NUVASIVE INC
Form 10-K
February 26, 2010

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

Form 10-K

(Mark One)

þ	**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** **For the fiscal year ended December 31, 2009**
	OR
o	**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** **For the transition period from to**

Commission file number: 000-50744

NUVASIVE, INC.
(Exact name of registrant as specified in its charter)

Delaware *(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 þ NO o

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $1.7 billion as of the last business day of the registrant s most recently completed second fiscal quarter (i.e. June 30, 2009), 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 19, 2010, there were 38,829,879 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, 2010.

NuVasive, Inc.

Form 10-K for the Fiscal Year ended December 31, 2009

EX-32.2

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PART I

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

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

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

Item 1. *Business.*

Overview

We are a medical device company focused on the design, development and marketing of products for the surgical treatment of spine disorders. Our currently-marketed product portfolio is focused on applications for spine fusion surgery, a market estimated to exceed $5.1 billion in the United States in 2010. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS®, as well as a growing offering of cervical, biologics and motion preservation products. In the spine surgery market, our currently-marketed products are primarily used to enable access to the spine and to perform restorative and fusion procedures. 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 approximately 400 to 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:

NeuroVision® a proprietary software-driven nerve avoidance system;

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

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

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

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 visibility and avoidance of critical nerves. The fundamental difference between our MAS platform

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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 leader and pioneer in lateral surgery. Our MAS platform, with the unique advantages provided by NeuroVision, 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 visibility and our NeuroVision system allows surgeons to avoid critical nerves. We believe that the procedures facilitated by our MAS platform reduce operating times, 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 clinical 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. Currently, the PCM investigational device has reached the two-year follow-up end point in its U.S. Food and Drug Administration (FDA) approved clinical trial in the United States. Approval, if obtained, will further strengthen our cervical product offering and will enable us to continue our trend of increasing our market share. Our biologic offering includes FormaGraft, a collagen synthetic product used to aid the fusion process, and Osteocel, an allograft cellular matrix containing viable mesenchymal stem cells, or MSCs, to aid in spinal fusion. In 2009, we invested in Progentix Orthobiology, B.V., a company organized under the laws of the Netherlands involved in the development of osteoinductive bone graft material technology. As part of the investment transaction, we became the exclusive distributor for certain Progentix biologic products.

Our corporate headquarters are located in San Diego, California. We lease approximately 202,000 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. 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 marked our entrance 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.

NeuroVision M5™ is, along with its predecessors, the enabling technology for the XLIF procedure, and utilizes proprietary technology and hunting algorithms to locate and avoid critical nerves during spine surgery.

NeuroVision 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.

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Biologics In 2008 we expanded our biologics offering by acquiring Osteocel, an allograft cellular matrix containing viable MSCs 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 osteoinductive bone graft material. This investment includes options and obligations to buy Progentix Orthobiology, B.V. over time as development 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 a 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 adopt our products and recognize their benefits. 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 on the clinical benefits of our products, and we intend to capitalize on patient 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 three years, we have introduced more than 40 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 generate, on average, greater revenues per spine surgery procedure while improving patient care.

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 achieve continued growth across product lines, greater market penetration and increased sales. In 2006, we completed our transition to an exclusive sales force, and we have seen the benefits of that effort. Our U.S. sales force is achieving deeper penetration in our accounts and further establishing NuVasive as a technology leader in the spine industry. In the United States, our exclusive sales force is managed by an Executive Vice President and four Area Vice Presidents, each of whom is responsible for a geographic region of the country. Each Area Vice President is responsible for Sales Directors, who in turn are responsible for Area Business Managers, or ABMs, who are NuVasive shareowners (our employees) responsible for a defined territory. The remainder of the U.S. sales force are both direct (our shareowners) and exclusive independent sales representatives or exclusive distributor agents, each acting as our sole representative and selling only NuVasive spine products in a given territory.

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

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, shorten procedures, reduce hospitalization and rehabilitation times and, as a result, reduce costs.

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Industry Background and Market

The spine is the core of the human skeleton, and provides a crucial balance between structural support and flexibility. It consists of 29 separate bones called vertebrae that are connected together by connective tissue 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 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 U.S., 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. It is estimated that over 600,000 spine fusion procedures are performed annually, and the vast majority are done using traditional open surgical techniques from either an anterior or posterior approach. These traditional open surgical approaches require a large incision in the patient s abdomen or back in order to enable the surgeon to see the spine and surrounding area. Most open procedures are invasive, lengthy and complex, and may result in significant blood loss, extensive dissection of tissue and lengthy 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 over $4.6 billion in 2009 and is estimated to grow to over $5.1 billion in 2010.

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

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.

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 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 demand a quicker return to activities of daily living following surgery than prior generations.

Surgical Alternatives with Less Tissue Disruption

The benefits of minimally invasive surgery procedures in other areas of orthopedics have significantly contributed to the strong and growing demand for surgical alternatives with less tissue disruption of the spine. Surgeons and

hospitals seek spine procedures that result in fewer operative complications, shorter surgery times and decreased hospitalization. At the same time, patients seek procedures that cause less trauma and allow for faster recovery times. 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

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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 a standard of care in spine fusion and non-fusion surgery.

Our MAS platform combines four product categories: NeuroVision, MaXcess, biologics and specialized implants. NeuroVision enables surgeons to 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 compliments our MAS platform by facilitating fusion. We also offer a variety of specialized implants that enable 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 over the nerve root or disc from under the nerve root to relieve pinching of the nerve; and
- Procedures designed to correct and/or stabilize the spine while simultaneously maintaining motion.

Importantly, our products also enable innovative procedures such as the XLIF. The XLIF procedure, which we developed with leading spine surgeons, allows surgeons to access the spine from the side of the patient s body rather than from the front or back, which results in less operating time and reduced patient trauma and blood loss.

MAS NeuroVision

NeuroVision utilizes electromyography, or EMG, proprietary algorithms and graphical user interfaces to provide surgeons with an enhanced nerve avoidance system. Our system functions 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 feedback during surgery. Our system analyzes and then translates 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 implant 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 NeuroVision, thus creating an interactive set of instruments that enable the safe navigation of neural anatomy. The connection is accomplished using a clip that is attached to the instrument, effectively providing the benefits of NeuroVision through an instrument already familiar to the surgeon. The system s 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 aspect of the spinal cord. The data developed using NeuroVision 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.

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MAS MaXcess

Our 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 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 with the use of NeuroVision, superior and inferior blades that kick-out at an angle to spread the tissue closest to the pathology point further than prior versions, and a removable fourth blade, which provides greater posterior surgical options and incorporates an improved tilted blade-locking mechanism. Further, our MaXcess products are used in the cervical spine for posterior application, the lumbar spine for decompression, transforaminal interbody fusion, or TLIF, fusion 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 operating time and patient morbidity, often through a single approach.

We also made significant progress in the last few years on our research and development initiatives related to motion preservation. The PCM clinical trial is complete and the trial protocol requires a two-year follow-up period, which was completed in the fourth quarter of 2009, on all patients before submitting to the FDA for potential approval. We anticipate submitting for FDA approval in the first quarter of 2010. The clinical trial for NeoDisc®, a nucleus-like total disc replacement device, is a prospective, randomized, controlled, multi-center clinical trial to evaluate the safety and efficacy of NeoDisc by comparing the outcomes of patients to traditional anterior cervical discectomy and fusion. Enrollment began in the third quarter of 2006 and is now complete.

Our motion preservation product development efforts also include our mechanical lateral total disc replacement (XL TDR™). We filed with the FDA for Investigational Device Exemptions, or IDEs, on the XL TDR in late 2007 and were granted an IDE in 2008.

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 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 product. We expanded this offering in 2008 by acquiring Osteocel, an

allograft cellular matrix containing viable MSCs 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 osteoinductive bone graft material.

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Development Projects

We are developing proprietary total disc replacement devices for lateral lumbar spine applications and separately for cervical spine applications. These devices are intended to allow surgeons to address a patient s pain and dysfunction while maintaining normal range of motion and avoiding future adjacent level degeneration that can occur after spine 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, has reached the two-year follow-up end point in its FDA-approved clinical trial in the United States. We anticipate submitting for FDA approval in the first quarter of 2010. Approval, if obtained, of PCM will further strengthen our cervical product offering and will 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 nucleus-like total disc replacement device in the United States is complete. The NeoDisc study s two-year follow-up period is scheduled for completion in late 2010.

Our lumbar motion preservation development efforts include XL TDR, a mechanical total disc replacement implanted through the XLIF approach. Enrollment in an FDA-approved XL TDR clinical trial in the United States was initiated in 2009 and will continue throughout 2010.

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 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 products. As of December 31, 2009, our research staff consists of 23 shareowners (employees), including six who hold Ph.D. degrees and three who hold other advanced degrees. Our research and development group has extensive experience in developing products to treat spine pathology 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, shorten procedures, 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. Outside the United States, we currently sell our products through a combination of exclusive distributors and direct sales representatives employed by us.

The transition to an exclusive sales force has been a very positive contributor to our growth in sales. There are many reasons that we believe strongly in an exclusive sales force, none more important than having a sales force that is properly 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. The Executive Vice President of the Americas manages four Area Vice Presidents. Each Area Vice President is responsible for a portion of the United States and manages the directly-employed and independent sales agents engaged in that territory. Outside of the United States, the Executive Vice Presidents manage directly-employed sales agents and independent distributors in that territory.

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Surgeon Training and Education

NuVasive devotes significant resources to training and educating surgeons regarding the safety and reproducibility of our surgical techniques and our complimentary instruments and implants. We maintain a state-of-the-art cadaver operating theatre and training facility at our corporate headquarters to help promote adoption of our products. Currently, we are training approximately 400 to 500 surgeons annually in the XLIF technique and our other MAS platform products including: NeuroVision, MaXcess and specialized implants. NuVasive has also helped to establish SOLAS®, the Society of Lateral Access Surgery, a group of spine surgeons dedicated to the development and expanded application of lateral spine surgery techniques that offer significant patient benefits and improved clinical outcome through peer-to-peer communication, clinical education efforts, and 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 NeuroVision, 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 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 appropriate to do so.

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

We acquired NeoDisc, an investigational cervical disc replacement device, from Pearsalls Limited. NeoDisc is currently the subject of a clinical trial, and our supply of the product comes solely from Pearsalls Limited.

We acquired rights to FormaGraft, a ceramic/collagen bone graft matrix used to promote spinal fusion, from Radius Medical, LLC. Our supply of the product comes solely from Maxigen Biotech.

We acquired PCM, a motion preserving total disc replacement device, through our acquisition of Cervitech, Inc. Our supply of the product comes solely from Waldemar Link GmbH & Co. KG, a company that was affiliated with Cervitech prior to the acquisition. We are in the process of establishing alternate suppliers.

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. The FDA may impose enforcement, inspections or audits at any time.

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Loaned Instrument Sets

We seek to deliver surgical instrument sets, including our NeuroVision systems, just in time 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 instrument sets are returned to us and we prepare them for shipment to meet future surgeries. This strategy minimizes backlogs, while increasing asset turns and maximizing 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 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, 2009, we had 66 issued U.S. patents, 45 foreign national patents, and 272 pending patent applications, including 210 U.S. applications, 8 international (PCT) applications and 54 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, navigated guidance, and surgical access systems;

Implants and related instrumentation and targeting systems;

Biologics, including Osteocel 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 the NeuroVision nerve monitoring system, through a comprehensive strategy covering various important aspects of our neurophysiology-enabled instrumentation, including, screw test, navigated guidance, surgical access and related methodology. Our NeuroVision 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 this system 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 56 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 IP portfolio includes 4 U.S. patent applications, 2 foreign applications, and 1 International Application (PCT) owned outright by NuVasive. It also includes 4 U.S. patents and 4 foreign patents exclusively licensed from Osiris Therapeutics.

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We acquired a substantial intellectual property portfolio as part of our purchase of Cervitech, Inc. This portfolio includes 9 issued U.S. patents, 18 U.S. applications, 167 issued foreign national patents, 1 international (PCT) application, and 182 foreign national applications, directed at the PCM cervical arthroplasty 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 claim 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, 2009, we had 84 trademark registrations, both domestic and foreign, including the following U.S. trademarks: NuVasive, NeuroVision, MAS, MaXcess, XLIF, SpheRx, DBR, CoRoent, SmartPlate, Creative Spine Technology, Triad, InStim, NeoDisc, ExtenSure, FormaGraft, Osteocel, Nerve Avoidance Leader, Absolute Responsiveness, Affix, Gradient Plus, Halo, SOLAS, VuePoint, XL TDR and XLP. We also had 46 trademark applications pending, both domestic and foreign, including the following trademarks: ExtenSure, Embrace, Embody, ILIF, Magnitude, M5, NVM5, Acuity, Armada, Attrax, The Better Way Back, and Leverage.

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. Many 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, many of these competitors 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 NeuroVision system competes with the conventional nerve monitoring systems offered by Medtronic Sofamor Danek (Medtronic), Cadwell, and Nicolet Biomedical. We believe our system competes favorably with these systems on ease of use for the spine surgeon, with the added advantage that our NeuroVision System was designed to support surgeon directed applications with automated, real-time information. Medtronic s NIM-Eclipse neuromonitoring system, acquired from Axon, while surgeon directed, requires manual interpretation for neuromonitoring. Several companies offer products that compete with our MaXcess system, SpheRx pedicle screw system and implants, including competitive offerings by DePuy Spine, Inc. (Depuy), a Johnson & Johnson company, Medtronic and Stryker Spine.

Competition is intense in the fusion product market. We believe that our most significant competitors are Medtronic, DePuy, Stryker Spine and Synthes, Inc., each of which has substantially greater sales and financial resources than we

do. Medtronic, in particular, has a broad classic fusion product line. We believe our differentiation in the market is an innovative portfolio of products elegantly delivered through our MaXcess system, as well as through our XLIF approach, complemented by additional innovative and pull-though products along the entirety of the spine. However, with the introduction of competing lateral techniques, such as Medtronic s DLIF, we face more competition in the market.

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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 and NeoDisc, currently in clinical trials, 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 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 and Osteotech.

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

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

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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 Pathway

A premarket approval (PMA) application must be submitted if the device cannot be cleared through the 510(k) process. A premarket approval 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 require 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 products are regulated by FDA as Human Cell, Tissue, and Cellular and Tissue Based Products. FDA regulations do not currently require products regulated as minimally manipulated human tissue-based products to be 510(k) cleared or PMA approved before they are marketed. We are, however, required to register our establishment, list these products with the FDA and comply with Current Good Tissue Practices for Human Cell, Tissue, and Cellular and Tissue Based Product Establishments. The FDA periodically inspects tissue processors to determine compliance with these requirements. Violations of applicable regulations noted by the FDA during facility inspections could adversely affect the continued marketing of our products. We believe we comply with all aspects of the Current Good Tissue Practices, although there can be no assurance that we will comply, or will comply on a timely basis, in the future. Entities that provide us with allograft bone tissue are responsible for performing donor recovery, donor screening and donor testing and our compliance with those aspects of the Current Good Tissue Practices regulations that regulate those functions are dependent upon the actions of these independent entities.

The procurement and transplantation of allograft bone tissue is subject to U.S. federal law pursuant to the National Organ Transplant Act, or NOTA, a criminal statute which prohibits the purchase and sale of human organs used in human transplantation, including bone and related tissue, for valuable consideration. NOTA permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human bone tissue. With the exception of removal and implantation, we provide services in all of these areas. We make payments to vendors in consideration for the services they provide in connection with the recovery and screening of donors. Failure to comply with the requirements of NOTA could result in enforcement action against us.

The procurement of human tissue is also subject to state anatomical gift acts and some states have statutes similar to NOTA. In addition, some states require that tissue processors be licensed by that state. Failure to comply with state laws could also result in enforcement action against us.

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Clinical Trials

A clinical trial is almost always required to support a PMA application and is sometimes required for a 510(k) premarket notification. These trials generally require approval of a submitted application for an 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. Currently, the PCM investigational device is in an FDA-approved clinical trial in the United States with two-year follow-up completed in the fourth quarter of 2009. We anticipate submitting for FDA approval in the first quarter of 2010. 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.

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Sales and Marketing Commercial Compliance

Federal anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation or receipt of any form of remuneration by an individual or entity in return for, or to induce:

- the referral of an individual for a service or product for which payment may be made by Medicare, Medicaid or other government-sponsored healthcare program; or

- purchasing, leasing, ordering or arranging for any service or product for which payment may be made by a government-sponsored healthcare program.

Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of such prohibitions.

In addition to the anti-kickback law, federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Off-label promotion has been pursued as a violation of the federal false claims laws. 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. Additionally, the majority of states in which we market our products have similar anti-kickback, false claims, anti-fee splitting and self-referral laws, imposing substantial penalties for violations.

To enforce compliance with the federal laws, the U.S. Department of Justice (DOJ) has increased its scrutiny of interactions between healthcare companies and healthcare providers which has led to an unprecedented level of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming. Additionally, if a healthcare company settles an investigation with the DOJ or other law enforcement agencies, the company may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement.

Additionally, the commercial compliance environment is continually evolving in the healthcare industry as some states, including California, Massachusetts and Vermont, mandate implementation of commercial compliance programs, along with the tracking and reporting of gifts, compensation, and other remuneration to physicians. Federal legislation, pursuant to the Physician Payments Sunshine Act of 2009 (Sunshine Act), has been proposed and is moving forward in Congress under the Healthcare Reform Act of 2009. The Sunshine Act would require public disclosure to the federal government of payments to physicians, including in-kind transfers of value such as free gifts or meals. These requirements all provide for penalties for non-compliance. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

International

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ.

The European Union, which consists of 27 countries in Europe, has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Other

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

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granting us ISO registration and allowing the CE conformity marking to be applied to certain of our devices under the European Union Medical Device Directive. We have expanded our certification scope and are now working with two different Notified Bodies overseeing our currently released, as well as forthcoming, product development projects.

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 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 (AMA). For coding related to spine surgery, the North American Spine Society (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 in January 2010. Hospital coding is established by the Centers for Medicare and Medicaid Services (CMS). XLIF is not currently included in the nomenclature for hospital codes but has been proposed as an additional descriptor of existing codes. CMS proposal is slated for review and ratification in 2010. 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. In December 2007, a certain third-party payer, Cigna Healthcare, established a national policy that labels XLIF as experimental or investigational and states that they do not provide reimbursement for the XLIF procedure. Since December 2007, other third-party payers also established similar non-coverage policies, which are both national and local in scope. Such policies are not customarily intended to dictate the practice of medicine or override the judgment of the regional medical directors of a given third-party payer and these policies have not materially impacted our operating results. NuVasive will continue to provide the appropriate resources to patients, physicians, hospitals, and insurers in order to ensure the best in patient care and clarity regarding XLIF reimbursement and work to remove the 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 medical products and services.

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.

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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.

Healthcare Fraud and Abuse

Healthcare fraud and abuse laws apply to our business when a customer submits a claim for an item or service that is reimbursed under Medicare, Medicaid or most other federally-funded health care programs. The federal Anti-Kickback Law prohibits unlawful inducements for the referral of business reimbursable under federally-funded health care programs, such as remuneration provided to physicians to induce them to use certain tissue products or medical devices reimbursable by Medicare or Medicaid. The Anti-Kickback Law is subject to evolving interpretations. For example, the government has enforced the Anti-Kickback Law to reach large settlements with healthcare companies based on sham consultant arrangements with physicians. The majority of states also have anti-kickback laws which establish similar prohibitions. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil penalties including, for example, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid.

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigations of health care providers, suppliers and manufacturers throughout the country for a wide variety of Medicare billing practices, and has obtained multi-million and multi-billion dollar settlements in addition to individual criminal convictions. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating health care providers , suppliers , and manufacturers compliance with the health care billing, coverage and reimbursement rules and fraud and abuse laws.

Shareowners (our employees)

We refer to our employees as shareowners. As of December 31, 2009, we had 665 shareowners, of which 118 were employed in research and development, 21 in regulatory and quality assurance, 236 in general and administrative and operations and 290 in sales and marketing (including 37 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, respectively. None of our shareowners are represented by a labor union and we believe our shareowner relations are good.

NuVasive Cheetah Gives Back Foundation

NuVasive Cheetah Gives Back Foundation™ is a non-profit organization that has common management with the Company. NuVasive Cheetah Gives Back Foundation is committed to providing innovative medical devices,

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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, 2009.

Corporate Information

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

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to those reports, electronically with the Securities and Exchange Commission (the Commission). We make these reports available free of charge on our website under the investor relations page as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Commission. All such reports were made available in this fashion during 2009.

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

Certain third-party payers have stated non-coverage decisions concerning our XLIF technology, additional third-party payers may adopt similar policies and such medical reimbursement decisions may negatively impact our ability to sell our complete product portfolio and 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 XLIF technology and implementation of such policies could significantly alter our ability to sell any products that the payers categorize under XLIF. Additional payers may also state that our XLIF technology is not covered. The inability to successfully market XLIF 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.

The XLIF procedure is a significant feature of our Maximum Access Surgery, or MAS, product platform, which is our principal product offering. Lack of XLIF reimbursement coverage may deter physician interest in XLIF, and in turn MAS and the entirety of our product offering. Any such decisions could adversely impact our ability to sell our products.

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We also believe that future reimbursement may be subject to increased restrictions 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.

To the extent we sell our products internationally, market acceptance may depend, in part, upon the availability of reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance.

Pricing pressure from our competitors may impact our ability to sell our products at prices necessary to expand our operations 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 growing pricing pressure in the near future. If competitive forces drive down the price we are able to charge for our products, our profit margins will shrink, which will hamper our ability to invest in and grow our business and increase profitability.

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 NeuroVision, our nerve avoidance system, we compete with Medtronic Sofamor Danek, Inc., a wholly owned subsidiary of Medtronic, Inc., and Nicolet Biomedical, a VIASYS Healthcare company, 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-Stratec, 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.

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

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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, 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, and lateral TDR (XL TDR), will require premarket approval, or 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, XLTDR 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 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 XLTDR 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;

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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. Specifically, our Osteocel acquisition is the largest acquisition we have ever completed, with a total acquisition price of $85 million. If we failed to properly value that business, or fail to generate expected revenues or profits from operation of that business, our results of operations will suffer. Additionally, our investment in Progentix Orthobiology B.V., a private company working to develop a novel synthetic biologic, 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 value of the 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 Osteocel biologic product). For example, we may not be able to successfully integrate an acquired company s operations, 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 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. is our exclusive supplier of polyetheretherketone, 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 Delphi Corporation (Delphi) pursuant to which Delphi is our exclusive supplier of NeuroVision® 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.

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Maxigen Biotech, Inc., or MBI, is our exclusive supplier of our FormaGraft® product. We are party to a supply agreement with MBI, pursuant to which we have agreed to purchase our entire supply of FormaGraft from MBI. 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. Our supply of the product comes solely from Waldemar Link GmbH & Co. KG, a company that was affiliated with Cervitech prior to the acquisition. We are in the process of determining 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. and AlloSource, Inc. collectively supply us with all of our allograft implants, and will continue to be our only sources for the foreseeable future. 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, which is processed from allograft and was acquired from Osiris Therapeutics, Inc. 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 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 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 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 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 agreements 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.

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

The rapid growth of our business has placed a significant strain on our managerial, operational and financial resources and systems. To execute our anticipated growth successfully, we must:

- generate higher revenues to cover a higher level of operating expenses, and our ability to do so may depend on factors that we do not control;

- attract and retain highly qualified management, scientific, manufacturing and sales and marketing personnel;

assimilate new staff members and 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;

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expand our sales and marketing resources for international expansion and to launch an increasing number of new products from our product pipeline;

accurately anticipate demand for the products we manufacture and maintain adequate manufacturing capacity for both commercial and clinical supply while maintaining quality standards; and

upgrade our internal business processes and capabilities (e.g., information technology platform and systems, product distribution and tracking) to create the scalability that a growing business demands.

Further, our anticipated growth, both internationally and domestically, 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 premarket approval application, or 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. 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.

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

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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 an FDA inspection in April 2005 regarding our allograft implant business and another FDA inspection in June 2007 regarding our medical device activities. In connection with these inspections as well as prior inspections, the FDA requested minor corrective actions, which we have taken to satisfy the corrective actions. 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 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 $370.3 million in 2009. We anticipate continued growth and have provided guidance related to such growth for 2010. 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-term, operating results may be adversely impacted if we do not achieve our anticipated growth.

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

At December 31, 2009, we had $65.4 million in cash and cash equivalents and $139.2 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.

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.

Our quarterly financial results are likely to fluctuate significantly because our sales prospects are uncertain.

Our quarterly operating results are difficult to predict and may fluctuate significantly from period to period, particularly because our sales prospects are uncertain. These fluctuations may also affect our annual operating results and may cause those results to fluctuate unexpectedly from year to year. The level of our revenues and results of operations at any given time will be based primarily on the following factors:

our ability to increase sales of our products to hospitals and surgeons;

the efficiency of our distribution network to maximize our inventory of products and instruments in order to meet the demands of our customers;

our ability to expand and maintain an effective and dedicated sales force;

pricing pressure applicable to our products, including adverse third-party reimbursement outcomes;

results of clinical research and trials on our existing products and products in development and our ability to obtain FDA approval or clearance;

the mix of our products sold and the geographic markets in which our products are sold (i.e., profit margins differ between our products and between different geographic markets, both domestically and internationally);

timing of new product launches, acquisitions, licenses or other significant events by us or our competitors;

the ability of our suppliers to timely provide us with an adequate supply of materials and components and meet our quality requirements;

the evolving product offerings of our competitors and the potential introduction of new and competing technologies; and

regulatory approvals and legislative and reimbursement policy changes affecting the products we may offer or those of our competitors.

Many of the products we may seek to develop and introduce in the future will require FDA approval or clearance, without which we cannot begin to commercialize them in the United States, and commercialization of them outside of the United States would likely require other regulatory approvals and import licenses. As a result, it will be difficult for us to forecast demand for these products with any degree of certainty. In addition, we will be increasing our operating expenses as we build our commercial capabilities. Accordingly, we may experience significant, unanticipated quarterly losses. Because of these factors, our operating results in one or more future quarters may fail to meet the expectations of securities analysts or investors.

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

In connection with our recent acquisitions, we may be obligated to make payments in the future upon the achievement of certain milestones. We currently have $33.0 million in outstanding potential milestone obligations under our agreement with the shareholders of Cervitech and may be required to make milestone payments upon the completion of certain milestones and purchase the remaining sixty (60) percent of Progentix Orthobiology B.V. for an aggregate amount up to $69 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.

We expect our operating expenses to continue to increase as we attempt to expand into international markets, which could disrupt our U.S. business operations, present risks not originally contemplated and harm our operating results.

We have invested, and expect to increase our investment for the foreseeable future, in our expansion into international markets. We currently expect that our operating expenses will continue to increase as we 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 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 current 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.

Risks Related to Our Intellectual Property and Potential Litigation

We are currently involved in a patent litigation action involving Medtronic and, if we do not prevail in this action, 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.

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

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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.

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 (in the U.S.) and/or opposition proceedings (outside the U.S.), 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

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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 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.

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.

Any claims relating to us making improper payments to physicians for consulting services, or other potential violations of laws or regulations governing interactions between us and healthcare providers, could be time consuming and costly.

Our relationship with surgeons, hospitals and the marketers of our products are subject to scrutiny under various state and federal anti-kickback, self-referral, false claims and similar laws, often referred to collectively as healthcare fraud and abuse laws. Healthcare fraud and abuse laws are complex, and even minor, inadvertent violations can potentially

give rise to claims that the relevant law has been violated. Any violations of these laws could result in a material adverse effect on the market price of our common stock, as well as our business, financial condition and results of operations. We cannot assure you 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 surgeons, hospitals and marketers of our products.

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Federal anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation or receipt of any form of remuneration by an individual or entity in return for, or to induce:

- the referral of an individual for a service or product for which payment may be made by Medicare, Medicaid or other government-sponsored healthcare program; or

- purchasing, leasing, ordering or arranging for any service or product for which payment may be made by a government-sponsored healthcare program.

Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of such prohibitions. From 2007 through 2009, numerous medical device manufacturers have entered into deferred prosecution agreements and corporate integrity agreements with the federal government and paid hundreds of millions of dollars, in aggregate, to the government over allegations that the companies had paid kickbacks to surgeons to reward and incentivize use of their surgical implant products. In addition, the government has indicted and prosecuted employees of companies for their alleged involvement in kickback arrangements. Furthermore, the majority of states in which we market our products have similar anti-kickback laws, imposing substantial penalties for violations. To enforce compliance with federal laws, the U.S. Department of Justice, or DOJ, has increased its scrutiny of the interactions between healthcare companies and healthcare providers, which has led to an unprecedented level of investigations and settlements in the healthcare industry. Dealing with DOJ investigations can be time- and resource-consuming. Additionally, if a healthcare company settles an investigation with the DOJ, or other law enforcement agencies, it may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Further, the commercial compliance environment is continually evolving in the healthcare industry with certain states mandating implementation of commercial compliance programs and disclosure requirements while similar legislation has been proposed and is proceeding on the federal level in the form of the Physician Payment Sunshine Act.

In addition to the anti-kickback law, federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Examples of enforcement under this law include the prosecution of several pharmaceutical and device companies for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company s marketing of the product for unapproved, and thus non-reimbursable, uses. 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. We market our products and provide promotional materials and training programs to surgeons regarding the use of our products. Although we believe our marketing, promotional materials and training programs for surgeons 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.

We must comply with a variety of other laws, such as the Healthcare Insurance Portability and Accountability Act of 1996, which protects the privacy of individually identifiable healthcare information, and the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections.

The scope and enforcement of these laws is uncertain and subject to rapid change, especially in light of the lack of applicable precedent and regulations. There can be no assurance that federal or state regulatory authorities will not challenge or investigate our current or future activities under these laws. Any such challenge or investigation could

have a material adverse effect on our business, financial condition and results of operations. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

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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 generally. 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: $31.38 on March 31, 2009; $44.60 on June 30, 2009; $41.76 on September 30, 2009; and $31.98 on December 31, 2009. 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;

volume and timing of orders for our products;

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 securities analysts.

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

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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 662/3% 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.***

Our current corporate headquarters are located in San Diego, California. We lease approximately 202,000 square feet in San Diego, with approximately 62,000 square feet leased through August 2012 and an additional 140,000 square feet leased to us until August 2023. Under a master lease agreement relating to the 140,000 square foot facility, through options to acquire additional space in the project and to require the construction of an additional building on the campus, we have facility expansion rights to an aggregate of more than 300,000 leased square feet. In 2006, we purchased an approximately 100,000 square foot building in Memphis, Tennessee that we use as our primary

distribution and warehouse facility.

Item 3. ***Legal Proceedings.***

We have been involved in a series of related lawsuits involving families of decedents who donated their bodies through UCLA s willed body program. The complaint alleges that the head of UCLA s willed body program, Henry G. Reid, and a third party, Ernest V. Nelson, improperly sold some of the donated cadavers to the defendants (including NuVasive). Plaintiffs allege the following causes of action: (i) breach of fiduciary duty; (ii) negligence;

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(iii) fraud; (iv) negligent misrepresentation; (v) negligent infliction of emotional distress; (vi) intentional infliction of emotional distress; (vii) intentional interference with human remains; (viii) negligent interference with human remains; (ix) violation of California Business and Professions Code Section 17200; and (x) injunctive and declaratory relief. We had been dismissed from these lawsuits by the trial court but the decision was appealed and in July 2008, the appellate court reversed the trial court s decision to dismiss us from these lawsuits. We have appealed this decision, the appellate court has heard our appeal and we are currently awaiting the decision of the Court.

Although the outcome of this lawsuit cannot be determined with certainty, we believe that we acted within the relevant law in procuring the cadavers for our clinical research and intend to vigorously defend ourselves against the claims contained in the complaint.

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: 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. This initial phase of the case is in a discovery phase. A full schedule for the initial phase of the lawsuit, including a trial date for the patents included in the initial phase of the lawsuit, has not yet been set by the Court.

On September 25, 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 is seeking cancellation of NuVasive s NeuroVision trademark registrations, injunctive relief and damages based on NMP s valuation of the NeuroVision mark. NuVasive intends to vigorously pursue defense of the claims, and on November 23, 2009, denied the allegations in the NMP s complaint and filed a counterclaim against NMP for unfair competition and declaratory relief. The case is pending in the United States District Court and is in the early stages of the proceedings. An order establishing a schedule for the case is expected in the middle of 2010.

Item 4. ***Submission of Matters to a Vote of Security Holders.***

No matter was submitted to a vote of our security holders during the quarter ended December 31, 2009.

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PART II

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

Common Stock Market Price

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

	High	Low
2008:		
First Quarter	$ 43.85	$ 31.17
Second Quarter	46.06	34.48
Third Quarter	58.88	42.88
Fourth Quarter	51.17	29.27
2009:		
First Quarter	$ 39.95	$ 24.17
Second Quarter	45.06	28.39
Third Quarter	45.01	38.25
Fourth Quarter	44.08	27.45

We had approximately 146 stockholders of record as of January 31, 2010. 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, 2009, we did not issue any securities that were not registered under the Securities Act of 1933, except as disclosed in previous filings with the Commission.

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.

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PERFORMANCE GRAPH

The following graph compares the cumulative total stockholder return data (through December 31, 2009) for the Company s common stock since May 13, 2004 (the date on which the Company s common stock was first registered under Section 12 of the Exchange Act) to the cumulative return over such period of (i) The NASDAQ Stock Market Composite Index, and (ii) NASDAQ Medical Equipment Index. The graph assumes that $100 was invested on the date on which the Company completed the initial public offering of its common stock, in the common stock and in each of the comparative indices. The graph further assumes that such amount was initially invested in the Common Stock of the Company at the price to which such stock was first offered to the public by the Company on the date of its initial public offering. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

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

* $100 invested on 12/31/04 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

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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.

	Year Ended December 31,				
	2009	2008	2007	2006	2005
	(In thousands, except per share amounts)				
Statement of Operations Data:					
Total revenues	$ 370,340	$ 250,082	$ 154,290	$ 98,091	$ 62,606
Gross profit (1)(2)	309,230	211,074	130,522	81,954	52,053
Total operating expenses (1)(2)	297,913	238,934	147,774	136,180	83,547
Consolidated net income (loss) (3)	4,437	(27,528)	(11,265)	(47,910)	(30,339)
Net income (loss) attributable to NuVasive, Inc.	5,808	(27,528)	(11,265)	(47,910)	(30,339)
Net income (loss) per share attributable to NuVasive, Inc.:					
Basic	$ 0.16	$ (0.77)	$ (0.32)	$ (1.47)	$ (1.24)
Diluted	$ 0.15	$ (0.77)	$ (0.32)	$ (1.47)	$ (1.24)

	December 31,				
	2009	2008	2007	2006	2005
	(In thousands)				
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 204,660	$ 223,361	$ 89,698	$ 117,402	$ 19,490
Working capital	262,355	256,491	118,188	136,236	32,829
Total assets	653,764	487,406	225,687	196,184	71,490
Convertible senior notes	230,000	230,000			
Other long-term liabilities	59,166	24,288	1,119	1,399	1,665
Noncontrolling interests	13,629				
Total stockholders equity	296,222	187,631	196,578	176,303	58,136

(1) Expenses incurred for royalties have been reclassified from sales, marketing and administrative expense to cost of goods sold. Royalty expense was $8.7 million, $6.5 million, $5.2 million, $3.0 million and $1.2 million for the years ended December 31, 2009, 2008, 2007, 2006 and 2005, respectively.

(2) Expenses incurred for depreciation of loaned instrument sets have been reclassified from cost of goods sold to sales, marketing and administrative expense. Depreciation expense for loaned instrument sets was $18.2 million, $11.8 million, $8.8 million, $5.9 million and $3.0 million for the years ended December 31, 2009, 2008, 2007, 2006 and 2005, respectively.

(3) Consolidated net income (loss) for the year ended December 31, 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).

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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 the design, development and marketing of products for the surgical treatment of spine disorders. Our currently-marketed product portfolio is focused on applications for spine fusion surgery, a market estimated to exceed $5.1 billion in the United States in 2010. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS®, as well as a growing offering of biologics, cervical and motion preservation products. In the spine surgery market, our currently-marketed products are primarily used to enable access to the spine and to perform restorative and fusion procedures. 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 to our sales and marketing efforts, including training spine surgeons on our unique technology and products. Currently, we are training approximately 400 to 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:

NeuroVision® a proprietary software-driven nerve avoidance system;

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

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

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

Our MAS platform, with the unique advantages provided by NeuroVision, 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 visibility and our NeuroVision system allows surgeons to avoid critical nerves. Certain insurance providers have stated a policy of not providing reimbursement for the XLIF procedure. NuVasive cannot offer definitive time frames nor final outcomes regarding reversal of the non-coverage policies, as the process is dictated by third-party insurance providers. To date, these policies have not materially impacted our operating results.

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. (Cervitech), a company focused on clinical 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. Currently, the PCM investigational device has reached the two-year follow-up end point in its FDA-approved clinical trial in the United States. Approval, if obtained, will further strengthen our cervical product offering and will enable us to continue our trend of increasing our market share. Our biologic offering includes FormaGraft, a collagen synthetic product used to aid the fusion process, and Osteocel, an allograft cellular matrix containing viable mesenchymal stem cells, or MSCs, to aid in spinal fusion.

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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 million in cash (the Initial Investment). Progentix has as its objective the development and exploitation of knowledge and products in the field of bone defects and the recovery of bone tissue in general. Progentix wishes to further extend the existing knowledge and patent position in the field of Osteoinductive Bone Graft Material Technology.

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

At December 31, 2009, we had an accumulated deficit of $189.7 million.

Revenues. The majority of our revenues are derived from the sale of disposables and implants and we expect this trend to continue in the near term. We loan our NeuroVision systems and surgical instrument sets at no cost to surgeons and hospitals that purchase disposables and implants for use in individual procedures; there are no minimum purchase requirements of disposables and implants related to these loaned surgical instruments. In addition, we place NeuroVision, MaXcess and other MAS or cervical surgical instrument sets with hospitals for an extended period at no up-front cost to them provided they commit to minimum monthly purchases of disposables and implants. 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 NeuroVision systems. To date, we have derived less than 5% of our total revenues from these sales.

Sales and Marketing. Through 2009, substantially all of our operations are located in the United States and substantially all of our sales to date 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 both European and Asian markets. Our international sales force is made up of a combination of independent distributors and direct sales personnel.

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, 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

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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.

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 their 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, history of earnings, and reliability of forecasting. At December 31, 2009, we have maintained a valuation allowance equal to substantially all of the U.S. deferred tax assets as we concluded we are not able to meet the more likely than not future realization threshold required.

At December 31, 2009, we have federal and state net operating loss carryforwards of approximately $115.0 million and $74.0 million, respectively. The federal and state loss carryforwards begin to expire in 2017 and in the year prescribed by state statute, respectively, unless previously utilized. At December 31, 2009, we have federal and state research and development tax credit carryforwards of $2.2 million and $2.1 million, respectively. The federal research

and development tax credits begin to expire in 2017 unless previously utilized and the state tax credits carry forward indefinitely.

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

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

For purposes of calculating stock-based compensation, we estimate the fair value of stock options and shares issued under the Employee Stock Purchase Plan using a Black-Scholes option-pricing model. The determination of the fair value of 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 2009, and have determined there has been no impairment of goodwill or intangible assets with indefinite lives through December 31, 2009.

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, 2009.

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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 the 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,			2008 to 2009		2007 to 2008	
	2009	2008	2007	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Revenue	$ 370,340	$ 250,082	$ 154,290	$ 120,258	48%	$ 95,792	62%

Revenues have increased over time due primarily to continued market acceptance of our products within our MAS platform, including NeuroVision and MaXcess disposables, and our specialized implants such as our XLP™ lateral plate, SpheRx® pedicle screw systems, and CoRoent® suite of products. 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 revenue growth in each year. We expect revenue to continue to increase, which can be attributed to the continued adoption of our XLIF procedure and deeper penetration into existing accounts as our sales force executes on the strategy of selling the full mix of our products. In addition, the expansion of our biologics offering, including Osteocel, acquired in July 2008, other strategic business and asset acquisitions and new product introductions are expected to lead to continued revenue growth.

Cost of Goods Sold, excludes amortization of purchased technology

	Year Ended December 31,			2008 to 2009		2007 to 2008	
	2009	2008	2007	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Cost of Goods Sold	$ 61,110	$ 39,008	$ 23,768	$ 22,102	57%	$ 15,240	64%
% of total revenue	17%	16%	15%				

Cost of goods sold consists of costs of purchased goods and royalty expense.

Cost of goods sold as a percentage of revenue increased slightly in 2009 over 2008, primarily driven by the mix shift in total revenues represented by our biologic product line that have a lower margin relative to other product lines. The increase in cost of goods sold in total dollars in 2009 compared to 2008 and in 2008 compared to 2007 resulted primarily from increased material costs of $19.9 million and $13.9 million, respectively, associated with higher revenues in each year. We expect cost of goods sold, as a percentage of revenue, to remain relatively consistent for the foreseeable future.

Consistent with our philosophy of continual product innovation and obsoleting our own products, we have launched several new products and enhancements over the last few years. In connection with the product launches, certain implants were rendered obsolete. As a result, we incurred additional expenses of $873,000, $119,000 and $461,000 in 2009, 2008 and 2007, respectively, related to inventory rendered obsolete. This expense is included in cost of goods sold in the accompanying consolidated statement of operations for the respective years.

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Operating Expenses

Sales, Marketing and Administrative

	Year Ended December 31,			2008 to 2009		2007 to 2008	
	2009	2008	2007	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Sales, Marketing and Administrative	$ 254,997	$ 189,126	$ 121,676	$ 65,871	35%	$ 67,450	55%
% of total revenue	69%	76%	79%				

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

The increases in sales, marketing and administrative expenses principally result from growth in our revenue and the overall growth of the Company, including expenses that fluctuate with sales and expenses associated with investments in our infrastructure and headcount growth.

Increases in costs based on revenue, such as sales force compensation and other direct costs related to the sales force, and shipping costs were $31.2 million, $17.1 million, and $10.5 million in 2009, 2008 and 2007, respectively, compared to the prior years. The increases are consistent with our increased revenue growth of approximately 48% in 2009 as compared to 2008 and 62% percent in 2008 as compared to 2007; and an overall increase in sales force headcount of approximately 42% in 2009 compared to 2008 and 26% in 2008 as compared to 2007. Total costs related to our sales force, as a percent of revenue, were 30.0%, 31.3%, and 33.4% in 2009, 2008, and 2007, respectively.

We also experienced increased costs as a result of overall company growth and headcount additions in our marketing and administrative support functions. Our marketing and administrative headcount increased over 35% during 2009. Marketing and administrative compensation and personnel costs increased $17.5 million and $19.6 million in 2009 and 2008, respectively, compared to the prior years. Depreciation expense related to our loaned instrument sets increased $6.4 million and $3.0 million in 2009 and 2008, respectively, as compared to previous years, due to higher capital levels of instrument sets used in surgeries. Equipment and computer expenses increased by $3.1 million and $2.1 million in 2009 and 2008, respectively, compared to the same periods in prior years, primarily as a result of headcount growth and increased costs to support the increasing number of shareowners (employees). Stock-based compensation increased $1.7 million and $6.4 million in 2009 and 2008, respectively, compared to the prior years. The increase in 2009 as compared to 2008 and 2008 as compared to 2007 is primarily related to an increase in the number of option grants due to increased headcount year over year for all years presented and valuation-related changes for all options granted, most significantly, the market value of our common stock.

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 approximately $2.4 million in acquisition related costs in connection with our investment in Progentix and acquisition of Cervitech in 2009 with no comparable expense during the same periods in 2008 or 2007.

As previously disclosed, in 2008, Medtronic Sofamor Danek USA, Inc. and its related entities (Medtronic) filed an intellectual property suit against us. As a result of the litigation, our sales, marketing and administrative expenses increased $3.1 million and $1.5 million during 2009 and 2008, respectively.

The increases in costs discussed above were offset by decreases in costs for 2009 compared to the same period in 2008, related to charges totaling $7.4 million for vacating the Company s previous corporate headquarters and incremental transition costs related to our ERP system which were recorded in 2008. In August 2008, we relocated our corporate headquarters to a two-building campus style complex in San Diego. In connection with vacating our former corporate headquarters, we recorded a charge of approximately $4.8 million to sales, marketing, and

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administrative expenses for lease termination costs and other related items. In addition, during 2008, we incurred non-capitalizable expenses totaling $2.6 million related to the implementation of our new ERP system which was completed in the third quarter of 2008. During the third quarter of 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 is recorded as a reduction of sales, marketing, and administrative expenses for the year ended December 31, 2009.

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

Research and Development

	Year Ended December 31,			2008 to 2009		2007 to 2008	
	2009	2008	2007	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Research and Development	$ 37,581	$ 25,943	$ 24,581	$ 11,638	45%	$ 1,362	6%
% of total revenue	10%	10%	16%				

Research and development expense consists primarily of product research and development, clinical trial and study costs, regulatory and clinical functions, and shareowner (employee) 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 marked our entrance 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.

The increases in research and development costs in 2009 compared to 2008 and in 2008 compared to 2007 are primarily due to increases in compensation and other shareowner related expenses of $5.3 million and $3.1 million in 2009 and 2008, respectively, primarily due to increased headcount to support our product development and enhancement efforts, including an increase in stock based compensation of $1.1 million in 2009 as compared to 2008, and increased expenses related to ongoing clinical trial and other research activities of $4.0 million in 2009 as compared to 2008, including $2.4 million in research expenses related to our investment in Progentix Orthobiology. These increases are offset by decreased clinical trial and related study costs of $0.6 million in 2008 compared to 2007 due in part to the NeoDisc® trial becoming fully enrolled during August 2008, with no comparable costs for NeoDisc in 2009.

We expect research and development costs to continue to increase in absolute dollars for the foreseeable future in support of our ongoing development activities and planned clinical trial activities.

Amortization of Intangible Assets

	Year Ended December 31,			2008 to 2009		2007 to 2008	

	2009	2008	2007	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Amortization of intangible assets	$ 5,335	$ 2,989	$ 1,517	$ 2,346	79%	$ 1,472	97%
% of total revenue	1%	1%	1%				

Amortization of intangible assets relates to amortization of finite-lived intangible assets acquired. The increase in amortization expense in 2009 compared to 2008 and in 2008 compared to 2007 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 upon it reaching technological feasibility.

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In-Process Research and Development

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. As of the date of the acquisitions, 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 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, 2009, we have recorded approximately $46.0 million on our balance sheet related to IPR&D in conjunction with our investment in Progentix and acquisition of Cervitech as further development is required and regulatory approval has not 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. Currently, the PCM investigational device acquired from Cervitech, which represents approximately $34.8 million of the $46.0 million total capitalized IPR&D, has reached the two-year follow-up end point in its FDA approved clinical trial in the United States. We anticipate submitting for FDA approval in the first quarter of 2010.

Interest and Other Income (Expense), Net

	Year Ended December 31,			2008 to 2009		2007 to 2008	
				$	%	$	%
	2009	2008	2007	Change	Change	Change	Change
	(Dollars in thousands)						
Interest income	$ 1,507	$ 5,599	$ 5,216				
Interest expense	(7,116)	(5,571)	(1)				
Other income, net	461	304	772				
Total interest and other income (expense), net	$ (5,148)	$ 332	$ 5,987	$ (5,480)	(1651)%	$ (5,655)	(94)%
% of total revenue	(1)%	%	4%				

Interest and other income (expense), net, consists primarily of interest income earned on marketable securities offset by interest expense incurred related to the Company s convertible debt financing signed in March 2008. The net change in these amounts in the years presented is principally due to (i) an increase in interest expense of $1.3 million and $5.4 million in 2009 and 2008, respectively, 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 same 2008 period; and (ii) lower average balances in marketable securities in 2009, coupled with lower interest rates, resulting in a decrease of $4.1 million in interest income in 2009 as compared to 2008.

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,			2008 to 2009		2007 to 2008	
	2009	2008	2007	$ Change	% Change	$ Change	% Change
	(Dollars in thousands)						
Stock-Based Compensation							
Sales, Marketing & Administrative	$ 19,549	$ 17,837	$ 11,404	$ 1,712	10%	$ 6,433	56%
Research & Development	4,244	3,110	2,217	1,134	37%	893	40%
Total Stock-Based Compensation	$ 23,793	$ 20,947	$ 13,621	$ 2,846	14%	$ 7,326	54%
% of total revenue	6%	8%	9%				

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Stock-based compensation related to stock options is recognized and amortized on an accelerated basis in accordance with authoritative guidance. The increase in stock-based compensation in 2009 of approximately $2.8 million as compared to 2008 and $7.3 million in 2008 as compared 2007, can be attributed to an increase in number of option grants due to increased headcount year over year for all years presented and changes in valuation assumptions utilized in the Black-Scholes option pricing model, most significantly, the market value of our common stock. In addition, during 2009, we 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, 2009, there was $13.5 million and $6.1 million of unrecognized compensation expense for stock options and RSUs, respectively, which is expected to be recognized over a weighted-average period of approximately 1.1 years and 3.3 years, respectively. In addition, as of December 31, 2009, there was $2.4 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 2011.

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 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 an estimated purchase price of approximately $79 million, consisting of cash totaling approximately $25 million and the issuance of 638,261 shares of NuVasive common stock to certain stockholders of Cervitech and

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$29.7 million of contingent consideration due upon FDA approval of the PCM device. Of the estimated total purchase price of $79 million, $34.8 million and $55.8 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. Currently, the PCM investigational device has reached the two-year follow-up end point in its FDA approved clinical trial in the United States. We anticipate submitting for FDA approval in the first quarter of 2010. Approval, if obtained, will further strengthen our cervical product offering and will enable us to continue our trend of increasing our market share.

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 a comprehensive stem cell biologic platform with benefits similar to autograft, as well as rights to acquire the next generation cultured version of the product. Osteocel is a unique bone matrix product that provides the three beneficial properties similar to autograft: osteoconduction (provides a scaffold for bone growth), osteoinduction (bone formation stimulation) and osteogenesis (bone production). Osteocel allows 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 is produced for use in spinal applications through a proprietary processing method that preserves the native stem cell population that resides in marrow rich bone. The acquisition is consistent with our objective of developing or acquiring innovative technologies. Of the total purchase price of $85 million, $35 million was paid to Osiris at closing (the Initial Purchase Price) and additional payments of $45 million were made in 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.

Radius Medical LLC. In January 2007, we acquired assets used by Radius Medical LLC, or Radius, in connection with the design, development, marketing and distribution of collagen-based medical biomaterials, together with the intellectual property rights, contractual rights, inventories, and certain liabilities related thereto. In connection with the transaction, we made net cash payments totaling $7.0 million and issued 451,677 unregistered shares of our common stock, which were subsequently registered. As part of the acquisition, we also acquired certain rights and obligations under a supply agreement with Maxigen Biotech, Inc. (MBI) with respect to product manufacturing and distributor rights. MBI is a Taiwanese company that manufactures FormaGraft and owns a portion of the core technology.

In connection with the acquisition of Radius, we made a separate $2.0 million equity investment in MBI. In May 2007, the equity investment in MBI was completed resulting in NuVasive ownership of approximately 9% of MBI. We account for this investment at cost and is included in other assets on the consolidated balance sheets.

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

Liquidity and Capital Resources

Since our inception in 1997, we have incurred significant losses and as of December 31, 2009, we had an accumulated deficit of approximately $189.7 million. To date, our operations have been funded primarily with proceeds from the sale of our equity securities which total $297.1 million since inception, including $210.1 million sold in the public markets.

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In March 2008, we issued $230.0 million principal amount of 2.25% Convertible Senior 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 will 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. The Notes mature on March 15, 2013 and can be settled only in shares of our common stock.

Cash, cash equivalents and marketable securities was $204.7 million at December 31, 2009 and $223.4 million at December 31, 2008. The decrease was due primarily to the payments of $78.9 million in connection with purchases of property and equipment and business acquisitions, offset by an increase in cash flows provided by operations.

Net cash provided by operating activities was $46.4 million in 2009 compared to cash used in operating activities of $5.0 million in 2008. The increase in cash provided from operating activities is from our improved operating results in 2009 as compared to 2008, as well as improved collections from accounts receivable representing a net increase in cash of $16.6 million in 2009 as compared to 2008. We spent an incremental $14.4 million during 2008 as compared to 2007 for inventory to support our increased operations and growing business and in preparation for the introduction of NeuroVision M5, representing a significant upgrade to our core MAS platform, which was introduced at the beginning of the fourth quarter of 2008.

Net cash used by investing activities was $127.9 million in 2009 compared to net cash used by investing activities of $144.6 million in 2008. The decrease in net cash used by investing activities of $16.7 million is primarily due to the net change of $14.3 million in the activity in our investment portfolio, the net change of $4.8 million in cash used to fund the acquisition and investments and a $6.9 million decrease in capital asset purchases. Included in the $15.4 million net increase of capital expenditures in 2008 as compared to 2007, is approximately $9.5 million and $10.9 million of expenditures related to the new San Diego facility and for the implementation of our new ERP system, respectively.

Net cash provided by financing activities was $14.5 million in 2009 compared to $220.0 million in 2008. The decrease in cash provided by financing activities of $205.6 million is primarily due to the receipt of net proceeds of $208.4 million from the issuance of the Notes in March 2008, which financing was not replicated or needed in 2009.

We expect that our cash, cash equivalents and marketable securities balance may fluctuate in future periods as a result of a number of factors, including fluctuations in our working capital requirements and of our capital expenditures for additional loaner instrument sets, our operating results, and cash used in any future acquisitions. We have sufficient cash and investments on hand to finance our operations for the foreseeable future.

Contractual Obligations and Commitments

Contractual obligations and commitments represent future cash commitments and liabilities under agreements with third parties, including our Convertible Senior Notes, operating leases and other contractual obligations. The following summarizes our long-term contractual obligations and commitments as of December 31, 2009 *(in thousands)*:

		Payments Due by Period		
Total	**Less Than 1 Year**	**1 to 3 Years**	**4 to 5 Years**	**After 5 Years**

Convertible Senior Notes(1)	$ 18,113	$ 5,175	$ 12,938	$	$
Operating leases	82,214	7,214	14,316	11,000	49,684
Royalty obligations	1,110	180	360	360	210
Clinical advisory agreements	1,498	308	480	480	230
Total	$ 102,935	$ 12,877	$ 28,094	$ 11,840	$ 50,124

(1) The Convertible Senior Notes in the above table include only the interest payments totaling 2.25% per annum as the Convertible Senior Notes are only convertible into the Company s common stock and not settled using cash. See Note 7 to the consolidated financial statements for further discussion of the terms of the Convertible Senior Notes.

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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.

As a result of our acquisition of Radius Medical LLC in January 2007, we are obligated to purchase, on an annual basis, a minimum number of units of FormaGraft® from Maxigen Biotech, Inc. at an annual cost of approximately $900,000.

In connection with the investment in Progentix, we are contingently obligated to make additional payments of up to $69 million based upon the achievement of specified milestones. In addition, we are obligated to advance an additional $2 million to Progentix in accordance with the terms of a loan agreement entered into in conjunction with the investment.

In connection with the acquisition of Cervitech, we are contingently obligated to make additional payments 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 the Company s discretion.

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, 2009, 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, 2009 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, 2009, we do not hold any material asset-backed investment securities and in 2009, we did not realize any losses related to asset-backed investment securities. Based upon our overall interest rate exposure as of December 31, 2009, a change of 10 percent in interest rates, assuming the amount of our investment portfolio remains constant, would not have a material effect on interest expense. Further, this analysis does not consider the effect of the change in the level of the overall economic activity that could exist in such an environment.

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.

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The following table presents the carrying value and related weighted-average rate of return for our investment portfolio as of December 31, 2009 (dollars in thousands):

	Carrying Value	Weighted Average Rate of Return
Money market funds	$ 41,423	0.5%
Certificates of deposit	1,973	1.1%
Corporate notes	4,959	1.1%
U.S. government treasury securities	27,983	0.2%
Securities of government-sponsored entities	104,332	0.5%
Total interest bearing instruments	$ 180,670	

As of December 31, 2009, the stated maturities of our investments are $99.3 million within one year and $40.0 million from one to three 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 Convertible Senior 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.

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, 2009. Based on such evaluation, our management has concluded as of December 31, 2009, the Company s disclosure controls and procedures are effective.

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Management s Report on Internal Control over Financial Reporting. 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 accounting principles generally accepted in the United States.

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, 2009. Ernst & Young LLP, the Company s independent registered public accounting firm, has issued an attestation report on the Company s internal control over financial reporting which is included herein.

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

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
NuVasive, Inc.

We have audited NuVasive, Inc. s internal control over financial reporting as of December 31, 2009, 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