NUVASIVE INC
Form 10-K
March 15, 2007

Table of Contents

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

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)**
OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2006

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)**
OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number: 000-50744

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

Delaware	**33-0768598**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
4545 Towne Centre Court, San Diego, California	**92121**
(Address of principal executive offices)	*(Zip Code)*

Registrant s telephone number, including area code:
(858) 909-1800
Securities registered pursuant to Section 12(b) of the Act

Title of Each Class:	**Name of Each Exchange on Which Registered:**
Common Stock, par value $0.001 per share	**The NASDAQ Stock Market**

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 o NO þ

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 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, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer þ Non-accelerated filer 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 $596.8 million as of the last business day of the registrant s most recently completed second fiscal quarter (i.e. June 30, 2006), based upon the closing sale price for the registrant s common stock on that day as reported by the Nasdaq National Market. Shares of common stock held by each officer and director have been excluded in that such persons may be deemed to be affiliates.

There were 34,432,397 shares of the registrant s common stock issued and outstanding as of February 28, 2007.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Form 10-K incorporates information by reference to the registrant s definitive Proxy Statement for the Annual Meeting of Stockholders to be held on May 24, 2007.

NuVasive, Inc.

Form 10-K for the Fiscal Year ended December 31, 2006

Table of Contents

PART I

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

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

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

Item 1. *Business.*

Overview

We are a medical device company focused on 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 $3.6 billion in the U.S. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS™, as well as a growing offering of cervical and motion preservation products. Our currently-marketed products are used predominantly in spine fusion surgeries, both to enable access to the spine and to perform restorative and fusion procedures. We focus significant research and development efforts on both MAS and motion preservation products in the areas of (i) fusion procedures in the lumbar and thoracic spine, (ii) cervical fixation products, and (iii) motion preservation products such as total disc replacement and nucleus-like cervical disc replacement. We dedicate significant resources toward training spine surgeons on our unique technology and products. As of December 31, 2006, we have conducted over 1,200 surgeon training sessions in the use of our products.

Our MAS platform combines three 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; and

Specialized implants, like our SpheRx® pedicle screw system, and CoRoent® suite of implants.

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 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 into reinventing approaches that add complexity and

Table of Contents

undermine safety, ease and efficacy. An important ongoing objective has been to maintain our #1 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.

We also offer a suite of traditional spine surgery products, including a line of precision-machined cervical and lumbar allograft implants, a titanium surgical mesh system, and related instrumentation. Our line of bone allograft, in our patented saline packaging, is human bone that has been processed and precision shaped for transplant. We also offer fusion plates such as our SmartPlate Gradient CLP, a dynamic cervical plate that encompasses a gradient locking mechanism which gradually loads the screws based upon the anatomic requirements. This allows the plate to settle in concert with the settling of the allograft implant that occurs within the disc space over time, offering a better anatomical fit.

Our corporate headquarters are located in a 62,000 square foot, state-of -the-art facility in San Diego, California. This facility has a six-suite cadaver operating theatre designed to accommodate the training of spine surgeons. In 2006, we relocated our primary distribution and warehousing operations to a facility we purchased 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 new facility greatly enhances our ability to meet demanding delivery schedules and provide a greater level of customer service.

Recent Product Introductions

In the last several years, we have introduced numerous new products and product enhancements that have significantly expanded our MAS platform, marked our entrance into the growing motion preservation market and increased our revenue opportunities for each surgery performed using our products. We have also acquired complementary and strategic assets and technology. Our newly-launched products are exemplified by the following categories:

Implants our implant products have historically focused on the lumbar spine; with our recent and planned product introductions, we will increasingly address the cervical and thoracic spine as well. These include:

SpheRx Pedicle Screw System a pedicle screw system designed for a posterior approach, which has been enhanced with a Dual Ball Rod feature to allow for instrument-free compression of the vertebrae, thereby minimizing the incidence of tissue trauma associated with rod-overhang and effecting secure rod placement with minimal rod migration. Our redesigned SpheRx II Pedicle Screw System is currently in limited launch and should be widely available in 2007.

Lateral Plate a fixation plate designed for placement through the same incision used in an XLIF procedure and that is, designed to perform the same fixation function as pedicle screws without the need for an additional incision.

SmartPlate Gradient PLUS a cervical plating system that provides construct options (constrained, semi-constrained, or translational) that best satisfy the patient specific requirements. Whether using controlled translation that allows the plate to settle in concert with the eventual allograft implant or a fixed construct for trauma application, SmartPlate Gradient PLUS provides the benefit of intraoperative choice

when selecting the construct that best satisfies patient need.

CoRoent Offering designed in response to the demand from spine surgeons for implants with superior anatomical fit that are simple to position and align. The CoRoent family of products consists of multiple shapes and sizes, several designed to be inserted using a patented Insert and Rotate technique, which minimizes damage to the surrounding bone. Each of these CoRoent products is made of PEEK OPTIMA®, a biocompatible polymer commonly used in implantable devices.

Table of Contents

Access a key element of our MAS platform is the safe and customizable access it affords to the spine. The core of this offering is our MaXcess retractor system. We continue to maintain a competitive advantage through the introduction of products such as:

MaXcess retractor we have launched two completely revised versions of our retractor system over the last 2 years, with the current version being MaXcess III. MaXcess III maintains the split-blade design of the original product and incorporates our NeuroVision nerve avoidance technology within the posterior retraction blade. MaXcess III also adds a removable fourth blade, which provides greater posterior surgical options and incorporates an improved tilted blade-locking mechanism.

MaXcess Micro-Access System the smallest, lightest version of our MaXcess retractor systems, designed to provide access during posterior lumbar and cervical decompression surgeries. The MaXcess Micro-Access System adds more surgical applications to our MAS platform by enabling minimally disruptive maximum access approaches for lumbar stenosis decompression, foraminal discectomy and posterior cervical foraminotomy.

NeuroVision the key ingredient for the XLIF procedure, NeuroVision utilizes proprietary technology and hunting algorithms to locate and avoid critical nerves during surgery. We continually advance and enhance the system, with new features such as:

MEP Technology NeuroVision now incorporates motor evoked potentials, or MEP technology, for complete monitoring of nerve activity in the thoracic and cervical regions of the spine.

Remote Monitoring NeuroVision has also been upgraded to allow for Remote Monitoring, providing the ability to monitor surgeries both intraoperatively and remotely, allowing for more efficient case coverage.

System upgrades A software upgrade providing a new graphical user interface that allows for greater ease of use by the surgical staff. NeuroVision has also been given a new harness and dual electrodes, or redesigned connectors, to streamline the application of surface electrodes that relay muscle activity to the monitoring system.

We also made significant progress in 2006 on our research and development initiatives related to motion preservation. Our clinical trial for NeoDisc^{tm} began in the third quarter. The NeoDisc clinical trial 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 is fully underway in this clinical trial and we look forward to analyzing the data collected.

Our motion preservation product development efforts include our lateral access total disc replacement, or TDR, and our elastomeric lateral TDR, which is based on an embroidery design. We are anticipating filing Investigational Device Exemptions, or IDEs, in late 2007 and early 2008, respectively. Lastly, our cervical ceramic-on-ceramic TDR CerPass device remains in biomechanical testing and we expect to be in a position to file an IDE for its US clinical trial in the second half of 2007.

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 minimally invasive 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 minimally invasive 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.

Table of Contents

Continue to Introduce New Creative Products. One of our core competencies is our ability to develop and commercialize creative spine surgery products. In the recent past, we have introduced more than 20 new products and product enhancements. We have several additional products currently under development that will expand our presence in fusion surgery as well as provide a formidable entrance into the motion preservation market segment. All of this will be accomplished 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.

Establish Exclusive Sales Force with Broad Reach. 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. 2006 marked the completion of our transition to an exclusive sales force, and we are already seeing the benefits of that effort. Our sales force is achieving deeper penetration in our accounts and further establishing NuVasive as a technology leader in the spine industry. Our exclusive sales force is comprised partially of Area Business Managers, or ABMs, who are NuVasive shareowners (our employees) responsible for a defined territory. The remainder of the sales force are exclusive independent sales 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 though internal product development efforts, we intend to selectively license or acquire complementary products and technologies. By acquiring complementary products, we believe we can leverage our expertise at bringing new products to market and provide additional selling opportunities for our sales force. We have acquired complementary and strategic assets, including cervical plate technology, which we re-launched as our SmartPlate Gradient CLP product, surgical embroidery technology, including the NeoDisc investigational nucleus-like cervical disc replacement, and our newly-acquired Formagraft® bone graft product for use in fusion surgeries. We will continue to be opportunistic in this regard as we seek to expand our market share.

Industry Background and Market

Back pain is the number one cause 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 $3 billion in 2006, growing to over $3.6 billion in 2007.

We believe that the 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 it is estimated that over 95% of all spine fusion surgeries now involve implants.

Demand for Minimally Invasive Alternatives. As with other surgical markets, we anticipate that the broader acceptance of minimally invasive spine surgery will result in increased demand for these types of surgical procedures.

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.

Table of Contents

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 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.

The prescribed treatment for spine disorders depends on the severity and duration of the disorder. Initially, physicians will prescribe non-operative 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, many patients require spine surgery. It is estimated that in excess of one million patients undergo spine surgery each year in the United States. The most common spine surgery procedures are: discectomy, the removal of all or part of a damaged disc; laminectomy, the removal of all or part of a lamina, or thin layer of bone, to relieve pinching of the nerve and narrowing of the spinal canal; and fusion, where two or more adjoining vertebrae are fused together to provide stability. All three of these procedures require access to the spine. Traditional open surgical approaches require large incisions to be made in the back so that surgeons can 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.

Minimally Invasive Surgical Procedures

The benefits of minimally invasive surgery procedures in other areas of orthopedics have significantly contributed to the strong and growing demand for minimally invasive surgery 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 minimally invasive surgical procedures has been relatively slow with respect to the spine.

We believe the two principal factors contributing to spine surgeons slow adoption of minimally invasive alternatives are: (i) the limited or lack of direct access to and visibility of the surgical anatomy, as well as (ii) the associated complex instruments that have been required to perform these procedures. Most minimally invasive systems do not allow the surgeon to directly view the spine and provide only restrictive visualization through a camera system or endoscope, while also requiring the use of complex surgical techniques. In addition, most minimally invasive 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 alternative minimally invasive 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 3 product categories: NeuroVision, MaXcess, 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. 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 spine applications of the following spine surgery procedures, among others:

- Posterior lumbar fusion procedures in which the surgeon utilizes a direct or off-midline approach through the patient s back;

Table of Contents

Anterior lumbar fusion procedures in which the surgeon approaches the spine through the patient s abdomen;

Cervical fusion procedures in which the surgeon approaches the spine through the patient s neck.

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 an 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.

We believe procedures enabled by our MAS platform have significant benefits. A multi-center evaluation study of 145 XLIF procedures performed in 2003 and 2004 and subsequent single-surgeon reports presented at multiple meetings through 2006 support our belief that our MAS platform provides the following benefits:

Reduced Surgery Times. XLIF procedures utilizing our MAS platform, which we refer to as MAS XLIF, have averaged about 1 hour to perform which we believe is substantially shorter than it takes to perform an equivalent open procedure.

Reduced Hospital Stays. Hospital stays following a MAS XLIF procedure have averaged one to two days which we believe is substantially shorter than the hospital stays associated with an equivalent open procedure.

Reduced Pain and Recovery Times. Due to smaller incisions and less trauma and blood loss for the patient, we believe that the pain and recovery time for patients following a MAS XLIF procedure is significantly less than with an equivalent open procedure. In most cases, patients are walking the same day as surgery following a MAS XLIF.

MAS NeuroVision

NeuroVision utilizes electromyography, or EMG, and proprietary software 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. In addition, 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. The initial application of NeuroVision, Screw Test with our INS-1® system, was cleared by the FDA in November 2000 and commercially launched in 2001.

Surgeons can dynamically link familiar surgical instruments to NeuroVision, thus creating an interactive set of instruments that enable the safe navigation of neural anatomy. This 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. We

have recently introduced significant enhancements to NeuroVision in the form of MEP technology, remote reading capability, a software upgrade and improved nerve monitoring capabilities.

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

Table of Contents

fixed tube design of other minimally invasive 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. During the fourth quarter of 2004, we introduced an extension of our MaXcess product with our MaXcess-Micro Access System. This brings all of the benefits of minimally disruptive surgery to both the cervical spine for posterior application and the lumbar spine for decompression.

In 2005, we introduced MaXcess II, a second generation of our MaXcess retractor that incorporates NeuroVision within the posterior retraction blade, providing built-in nerve monitoring capabilities. MaXcess II features superior and inferior blades that kick-out at an angle to spread the tissue closest to the pathology point further than original MaXcess.

In 2006, we launched MaXcess III, our most advanced retractor system. MaXcess III is a further enhancement of the MaXcess and MaXcess II systems, with the addition of several features that improve access to the spine. MaXcess III maintains the split-blade design and continues to incorporate NeuroVision nerve avoidance technology within the posterior retraction blade. MaXcess III adds a removable fourth blade, which provides greater posterior surgical options and incorporates an improved tilted blade-locking mechanism.

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, partial vertebral body replacement and stabilization of the spine. These implants include our SpheRx and SpheRx DBR pedicle screw systems, our CoRoent family of unique implants for partial vertebral body replacement, precision-machined allograft, as well as numerous new implants currently under development.

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 posterior spine. These systems enable minimally disruptive placement of implants and are intended to reduce operating time and patient morbidity.

Our implants can also be used in procedures not employing our MAS platform.

Classic Fusion

We have developed a suite of traditional spine surgery products, which we refer to as classic fusion, including a line of precision-machined cervical and lumbar allograft implants, a titanium surgical mesh system, and related instrumentation. Allograft implant tissue is recovered from deceased human donors, which is processed into specified sizes and shapes and sterilized for implantation. Unlike other suppliers of allograft implants, our patented packaging process allows us to provide a ready-to-use structural graft eliminating the need for refrigeration and re-hydration. We package all of our allograft implants in a sterile saline solution. In addition, our allograft packaging and instrumentation are color-coded to assist the surgeon in selecting the proper size implant for use with the appropriate size instrument.

Our classic fusion product offerings also include fusion plates such as our SmartPlate Gradient CLP, a dynamic cervical plate that encompasses a gradient locking mechanism which gradually loads the screws based upon the anatomic requirements. This allows the plate to settle in concert with the settling of the allograft implant settling that occurs within the disc space over time, offering a better anatomical fit.

Table of Contents

Development Projects

We are developing proprietary total disc replacement devices for lateral lumbar spine applications and separately for cervical spine applications. These devices are intended to allow surgeons to address a patient s pain and dysfunction while maintaining normal range of motion and avoiding future adjacent level degeneration that can occur after spine fusion. Commercialization of these devices will require premarket approval rather than 510(k) clearance, including NeoDisc, which has recently been granted an Investigational Device Exemption and is undergoing a clinical trial. NeoDisc is a nucleus-like cervical disc replacement device designed to preserve motion in the cervical region of the spine and provide an alternative pre-surgical treatment and mechanical total disc replacement (TDR) or spinal fusion. The design has an elastomeric core with a novel embroidered jacket to envelop the core in a similar manner as the annulus with anterior fixation flanges which simulate the anterior longitudinal ligament. We believe that NeoDisc could be attractive for use in broad indications and pathologies because of the relatively simple surgical placement procedure and the easily revisable nature of the implant.

In addition to the motion preservation platform, we have many product development projects that are intended to broaden surgical application and increase fixation options for greater vertical integration of our MAS techniques. Additionally, we are expanding our cervical fixation product portfolio to provide for a comprehensive cervical offering that will include segmentation of both fixation and motion markets.

In January 2007, we also completed the acquisition of rights to a biologic product we call Formagraft. This synthetic bone void filler is designed to aid in bone growth with fusion procedures.

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. Our research and development staff consists of 30 shareowners, including four 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; 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

We currently sell our products through a combination of independent sales agencies and direct sales representatives employed by us. We historically sold our products through independent sales agencies that were also free to promote the sale of competitive products. In 2006 we completed the process of transitioning to a sales force that is entirely exclusive to NuVasive in the sale of spine surgery products. Our efforts have resulted in a sales force comprised partially of sales professionals, who are NuVasive shareowners responsible for a defined territory. The remainder of the sales force consists of independent sales agents, each acting as our sole representative in a given territory. The determination of whether to engage an ABM or exclusive distributor is made on a territory by territory basis, with a focus on the candidate who brings the best skills, experience and contacts. Currently, the split between ABM s and independent sales agents in our sales force is roughly equal. Our sales force is managed by a Senior Vice President of U.S. Sales and five Divisional Sales Directors, or DSDs. Each DSD is responsible for a portion of the United States and manages the ABMs and independent sales agents engaged in that territory.

The transition to an exclusive sales force was an investment that consumed significant management time and focus, but we believe it was critical to our continued growth. There are many reasons that we believe strongly in an exclusive

sales force, none more important than having a sales force that is properly incentivized to sell our products across all product lines.

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

Table of Contents

products. To date, we have trained more than 1,200 spine surgeons in the XLIF® technique and our other Maximum Access Surgery, or MAS platform products including: NeuroVision jjb, MaXcess and SpheRx DBR. NuVasive has also helped to create 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.

Manufacturing and Supply

We rely on third parties for the manufacture of our products and their components and servicing, and we do not currently maintain alternative manufacturing sources for some components of NeuroVision, MaXcess, and SpheRx, as well as some of our other finished goods products. We are in the process of identifying and qualifying alternative 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 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 and 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 as our only suppliers of allograft implants. Our agreements with each of these suppliers automatically renew for successive one-year terms unless otherwise terminated by either party in accordance with the terms of the respective agreement.

In August 2005, we acquired NeoDisc, an investigational nucleus-like 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 under a non-exclusive arrangement. We are in the process of determining whether to establish 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 and Florida, the only states that require licenses. For our 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.

Loaner Equipment

We seek to obtain instrument assets just in time to fulfill our customer obligations to meet surgery schedules. This strategy minimizes backlogs, while increasing asset turns and maximizing cash flow. Our pool of MAS platform and classic fusion loaner 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 loaners 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

Table of Contents

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, 2006 we had 44 issued U.S. patents, 20 foreign national patents, and 189 pending patent applications, including 122 U.S. applications, 14 international (PCT) applications and 53 foreign national applications. Since then we acquired one additional patent application as part of our acquisition of FormaGraft® from Radius Medical, LLC. Our issued and pending patents cover, among other things:

targeting systems;

MAS surgical access and spine systems;

implants and related instrumentation; and

neurophysiology enabled instrumentation and methodology, including pedicle screw test systems, nerve root retraction systems and surgical access systems.

Our issued patents begin to expire in 2018. We have multiple patents covering unique aspects and improvements for many of our products. 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 NeuroVision®, through a comprehensive strategy covering various important aspects of our neurophysiology-enabled instrumentation, including, screw test, nerve root retraction, surgical access and related methodology. Our NeuroVision patent portfolio includes 9 issued U.S. patents, 27 U.S. patent applications (including 25 U.S. utility applications, 1 U.S. provisional application, and 1 U.S. design application), 8 issued foreign national patents, 6 international (PCT) patent applications, and 24 foreign national applications on this system and related instrumentation.

We obtained a U.S. Patent with broad claims protecting our SpheRx® pedicle screw system. In addition to this issued patent, we have several patent applications pending on the SpheRx pedicle screw system and related instrumentation, including 6 U.S. utility applications, 2 U.S. provisional applications, 1 international (PCT) application, and 3 foreign national applications.

We acquired a substantial intellectual property portfolio as part of our purchase of the NeoDisc investigational device from Pearsalls Limited. This portfolio has been expanded since acquisition and now includes 1 issued U.S. patent, 9 U.S. applications (including 4 U.S. utility applications and 5 U.S. provisional applications), 10 issued foreign national patents, 3 international (PCT) applications, and 11 foreign national applications.

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. Any claim relating to infringement of patents that is successfully asserted against us may require us to pay substantial damages. Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Our success will also depend in part on our not infringing patents issued to others, including our competitors and potential competitors. If

our products are found to infringe the patents of others, our development, manufacture and sale of such potential products could be severely restricted or prohibited. In addition, our competitors may independently develop similar technologies. Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to 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.

Table of Contents

A patent infringement suit brought 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. 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. 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. 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.

Trademarks

As of December 31, 2006, we have 57 trademark registrations, both domestic and foreign, including the following U.S. trademarks: NuVasive, NeuroVision, MaXcess, XLIF, SpheRx, DBR, CoRoent, SmartPlate, Creative Spine Technology, Triad, INS-1, Spine Evolution Nucleus, SEN, InStim, and Absolute Responsiveness. We have 16 trademark applications pending, both domestic and foreign, for the following trademarks: MAS, NeoDisc, ExtenSure, CerPass, Nerve Avoidance Leader, XL TDR, XTDR, XLDR, and XLP.

Competition

We are aware of a number of major medical device companies that have developed or plan to develop products for minimally invasive spine surgery 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 Nicolet Biomedical and Axon Systems. We believe our system competes favorably with Nicolet s and Axon s systems on both price and ease of use for the spine surgeon, with the added advantage that our NeuroVision System was designed to support surgeon directed applications. Medtronic Sofamor Danek has also introduced its NIM system for nerve monitoring. The NIM system is not surgeon directed and requires manual interpretation. Several companies offer products that compete with our MaXcess system, SpheRx pedicle screw system and implants, including competitive offerings by DePuy Spine, Inc., a Johnson & Johnson company, Medtronic Sofamor Danek and Stryker Spine.

Competition is intense in the fusion product market. We believe that our most significant competitors are Medtronic Sofamor Danek, DePuy Spine, Stryker Spine and Synthes-Stratec, Inc., each of which has substantially greater sales and financial resources than we do. Medtronic Sofamor Danek, in particular, has a broad classic fusion product line. We believe our differentiation in the market is based on packaging the allograft in a saline solution, which allows the product to be used immediately and does not require specialized handling.

We also face competition from a growing 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 Abbott Spine, Inc. (an Abbott Laboratories company), Orthofix International N.V. (Blackstone Medical, Inc.), Alphatec Spine Inc., OsteoTec Ltd, and others.

Table of Contents

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. Both premarket clearance and premarket approval applications are subject to the payment of user fees, paid at the time of submission for FDA review.

510(k) Clearance Pathway

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

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require premarket approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer s determination. If the FDA disagrees with a manufacturer s determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. If the FDA requires us to seek 510(k) clearance or

premarket approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties. We have made and plan to continue to make additional product enhancements that we believe do not require new 510(k) clearances.

Premarket Approval Pathway

A premarket approval 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, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA s satisfaction the safety and efficacy of the device for its intended use.

Table of Contents

After a premarket approval application is complete, the FDA begins an in-depth review of the submitted information, 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 premarket approval applications or premarket approval application supplements are required for significant modifications to the manufacturing process, labeling and design of a device that is approved through the premarket approval process. Premarket approval supplements often require submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials

A clinical trial is almost always required to support a premarket approval 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 investigational device exemption 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 investigational device exemption requirements. Clinical trials for a significant risk device may begin once the investigational device exemption application is approved by the FDA and the responsible institutional review boards. Future clinical trials of our motion preservation designs and interbody implants will likely require that we obtain an IDE from the FDA prior to commencing clinical trials. In 2005, we filed for IDE from the FDA with respect to NeoDisc, our embroidery cervical disc replacement device, and CerPass, our other cervical total disc replacement device. Our clinical trials must be conducted in accordance with FDA regulations and other federal regulations concerning human subject protection and privacy. 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;

Table of Contents

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 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.

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 25 of the major 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. In 2001, we successfully passed our initial Notified Body audit, 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.

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. These third-party payers may deny reimbursement if they feel that a device is not the most cost-effective treatment available, or was used for an unapproved indication. Also, 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 considered cost-effective by third-party payers, that reimbursement will be available or, if available, that the third-party payers reimbursement policies will not adversely affect our ability to sell our products profitably.

Particularly in the United States, third-party payers carefully review, and increasingly challenge, the prices charged for procedures and medical products. 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.

Table of Contents

Shareowners (our employees)

As of December 31, 2006, we had 233 shareowners, of which 30 were employed in research and development, 6 in clinical and regulatory, 118 in general and administrative and operations and 79 in sales and marketing. None of our shareowners is represented by a labor union and we believe our shareowner relations are good.

Corporate Information

Our business was incorporated in Delaware in July 1997. Our principal executive offices are located at 4545 Towne Centre Court, 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 2006.

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***

An investment in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below together with all other information contained or incorporated by reference in this prospectus before you decide to invest in our common stock. 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.

Risks Related to Our Business and Industry

Pricing pressure from our competitors and sources of medical reimbursement may impact our ability to sell our products at prices necessary to expand our operations and reach 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.

Further, sales of our products will depend on the availability of adequate reimbursement from third-party payors. Healthcare providers, such as hospitals that purchase medical devices for treatment of their patients, generally rely on third-party payors to reimburse all or part of the costs and fees associated with the procedures performed with these devices. 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. 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 payors 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

Table of Contents

in international markets vary significantly by country, and include both government sponsored healthcare and private insurance.

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., 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 spine surgeons, hospitals, other healthcare providers and third-party payors;
- large and established distribution networks with significant international presence;
- products supported by long-term clinical data;
- greater experience in obtaining and maintaining United States Food and Drug Administration, or FDA, and other regulatory approvals or clearances for products and product enhancements;
- more expansive portfolios of intellectual property rights; and
- greater financial and other resources for product research and development, sales and marketing and litigation.

In addition, the spine industry is becoming increasingly crowded with new market entrants, including companies owned at least partially by spine surgeons. Many of these new competitors focus on a specific product or market segment, making it more difficult for us to expand our overall market position. If these companies become successful, we expect that competition will become even more intense, leading to greater pricing pressure and making it more difficult for us to expand.

To be commercially successful, we must convince spine surgeons that our products are an attractive alternative to existing surgical treatments of spine disorders.

We believe spine surgeons may not widely adopt our products unless they determine, based on experience, clinical data and published peer reviewed journal articles, that our products provide benefits or an attractive alternative to conventional modalities of treating spine disorders. Surgeons may be slow to change their medical treatment practices for the following reasons, among others:

lack of experience with our products;

lack of evidence supporting additional patient benefits;

perceived liability risks generally associated with the use of new products and procedures;

limited availability of reimbursement within healthcare payment systems;

costs associated with the purchase of new products and equipment; and

Table of Contents

the time that must be dedicated for training.

In addition, we believe recommendations and support of our products by influential surgeons are essential for market acceptance and adoption. If we do not receive support from such surgeons or have favorable long-term data, surgeons and hospitals may not use our products. In such circumstances, we may not achieve expected revenues and may never become profitable.

Our failure to continue building an effective and exclusive distribution network for our products could significantly impair our ability to increase sales of our products.

We utilize a hybrid model of independent sales agencies and directly-employed sales professionals for product sales. The majority of the sales professionals selling our products are paid on a commission basis. We have recently completed a significant effort to convert our sales force to exclusivity, meaning their spine sales efforts are focused exclusively on our products. This transition process has been lengthy and expensive. In order to realize benefits from this large investment of time, money and resources, our sales force must continue to grow and expand sales of our products, which all of our sales projections and budgeting processes have assumed. Since this sales force is extremely new, there is risk that unanticipated problems will be encountered with generating sales and introducing customers to our products. Any failure to generate expected sales would adversely affect our operational results.

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

It is important to our business that we continue to build a more complete product offering to surgeons and hospitals. As such, our success will depend in part on our ability to 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 develop, obtain regulatory approval for or market new products or that any of our future products will be accepted by the surgeons who use our products or the payors who financially support many of the procedures performed with our products.

The success of any new product offering or enhancement to an existing product will depend on several factors, including our ability to:

properly identify and anticipate surgeon and patient needs;

develop and introduce new products or product enhancements in a timely manner;

develop products based on technology that we acquire, such as the technology recently acquired from Pearsalls Limited, RSB Spine LLC, and Radius Medical, LLC;

avoid infringing upon the intellectual property rights of third parties;

demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials;

obtain the necessary regulatory clearances or approvals for new products or product enhancements;

provide adequate training to potential users of our products;

Receive adequate reimbursement; and

develop an effective and dedicated marketing and distribution network.

If we do not develop new products or product enhancements in time to meet market demand or if there is insufficient demand for these products or enhancements, our results of operations will suffer.

We may encounter difficulties in integrating acquired products, technologies or businesses, which could adversely affect our business.

We recently acquired products and/or assets from each of Radius Medical, LLC, Pearsalls Limited, RSB Spine LLC, and RiverBend Design LLC, and may in the future acquire technology, products or businesses related to our

Table of Contents

current or future business. We have limited experience in acquisition activities and may have to devote substantial time and resources in order to complete any future acquisitions. Further, these 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 biologic product rights we recently acquired from Radius Medical, LLC). 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. Further, products we acquire, such as the biologic product we acquired from Radius Medical, LLC or the cervical plate we acquired from RSB Spine LLC, may not provide the intended complementary fit with our existing products. In addition, certain acquired technology, such as that acquired from Pearsalls Limited, requires significant additional development work and efforts to obtain regulatory clearance or approval. An acquisition may further strain our existing financial and managerial controls, and divert management s attention away from our other business concerns. In connection with in-process research and development activities, we would likely experience an increase in development expenses and capital expenditures. There may also be unanticipated costs and liabilities associated with an acquisition that could adversely affect our operating results.

We are dependent on single source suppliers and manufacturers for certain of our products and components, and the loss of any of these suppliers or manufacturers, or their inability to supply us with an adequate supply of materials could harm our business.

We rely on third-party suppliers and manufacturers to manufacture and supply 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. Manufacturers often experience difficulties in scaling up production, including problems with production yields and quality control and assurance, especially with products such as allograft which is processed human tissue. 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.

Additionally, 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 from Invibio.

In addition, we have an exclusive supply arrangement with Peak Industries, Inc., pursuant to which Peak Industries is our exclusive supplier of NeuroVision systems. In the event Peak Industries ceases to supply us, which it may do at any time, we would be forced to locate a suitable alternative supplier. We believe the start-up time to establish a new supply of NeuroVision would be approximately 16 to 20 weeks. We have established an inventory of NeuroVision systems to help us bridge any downtime in the event Peak Industries ceases to supply us; however, this inventory may be depleted before we are able to engage an alternate supplier. Any inability to meet our customers demands for NeuroVision systems could lead to decreased sales and harm our reputation, which could cause the market price of our common stock to decline.

Maxigen Biotech, Inc., or MBI, is our exclusive supplier of our recently-acquired 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. As this is a new relationship, we have no prior experience dealing with MBI and there can be no assurance that this supply arrangement will function as successfully as we hope. Specifically, we will require that

Table of Contents

MBI significantly expand its manufacturing capacity to meet our 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, our ability to integrate our Formagraft product into our product line will be substantially harmed, 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. In addition, due to seasonal changes in mortality rates, some scarce tissues used for our allograft implants are at times in particularly short supply. We cannot be certain that our supply of allograft implants from Tissue Banks International and U.S. Tissue and Cell will be available at current levels or will be sufficient to meet our needs. If we are no longer able to obtain allograft implants from these sources in amounts sufficient to meet our needs, we may not be able to locate and engage replacement sources of allograft implants on commercially reasonable terms, if at all. Any interruption of our business caused by the need to locate additional sources of allograft implants could significantly harm our revenues, which could cause the market price of our common stock to decline.

Any failure in our efforts to successfully generate business from hospitals following surgeon training could significantly reduce the market acceptance of our products.

There is a learning process involved for spine surgeons to become proficient in the use of our products. It is critical to the success of our commercialization efforts to train a sufficient number of spine surgeons and to provide them with adequate instruction in the use of our products. This training process may take longer than expected and may therefore affect our ability to increase sales. Convincing surgeons to dedicate the time and energy necessary for adequate training is challenging, and we cannot assure you we will be successful in these efforts. If surgeons are not properly trained, they may misuse or ineffectively use our products. This may also result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us, any of which could have an adverse effect on our business.

Although we believe our training methods regarding surgeons are conducted in compliance with FDA and other applicable regulations, if the FDA determines that our training constitutes promotion of an unapproved use, they could request that we modify our training or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalty.

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, 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 attract and retain qualified personnel and manage and train them effectively. We must also 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. We will be dependent on our personnel and third parties to accomplish this, as well as to effectively market our products to an increasing number of surgeons. We will also depend on our personnel to develop next generation technologies.

Table of Contents

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

Several investigational devices in our development pipeline, including our NeoDisc cervical disc replacement device, Cerpass cervical total disc replacement, or TDR,and lateral lumbar 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, Cerpass 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.

We depend on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control.

As a company, we have limited experience in conducting clinical trials, demonstrated by the fact that all of our commercialized products to date have been cleared via 510(k). We recently received conditional approval of an Investigational Device Exemption, or IDE, from the FDA to begin clinical trial enrollment of our NeoDisc cervical disc replacement device. In connection with this and other planned studies, we will rely on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trial and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials or fail to ensure compliance by patients with clinical protocols or fail to comply with regulatory requirements, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for our products. Our agreements with clinical investigators and clinical sites for clinical testing place substantial responsibilities on these parties and, if these parties fail to perform as expected, our trials could be delayed or terminated. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, or the clinical data may be rejected by the FDA, and we may be unable to obtain regulatory approval for, or successfully commercialize, our devices.

Delays in the commencement or completion of clinical testing could significantly affect our product development costs. Delays in the clinical trial process may require us to engage additional clinical sites and extend our agreements with the third parties who monitor the clinical trials and collect and analyze data. Additionally, delays in the completion of, or the potential termination of, our clinical trials, will cause the commercial prospects for our investigational devices to be harmed, and our ability to generate product revenues will be delayed. In addition, many

of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a device.

Table of Contents

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. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA s satisfaction the safety and efficacy of the device for its intended use. To date, all of our products, unless exempt, have been cleared through the 510(k) process. We have no experience in obtaining premarket approval.

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. Certain of our products may be used by physicians for indications other than those cleared or approved by the FDA, but we cannot promote the products for such off-label 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.

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 may therefore prove to be less safe and effective than initially thought.

We obtained clearance to offer almost all of our products that require FDA clearance or approval through the FDA s 510(k) clearance process. The FDA s 510(k) clearance process is less rigorous than the PMA process and requires less supporting clinical data. As a result, we currently lack the breadth of published long-term clinical data supporting the safety of our products and the benefits they offer that might have been generated in connection with the PMA process. For these reasons, spine surgeons may be slow to adopt our products, we may not have comparative data that our competitors have or are generating and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes. Such results would reduce demand for our products, significantly reduce our ability to achieve expected revenues and could prevent us from becoming profitable. 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.

Table of Contents

If we or our suppliers fail to comply with the FDA s quality system regulations, the manufacture of our products could be delayed.

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 August 2003 regarding our allograft implant business, and another FDA inspection in April 2004 regarding our medical device activities. In connection with these inspections, the FDA requested minor corrective actions, which we believe we have taken, but there can be no assurance the FDA will not subject us to further enforcement action. The FDA may impose additional inspections or audits at any time.

Modifications to our marketed products may require new 510(k) clearances or premarket approvals, or may require us to cease marketing or recall the modified products until clearances are obtained.

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 requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer s decision. The FDA may not agree with any of our decisions regarding whether new clearances or approvals are necessary. If the FDA requires us to seek 510(k) clearance or premarket approval for any modification to a previously cleared product, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement that we seek additional approvals or clearances could result in delays, fines, costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA.

Risks Related to Our Financial Results and Need for Financing

We have a limited operating history, have incurred significant operating losses since inception and expect to continue to incur losses, and we cannot assure you that we will achieve profitability.

We were incorporated in Delaware in 1997, began commercial sales in 2001 and have several product offerings in both MAS and classic fusion. We have yet to demonstrate that we can generate sufficient sales of our products to become profitable. The extent of our future operating losses and the timing of profitability are difficult to predict. At December 31, 2006, we had an accumulated deficit of approximately $157 million, and cash, cash equivalents and short term investments totaling approximately $115 million, compared to approximately $19 million as of December 31, 2005. Our net loss for the twelve months ended December 31, 2006 was approximately $48 million. Even if we do achieve profitability as planned, we may not be able to sustain or increase profitability on an ongoing basis. In addition, our independent sales agents are entitled to certain payments in the event their services are terminated in connection with (or shortly following) a change of control of our company. These payments are the responsibility of our successor, but may represent an additional significant expense or reduce the price paid in connection with any such event.

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 will 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;

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

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

Table of Contents

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 (i.e., profit margins differ between our products);

timing of new product offerings, 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;

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

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

interruption in the manufacturing or distribution of our products.

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.

Risks Related to Our Intellectual Property and Potential Litigation

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. 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 the event a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time consuming and could divert our management s attention. 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 pedicle screw system, 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. Patent litigation can involve complex factual and legal

Table of Contents

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. Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Our success will also depend in part on our not infringing patents issued to others, including our competitors and potential competitors. If our products are found to infringe the patents of others, our development, manufacture and sale of such potential products could be severely restricted or prohibited. In addition, our competitors may independently develop similar technologies. Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to 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 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. 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. 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. 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 implants, 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.

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, if such reserves are not sufficient, 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 our making improper payments to physicians for consulting services, or other potential violations of 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

Table of Contents

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.

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. Certain states in which we market our products have similar anti-kickback, anti-fee splitting and self-referral laws, imposing substantial penalties for violations.

We must comply with a variety of other laws, such as laws prohibiting false claims for reimbursement under Medicare and Medicaid, which can also be triggered by violations of federal anti-kickback laws; Healthcare Insurance Portability and Accounting Act of 1996, which makes it a federal crime to commit healthcare fraud and make false statements; and the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections. In certain cases, federal and state authorities pursue actions for false claims on the basis that manufacturers and distributors are promoting unapproved or off-label uses of their products. 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.

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 our current or future activities under these laws. Any such challenge 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.

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 implants.

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 implants 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.

27

Table of Contents

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 due to many factors, including:

volume and timing of orders for our products;

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

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;

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

the acquisition or divestiture of products, assets or technology;

changes in earnings estimates or recommendations by securities analysts; and

general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

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

Recent changes in the required accounting treatment for stock options have had a material negative impact on our financial statements and may affect our stock price.

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 123R, which focuses primarily on accounting for transactions in which an entity obtains employee services through share-based payment transactions. SFAS 123R requires us to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The cost will be recognized over the period during which an employee is required to provide services in exchange for the award. We adopted SFAS 123R in the first quarter of 2006, as required. As a result, our reported earnings have been reduced, which may affect our stock price.

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;

Table of Contents

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 headquarters were relocated in January 2005 to an approximately 62,000 square foot facility in San Diego, California that is leased to us until August 2012. In 2006, we purchased an approximately 100,000 square foot building in Memphis, Tennessee that we use as our primary distribution and warehouse facility. We intend to lease additional space in 2007 to accommodate our growing business.

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. We have been dismissed from these but appeals of those dismissals are pending and the litigation is still ongoing. 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, (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.

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.

We have been involved in litigation with a former independent distributor of our products, Synergy Orthopedic Products, LLC. This case was filed on December 20, 2005, in the Superior Court of California, County of Orange. This litigation has since been settled. The settlement is not material to our business.

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, 2006.

Table of Contents

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 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
2005:		
First Quarter	$ 14.17	$ 9.86
Second Quarter	17.46	12.04
Third Quarter	21.08	16.05
Fourth Quarter	19.75	15.57
2006:		
First Quarter	$ 21.57	$ 17.19
Second Quarter	20.21	15.14
Third Quarter	21.38	15.21
Fourth Quarter	25.29	19.35

We had approximately 210 stockholders of record as of February 28, 2006. 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, 2006, 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.

Table of Contents

PERFORMANCE GRAPH

The following graph compares the cumulative total stockholder return data (through December 31, 2006) 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, and reinvestment of any dividends. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

COMPARISON OF CUMULATIVE TOTAL RETURN*
AMONG NUVASIVE, INC.,
THE NASDAQ STOCK MARKET (U.S.) INDEX
AND THE NASDAQ MEDICAL EQUIPMENT INDEX

* $100 invested on May 13, 2004 in stock or index including reinvestment of dividends.

Table of Contents

Item 6. ***Selected Financial Data.***

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

	2006	2005	2004	2003	2002
	(In thousands, except per share data)				
Statement of Operations Data:					
Total revenues	$ 98,091	$ 62,606	$ 39,090	$ 23,029	$ 12,304
Gross profit	79,063	50,214	28,862	16,238	7,001
Total operating expenses	133,289	81,708	43,502	25,473	21,768
Net loss	(47,910)	(30,339)	(14,210)	(10,127)	(15,110)
Net loss per share					
Basic and diluted	$ (1.47)	$ (1.24)	$ (0.91)	$ (6.30)	$ (13.20)
Balance Sheet Data:					
Working capital	$ 136,236	$ 32,829	$ 62,656	$ 6,139	$ 7,251
Total assets	196,184	71,490	80,752	22,371	14,932
Long-term liabilities	1,399	1,665	13	1,224	329
Total stockholders equity	$ 176,303	$ 58,136	$ 71,397	$ 10,070	$ 9,384

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 $3.6 billion in the U.S. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS[tm], as well as a growing offering of cervical and motion preservation products. Our currently-marketed products are used predominantly in spine fusion surgeries, both to enable access to the spine and to perform restorative and fusion procedures. We also focus significant research and development efforts on both MAS and motion preservation products in the areas of (i) fusion procedures in the lumbar and thoracic spine, (ii) cervical fixation products, and (iii) motion preservation products such as total disc replacement and nucleus-like cervical disc replacement. We dedicate significant resources to our sales and marketing efforts, including training spine surgeons on our unique technology and products. As of December 31, 2006, we have trained over 1,200 surgeons in the use of our products.

Our MAS platform combines three 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; and

Specialized implants, like our SpheRx® pedicle screw system and CoRoent® suite of implants.

Table of Contents

We also offer a suite of traditional spine surgery products, including a line of precision-machined cervical and lumbar allograft implants, a titanium surgical mesh system, and related instrumentation. Our line of bone allograft, in our patented saline packaging, is human bone that has been processed and precision shaped for transplant. We also offer fusion plates such as our SmartPlate Gradient CLP, a dynamic cervical plate that encompasses a gradient locking mechanism which gradually loads the screws based upon the anatomic requirements. This allows the plate to settle in concert with the settling of the allograft implant settling that occurs within the disc space over time, offering a better anatomical fit.

We also have an active product development pipeline focused on expanding our current fusion product platform as well as products designed to preserve spinal motion. In particular, we have a pivotal clinical study underway with respect to our NeoDisc cervical disc replacement device.

Since inception, we have been unprofitable. As of December 31, 2006, we had an accumulated deficit of $156.7 million.

Revenues. From inception to December 31, 2006, we have recognized $237.7 million in revenue from sales of our products. 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 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 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. These extended loan transactions historically represent less than 10% of our total stock of loaner surgical assets. Our implants and disposables are currently sold and shipped from our San Diego and Memphis facilities or from limited disposable inventories stored at our sales agents sites. We recognize revenue for disposables or implants used upon receiving a purchase order from the hospital indicating product use or implantation. In addition, we sell a small 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. 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 distribute our products through a sales force comprised of independent agencies and our own sales personnel. 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. The 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. In the second quarter of 2006, we completed our efforts to transition our sales force to one that is exclusive to us with respect to the sale of spine products. Our exclusive sales force includes independent exclusive sales agents and directly-employed sales professionals.

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) and regulations of the Securities and Exchange Commission. 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, 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

Table of Contents

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) collectibility is reasonably assured. Specifically, revenue from the sale of implants and disposables is recognized upon receipt of a purchase order from the hospital indicating product use or implantation or upon shipment to third party customers who immediately accept title. Revenue from the sale of our NeuroVision units and instrument sets is recognized upon receipt of a purchase order and the subsequent shipment to customers who immediately accept title.

Allowance for Doubtful Accounts. 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. As a result of this review, the allowance is adjusted on a specific identification basis. Increases to the allowance for doubtful accounts result in a corresponding expense. We maintain a relatively large customer base that mitigates the risk of concentration with one 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 reflect our customer s future failure to pay outstanding receivables, significant additional allowances could be required.

Excess and Obsolete Inventory and Instruments. We calculate 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 implants have a four-year shelf life and are subject to demand fluctuations based on the availability and demand for alternative implant products. Our MAS 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 expense 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 the end of their anticipated useful lives. If we introduce new products or next-generation products prior to the end of the useful life of a prior generation, we may be required to dispose of existing inventory and related capital instruments and/or write off the value or accelerate the depreciation of the these assets. We have recorded expense related to accelerated depreciation of $646,000 in the year ended December 31, 2006 related to the introduction of next generation products. These charges are more fully described below under the caption Cost of Goods Sold .

Long Term Assets. Property and equipment is carried at cost less accumulated depreciation. Depreciation is computed using the straight-line method based on the estimated useful lives of three to seven years for machinery and equipment and three years for loaner instruments. We own land and a building in Memphis, Tennessee that we use as a warehouse and distribution facility. The building is depreciated over a period of 20 years. Maintenance and repairs are expensed as incurred. Intangible assets consist of purchased technology and are amortized on a straight-line basis over their estimated useful lives of 17 years, the life of related patents.

We evaluate our long-term assets for indications of impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If this evaluation indicates that the value of the long-term 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 long-term asset is not recoverable, we reduce the net carrying value of the related asset to fair value and may adjust the remaining depreciation or amortization period. We have not recognized any impairment losses on long-term intangible assets through December 31, 2006.

Accounting for Income Taxes. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have recorded a full valuation allowance on our net deferred tax assets as of December 31, 2006 due to uncertainties related to our ability to utilize our deferred tax assets in the foreseeable future.

Table of Contents

Valuation of Stock-Based Compensation. On January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), which establishes accounting for share-based awards exchanged for employee and non-employee director services and requires us to expense the estimated fair value of these awards over the requisite service period. In March 2005, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) 107, which provided supplemental implementation guidance for SFAS 123(R). We have applied the provisions of SAB 107 in our adoption of SFAS 123(R). Prior to January 1, 2006, we accounted for our share-based employee compensation plans using the intrinsic value method under the recognition and measurement provisions of Accounting Principles Board Opinion (APB) 25, *Accounting for Stock Issued to Employees,* and related guidance. Option awards issued to non-employees are recorded at their fair value as determined in accordance with Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services,* and are periodically revalued as the options vest and are recognized as expense over the related service period.

For purposes of calculating the 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 Black-Scholes option-pricing model was developed for use in estimating the fair value of short lived exchange traded options that have no vesting restrictions and are fully transferable. In addition, the Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and interest rates. Stock-based compensation related to stock options is recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option Award Plans* (FIN 28). If there is a difference between the assumptions used in determining stock-based compensation cost and the actual factors which become known over time, we may change the input factors used in determining stock-based compensation costs. These changes, if any, may materially impact our results of operations in the period such changes are made.

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 generally accepted accounting principles (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,			2005 to 2006		2004 to 2005	
	2006	2005	2004	$ Change	% Change	$ Change	% Change
Revenue	$ 98,091	$ 62,606	$ 39,090	$ 35,485	57%	$ 23,516	60%

Revenues have increased over time due primarily to continued market acceptance of our products within our MAS platform, including NeuroVision, MaXcess disposables, and our specialized implants such as our SpheRx pedicle screw system and CoRoent suite of products. In addition, in mid-2006, we completed our transition to an exclusive sales force, which has increased the amount of effort focused on selling our products as well as the overall market penetration.

Over time, the percentage contribution to total revenue from our non-MAS products has decreased. This is in due in large part to the focus of the product development and commercialization efforts to our MAS platform.

Cost of Goods Sold

	Year Ended December 31,			2005 to 2006		2004 to 2005	
	2006	2005	2004	$ Change	% Change	$ Change	% Change
Cost of Goods Sold	$ 19,028	$ 12,392	$ 10,228	$ 6,636	54%	$ 2,164	21%
% of total revenue	19%	20%	26%				

Cost of goods sold consists of purchased goods and overhead costs, including depreciation expense for instruments.

Table of Contents

Cost of goods sold as a percentage of revenue has decreased over time due to (i) a higher portion of our sales coming from products with higher margins and (ii) efficiencies gained with growth. The year-over-year increase in cost of goods sold in total dollars in 2006 compared to 2005 and in 2005 compared to 2004 resulted primarily from (i) increased material costs of $4.2 million and $1.0 million, respectively, primarily as a result of revenue growth; and (ii) increased depreciation expense of $2.9 million and $1.2 million, respectively, due to higher capital levels of surgical instrument sets used in surgeries. We expect cost of goods sold, as a percentage of revenue, to remain relatively consistent for the foreseeable future.

In the third quarter of 2006, we launched several new products and/or product enhancements, including the MaXcess III retractor system, next generation instrument sets for spine fusion procedures and three new radiolucent CoRoent® implants. In connection with these launches, certain instruments were rendered obsolete as of the launch date. As a result, we reduced the useful life of such instruments to end on the respective launch dates and incurred additional depreciation expense of $646,000 in the second half of 2006. This depreciation expense is included in cost of goods sold in the accompanying statement of operations for the year ended December 31, 2006.

Operating Expenses

Sales, Marketing and Administrative

	Year Ended December 31,			2005 to 2006		2004 to 2005	
	2006	2005	2004	$ Change	% Change	$ Change	% Change
Sales, Marketing and Administrative	$ 95,426	$ 57,020	$ 34,142	$ 38,406	67%	$ 22,878	67%
% of total revenue	97%	91%	87%				

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; surgeon training costs; shareowner related expenses for our administrative functions; third party professional service fees; and facilities and insurance expenses. We refer to our employees as shareowners.

The year-over-year increases in sales, marketing, and administrative expenses in 2006 compared to 2005 and in 2005 compared to 2004 resulted primarily from (i) increases in compensation, commission and other shareowner-related costs, all relating to the sales force and including distributor commissions, of $20.7 million and $13.4 million in 2006 and 2005, respectively, primarily as result of our transition to sales force exclusivity in 2006 and to support revenue growth in 2006 and 2005; (ii) increases in compensation, commission and other shareowner-related costs of $2.6 million and $1.0 million in 2006 and 2005, respectively, for administrative personnel, to support overall company growth (iii) increases in royalty expense of $1.9 million and $1.2 million in 2006 and 2005, respectively, reflecting the revenue growth in all product lines; (iv) increases in postage and shipping of $1.8 million and $0.6 million in 2006 and 2005, respectively, reflecting increased sales; (v) an increase in stock-based compensation expense of $10.6 million in 2006 as a result of the adoption of SFAS 123(R); and (vi) increases in equipment and computer expenses of $1.2 million and $1.0 million in 2006 and 2005, respectively, reflecting increased headcount and overall company growth. The 2005 increases were offset by a decrease compared to 2004 in stock-based compensation of $2.3 million related to (i) amortization of deferred stock-based compensation amounts determined at the time of our initial public offering and (ii) options issued to non-employees.

In June 2006, we purchased a warehouse and distribution facility in Memphis, Tennessee. As of December 31, 2006, the total cost, including improvements, is approximately $4,840,000. The location of the facility will allow us to provide improved service to our customers. We moved substantially all of our distribution operations to this location in the third quarter of 2006.

In the second quarter of 2006, we completed our efforts to transition our sales force to one that is exclusive to us with respect to the sale of spine products. Our exclusive sales force consists of independent sales agents and directly-employed sales personnel. As expected, we incurred higher costs in the second half of 2006 associated with this sales force transition. On a long-term basis, as a percentage of revenue, we expect sales, marketing and administrative costs to decrease over time as we begin to see the synergies of investments we have made (such as our sales force exclusivity transition).

Table of Contents

Research and Development

	Year Ended December 31,			2005 to 2006		2004 to 2005	
	2006	2005	2004	$ Change	% Change	$ Change	% Change
Research & Development	$ 17,747	$ 11,791	$ 9,360	$ 5,956	51%	$ 2,431	26%
% of total revenue	18%	19%	24%				

Research and development expense consists primarily of product research and development, regulatory and clinical functions, and shareowner-related expenses. During 2006 and 2005, we launched a number of products and product enhancements, including in 2006, our next generation instrument sets for spine fusion procedures, the MaXcess III retractor system, and CoRoent implant line extensions, and in 2005, NeuroVision upgrades, SpheRx DBR and CoRoent line extensions. In addition, in 2006, we commenced patient enrollment in our NeoDisc clinical trial, all of which resulted in increased research and development costs.

The year-over-year increases in research and development costs in 2006 compared to 2005 and in 2005 compared to 2004 are primarily due to increases in (i) compensation and other shareowner related expenses of $2.2 million and $2.0 million in 2006 and 2005, respectively, primarily due to increased headcount to support our product development and enhancement efforts; (ii) lab supplies and equipment expenses of $1.6 million and $1.2 million in 2006 and 2005, respectively, to support the development of new products in all product lines; and (iii) stock-based compensation expense of $2.8 million in 2006, as a result of the adoption of SFAS 123(R). The 2005 increases were offset by a decrease compared to 2004 in stock based compensation of $811,000 related to (i) amortization of deferred stock-based compensation amounts determined at the time of our initial public offering and (ii) options issued to non-employees.

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

Interest and Other Income/(Expense), Net

	Year Ended December 31,			2005 to 2006		2004 to 2005	
	2006	2005	2004	$ Change	% Change	$ Change	% Change
Interest and Other Income (Expense), net	$ 6,316	$ 1,155	$ 430	$ 5,161	447%	$ 725	169%
% of total revenue	6%	2%	1%				

Interest and other income (expense), net consists primarily of interest income. The increases in net interest income in 2006 compared to 2005 and in 2005 compared to 2004 are due primarily to interest earned on the investment of proceeds of (i) $142.0 million received from our secondary public offering completed in February 2006 and (ii) $68.1 million received from our initial public offering completed in May 2004.

Stock-Based Compensation

The compensation cost that has been included in the statement of operations for all share-based compensation arrangements was as follows for the years ended December 31, 2006, 2005 and 2004:

	Year Ended December 31,			2005 to 2006		2004 to 2005	
	2006	2005	2004	$ Change	% Change	$ Change	% Change
Stock-Based Compensation							
Sales, Marketing & Administrative	$ 10,581	$ 1,635	$ 3,927	$ 8,946	547%	$ (2,292)	(58)%
Research & Development	2,764	1,405	2,216	$ 1,359	97%	$ (811)	(37)%
Total Stock-Based Compensation	$ 13,345	$ 3,040	$ 6,143	$ 10,305	339%	$ (3,103)	(51)%
% of total revenue	14%	5%	16%				

Table of Contents

On January 1, 2006, we adopted the fair value recognition provisions of SFAS 123(R), which establishes accounting for share-based awards exchanged for shareowner and non-employee director services and requires us to expense the estimated fair value of these awards over the requisite service period. In March 2005, the SEC issued Staff Accounting Bulletin (SAB) 107, which provided supplemental implementation guidance for SFAS 123(R). We have applied the provisions of SAB 107 in our adoption of SFAS 123(R). Prior to January 1, 2006, we accounted for our share-based awards to shareowners and directors using the intrinsic value method under the recognition and measurement provisions of APB 25.

Through December 31, 2005, we recorded deferred stock-based compensation for certain options granted during 2003 and 2004, of $0.8 million and $7.8 million, respectively, for the incremental difference at the grant date between the fair value per share determined by the board of directors and the deemed fair value per share determined solely for financial reporting purposes in conjunction with our initial public offering. Amortization of deferred stock-based compensation through December 31, 2005, net of terminations, was $7.2 million; $2.3 million and $4.9 million in 2005 and 2004, respectively. Upon adoption of SFAS 123(R), the unamortized balance of deferred compensation of $1.2 million at December 31, 2005 was reclassified to additional paid in capital in our consolidated balance sheet. Future compensation expense calculated using the fair value provisions of SFAS 123 related to these options will be included as a component of stock-based compensation included in our statement of operations.

We have elected to adopt the modified prospective transition method permitted by SFAS 123(R) and accordingly prior periods have not been restated to reflect the impact of SFAS 123(R). The modified prospective transition method requires that stock-based compensation expense be recorded for (i) any share-based awards granted to shareowners and non-employee directors through, but not yet vested as of December 31, 2005, based on the grant-date fair value estimated in accordance with the pro forma provisions of SFAS 123, *Accounting for Stock-Based Compensation* (SFAS 123), and (ii) any share-based awards granted to shareowners and non-employee directors subsequent to December 31, 2005, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R).

Stock-based compensation related to stock options is recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option Award Plans* (FIN 28). As of December 31, 2006, there was $9.1 million of unrecognized compensation expense for stock options which is expected to be recognized over a weighted-average period of approximately 1.2 years. In addition, as of December 31, 2006, there was $0.5 million of unrecognized compensation expense for shares expected to be issued under the employee stock purchase plan that will be recognized through April 2007.

Business Combination and Asset Acquisitions

RSB Spine LLC. On June 3, 2005, we acquired intellectual property and related assets for cervical plate technology from RSB Spine LLC, or RSB,, a privately owned company focused on spine technology (the RSB Acquisition), providing us with cervical plate technology that received FDA 510(K) clearance and was first commercialized in 2004. We made a closing payment of $7.3 million, consisting of $3.8 million in cash and $3.5 million in unregistered common stock which has since been registered for resale. In addition, the acquisition agreement provides for additional payments of $1.2 million over a period of four years and contingent payments over a period of 12 years based upon the sale of the products derived from the cervical plate technology. We re-launched the cervical plate under our own product name (the SmartPlate Gradient CLP) in July 2005. The RSB Acquisition and its impact to our consolidated statement of position and results of operations are fully described in Note 2 to the consolidated financial statements included in this report.

Pearsalls Limited. On August 4, 2005, we acquired technology and assets from Pearsalls Limited, or Pearsalls, a privately-owned company based in the United Kingdom (Pearsalls). The acquired assets include an investigational

nucleus-like cervical disc replacement device called NeoDisc[tm] . Also acquired was all of Pearsall s intellectual property related to embroidery technology for use in surgical implants. We made a closing payment of $12.0 million, consisting of $5.0 million in cash and $7.0 million in unregistered common stock which has since been registered for resale. In addition, the original transaction provided for us to make additional milestone

Table of Contents

payments totaling up to $31.5 million as progress is made towards FDA approval for marketing of the NeoDisc investigational device and to pay a royalty of 5% on NeoDisc product sales.

In June 2006, we received conditional FDA approval of our Investigational Device Exemption to begin clinical trial enrollment for our NeoDisc cervical disc replacement device. This FDA approval was a development milestone under the agreement by which we acquired the underlying technology, and resulted in a payment obligation by us of $10.5 million which we accrued in the second quarter of 2006. In September 2006, we entered into an agreement with Pearsalls Limited, the seller of the underlying technology, resulting in a total payment of $20.0 million in settlement of (i) the $10.5 million liability recorded in the second quarter of 2006; (ii) future contingent milestone payments of $21.0 million; and (iii) all future contingent royalty payments to Pearsalls; all of which relate to NeoDisc and related technology. The terms of the agreement also render the manufacturing relationship for NeoDisc non-exclusive, giving us control over the manufacturing of NeoDisc, and effects the full transfer of intellectual property rights to NuVasive. The $20 million payment consisted of $12 million in cash and $8 million in common stock. The total charge recorded in 2006 was $20.1 million, including transaction costs.

This transaction and its impact to our consolidated statement of position and results of operations are fully described in Note 3 to the consolidated financial statements included in this report.

RiverBend Design LLC. On August 12, 2005, we acquired assets and intellectual property from RiverBend Design LLC, or RiverBend, pursuant to the terms of an Intellectual Property Purchase Agreement. The acquired intellectual property includes a patent application and related technology and know-how for use in developing dynamic stabilization products. We made a closing payment to RiverBend of 51,308 unregistered shares of common stock valued at $1.0 million for accounting purposes. In addition, we will make royalty payments to RiverBend based on sales of products based on the acquired technology. The purchase price of $1.0 million has been allocated to purchased technology and is being amortized over a useful life of 17 years.

Radius Medical LLC. On January 23, 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. We made a closing payment of $5,663,000 in cash and 451,677 unregistered shares of our common stock, which were subsequently registered. We also funded at closing $2,000,000 in cash into an escrow account for the benefit of Radius, which will be maintained for a period of 18 months. In addition, on the effective date of the registration statement to register the common shares issued on the closing date, a cash payment will be made (i) by Radius to NuVasive in the amount by which the trading value of the shares, as defined, exceeds $10,200,000, or (ii) by NuVasive to Radius in the amount by which the trading value of the Shares, as defined, is less than $10,200,000. On February 13, 2007, the registration statement was declared effective and the adjustment to the purchase was determined to be $694,000, payable by Radius to NuVasive. As part of the acquisition, we also acquired certain rights and obligations under a supply agreement with Maxigen Biotech, Inc with respect to product manufacture.

This transaction and its impact to our consolidated statement of position and results of operations are fully described in Note 8 to the consolidated financial statements included in this report.

In-Process Research and Development

In 2005, we recorded an in-process research and development (IPRD) charge of $12.9 million related to our acquisition of the technology assets of Pearsalls Limited in the third quarter of 2005. At the date of the acquisition, the projects associated with the IPRD 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 date.

Valuation of IPRD. The value assigned to acquired in-process technology is determined by identifying products under research in areas for which technological feasibility had not been established. The value of the in-process technology was determined using a discounted cash flow model similar to the income approach, focusing on the income producing capabilities of the in-process technologies. Under this approach, the value is determined by estimating the revenue contribution generated by each of the identified technologies. Revenue estimates were based on (i) individual product revenues, (ii) anticipated growth rates, (iii) anticipated product development and

Table of Contents

introduction schedules, (iv) product sales cycles, and (v) the estimated life of a product s underlying technology. From the revenue estimates, operating expense estimates, including costs of sales, general and administrative, selling and marketing, and income taxes, were deducted to arrive at operating income. Revenue growth rates were estimated by management for the product and gave consideration to relevant market sizes and growth factors, expected industry trends, the anticipated nature and timing of new product introductions by us and our competitors, individual product sales cycles and the estimated life of the product s underlying technology. Operating expense estimates reflect NuVasive s historical expense ratios. Additionally, these projects will require continued research and development after they have reached a state of technological and commercial feasibility. The resulting operating income stream was discounted to reflect its present value at the date of acquisition.

The rate used to discount the net cash flows from purchased in-process technology is our weighted-average cost of capital (WACC), taking into account our required rates of return from investments in various areas of the enterprise and reflecting the inherent uncertainties in future revenue estimates from technology investments including the uncertainty surrounding the successful development of the acquired in-process technology, the useful life of such technology, the profitability levels of such technology, if any, and the uncertainty of technological advances, all of which are unknown at this time.

Liquidity and Capital Resources

Since our inception in 1997, we have incurred significant losses and as of December 31, 2006, we had an accumulated deficit of approximately $156.7 million. We have not yet achieved profitability, and do not expect to be profitable in 2007 after considering stock compensation expense. We expect our research and development, sales, marketing and general and administrative expenses will continue to grow and, as a result, we will need to generate significant net sales to achieve profitability. To date, our operations have been funded primarily with proceeds from the sale of our equity securities. Gross proceeds from our preferred stock sales, which occurred from inception through 2003, total $74.4 million. In May 2004, we completed our initial public offering, resulting in net proceeds to us of approximately $68.1 million. In February 2006, we completed the sale of 7,829,120 shares of our common stock resulting in total net proceeds of approximately $142.0 million.

Cash, cash equivalents and short-term investments was $115.4 million at December 31, 2006 and $19.5 million at December 31, 2005. The increase was due primarily to proceeds from the February 2006 sale of common stock.

Net cash used in operating activities was $25.6 million in 2006 compared to $19.9 million in 2005. The increase of net cash used in operating activities of $5.7 million was primarily due to increased inventory purchases to support 2006 product launches of $8.9 million and increased accounts receivable of $7.4 million as a result of increased sales, offset by increased accounts payable and accrued liabilities of $6.7 million, both as a result of company growth.

Net cash used in investing activities was $89.8 million in 2006 compared to net cash provided by investing activities of $22.1 million in 2005. The increase in net cash used by investing activities of $111.9 million is primarily due to the investment of the net proceeds of $142.0 million from the February 2006 sale of our common stock, offset by purchases of capital equipment, instruments and the distribution center in Memphis, Tennessee.

Net cash provided by financing activities was $144.4 million in 2006 compared to $1.7 million in 2005. The increase in net cash provided by financing activities of $142.7 million is primarily due to the receipt of net proceeds of $142.0 million from the issuance of common stock in February 2006.

We believe our current cash and cash equivalents together with our short-term investments and the cash to be generated from expected product sales, will be sufficient to meet our projected operating requirements for at least the next 12 months.

Contractual Obligations and Commitments

We are committed under operating leases and other contractual obligations. Our operating lease commitments are related to our corporate headquarters lease which continues through August 2012. The rent expense related to our corporate headquarters lease will be recorded on a straight-line basis in accordance with generally accepted accounting principles.

Table of Contents

The following summarizes our long-term contractual obligations and commitments as of December 31, 2006 *(in thousands)*:

	Payments Due by Period				
	Total	Less Than 1 Year	1 to 3 Years	4 to 5 Years	After 5 Years
Operating leases	$ 7,260	$ 1,194	$ 3,801	$ 2,265	$
Deferred consideration payments under acquisition agreements	950	300	650		
Royalty obligations	13,072	1,665	4,323	2,731	4,353
Total	$ 21,282	$ 3,159	$ 8,774	$ 4,996	$ 4,353

In connection with the 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 the cervical plate technology.

In addition, 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.

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.

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

Our exposure to interest rate risk at December 31, 2006, 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.

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 not had any material exposure to foreign currency rate fluctuations.

Interest Rate Risk. 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.

41

Table of Contents

The following table presents the carrying value and related weighted-average rate of return for our investment portfolio as of December 31, 2006:

	Carrying Value (In thousands)	Weighted Average Rate of Return
Classified as Current Assets:		
Money Market Funds	$ 8,910	5.27%
Commercial Paper with initial maturities of 90 days or less	19,378	5.34%
Commercial Paper with initial maturities of greater than 90 days	47,330	5.21%
Auction Rate Securities	26,600	5.28%
	102,218	
Less cash equivalents	28,288	
Short-term investments	73,930	
Classified as Non-Current Assets:		
Federal Agencies	1,996	5.28%
Total interest bearing instruments	$ 75,926	

As of December 31, 2006, the stated maturities of our investments are $102.2 million within one year and $2.0 million within one to two years. These investments are recorded on the balance sheet at fair market value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income.

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, 2006. Based on such evaluation, our management has concluded as of December 31, 2006, the Company s disclosure controls and procedures are effective.

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

Table of Contents

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, 2006. Ernst & Young LLP, the Company s independent registered public accounting firm, has issued an attestation report on management s assessment of the Company s internal control over financial reporting which is included herein.

Changes in Internal Control over Financial Reporting. There has been no change to our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The Board of Directors and Stockholders
NuVasive, Inc.

We have audited management s assessment, included in the accompanying Management s Report on Internal Control over Financial Reporting, that NuVasive, Inc. maintained effective internal control over financial reporting as of December 31, 2006, 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. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the company s internal control over financial reporting based on our audit.

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

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

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

In our opinion, management s assessment that NuVasive, Inc. maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, NuVasive, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of NuVasive, Inc. as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2006 of NuVasive, Inc. and our report dated March 12, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
March 12, 2007

Table of Contents

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

None

PART III

Certain information required by Part III is omitted from this report because the Company will file a definitive proxy statement within 120 days after the end of its fiscal year pursuant to Regulation 14A (the Proxy Statement) for its annual meeting of stockholders to be held on May 24, 2007, and certain information included in the Proxy Statement is incorporated herein by reference.

Item 10. ***Directors and Executive Officers of the Registrant.***

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

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

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

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

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

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

Item 13. ***Certain Relationships and Related Transactions.***

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

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

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

PART IV

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

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

(1) Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2006 and 2005

Consolidated Statements of Operations for the years ended December 31, 2006, 2005 and 2004

Consolidated Statements of Stockholders Equity for the years ended December 31, 2006, 2005 and 2004

Table of Contents

Consolidated Statements of Cash Flows for the years ended December 31, 2006, 2005 and 2004

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules: Schedule II Valuation Accounts

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

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

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

Exhibit Number	Description
2.1(1)	Asset Purchase Agreement, dated as of June 3, 2005, by and between NuVasive, Inc. and RSB Spine LLC
2.2(2)	Agreement, dated as of January 3, 2007, by and between NuVasive, Inc. and RSB Spine LLC
2.3(3)	Asset Purchase Agreement, dated as of August 4, 2005, by and among NuVasive, Inc., Pearsalls Limited and American Medical Instruments Holdings, Inc.
2.4(4)	Amendment No. 1 to Asset Purchase Agreement, dated as of September 26, 2006, by and among NuVasive, Inc., Pearsalls Limited and American Medical Instruments Holdings, Inc.
2.5(5)	Intellectual Property Purchase Agreement, dated as of August 12, 2005, by and between NuVasive, Inc. and RiverBend Design LLC
2.6(6)	Asset Purchase Agreement, dated as of January 23, 2007, by and among NuVasive, Inc. and Radius Medical, LLC, Biologic, LLC, Antone Family Partners, Russel Cook and Duraid Antone
3.1(7)	Restated Certificate of Incorporation
3.2(7)	Restated Bylaws
4.1(8)	Second Amended and Restated Investors Rights Agreement, dated July 11, 2002, by and among NuVasive, Inc. and the other parties named therein
4.2(8)	Amendment No. 1 to Second Amended and Restated Investors Rights Agreement, dated June 19, 2003, by and among NuVasive, Inc. and the other parties named therein
4.3(8)	Amendment No. 2 to Second Amended and Restated Investors Rights Agreement, dated February 5, 2004, by and among NuVasive, Inc. and the other parties named therein
4.4(3)	Registration Rights Agreement, dated as of August 4, 2005, between NuVasive, Inc. and Pearsalls Limited
4.5(4)	Registration Rights Agreement Termination Agreement, dated as of September 26, 2006, between NuVasive, Inc. and Pearsalls Limited
4.6(19)	Specimen Common Stock Certificate
10.1(8)#	1998 Stock Option/ Stock Issuance Plan
10.2(8)#	Form of Notice of Grant of Stock Option under our 1998 Stock Option/ Stock Issuance Plan
10.3(8)#	Form of Stock Option Agreement under our 1998 Stock Option/ Stock Issuance Plan, and form of addendum thereto
10.4(8)#	Form of Stock Purchase Agreement under our 1998 Stock Option/ Stock Issuance Plan
10.5(9)#	Form of Stock Issuance Agreement under our 1998 Stock Option/ Stock Issuance Plan
10.6(9)#	

	Form of Stock Issuance Agreement under our 1998 Stock Option/ Stock Issuance Plan, dated April 21, 2004, and May 4, 2004
10.7(10)#	2004 Equity Incentive Plan
10.8(10)#	Form of Stock Option Award Notice under our 2004 Equity Incentive Plan
10.9(10)#	Form of Option Exercise and Stock Purchase Agreement under our 2004 Equity Incentive Plan
10.10(10)#	Forms of Restricted Stock Grant Notice and Restricted Stock Agreement under our 2004 Equity Incentive Plan
10.11(10)#	Form of Restricted Stock Unit Award Agreement under our 2004 Equity Incentive Plan

Table of Contents

Exhibit Number	Description
10.12(10)#	2004 Employee Stock Purchase Plan
10.13(11)#	Employment Letter Agreement, dated July 12, 1999, as amended on January 20, 2004 and May 23, 2006, between NuVasive, Inc. and Alexis V. Lukianov
10.14(8)#	Bonus Agreement, dated February 25, 2000, between NuVasive, Inc. and Alexis V. Lukianov
10.15(8)#	Employment Agreement, dated December 20, 2002, as amended on January 20, 2004, between NuVasive, Inc. and Kevin C. O Boyle
10.16(11)#	Employment Agreement, dated January 20, 2004, as amended on May 23, 2006, between NuVasive, Inc. and Keith Valentine
10.17(8)#	Employment Agreement, dated January 20, 2004, between NuVasive, Inc. and Patrick Miles
10.18(8)#	Employment Agreement, dated January 20, 2004, between NuVasive, Inc. and James J. Skinner
10.19(8)#	Employment Agreement, dated January 20, 2004, between NuVasive, Inc. and G. Bryan Cornwall
10.20(8)#	Employment Agreement, dated January 20, 2004, between NuVasive, Inc. and Jonathan D. Spangler
10.21(12)#	Employment Agreement, dated December 5, 2005, between NuVasive, Inc. and Jeffrey P. Rydin
10.22(12)#	Employment Agreement, dated December 5, 2005, between NuVasive, Inc. and Jason M. Hannon
10.23(8)#	Form of Indemnification Agreement between NuVasive, Inc. and each of our directors and officers
10.24	Patent Purchase Agreement, dated June 21, 2002, by and among NuVasive, Inc. and Drs. Anthony Ross and Peter Guagliano
10.25(8)	Intellectual Property Purchase Agreement, dated October 10, 2002, between NuVasive, Inc. and Spine Partners, LLC
10.26(5)	Intellectual Property Purchase Agreement Addendum, dated as of August 12, 2005, by and between NuVasive, Inc. and Spine Partners, LLC
10.27(10)	Development, Production and Marketing Services Agreement, dated December 30, 1999, as amended, by and between NuVasive, Inc. and Tissue Banks International, Inc.
10.28(10)	Supply Agreement, dated January 21, 2002, by and between NuVasive, Inc. and Intermountain Tissue Center
10.29(10)	Clinical Advisor, Patent Purchase and Development Agreement, dated March 31, 2004, by and between NuVasive, Inc. and James L. Chappuis
10.30(13)	Sublease, dated October 12, 2004, by and between NuVasive, Inc. and Gateway, Inc.
10.31(14)	Supply Agreement, dated January 14, 2005, by and between NuVasive, Inc. and Blood and Tissue Center of Central Texas
10.32(3)	Exclusive Manufacturing Agreement, dated as of August 4, 2005, by and between NuVasive, Inc. and Pearsalls Limited
10.33(4)	Amendment No. 1 to Exclusive Manufacturing Agreement and Services Agreement, dated as of September 26, 2006, by and between NuVasive, Inc. and Pearsalls Limited
10.34(15)	Master Technology and Services Agreement, dated September 2, 2005, and Master Technology and Services Agreement Amendment #1, dated December 16, 2005, each by and between NuVasive, Inc. and Medidata Solutions, Inc.
10.35(11)	Earnest Money Contract and Agreement, dated May 26, 2006, between NuVasive, Inc. and New York Life Insurance Company
10.36(16)#	Description of 2006 performance bonus arrangements for our executive officers
10.37(17)#	Description of 2007 annual salaries for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
10.38(18)#	Summary of the 2007 bonus payments to our Chief Executive Officer, our Chief Financial Officer and our other named executive officers

21.1	List of subsidiaries of NuVasive, Inc.
23.1	Consent of Independent Registered Public Accounting Firm

Table of Contents

Exhibit Number	Description
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
32.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350
32.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350

(1) Incorporated by reference to our Current Report on Form 8-K filed with the Securities and Exchange Commission (the Commission) on June 9, 2005.

(2) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 9, 2007.

(3) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 10, 2005.

(4) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on September 29, 2006.

(5) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 17, 2005.

(6) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 25, 2006.

(7) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 13, 2004.

(8) Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004.

(9) Incorporated by reference to Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on May 11, 2004.

(10) Incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on April 8, 2004.

(11) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on May 30, 2006.

(12) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on December 7, 2005.

(13) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on November 15, 2004.

(14) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 21, 2005.

(15) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on December 22, 2005.

(16) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 13, 2006.

(17) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 22, 2007.

(18) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on February 23, 2007.

(19) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 15, 2006.

The Commission has granted confidential treatment to us with respect to certain omitted portions of this exhibit (indicated by asterisks). We have filed separately with the Commission an unredacted copy of the exhibit.

# Indicates management contract or compensatory plan.

Table of Contents

SUPPLEMENTAL INFORMATION

Copies of the Registrant s Proxy Statement for the Annual Meeting of Stockholders to be held on May 24, 2007, and copies of the form of proxy to be used for such Annual Meeting, will be furnished to the SEC prior to the time they are distributed to the Registrant s Stockholders.

Table of Contents

SIGNATURES

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

NUVASIVE, INC.

By: /s/ Alexis V. Lukianov

Alexis V. Lukianov
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: March 15, 2007

By: /s/ Kevin C. O Boyle

Kevin C. O Boyle
Executive Vice President and
Chief Financial Officer
(Principal Financial Officer)

Date: March 15, 2007

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Alexis V. Lukianov Alexis V. Lukianov	Chairman and Chief Executive Officer (Principal Executive Officer)	March 15, 2007
/s/ Kevin C. O Boyle Kevin C. O Boyle	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 15, 2007
/s/ Jack R. Blair	Director	March 15, 2007

Jack R. Blair		
/s/ James C. Blair	Director	March 15, 2007
James C. Blair		

Table of Contents

Signature	Title	Date
/s/ Peter C. Farrell	Director	March 15, 2007
Peter C. Farrell		
/s/ Robert J. Hunt	Director	March 15, 2007
Robert J. Hunt		
/s/ Lesley H. Howe	Director	March 15, 2007
Lesley H. Howe		
/s/ Hansen Yuan	Director	March 15, 2007
Hansen Yuan		

Table of Contents

NUVASIVE, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
NuVasive, Inc.

We have audited the accompanying consolidated balance sheets of NuVasive, Inc. as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2006. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require