was nontaxable and, as a result, there is no tax basis in goodwill. Accordingly, none of the goodwill associated with the Cervitech acquisition is deductible for tax purposes.

*Results of Operations*

The accompanying consolidated statement of operations reflects the operating results of Cervitech since the date of the acquisition. The amount of loss attributable to Cervitech included in the Company's consolidated statement of operations from the acquisition date to December 31, 2009 was \$3.3 million. For the year ended December 31, 2009, the Company's consolidated results of operations include acquisition-related expenses of \$1.3 million which are included in sales, marketing and administrative expenses.

The Company has prepared the following unaudited pro forma financial statement information to compare results of the periods presented assuming the Cervitech acquisition had occurred as of the beginning of the periods presented. These unaudited pro forma results have been prepared for comparative purposes only and do not purport to be an indicator of the results of operations that would have actually resulted had the acquisition occurred at the beginning of each of the periods presented, or of future results of operations.

The unaudited pro forma is as follows (*in thousands, except per share amounts*):

	<b>Year Ended December 31,</b>	
	<b>2009</b>	<b>2008</b>
Revenue	\$ 370,878	\$ 252,625
Net income (loss) attributable to NuVasive, Inc.	\$ 3,879	\$ (38,427)
Net income (loss) per share – basic and diluted	\$ 0.10	\$ (1.05)

The above pro forma unaudited results of operations do not include pro forma adjustments relating to costs of integration or post-integration cost reductions that may be incurred or realized by the Company in excess of actual amounts incurred or realized through December 31, 2009.

***Investment in Progentix Orthobiology, B.V.***

In 2009, the Company completed the purchase of forty percent (40%) of the capital stock of Progentix, a company organized under the laws of the Netherlands, from existing shareholders (the Progentix Shareholders) pursuant to a Preferred Stock Purchase Agreement for \$10.0 million in cash (the Initial Investment). Concurrent with the Initial Investment, NuVasive and Progentix also entered into a Senior Secured Facility Agreement,

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

whereby Progentix may borrow up to \$5.0 million from NuVasive to fund ongoing clinical and regulatory efforts (the Loan). The proceeds of the Loan are to be utilized towards achievement of all milestones, as defined in the Preferred Stock Purchase Agreement. The Loan accrues interest at a rate of six percent (6%) per year. Other than its obligations under the Loan Agreement, NuVasive is not obligated to provide additional funding to Progentix. At December 31, 2010, the Company had advanced Progentix the full \$5.0 million in accordance with the Loan Agreement. The Company has not provided additional financing to Progentix other than this contractually required amount.

Also concurrent with the Preferred Stock Purchase Agreement, NuVasive, Progentix and the Progentix Shareholders entered into an Option Purchase Agreement dated January 13, 2009, as amended on December 30, 2009 (the Option Agreement), whereby NuVasive may be obligated (the Put Option), upon the achievement within a specified period of time of certain milestones by Progentix, to purchase the remaining sixty percent (60%) of capital stock of Progentix from its shareholders (the Remaining Shares) for an amount up to \$45.0 million, payable in a combination of cash or NuVasive common stock, at NuVasive's sole discretion, subject to certain adjustments (at December 31, 2010, the aggregate amount of additional payments NuVasive may be obligated to pay for the Remaining Shares is \$36.0 million).

NuVasive may also be obligated, in the event that Progentix achieves the milestones specified in the agreements and completes additional milestones and NuVasive achieves specified sales targets, within a specified time period, to make additional payments to the Progentix Shareholders, excluding NuVasive, of up to an aggregate total of \$25.0 million, payable in a combination of cash and NuVasive common stock, at NuVasive's sole discretion, subject to certain adjustments (at December 31, 2010 and January 14, 2011, the aggregate amount of additional payments NuVasive may be obligated to pay related to these milestones is \$25.0 million and \$20.0 million, respectively). NuVasive also has the right under the Option Agreement, as amended, to purchase the Remaining Shares (the Call Option) during a stated period of time of the Option Agreement (the Option Period) for an amount up to \$35.0 million, payable in a combination of cash and NuVasive common stock, at the Company's sole discretion, subject to certain adjustments. In the event NuVasive achieves in excess of a specified annual sales run rate on Progentix products during the Option Period, NuVasive may be required to purchase the Remaining Shares for an amount up to \$35.0 million. NuVasive and Progentix also entered into a Distribution Agreement, as amended, whereby Progentix appointed NuVasive as its exclusive distributor for certain Progentix products. The Distribution Agreement will be in effect for a term of ten years unless terminated earlier in accordance with its terms.

In accordance with revised authoritative guidance issued by the FASB, the Company has determined that Progentix is a variable interest entity (VIE) as it does not have the ability to finance its activities without additional subordinated financial support and its equity investors will not absorb their proportionate share of expected losses and will be limited in the receipt of the potential residual returns of Progentix. Additionally, pursuant to this guidance, NuVasive is considered its primary beneficiary as NuVasive has both (1) the power to direct the economically significant activities of Progentix and (2) the obligation to absorb losses of, or the right to receive benefits from, Progentix. Accordingly, the financial position and results of operations of Progentix have been included in the consolidated financial statements from the date of the Initial Investment. The liabilities recognized as a result of consolidating Progentix do not represent additional claims on the Company's general assets. The creditors of Progentix have claims only on the assets of Progentix, which are not material, and the assets of Progentix are not available to NuVasive.

Pursuant to authoritative guidance, the equity interests in Progentix not owned by the Company, which includes shares of both common and preferred stock, are reported as noncontrolling interests on the consolidated balance sheet of the Company. The preferred stock represents 18% of the noncontrolling equity interests and provides for a cumulative 8%

dividend, if and when declared by Progentix's Board of Directors. As the rights and conversion features of the preferred stock are substantially the same as those of the common stock, the preferred stock is classified as noncontrolling interest and shares in the allocation of the losses incurred by Progentix. Losses incurred by Progentix are charged to the Company and to the noncontrolling interest holders based on their

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

ownership percentage. The Remaining Shares and the Option Agreement that was entered into between NuVasive, Progentix and the Progentix Shareholders are not considered to be freestanding financial instruments as defined by authoritative guidance. Therefore the Remaining Shares and the Option Agreement are accounted for as a combined unit on the consolidated financial statements as a noncontrolling interest that was initially recorded at fair value and classified as mezzanine equity.

Pursuant to authoritative guidance, when the embedded Put Option is exercisable and therefore the Remaining Shares considered currently redeemable (i.e., at the option of the holder), the instrument will be adjusted to its maximum redemption amount. If the embedded Put Option is considered not currently exercisable (e.g., because a contingency has not been met), and it is not probable that the embedded Put Option will become exercisable, an adjustment is not necessary until it is probable that the embedded Put Option will become exercisable. At December 31, 2010, the embedded Put Option was not deemed currently exercisable and therefore the Remaining Shares were not redeemable because the milestones referred to previously had not been met. Furthermore, at December 31, 2010, the Company concluded it is not probable that the milestones will be met, therefore the Remaining Shares are not expected to become redeemable. The probability of redemption is reevaluated at each reporting period.

Total assets and liabilities of Progentix as of December 31, 2010 included in the accompanying consolidated balance sheet are as follows (*in thousands*):

Total current assets	\$	735
Identifiable intangible assets, net		15,792
Goodwill		12,654
Other long-term assets		399
Accounts payable & accrued expenses		512
Other long-term liabilities		328
Deferred tax liabilities, net		3,685
Noncontrolling interests		11,877

The following is a reconciliation of equity (net assets) attributable to the noncontrolling interests (*in thousands*):

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Noncontrolling interests at beginning of period	\$ 13,629	\$
Noncontrolling interests acquired		15,000
Less: Net loss attributable to the noncontrolling interests	1,752	1,371
Noncontrolling interests at end of period	\$ 11,877	\$ 13,629

Intangible assets consolidated pursuant to the Progentix investment are included in the Intangible assets, net balance in the consolidated balance sheet as of December 31, 2010 and consist of the following (*in thousands*):



	<b>Weighted- Average Amortization Period (in years)</b>	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Intangible Assets, Net</b>
Non-competition agreement	2	\$ 300	\$ 295	\$ 5
Existing technology	13	5,400	813	4,587
In-process research and development		11,200		11,200
Total Progentix intangible assets		\$ 16,900	\$ 1,108	\$ 15,792

***Osteocel® Biologics Business Acquisition***

On July 24, 2008, NuVasive completed the acquisition of certain assets of Osiris Therapeutics, Inc. (Osiris) (the Osteocel Biologics Business Acquisition) for \$35.0 million in cash paid at closing pursuant to the Asset

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Purchase Agreement, as amended. The completion date of this transaction is referred to as the Technology Closing Date. At the Technology Closing Date, the Company also entered into a Manufacturing Agreement, as amended (collectively with the Asset Purchase Agreement, the Agreements) with Osiris.

Under the terms of these Agreements, NuVasive was obligated to make additional payments of up to \$50.0 million, including milestone-based contingent payments not to exceed \$20.0 million and a non-contingent \$30.0 million payment. The contingent payments were based on achieving specified sales amounts and were not included in the preliminary estimate of the purchase price of the Osteocel Biologics Business. The Company paid the first milestone of \$5.0 million in cash during the fourth quarter of 2008. During the year ended December 31, 2009, the Company paid all remaining obligations in cash totaling \$5.0 million and through the issuance of 1,001,421 shares of the Company's common stock with a market value of \$40.0 million.

The Company's purchase price allocation was updated in 2009 to reflect the milestone-based payments made in 2009 and to reflect the impact of the amendments made to the Agreements in March 2009, which eliminated the performance contingencies applicable to \$30.0 million of the \$45.0 million in then-remaining milestones.

This acquisition provides NuVasive with an allograft cellular matrix that is designed to mimic the biologic profile of autograft, as well as rights to acquire the next generation cultured version of the product. Osteocel Plus is a unique bone matrix product that contains viable mesenchymal stem cells, or MSCs, to aid in spinal fusion and provides the three beneficial properties similar to autograft: osteoconduction (provides a scaffold for bone growth), osteoinduction (bone formation stimulation) and osteogenesis (bone production). Osteocel Plus is designed to allow surgeons to offer the benefits of these properties to patients without the discomfort and potential complications of autograft harvesting, in addition to eliminating the time spent on a secondary surgical procedure. Osteocel Plus is produced for use in spinal applications through a proprietary processing method that preserves the endogenous cells.

*Purchase Price*

The purchase price has been allocated to the tangible and intangible assets acquired based on their respective fair values as of the Technology Closing Date. The allocation of the purchase price resulted in an excess of the total purchase price over the fair value of net tangible and intangible assets acquired by approximately \$33.7 million.

The purchase price is determined as follows (*in thousands*):

Cash paid on Technology Closing Date	\$ 35,000
Cash payments	10,000
Market value of NuVasive common stock issued	39,371
Transaction costs and other	544
Total purchase price	\$ 84,915

The following table summarizes the allocation of the purchase price (*in thousands*):

	<b>Fair Value</b>	<b>Estimated Useful Life</b>
Manufacturing know-how and trade secrets	\$ 19,800	13 years
Developed technology	7,200	10 years
Discounted price purchase contract	2,500	0.5 years
Trade name and trademarks	4,700	15 years
Customer contracts and relationships	330	0.5-2 years
In-process research and development	16,700	
Goodwill	33,685	
 Total estimated initial purchase price allocation	 \$ 84,915	

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company recorded an IPR&D charge of \$16.7 million related to the Osteocel Biologics Business Acquisition. As of the date of the acquisition, the projects associated with the IPR&D efforts had not yet reached technological feasibility and the research and development in-process had no alternative future uses. Accordingly, the amount was charged to expense on the acquisition date and is reported as a separate IPR&D line item on the statement of operations.

Goodwill totaling \$33.7 million represents the excess of the purchase price over the fair value of tangible and identifiable intangible assets acquired and is due primarily to increased market penetration from future products and customers and synergies expected from combining Osteocel Plus with the Company's existing biologics product line offerings.

*Results of Operations*

The Company has prepared the following unaudited pro forma financial statement information to compare results of the periods presented assuming the Osteocel Biologics Business Acquisition had occurred as of the beginning of the period presented. These unaudited pro forma results have been prepared for comparative purposes only and do not purport to be an indicator of the results of operations that would have actually resulted had the acquisition occurred at the beginning of each of the periods presented, or of future results of operations.

The unaudited pro forma is as follows (*in thousands, except per share amounts*):

	<b>Year Ended December 31, 2008</b>
Revenue	\$ 269,086
Net (loss) attributable to NuVasive, Inc.	\$ (21,379)
Net (loss) per share – basic and diluted	\$ (0.10)

The above proforma results exclude the \$16.7 million non-cash acquired IPR&D charge recorded upon the closing of the acquisition during the third quarter of 2008. The Company's consolidated financial statements include the operating results of the Osteocel Biologics Business from the date of acquisition.

**3. Asset Acquisition**

In March 2008, NuVasive completed a buy-out of royalty obligations on SpheRx<sup>®</sup> pedicle screw and related technology products and acquired new pedicle screw intellectual property for cash payments aggregating \$6.3 million. Of the aggregate purchase price, \$2.1 million, representing the present value of the expected future cash flows associated with the terminated royalty obligations, was allocated to intangible assets to be amortized on a straight-line basis over a seven-year period. The remaining \$4.2 million was allocated to in-process research and development as the associated projects had not yet reached technological feasibility and had no alternative future uses.

**4. Marketable Securities**

Marketable securities consist of corporate debt securities, U.S. government treasury securities and government sponsored entities. The Company classifies all securities as available-for-sale, as the sale of such securities may be required prior to maturity to implement management strategies. These securities are carried at fair value, with the unrealized gains and losses reported as a component of other comprehensive income (loss) in stockholder's equity until realized. A decline in the market value of any marketable security below cost that is determined to be other-than-temporary will result in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. No such impairment charges were recorded for any period presented.

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Realized gains and losses from the sale of marketable securities, if any, are determined on a specific identification basis. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense on the consolidated statements of operations. Realized gains and losses during the periods presented were immaterial. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method and are included in interest income on the consolidated statements of operations. Interest and dividends on securities classified as available-for-sale are included in interest income on the consolidated statements of operations.

The composition of marketable securities is as follows (*in thousands*):

	<b>Contractual Maturity (in Years)</b>	<b>Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
December 31, 2010:					
Classified as current assets					
Certificates of deposit	Less than 1	\$ 938	\$ 1	\$ (1)	\$ 938
Corporate notes	Less than 1	12,076	3		12,079
U.S. government treasury securities	Less than 1	16,550	12	(1)	16,561
Securities of government-sponsored entities	Less than 1	56,870	24	(14)	56,880
Short-term marketable securities		86,434	40	(16)	86,458
Classified as non-current assets					
Certificates of deposit	1 to 2	456			456
Corporate notes	1 to 2	3,123		(9)	3,114
U.S. government treasury securities	1 to 2	4,023			4,023
Securities of government-sponsored entities	1 to 2	43,056	6	(20)	43,042
Long-term marketable securities		50,658	6	(29)	50,635
Total marketable securities at December 31, 2010		\$ 137,092	\$ 46	\$ (45)	\$ 137,093

	<b>Contractual Maturity (in Years)</b>	<b>Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
December 31, 2009:					
Classified as current assets					
Certificates of deposit	Less than 1	\$ 1,979	\$	\$ (6)	\$ 1,973
Corporate notes	Less than 1	4,955	4		4,959
U.S. government treasury securities	Less than 1	27,963	24	(4)	27,983
Securities of government-sponsored entities	Less than 1	64,317	67	(20)	64,364

Edgar Filing: NUVASIVE INC - Form 10-K

Short-term marketable securities		99,214	95	(30)	99,279
Classified as non-current assets					
Securities of government-sponsored entities	1 to 2	40,026	8	(66)	39,968
Long-term marketable securities		40,026	8	(66)	39,968
Total marketable securities at December 31, 2009		\$ 139,240	\$ 103	\$ (96)	\$ 139,247

As of December 31, 2010, the Company had no investments that were in a significant unrealized loss position. The Company reviews its investments to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. The Company maintains an investment portfolio of various holdings, types and maturities. The Company does not hold derivative financial instruments. The Company places its cash investments in instruments that meet high credit quality standards, as specified in its investment policy guidelines. These guidelines also limit the amount of credit exposure to any one issue, issuer or type of instrument.

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****5. Fair Value Measurements**

The Company measures certain assets and liabilities in accordance with authoritative guidance which requires fair value measurements be classified and disclosed in one of the following three categories:

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

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

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

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy. The Company did not have any significant transfers of assets and liabilities between Level 1 and Level 2 and no transfers to or from Level 3 of the fair value measurement hierarchy during the year ended December 31, 2010.

The fair values of the Company's assets and liabilities at December 31, 2010, which are measured at fair value on a recurring basis, were determined using the following inputs (*in thousands*):

	<b>Total</b>	<b>Quoted Price in Active Market (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Marketable securities:				
U.S government treasury securities	\$ 20,584	\$ 20,584	\$	\$
Securities of government-sponsored entities	99,922	99,922		
Corporate notes	15,193	11,194	3,999	
Certificates of deposit	1,394	1,394		
Total marketable securities at December 31, 2010	\$ 137,093	\$ 133,094	\$ 3,999	\$
Contingent consideration:				
Acquisition-related liabilities	\$ 33,041	\$	\$	\$ 33,041

The fair and carrying value of the Company's Senior Convertible Notes is discussed in Note 7.

***Contingent Consideration Liability***



In connection with the acquisition of Cervitech in May 2009, the Company is required to pay an additional amount not to exceed \$33.0 million in the event that the PCM cervical total disc replacement device receives FDA approval. The fair value of the contingent consideration is determined using a probability-weighted discounted cash flow model, the significant inputs which are not observable in the market. The key assumptions in applying this approach are the interest rate, the timing of expected approval and the probability assigned to the milestone being achieved. Based on the expected timing of the milestone being achieved, the estimated fair value of the contingent consideration increased to \$31.7 million at December 31, 2010. The change in fair value is recorded in the statement of operations as sales, marketing and administrative expenses.

In connection with an immaterial acquisition in 2010, the Company is required to pay an additional amount not to exceed \$3.0 million in the event three specified milestones are met. The fair value of the contingent consideration is determined using a probability-weighted discounted cash flow model, the significant inputs which are not observable in the market. The key assumptions in applying this approach are the interest rate and the probabilities assigned to the milestones being achieved. Based on the probabilities assigned to the milestones being achieved, the

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

estimated fair value of the contingent consideration totaled \$1.3 million at December 31, 2010. Changes in fair value are recorded in the statement of operations as sales, marketing and administrative expenses.

The following table sets forth the change in the estimated fair value for the Company's liabilities measured using significant unobservable inputs (Level 3) for the years ended December 31, 2010 and December 31, 2009 (*in thousands*):

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Fair value measurement at beginning of period	\$ 30,694	\$
Contingent consideration liability recorded upon acquisition	1,339	29,722
Change in fair value measurement included in operating expenses	1,008	972
Fair value measurement at end of period	\$ 33,041	\$ 30,694

**6. Balance Sheet Details**

*Property and Equipment, net.* Property and equipment, net, consisted of the following (*in thousands*):

	<b>Useful Life</b>	<b>December 31,</b>	
		<b>2010</b>	<b>2009</b>
Instrument sets	3	\$ 117,760	\$ 85,730
Machinery and equipment	5	20,052	14,899
Computer equipment and software	3	13,792	12,449
Leasehold improvements	15	17,854	15,156
Furniture and fixtures	3 to 7	7,243	5,243
Building and improvements	20	6,871	4,970
Land		541	541
		184,113	138,988
Less: accumulated depreciation and amortization		(81,948)	(56,386)
		\$ 102,165	\$ 82,602

Depreciation expense was \$28.9 million, \$23.4 million, and \$17.0 million for the years ended December 31, 2010, 2009 and 2008, respectively.

*Goodwill and Intangible Assets.* Goodwill and intangible assets were acquired in connection with business combinations and asset acquisitions discussed in Notes 2 and 3.

Goodwill and intangible assets as of December 31, 2010 consisted of the following (*in thousands*):

	<b>Weighted- Average Amortization Period (in years)</b>	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Intangible Assets, net</b>
<b>Intangible Assets Subject to Amortization:</b>				
Purchased technology:				
Developed technology	14	\$ 39,975	\$ (7,946)	\$ 32,029
Manufacturing know-how and trade secrets	12	21,104	(4,207)	16,897
Trade name and trademarks	14	6,100	(956)	5,144
Customer relationships	13	10,035	(2,984)	7,051
	14	\$ 77,214	\$ (16,093)	\$ 61,121
<b>Intangible Assets Not Subject to Amortization:</b>				
In-process research and development				46,000
Goodwill				103,070
Total intangible assets, net				\$ 210,191

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Goodwill and intangible assets as of December 31, 2009 consisted of the following (*in thousands*):

	<b>Weighted- Average Amortization Period (in years)</b>	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Intangible Assets, net</b>
<b>Intangible Assets Subject to Amortization:</b>				
Purchased technology:				
Developed technology	15	\$ 31,975	\$ (5,548)	\$ 26,427
Manufacturing know-how and trade secrets	13	20,408	(2,394)	18,014
Trade name and trademarks	14	5,900	(520)	5,380
Customer relationships	14	9,730	(2,213)	7,517
	14	\$ 68,013	\$ (10,675)	\$ 57,338
<b>Intangible Assets Not Subject to Amortization:</b>				
In-process research and development				46,000
Goodwill				101,938
Total intangible assets, net				\$ 205,276

Total expense related to the amortization of intangible assets was \$5.4 million, \$5.3 million and \$3.0 million for the years ended December 31, 2010, 2009 and 2008, respectively. In-process research and development will be amortized beginning on the approval date of the respective acquired products and will be amortized over the estimated useful life determined at that time.

Total future amortization expense related to intangible assets subject to amortization at December 31, 2010 is set forth in the table below (*in thousands*):

2011	\$ 5,930
2012	5,904
2013	5,886
2014	5,849
2015	5,531
Thereafter through 2027	32,021
Total future amortization expense	\$ 61,121

The change to goodwill during the year ended December 31, 2010 is comprised of the following (*in thousands*):

Balance at December 31, 2009, as adjusted	\$ 101,938
Addition recorded in connection with acquisition	1,132
Balance at December 31, 2010	\$ 103,070

*Accounts Payable and Accrued Liabilities.* Accounts payable and accrued liabilities consisted of the following (*in thousands*):

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Accounts payable	\$ 6,508	\$ 10,608
Accrued expenses	28,781	17,105
Distributor commissions payable	7,462	6,424
Amounts payable in connection with supply agreement	8,000	
Non-income taxes payable	7,531	1,154
Other	713	345
	\$ 58,995	\$ 35,636

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Other Long-Term Liabilities.* Other long-term liabilities consisted of the following (*in thousands*):

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Deferred rent	\$ 12,503	\$ 10,333
Other	307	439
	<b>\$ 12,810</b>	<b>\$ 10,772</b>

**7. Senior Convertible Notes**

In March 2008, the Company issued \$230.0 million principal amount of 2.25% unsecured Senior Convertible Notes (the Notes), which includes the subsequent exercise of the initial purchasers' option to purchase an additional \$30.0 million aggregate principal amount of the Notes. The net proceeds from the offering, after deducting the initial purchasers' discount and costs directly related to the offering, were approximately \$208.4 million. The Company pays 2.25% interest per annum on the principal amount of the Notes, payable semi-annually in arrears in cash on March 15 and September 15 of each year. Any notes not converted prior to March 15, 2013, the Maturity Date, will be paid in cash. The fair value, based on quoted market prices, of the outstanding notes at December 31, 2010 is approximately \$225.4 million.

The Notes are convertible into shares of the Company's common stock, based on an initial conversion rate, subject to adjustment, of 22.3515 shares per \$1,000 principal amount of the Notes (which represents an initial conversion price of approximately \$44.74 per share). Holders may convert their notes at their option on any day up to and including the second scheduled trading day immediately preceding the Maturity Date. If a fundamental change to the Company's business occurs, as defined in the Notes, holders of the Notes have the right to require that the Company repurchase the Notes, or a portion thereof, at the principal amount plus accrued and unpaid interest.

In connection with the offering of the Notes, the Company entered into convertible note hedge transactions (the Hedge) with the initial purchasers and/or their affiliates (the Counterparties) entitling the Company to purchase up to 5.1 million shares of the Company's common stock at an initial stock price of \$44.74 per share, each of which is subject to adjustment. In addition, the Company sold to the Counterparties warrants to acquire up to 5.1 million shares of the Company's common stock (the Warrants), at an initial strike price of \$49.13 per share, subject to adjustment. The cost of the Hedge that was not covered by the proceeds from the sale of the Warrants was approximately \$14.0 million and was recorded as a reduction of additional paid-in capital as of December 31, 2008. The impact of the Hedge is to raise the effective conversion price of the Notes to approximately \$49.13 per share (or approximately 20.3542 shares per \$1,000 principal amount of the Notes). The Hedge is expected to reduce the potential equity dilution upon conversion of the Notes if the daily volume-weighted average price per share of the Company's common stock exceeds the strike price of the Hedge. The Warrants could have a dilutive effect on the Company's earnings per share to the extent that the price of the Company's common stock during a given measurement period (the quarter or year to date period) exceeds the strike price of the Warrants.

**8. Commitments**

*Leases*

The Company leases office facilities and equipment under various operating lease agreements. The initial terms of these leases range from three years to 15 years and generally provide for periodic rent increases and renewal options. Certain leases require the Company to pay taxes, insurance and maintenance. In connection with certain operating leases, the Company has issued irrevocable transferable letters of credit totaling \$5.5 million.

For financial reporting purposes, rent expense is recognized on a straight-line basis over the term of the lease. Accordingly, rent expense recognized in excess of rent paid is reflected as a liability in the accompanying consolidated balance sheets. Rent expense, including expenses directly associated with the facility leases, was

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

approximately \$8.1 million, \$6.4 million, and \$4.4 million for the years ended December 31, 2010, 2009, and 2008, respectively.

The Company's future minimum annual lease payments, including payments for costs directly associated with the facility leases, for years ending after December 31, 2010 are as follows (*in thousands*):

	<b>Operating Leases</b>
2011	\$ 8,935
2012	8,981
2013	8,036
2014	7,092
2015	7,245
Thereafter	55,568
Total minimum payments	\$ 95,857

***Lease Abandonment Charge Reversal***

In August 2008, the Company relocated its corporate headquarters to a two-building campus style complex in San Diego. In connection with this relocation, in the third quarter of 2008, the Company recorded a liability for approximately \$3.9 million related to lease termination costs in connection with vacating the Company's former corporate headquarters. During the third quarter of 2009, due to continued growth, the Company decided to reoccupy the former corporate headquarters facility and accordingly, reversed the remaining lease termination costs liability of \$2.0 million. This amount was recorded as a reduction of sales, marketing, and administrative expenses in the third quarter of 2009.

***Other Commitments***

In connection with the acquisition of RSB, the Company is contingently obligated to make additional annual payments over a period of 12 years based upon sales of the products derived from Smart Plate® Gradient CLP™ and related technology. Through December 31, 2010, these amounts have not been significant.

In connection with the investment in Progentix as described in Note 2, the Company is contingently obligated to make additional payments of up to \$61.0 million based upon the achievement of specified milestones (effective January 14, 2011, this amount is reduced to \$56.0 million).

In connection with the acquisition of Cervitech as described in Note 2, the Company is contingently obligated to make additional payments up to \$33.0 million upon FDA approval of the PCM device. The milestone payment may be made in cash or a combination of cash and up to half in NuVasive common stock, at the Company's discretion.

In connection with several purchase agreements, the Company is contingently obligated to make additional payments up to \$6.4 million primarily upon the achievement of specified milestones.



## 9. Stockholders Equity

*Preferred Stock.* There are 5,000,000 shares of preferred stock authorized and none issued or outstanding at December 31, 2010 and 2009.

*Stock Option and Restricted Stock Units.* In October 1998, the Company adopted the 1998 Stock Incentive Plan (the 1998 Plan) to grant options to purchase common stock to eligible employees, non-employee members of the board of directors, consultants and other independent advisors who provide services to the Company. Under the 1998 Plan, 4.3 million shares of common stock, as amended, were initially reserved for issuance upon exercise of options granted by the Company. The Board of Directors determined the terms of the stock option agreements, including vesting requirements. Options under the 1998 Plan have a 10-year term and generally vest over a period

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

not to exceed four years from the date of grant. All options granted under the 1998 Plan allowed for early exercise prior to the option becoming fully vested.

In April 2004, the Board of Directors replaced the 1998 Plan with the 2004 Equity Incentive Plan (the 2004 Plan) under which 7 million shares (plus the remaining shares available for grant under the 1998 Plan) of the Company's common stock are authorized for future issuance, and reserved for purchase upon exercise of options granted. In addition, the 2004 Plan provides for automatic annual increases in the number of shares reserved for issuance thereunder equal to the lesser of (i) 4% of the Company's outstanding shares on the last business day in December of the calendar year immediately preceding; (ii) 4,000,000 shares; or (iii) a number of shares determined by the Board of Directors. As of December 31, 2010, 282,838 shares remained available for future grant under the 2004 Plan.

The 2004 Plan provides for the grant of incentive and nonstatutory stock options, restricted stock units (RSUs) and rights to purchase stock to employees, directors and consultants of the Company. The 2004 Plan provides that incentive stock options will be granted only to employees and are subject to certain limitations as to fair value during a calendar year. Under the 2004 Plan, the exercise price of incentive stock options must equal at least the fair value on the date of grant and the exercise price of non-statutory stock options and the issuance price of common stock under the stock issuance program may be no less than 85% of the fair value on the date of grant or issuance. The options are exercisable for a period of up to ten years after the date of grant and generally vest 25% one year from date of grant and ratably each month thereafter for a period of 36 months. The RSUs generally vest 25% per year beginning one year from date of grant. In addition, the Board of Directors has provided for the acceleration of 50% of the unvested options of all employees upon a change in control and the vesting of the remaining unvested options for those employees that are involuntarily terminated within a year of the change in control.

Following is a summary of stock option activity for the year ended December 31, 2010 under all stock plans (*in thousands, except years and per share amounts*):

	<b>Underlying Shares</b>	<b>Weighted Avg. Exercise Price</b>	<b>Weighted-Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value as of December 31, 2010</b>
Outstanding at December 31, 2009	5,717	\$ 29.44		
Granted	1,141	\$ 32.61		
Exercised	(524)	\$ 20.37		
Cancelled	(216)	\$ 35.84		
Outstanding at December 31, 2010	6,118	\$ 30.59	6.94	\$ 12,912
Exercisable at December 31, 2010	3,858	\$ 28.19	6.19	\$ 12,863
Vested or expected to vest at December 31, 2010	6,060	\$ 30.56	6.92	\$ 12,912

The aggregate intrinsic value of options at December 31, 2010 is based on the Company's closing stock price on December 31, 2010 of \$25.65. The Company received \$10.7 million, \$9.3 million and \$8.8 million in proceeds from the exercise of stock options during the years ended December 31, 2010, 2009 and 2008, respectively. The total intrinsic value of options exercised was \$9.8 million, \$17.7 million, and \$28.1 million during the years ended December 31, 2010, 2009 and 2008, respectively.

*Restricted Stock Units.* A summary of restricted stock unit (RSU) activity for the period indicated was as follows:

	<b>Number of Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
Nonvested at December 31, 2009	276,350	\$ 36.62
Granted	427,350	33.64
Vested	(73,260)	36.32
Forfeited	(44,195)	36.43
Nonvested at December 31, 2010	586,245	\$ 34.51

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The total fair value of RSUs that vested during the year ended December 31, 2010 was \$2.4 million.

*Employee Stock Purchase Plan.* In 2004, the Board of Directors approved the Employee Stock Purchase Plan (ESPP). The ESPP initially allowed for the issuance of up to 100,000 shares of NuVasive common stock, increasing annually on December 31 by the lesser of (i) 600,000 shares; (ii) 1% of the outstanding shares of NuVasive common stock; or (iii) a lesser amount determined by the Board of Directors. Under the terms of the ESPP, employees can elect to have up to 15% of their annual compensation, up to a maximum of \$25,000 per year withheld to purchase shares of NuVasive common stock. The purchase price of the common stock is equal to 85% of the lower of the fair market value per share of the common stock on the commencement date of the two-year offering period or the end of each semi-annual purchase period. In the years ended December 31, 2010, 2009, and 2008, 157,359, 106,575, and 131,916 shares, respectively, were purchased under the ESPP and approximately 1.3 million shares remain available for issuance under the ESPP as of December 31, 2010.

*Stock-Based Compensation.* The compensation cost that has been included in the statement of operations for all share-based compensation arrangements was as follows (*in thousands*):

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Sales, marketing and administrative expense	\$ 24,945	\$ 19,549	\$ 17,837
Research and development expense	3,280	4,244	3,110
Total stock-based compensation expense	\$ 28,225	\$ 23,793	\$ 20,947

The Company estimates the fair value of stock options and shares issued to employees under the Employee Stock Purchase Plan using a Black-Scholes option-pricing model on the date of grant. The fair value of RSUs is based on the stock price on the date of grant. The fair value of equity instruments that are expected to vest are recognized and amortized on an accelerated basis over the requisite service period. The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and interest rates. The expected volatility is based on the historical volatility of the Company's common stock over the most recent period commensurate with the estimated expected term of the Company's stock options. The expected term of the Company's stock options is based on historical experience. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield in effect at the time of grant. The Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

The weighted average assumptions used to estimate the fair value of stock options granted and stock purchase rights under the Employee Stock Purchase Plan (ESPP) are as follows:

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
<b>Stock Options</b>			
Volatility	47%	45%	42%
Expected term (years)	4.5	4.3	4.0

Risk free interest rate	2.4%	1.6%	2.9%
Expected dividend yield	0.0%	0.0%	0.0%

**ESPP**

Volatility	57%	47%	52%
Expected term (years)	1.0	1.4	1.1
Risk free interest rate	0.4%	1.6%	4.1%
Expected dividend yield	0.0%	0.0%	0.0%

The weighted-average fair value of options granted in the years ended December 31, 2010, 2009, and 2008, was \$13.53, \$13.28, and \$14.46 per share, respectively. As of December 31, 2010, there was \$11.5 and \$9.9 million of unrecognized compensation expense for stock options and RSUs, respectively, which is expected to be recognized over a weighted-average period of approximately 1.6 years and 2.9 years, respectively. In addition,

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

as of December 31, 2010, there was \$3.3 million of unrecognized compensation expense for shares expected to be issued under the Employee Stock Purchase Plan which is expected to be recognized through October 2012.

*Common Stock Reserved for Future Issuance.* The following table summarizes common shares reserved for issuance at December 31, 2010 on exercise or conversion of (*in thousands*):

Common stock options:	
Issued and outstanding	6,118
Available for future grant	283
Available for issuance under the Employee Stock Purchase Plan	1,334
Issued and outstanding Restricted Stock Units	586
Senior Convertible Notes	5,141
Senior Convertible Note warrants	5,141
 Total shares reserved for future issuance	 18,603

**10. Income Taxes**

The income (loss) before income taxes by region is summarized as follows (*in thousands*):

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
United States	\$ 34,095	\$ 13,093	\$ (26,671)
Foreign	(8,181)	(6,924)	(857)
 Total income (loss) before income taxes	 \$ 25,914	 \$ 6,169	 \$ (27,528)

The components of income tax expense consist of the following (*in thousands*):

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Current income tax expense:			
Federal	\$ 140	\$ 715	\$
State	2,809	1,763	
Foreign	96	36	
 Total current	 3,045	 2,514	
Deferred income tax benefit:			
Federal	(41,429)		

Edgar Filing: NUVASIVE INC - Form 10-K

State	(11,994)		
Foreign	(241)	(782)	
Total deferred	(53,664)	(782)	
Total income tax (benefit) expense	\$ (50,619)	\$ 1,732	\$

The total income tax expense (benefit) differs from the statutory federal income tax rate (35%) primarily due to the release of the valuation allowance on the Company's domestic net deferred tax assets and due to the provision for state income tax expense. In the current year, the Company released its valuation allowance on the domestic deferred tax assets and accordingly, recorded an income tax benefit. The income tax benefit resulting from the release of the valuation allowance on the deferred tax asset associated with the hedge and tax original issue discount on the convertible debt, which totaled approximately \$17.0 million, was recorded as an offset to additional-paid-in-capital (APIC).

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

These differences are the result of the following items (*in thousands*):

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Provision at statutory rate	\$ 9,070	\$ 2,159	\$ (9,635)
Foreign provision in excess of federal statutory rate	443	498	52
State income taxes (benefit), net of federal benefit	(6,041)	1,146	97
Permanent differences	3,379	3,323	1,751
Other	1,755	471	253
Change in valuation allowance	(59,225)	(5,865)	7,482
<b>Total income tax expense</b>	<b>\$ (50,619)</b>	<b>\$ 1,732</b>	<b>\$</b>

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows (*in thousands*):

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Deferred Tax Assets:</b>		
Net operating loss carry-forwards	\$ 30,374	\$ 40,470
Capitalized assets	2,393	15,567
Stock based compensation	19,790	16,398
Original issue discount	8,421	12,222
General business credit carry-forwards	5,876	3,564
Other	6,837	5,449
Gross deferred tax assets	73,691	93,670
Valuation allowance	(3,831)	(93,058)
Net deferred tax assets	\$ 69,860	\$ 612
<b>Deferred Tax Liabilities:</b>		
Acquired intangibles	\$ (17,088)	\$ (16,756)
Deferred tax liabilities	(17,088)	(16,756)
Consolidated net deferred tax assets (liabilities)	52,772	(16,144)
Add: Deferred tax liability, net, attributable to noncontrolling interests	1,991	2,117
Net deferred tax assets (liabilities)	\$ 54,763	\$ (14,027)



During 2010, in connection with the finalization of the purchase accounting for the Cervitech acquisition, the Company adjusted the amounts recorded for deferred tax liabilities by \$0.9 million and for deferred tax assets and the corresponding valuation allowance by \$9.0 million retrospectively to May 2009, the Closing Date of the acquisition.

In assessing the realizability of deferred tax assets, the Company considered whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. During the fourth quarter of 2010, the Company concluded that it was more likely than not that it would be able to realize the benefit of the deferred tax assets in the future. As a result, the Company released all of the valuation allowance on the domestic net deferred tax assets.

In analyzing the realizability of the deferred tax assets in foreign country jurisdictions, the Company concluded that the deferred tax assets in its Netherlands company would not be realized on a more likely than not standard due to continued losses and expiring net operating loss carryforwards. Therefore, a valuation allowance was established against the net operating losses not expected to be utilized prior to expiration. With the exception of Puerto Rico, the Company continues to maintain a full valuation allowance on its net deferred tax assets in its other foreign jurisdictions.

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

At December 31, 2010, the Company has federal net operating loss carryovers of \$124.0 million that begin to expire in 2017. In addition, the Company has California net operating loss carryovers of approximately \$45.1 million. Net operating loss utilization is suspended through 2012 in California and expected expiration of California net operating losses will begin in 2013.

Included in the aforementioned federal net operating loss carryovers are \$55.0 million of excess tax benefit carryovers related to stock option deduction windfalls that will be realized in APIC following utilization of all continuing operations tax attributes.

During 2008, NuVasive elected the *with and without method direct effects only*, prescribed in accordance with authoritative guidance, with respect to recognition of stock option excess tax benefits within APIC and will utilize continuing operations net operating losses to offset taxable income before utilization of windfall tax benefits.

At December 31, 2010, the Company has federal research and development ( R&D ) credit carryovers of approximately \$6.5 million which will begin to expire in 2017. Additionally, the Company has California R&D credit carryovers of approximately \$4.3 million which can be carried forward indefinitely.

IRC §382 limits the utilization of tax attribute carryforwards that arise prior to certain cumulative changes in a corporation's ownership. During 2009, the Company completed a formal IRC §382 study with respect to potential ownership changes and additional limitations were not identified. Previous limitations due to §382 have been reflected in the deferred tax assets at December 31, 2010.

In accordance with authoritative guidance, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (*in thousands*):

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Unrecognized tax benefit at the beginning of the year			
Additions from tax positions taken in the current year	\$ 3,274	\$ 981	\$
Additions from tax positions taken in prior years	39		981
Reductions from tax positions taken in prior years	617	2,293	
Settlements of tax audits			
Unrecognized tax benefit at the end of the year	\$ 3,930	\$ 3,274	\$ 981

At December 31, 2010 and 2009, \$2.8 million and \$2.1 million, respectively, of the Company's total unrecognized tax benefits, if recognized, would affect the effective income tax rate. The Company does not anticipate there will be a significant change in unrecognized tax benefits within the next 12 months.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As the unrecognized tax benefits relate to un-utilized deferred tax assets and because the Company has generated net operating losses since inception for both federal and state income tax purposes through 2009, no additional tax liability, penalties or interest have been recognized for balance sheet or income statement purposes as of and for the period ended December, 31, 2010.

The Company is subject to taxation in the U.S. and various foreign and state jurisdictions. All of the Company's tax years are subject to examination due to the carry forward of un-utilized net operating losses and R&D credits.

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****11. Business Segment and Product Information**

The Company's business operates in one segment based upon the Company's organizational structure, the way in which the operations are managed and evaluated and the lack of availability of separate financial results. Substantially all of the Company's assets and sales are in the United States.

The Company's spine surgery product line offerings, which include thoracolumbar product offerings, cervical offerings, and a set of motion preservation products still under development, are primarily used to enable access to the spine and to perform restorative and fusion procedures in a minimally disruptive fashion. The Company's biologic product line offerings includes 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. Revenue by product line offerings was as follows (*in thousands*):

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Spine Surgery Products	\$ 388,252	\$ 308,934	\$ 221,356
Biologics	89,985	61,406	28,726
Total Revenue	\$ 478,237	\$ 370,340	\$ 250,082

**12. Legal Proceedings*****Medtronic Sofamor Danek USA, Inc. Litigation***

As previously disclosed, in August 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 (Medtronic Litigation), alleging that certain of NuVasive's products infringe, or contribute to the infringement of, twelve U.S. patents assigned or licensed to Medtronic. Three of the patents were later withdrawn by Medtronic, leaving nine patents. NuVasive brought counterclaims against Medtronic alleging infringement of certain of NuVasive's patents. Because of the number of patents involved, each side selected three patents to proceed with in the first phase of the litigation. The Medtronic Litigation is still in its early stages. The initial phase of the case includes three Medtronic patents and one NuVasive patent. Trial on the initial phase of the case is scheduled to begin May 10, 2011. A full schedule for the second phase of the lawsuit has not yet been set by the Court. NuVasive believes its own claims have merit and that Medtronic's claims lack merit. At December 31, 2010, the probable outcome of this litigation cannot be determined nor can the Company estimate a range of potential loss. Accordingly, in accordance with the authoritative guidance on the evaluation of contingencies, the Company has not recorded an accrual related to this litigation.

***Trademark Infringement Litigation***

In September 2009, Neurovision Medical Products, Inc. (NMP) filed suit against NuVasive in the U.S. District Court for the Central District of California (Case No. 2:09-cv-06988-R-JEM) alleging trademark infringement and unfair competition. NMP sought cancellation of NuVasive's NeuroVision trademark registrations, injunctive relief and damages based on NMP's common law use of the Neurovision mark. On November 23, 2009, the Company denied the

allegations in NMP's complaint. After trial of the matter, on October 25, 2010 an unfavorable jury verdict was delivered against the Company relating to its use of the NeuroVision trade name. The verdict awarded damages to NMP of \$60.0 million. On January 3, 2011, the Court ordered a judgment be entered in the case in the amount of \$60.0 million, and granted a permanent injunction prohibiting the Company's use of the NeuroVision name for marketing purposes. The Company sought emergency relief, and on February 3, 2011, the Ninth Circuit Court of Appeals stayed enforcement of the injunction. The Company intends to timely appeal the judgment and permanent injunction. During pendency of the appeal, the Company may be required to post a supersedeas bond or escrow funds to secure the amount of the judgment, plus interest, attorneys' fees and costs. However, any payment of damages will be delayed while the appeals process runs its course, which could take up to

**Table of Contents****NUVASIVE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

two years. The Company continues to believe that the verdict is not supported by the facts or by applicable law. The Company, based on its own assessment as well as that of outside counsel, believes that the trial court committed a number of prejudicial legal errors and that these errors were significant, making the possibility of reversal of the judgment on appeal and/or a new trial probable. Accordingly, at December 31, 2010, in accordance with the authoritative guidance on the evaluation of contingencies, the Company has not recorded an accrual related to this litigation. The Company may be required to record an expense related to this damage award in the future.

**Contingencies**

The Company is party to certain claims and legal actions arising in the normal course of business. The Company does not expect any such claims and legal actions to have a material adverse effect on its business, results of operations or financial condition.

**13. Quarterly Data (unaudited)**

The following quarterly financial data, in the opinion of management, reflects all adjustments, consisting of normal recurring adjustments necessary, for a fair presentation of results for the periods presented (*in thousands, except per share amounts*):

	<b>Year Ended December 31, 2010</b>			
	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter(1)</b>
Total revenues	\$ 109,087	\$ 119,584	\$ 120,262	\$ 129,304
Gross profit	89,644	98,570	98,682	106,202
Consolidated net income	706	6,190	8,104	61,533
Net income attributable to NuVasive, Inc.	1,088	6,723	8,542	61,932
Basic net income per common share	0.03	0.17	0.22	1.57
Diluted net income per common share	0.03	0.17	0.21	1.39

	<b>Year Ended December 31, 2009</b>			
	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
Total revenues	\$ 80,008	\$ 88,481	\$ 94,916	\$ 106,935
Gross profit	67,009	74,246	79,042	88,933
Consolidated net (loss) income	(4,532)	2,312	4,436	2,221
Net (loss) income attributable to NuVasive, Inc.	(4,302)	2,765	5,064	2,281
Basic and diluted net (loss) income per common share	(0.12)	0.07	0.13	0.06

- (1) Consolidated net income includes an income tax benefit of \$50.6 million resulting primarily from the reversal of the valuation allowance on the Company's domestic deferred income tax assets.



**Table of Contents**

Schedule

Valuation Accounts

**NuVasive, Inc.****Schedule II: Valuation Accounts  
(In thousands)**

	<b>Balance at Beginning of Period</b>	<b>Additions(1)</b>	<b>Deductions(2)</b>	<b>Other(3)</b>	<b>Balance at End of Period</b>
Accounts Receivable Valuation Accounts					
Year ended December 31, 2010	\$ 4,163	\$ 819	\$ 593	\$ 1,816	\$ 2,573
Year ended December 31, 2009	\$ 1,952	\$ 2,794	\$ 583		\$ 4,163
Year ended December 31, 2008	\$ 926	\$ 1,393	\$ 367		\$ 1,952

	<b>Balance at Beginning of Period</b>	<b>Additions(4)</b>	<b>Deductions(5)</b>	<b>Balance at End of Period</b>
Inventory Reserve				
Year ended December 31, 2010	\$ 5,075	\$ 6,093	\$ 4,486	\$ 6,682
Year ended December 31, 2009	\$ 2,778	\$ 6,507	\$ 4,210	\$ 5,075
Year ended December 31, 2008	\$ 3,614	\$ 3,208	\$ 4,044	\$ 2,778

(1) Amount represents customer balances deemed uncollectible.

(2) Uncollectible accounts written-off.

(3) Amount represents recoveries received.

(4) Amount represents excess and obsolete reserve recorded to cost of sales.

(5) Excess and obsolete inventory written-off against reserve.



**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
2.1	Asset Purchase Agreement, dated May 8, 2008, by and between the Company and Osiris Therapeutics, Inc. (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the Commission) on August 8, 2008)
2.2	Amendment to Asset Purchase Agreement, dated September 30, 2008, by and between the Company and Osiris Therapeutics, Inc. (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on November 7, 2008)
2.3	Amendment No. 2 to Asset Purchase Agreement, dated March 25, 2009, between the Company and Osiris Therapeutics, Inc. (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 8, 2009)
2.4	Share Purchase Agreement, by and among NuVasive, Inc. and the stockholders of Cervitech, Inc., as listed therein, dated April 22, 2009 (incorporated by reference to our Registration Statement on Form S-3 (File No. 333-159098) filed with the Commission on May 8, 2009)
3.1	Restated Certificate of Incorporation (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 13, 2004)
3.2	Restated Bylaws (incorporated by reference to our Current Report on Form 8-K filed with the Commission on December 15, 2008)
4.1	Second Amended and Restated Investors Rights Agreement, dated July 11, 2002, by and among NuVasive, Inc. and the other parties named therein (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)
4.2	Amendment No. 1 to Second Amended and Restated Investors Rights Agreement, dated June 19, 2003, by and among NuVasive, Inc. and the other parties named therein (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)
4.3	Amendment No. 2 to Second Amended and Restated Investors Rights Agreement, dated February 5, 2004, by and among NuVasive, Inc. and the other parties named therein (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)
4.4	Registration Rights Agreement, dated as of August 4, 2005, between NuVasive, Inc. and Pearsalls Limited (incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 10, 2005)
4.5	Registration Rights Agreement Termination Agreement, dated as of September 26, 2006, between NuVasive, Inc. and Pearsalls Limited (incorporated by reference to our Current Report on Form 8-K filed with the Commission on September 29, 2006)
4.6	Indenture, dated March 7, 2008, between the NuVasive Inc. and U.S. Bank National Association, as Trustee (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
4.7	Form of 2.25% Convertible Senior Note due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
4.8	Registration Rights Agreement, dated March 7, 2007, among NuVasive, Inc. and Goldman, Sachs & Co., and J.P. Morgan Securities Inc., related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
4.9	Specimen Common Stock Certificate (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 16, 2006)
10.1#	1998 Stock Option/Stock Issuance Plan (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)
10.2#	Form of Notice of Grant of Stock Option under our 1998 Stock Option/Stock Issuance Plan (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission

- on March 5, 2004)
- 10.3# Form of Stock Option Agreement under our 1998 Stock Option/Stock Issuance Plan, and form of addendum thereto (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
10.4#	Form of Stock Purchase Agreement under our 1998 Stock Option/Stock Issuance Plan (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)
10.5#	Form of Stock Issuance Agreement under our 1998 Stock Option/Stock Issuance Plan (incorporated by reference to Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on May 11, 2004)
10.6#	Form of Stock Issuance Agreement under our 1998 Stock Option/Stock Issuance Plan, dated April 21, 2004, and May 4, 2004 (incorporated by reference to Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on May 11, 2004)
10.7#	2004 Equity Incentive Plan, as amended (incorporated by reference to Appendix A to our Definitive Proxy Statement filed with the Commission on April 11, 2007)
10.8#	Form of Stock Option Award Notice under our 2004 Equity Incentive Plan (incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on April 8, 2004)
10.9#	Form of Option Exercise and Stock Purchase Agreement under our 2004 Equity Incentive Plan (incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on April 8, 2004).
10.10#	Form of Restricted Stock Unit Award Agreement under our 2004 Equity Incentive Plan (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.11#	2004 Employee Stock Purchase Plan (incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on April 8, 2004)
10.12#	Amendment No. 1 to 2004 Employee Stock Purchase Plan (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on November 7, 2008)
10.13#	Amendment No. 2 to 2004 Employee Stock Purchase Plan (filed herewith)
10.14#	Executive Employment Agreement, dated as of January 2, 2011, by and between NuVasive, Inc. and Alexis V. Lukianov (incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 2, 2011)
10.15#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Keith C. Valentine (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 8, 2008)
10.16#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Patrick Miles (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 8, 2008)
10.17#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Jeffrey P. Rydin (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 8, 2008)
10.18#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Jason M. Hannon (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 2, 2009)
10.19#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Keith C. Valentine (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 2, 2009)
10.20#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Patrick Miles (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 2, 2009)

- 10.21# Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Jeffrey P. Rydin (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 2, 2009)

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
10.22#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Jason M. Hannon (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 2, 2009)
10.23#	Compensation Letter Agreement, dated November 4, 2009, between NuVasive, Inc. and Pat Miles (incorporate by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.24#	Compensation Letter Agreement, dated November 4, 2009, between NuVasive, Inc. and Jeff Rydin (incorporate by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.25#	Compensation Letter Agreement, dated December 28, 2009, between NuVasive, Inc. and Jason Hannon (incorporate by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.26#	Offer Letter Agreement, dated October 19, 2009, between NuVasive, Inc. and Michael Lambert (incorporate by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.27#	Compensation Letter Agreement, dated February 24, 2010, between NuVasive, Inc. and Michael Lambert (incorporate by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.28#	Compensation Letter Agreement, dated February 3, 2009, between NuVasive, Inc. and Tyler P. Lipschultz (filed herewith)
10.29#	Amendment to Compensation Letter Agreement, dated January 3, 2011, between NuVasive, Inc. and Tyler P. Lipschultz (filed herewith)
10.30#	Compensation Letter Agreement, dated August 3, 2009, between NuVasive, Inc. and Craig E. Hunsaker (filed herewith)
10.31#	Amendment to Compensation Letter Agreement, dated January 3, 2011, between NuVasive, Inc. and Craig E. Hunsaker (filed herewith)
10.32#	Form of Indemnification Agreement between NuVasive, Inc. and each of our directors and officers (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004)
10.33	Sublease, dated October 12, 2004, by and between NuVasive, Inc. and Gateway, Inc. (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on November 15, 2004)
10.34#	Summary of 2009 annual salaries and annual stock grants for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers (incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 8, 2009)
10.35#	Summary of the 2010 annual salaries and annual stock grants for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers (incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 8, 2010)
10.36#	Summary of 2011 annual salaries and annual stock grants for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers (incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 6, 2011)
10.37	Customer Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on August 8, 2007)
10.38	IBM Global Services Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation (incorporated by reference to our Annual Report on

- 10.39 Form 10-K filed with the Commission on August 8, 2007)  
Lease Agreement for Sorrento Summit, entered into as of November 6, 2007, between the Company and HCPI/Sorrento, LLC. (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on November 8, 2007)

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
10.40	Purchase Agreement, dated March 3, 2008, among NuVasive, Inc. and Goldman, Sachs & Co., and J.P. Morgan Securities Inc., related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.41	Confirmation of Call Option Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.42	Confirmation of Call Option Transaction, dated March 3, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.43	Confirmation of Warrant Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.44	Confirmation of Warrant Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.45	Amendment to the Confirmation of Call Option Transaction, dated March 11, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.46	Amendment to the Confirmation of Call Option Transaction, dated March 11, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.47	Amendment to the Confirmation of Warrant Transaction, dated March 11, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.48	Amendment to the Confirmation of Warrant Transaction, dated March 11, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013 (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008)
10.49	Form of Voting Agreement, dated May 8, 2008, by and among each of Peter Friedli, Venturetec, Inc., U.S. Venture 05, Inc., Joyce, Ltd. and C Randal Mills, Ph.D, and the Company (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 8, 2008)
10.50	Preferred Stock Purchase Agreement, dated January 13, 2009, among the Company, Progentix Orthobiology, B.V. and the sellers listed on Schedule A thereto (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.51	Option Purchase Agreement, dated January 13, 2009, among the Company, Progentix Orthobiology, B.V. and the sellers listed on Schedule A thereto (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on February 26, 2010)
10.52	Exclusive Distribution Agreement, dated January 13, 2009, between the Company and Progentix Orthobiology, B.V. (incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 8, 2009)
21.1	List of subsidiaries of NuVasive, Inc.
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended

Edgar Filing: NUVASIVE INC - Form 10-K

- 32.1\* Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350
- 32.2\* Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350
- 101\*\* XBRL Instance Document



**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
101**	XBRL Taxonomy Extension Schema Document
101**	XBRL Taxonomy Calculation Linkbase Document
101**	XBRL Taxonomy Label Linkbase Document
101**	XBRL Taxonomy Presentation Linkbase Document
101**	XBRL Taxonomy Definition Linkbase Document

Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with an asterisk. We have filed separately with the Commission an unredacted copy of the exhibit.

# Indicates management contract or compensatory plan.

\* These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of NuVasive, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

\*\* Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these interactive data files are deemed not filed and otherwise are not subject to liability.