

NUVASIVE INC  
Form 10-K  
February 29, 2008

**Table of Contents**

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

**Form 10-K**

(Mark One)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2007**
- OR**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from        to**

**Commission file number: 000-50744**

**NUVASIVE, INC.**

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

**Delaware**

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

**33-0768598**

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

**4545 Towne Centre Court,  
San Diego, California**

*(Address of principal executive offices)*

**92121**

*(Zip Code)*

**Registrant's telephone number, including area code:  
(858) 909-1800**

**Securities registered pursuant to Section 12(b) of the Act**

**Title of Each Class:**

**Name of Each Exchange on which Registered:**

**Common Stock, par value \$0.001 per share**

**The NASDAQ Global Market LLC**

**Securities registered pursuant to Section 12(g) of the Act:  
None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act of 1933, as amended. YES  NO

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

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

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

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

Large accelerated  
filer

Accelerated filer

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

Smaller reporting  
company

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$795.1 million as of the last business day of the registrant's most recently completed second fiscal quarter (i.e. June 29, 2007), based upon the closing sale price for the registrant's common stock on that day as reported by the NASDAQ Global 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 35,413,933 shares of the registrant's common stock issued and outstanding as of February 22, 2008.

#### **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 22, 2008.

---

**NuVasive, Inc.**

**Form 10-K for the Fiscal Year ended December 31, 2007**

**PART I**

<u>Item 1.</u>	<u>Business</u>	2
<u>Item 1A.</u>	<u>Risk Factors</u>	17
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	29
<u>Item 2.</u>	<u>Properties</u>	29
<u>Item 3.</u>	<u>Legal Proceedings</u>	29
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>	29

**PART II**

<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	30
<u>Item 6.</u>	<u>Selected Financial Data</u>	32
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	32
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	41
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	42
<u>Item 9.</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	42
<u>Item 9A.</u>	<u>Controls and Procedures</u>	42
<u>Item 9B.</u>	<u>Other Information</u>	45

**PART III**

<u>Item 10.</u>	<u>Directors and Executive Officers and Corporate Governance</u>	45
<u>Item 11.</u>	<u>Executive Compensation</u>	45
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	45
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	45
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	45

**PART IV**

<u>Item 15.</u>	<u>Exhibits, Financial Statements and Schedules</u>	45
<u>SIGNATURES</u>		50
<u>Index to Consolidated Financial Statements</u>		52
<u>EXHIBIT 21.1</u>		
<u>EXHIBIT 23.1</u>		
<u>EXHIBIT 31.1</u>		
<u>EXHIBIT 31.2</u>		
<u>EXHIBIT 32.1</u>		
<u>EXHIBIT 32.2</u>		

**Table of Contents**

**PART I**

*This Annual Report on Form 10-K, particularly in Item 1. Business and Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, and the documents incorporated by reference, include forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including, but not limited to, statements regarding our future financial position, business strategy and plans and objectives of management for future operations. When used in this Annual Report, the words believe, may, could will, estimate, continue, anticipate, intend, expect and similar 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 \$4.2 billion in the United States in 2008. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS<sup>tm</sup>, 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 initiatives 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. Currently, we are training approximately 400 to 500 surgeons annually.

Our MAS platform combines three categories of our product offerings:

NeuroVision<sup>®</sup> 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 includes our SpheR® 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 to reinvent approaches that add complexity and

## **Table of Contents**

undermine safety, ease and efficacy. An important ongoing objective has been to maintain a leading position in access and nerve avoidance, as well as being the leader and pioneer in lateral surgery. Our MAS platform, with the unique advantages provided by NeuroVision, enables an innovative lateral procedure known as eXtreme Lateral Interbody Fusion, or XLIF®, in which surgeons access the spine for a fusion procedure from the side of the patient's body, rather than from the front or back. Our MaXcess instruments provide access to the spine in a manner that affords direct visibility and our NeuroVision system allows surgeons to avoid critical nerves. We believe that the procedures facilitated by our MAS platform reduce operating times, decrease trauma and blood loss, and lead to faster overall patient recovery times compared to open spine surgery.

We also offer a suite of traditional spine surgery products, including certain CoRoent® suite of implants, a titanium surgical mesh system, a line of precision-machined cervical and lumbar allograft implants, and related instrumentation. Our Triad® and Extensure™ lines of bone allograft, in our patented saline packaging, is human bone that has been processed and precision shaped for transplant. We also offer fusion fixation products that offer unique technological benefits such as our Gradient Plus™ cervical plate and SpheRx pedicle screw system.

Our corporate headquarters are located in a 62,000 square foot, facility in San Diego, California. This facility has a six-suite state-of-the-art cadaver operating theatre designed to accommodate the training of spine surgeons. We recently signed a lease to relocate our corporate headquarters to a new facility in San Diego, which we intend to occupy during 2008. 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 Memphis facility has greatly enhanced our ability to meet demanding delivery schedules and provide a greater level of customer service.

## **Recent Product Introductions**

In the last 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 products include:

*SpheRx II & DBR II Pedicle Screw Systems* pedicle screw systems designed for a posterior approach, which has been enhanced with a Dual Ball Rod feature to allow for instrument-free compression of the vertebrae, as well as minimally disruptive rod delivery features that minimize the incidence of associated tissue trauma. Additionally there is no rod-overhang affecting anatomic structures adjacent to the fusion construct.

*XLPTM Lateral Plate* is a fixation plate designed for placement through the same incision used in an XLIF procedure and that is designed to perform a similar fixation function as pedicle screws without the need for an additional incision or to reposition the patient. This single approach fixation saves the patient the morbidity of another approach to the spine for adjunctive fixation. Additionally, the surgeon and hospital save significant time and money related to applying posterior fixation.

*Thoracic XLIF* the thoracic spine can now be accessed in the same safe and reproducible way XLIF has demonstrated in the lumbar spine.

*Gradient Plus* continued evolution of our 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, Gradient Plus provides the benefit of intraoperative choice when selecting the construct that best satisfies patient need.



## **Table of Contents**

*Helix ACP™* is a fixation plate designed for the anterior approach in cervical surgeries. The plate features a one step canted coil locking mechanism for surgical ease and efficiency.

*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.

*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 seek to maintain a competitive advantage through the introduction of our MaXcess products.

We have launched two completely revised versions of our MaXcess retractor system over the last 3 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, is designed to provide access during posterior lumbar and cervical decompression surgeries.

*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:

*Full Spinal Cord Monitoring* NeuroVision now incorporates multiple monitoring modalities, allowing monitoring of the entire spinal cord.

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

*System updates* A software update 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.

*Motion Preservation* We also made significant progress in 2007 on our research and development initiatives related to motion preservation. 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 began in the third quarter of 2006 and we look forward to analyzing the data collected. Over 70% were enrolled through the end of 2007.

Our motion preservation product development efforts include our mechanical lateral total disc replacement (TDR), and our elastomeric lateral TDR, which is based on an embroidery design. We filed for Investigational Device Exemptions, or IDEs, on the mechanical lateral TDR as well as our ceramic-on-ceramic cervical TDR CerPass™ in late 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

## **Table of Contents**

resources to educating spine surgeons on the clinical benefits of our products, and we intend to capitalize on patient demand for minimally disruptive surgical alternatives.

*Continue to 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 30 new products and product enhancements. We have several additional products currently under development that should expand our presence in fusion surgery as well as provide an entry into the motion preservation market segment. We intend to accomplish this with an unwavering commitment to our MAS platform and building on our core technology. We believe that these additional products will allow us to generate, on average, greater revenues per spine surgery procedure while improving patient care.

*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. In 2006, we completed our transition to an exclusive sales force, and we have seen 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 of Sales Directors, each of whom is responsible for a geographic region of the country. Each Sales Director is responsible for Area Business Managers, or ABMs, who are NuVasive shareowners (our employees) responsible for a defined territory. The remainder of the sales force are both direct (our shareowners) and exclusive independent sales representatives or an exclusive distributor agent, 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<sup>®</sup>, is central to our corporate culture, critical to our success and, we believe, differentiates us from our competition. We solicit information and feedback from our surgeon customers and clinical advisors regarding the utility of and potential improvements to our products. For example, we have an on-site machine shop to allow us to rapidly manufacture product prototypes and a state-of-the-art cadaver operating theatre to provide clinical training and validate new ideas through prototype testing.

*Selectively License or Acquire Complementary Spine Products and Technologies.* In addition to building our company through internal product development efforts, we intend to selectively license or acquire complementary products and technologies. 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 (i) cervical plate technology, which we re-launched as our SmartPlate Gradient CLP product; (ii) surgical embroidery technology, including the NeoDisc investigational nucleus-like cervical disc replacement; and (iii) our FormaGraft<sup>®</sup> 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**

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

## **Table of Contents**

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.

Back pain is one of the number one causes of healthcare expenditures in the United States, with a direct cost of more than \$50 billion annually for diagnosis, treatment and rehabilitation. The U.S. market for lumbar and cervical spine fusion, the focus of our business, was estimated to be over \$3 billion in 2006, over \$3.6 billion in 2007, and is estimated to grow over \$4.2 billion in 2008.

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

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

*Increasing demand for motion-preserving treatments with potentially earlier intervention in the degenerative disease process for many patients.*

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

## **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

## **Table of Contents**

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 applications of the following spine surgery procedures, among others:

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

Decompression, which is removal of a portion of bone over the nerve root or disc from under the nerve root to relieve pinching of the nerve; and

Procedures designed to correct and/or stabilize the spine while simultaneously maintaining motion.

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

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 reports and publications presented at multiple meetings through 2007 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. The connection is accomplished using a clip that is attached to the instrument, effectively providing the benefits of NeuroVision through an instrument already familiar to

the surgeon. The system's proprietary software and easy to use graphical user interface enables the surgeon to make critical decisions in real time resulting in safer and faster procedures with the potential for improved patient outcomes. We have recently introduced significant enhancements to NeuroVision in the form of MEP technology, remote reading capability, a software update and improved nerve monitoring capabilities. The data developed using NeuroVision can now be ported to health care professionals for additional interpretation of interoperative information.



**Table of Contents**

***MAS MaXcess***

Our MaXcess system consists of instrumentation and specialized implants that provide maximum access to the spine with minimal soft tissue disruption. MaXcess has a split blade design consisting of three blades that can be positioned to build the surgical exposure in the shape and size specific to the surgical requirements rather than the fixed tube design of 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 product 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.

In 2007, our MaXcess products have been used in the thoracic region of the spine as the lateral approach has broadened from the lumbar to the thoracic region as well as into adult degenerative scoliosis procedures.

***MAS Specialized Implants***

We have a number of implants designed to be used with our MAS platform. These implants are used for interbody disc height restoration for fusion, partial vertebral body replacement and stabilization of the spine. These implants include our SpheRx, SpheRx II and SpheRx II DBR pedicle screw systems, our CoRoent family of unique implants for partial vertebral body replacement and interbody implants, 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 spine. These systems enable minimally disruptive placement of implants and are intended to reduce operating time and patient morbidity, often through a single approach.

We have developed 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. 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 traditional 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 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, including NeoDisc, will require premarket approval rather than 510(k) clearance. NeoDisc is currently 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 NeoDisc 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 applications 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 certain 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 staff consists of 18 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 and this group continues to work closely with our clinical advisors and spine surgeon customers to design products that are intended to improve patient outcomes, simplify techniques, shorten procedures, reduce hospitalization and rehabilitation times and, as a result, reduce costs.

### **Sales and Marketing**

We currently sell our products through a combination of exclusive independent sales agencies and direct sales representatives employed by us. Importantly, both our direct sales representatives as well as our independent sales agencies are exclusive and sell only NuVasive spine surgery products. Our sales force is comprised either of sales professionals, who are NuVasive shareowners responsible for a defined territory or independent sales representatives, each acting as our sole representative in a given territory. The determination of whether to engage a directly-employed shareowner or exclusive distributor is made on a territory by territory basis, with a focus on the candidate who brings the best skills, experience and contacts. Currently, the split between directly-employed 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 11 Sales Directors. Each Sales Director is responsible for a portion of the United States and manages the directly-employed and independent sales agents engaged in that territory.

The transition to an exclusive sales force has been a very positive contributor to our growth in sales. There are many reasons that we believe strongly in an exclusive sales force, none more important than having a sales force that is properly trained and incentivized to sell and represent only our portfolio of products.

## **Surgeon Training and Education**

NuVasive devotes significant resources to training and educating surgeons regarding the safety and reproducibility of our surgical techniques and our complimentary instruments and implants. We maintain a state-of-the-art cadaver operating theatre and training facility at our corporate headquarters to help promote adoption of our products. Currently, we are training approximately 400 to 500 surgeons annually in the XLIF® technique and our other Maximum Access Surgery, or MAS platform products including: NeuroVision, MaXcess and SpheRx DBR.

## **Table of Contents**

NuVasive has also helped to establish SOLAS<sup>™</sup>, the Society of Lateral Access Surgery, a group of spine surgeons dedicated to the development and expanded application of lateral spine surgery techniques that offer significant patient benefits and improved clinical 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, Inc. 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. We are in the process of determining whether to establish alternate suppliers.

Also, in January 2007, we acquired certain rights to FormaGraft<sup>®</sup>, a ceramic/collagen bone graft matrix used to promote spinal fusion, from Radius Medical, LLC. Our supply of the product comes solely from Maxigen Biotech. We 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. 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 deliver surgical instrument sets just in time to fulfill our customer obligations to meet surgery schedules. In most cases once the surgery is finished, the instrument sets are returned to us and we prepare them for shipment to meet future surgeries. This strategy minimizes backlogs, while increasing asset turns and maximizing cash flow. Our

pool of surgical equipment that we loan to or place with hospitals continues to increase as we expand our distribution channels and increase market penetration of our products. These 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

## **Table of Contents**

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

### ***Patents***

As of December 31, 2007 we had 50 issued U.S. patents, 31 foreign national patents, and 229 pending patent applications, including 168 U.S. applications, 7 international (PCT) applications and 54 foreign national applications. Our issued and pending patents cover, among other things:

Embroidery technology including the NeoDisc and additional advanced applications of the embroidery platform technology;

Motion preservation products;

MAS surgical access and spine systems;

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

Implants and related instrumentation and targeting 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<sup>®</sup>, through a comprehensive strategy covering various important aspects of our neurophysiology-enabled instrumentation, including, screw test, navigated guidance, surgical access and related methodology. Our NeuroVision patent portfolio includes 10 issued U.S. patents, 43 U.S. patent applications (including 37 U.S. utility patent applications, 5 U.S. provisional applications, and 1 U.S. design application), 8 issued foreign national patents, 3 international (PCT) patent applications, and 26 foreign national applications on this system and related instrumentation.

We have also undertaken to protect our XLIF<sup>®</sup> franchise, including methodology, implants, and systems used during XLIF procedures. In 2007, we obtained a U.S. Patent covering the use of neurophysiology (such as our NeuroVision system) and a split-blade retractor (such as our MaXcess retractor) to perform lateral access surgery. In addition to this issued patent, as well as 1 issued foreign patent, our XLIF patent portfolio includes 26 U.S. utility patent applications, 8 U.S. provisional patent applications, 2 international (PCT) patent applications, and 15 foreign national patent applications covering various additional aspects of XLIF methodology, implants, and systems.

We obtained a U.S. Patent with broad claims protecting our SpheRx<sup>®</sup> pedicle screw system, including SpheRx DBR. In addition to this issued patent, we have several patent applications pending on the SpheRx pedicle screw system and related instrumentation, including 9 U.S. utility applications, 1 U.S. provisional applications, 1 issued foreign national patent, 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 2 issued U.S. patents, 27 U.S. applications (including 15 U.S. utility applications and 12 U.S. provisional applications), 21 issued foreign national patents, 2 international (PCT) applications, and 13 foreign national applications, directed at both NeoDisc as well as additional applications of the embroidery technology.

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



## **Table of Contents**

time-consuming and would divert the attention of our management and key personnel from our business operations. Our success will 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 take extensive efforts to ensure that our products do not infringe other parties' patents and proprietary rights, our products and methods may be covered by patents held by our competitors. 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.

## ***Trademarks***

As of December 31, 2007, we have 64 trademark registrations, both domestic and foreign, including the following U.S. trademarks: NuVasive, NeuroVision, MaXcess, XLIF, SpheRx, DBR, CoRoent, SmartPlate, Creative Spine Technology, Triad, InStim, NeoDisc, ExtenSure, FormaGraft, and Absolute Responsiveness. We have 19 trademark applications pending, both domestic and foreign, including the following trademarks: MAS, ExtenSure, CerPass, Nerve Avoidance Leader, XLP, Halo, VuePoint, Embrace, Embody, and Envoy.

## **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 Medtronic Sofamor Danek, 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's neuromonitoring system, while surgeon directed, requires manual interpretation for neuromonitoring. Several companies offer products that compete with our MaXcess system, SpheRx pedicle screw system and implants, including competitive offerings by DePuy Spine, Inc., 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, Inc., each of which has substantially greater

## **Table of Contents**

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 an innovative portfolio of products elegantly delivered through our MaXcess system as well as through our XLIF approach, complemented by additional innovative and pull-through products along the entirety of the spine. Our allograft is packaged in a saline solution, which allows the product to be used immediately and does not require specialized handling, representing a unique product in the allograft market.

Competition in the motion preservation segment is increasing, with Medtronic, DePuy, Stryker and Synthes all investing in this rapidly growing market. In the cervical total disc replacement (TDR) segment, our NeoDisc currently in clinical trials, if approved, will face competition from several products that received FDA approval in 2007 including Medtronic's Prestige and Bryan TDRs as well as Synthes' ProDisc TDR. Competition in the dynamic stabilization space is also increasing, accompanied by acquisition activity including Kyphon's acquisition of St. Francis in 2007, followed by Medtronic's acquisition of Kyphon.

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., Globus Medical, Inc., and others.

## **Government Regulation**

Our products are medical devices and tissues subject to extensive regulation by the FDA and other regulatory bodies. FDA regulations govern, among other things, the following activities that we or our partners perform and will continue to perform:

product design and development;

product testing;

product manufacturing;

product labeling;

product storage;

premarket clearance or approval;

advertising and promotion; and

product sales and distribution.

## ***FDA's Premarket Clearance and Approval Requirements***

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either prior 510(k) clearance or prior premarket approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk are placed in either class I or II, which requires the manufacturer to submit to the FDA a premarket notification requesting permission for commercial distribution. This process is known as 510(k) clearance. Some low risk devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device are placed in class III, requiring premarket approval.

***510(k) Clearance Pathway***

To obtain 510(k) clearance, 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.

## **Table of Contents**

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

### ***Premarket Approval Pathway***

A premarket approval (PMA) application must be submitted if the device cannot be cleared through the 510(k) process. A premarket approval application must be supported by extensive data including, but not limited to, technical information, preclinical data, clinical trial data, manufacturing data and labeling to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use.

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

### ***Human Cell, Tissue, and Cellular and Tissue Based Products***

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

The procurement and transplantation of allograft bone tissue is subject to U.S. federal law pursuant to the National Organ Transplant Act, or NOTA, a criminal statute which prohibits the purchase and sale of human organs used in human transplantation, including bone and related tissue, for valuable consideration. NOTA permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human bone tissue. With the exception of removal and implantation, we provide services in all of these

areas. We make payments to vendors in consideration for the services they provide in connection with the recovery and screening of donors. Failure to comply with the requirements of NOTA could result in enforcement action against us.

## **Table of Contents**

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

### ***Clinical Trials***

A clinical trial is almost always required to support a PMA application and is sometimes required for a 510(k) premarket notification. These trials generally require approval of a submitted application for an IDE to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to evaluate the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the responsible institutional review boards. Future clinical trials of our motion preservation designs and interbody implants will likely require that we obtain IDEs from the FDA prior to commencing clinical trials. We have gained IDE approval from the FDA to begin a clinical trial relating to NeoDisc<sup>®</sup>, our embroidery cervical disc replacement device, and are currently enrolling patients in this trial. We have also filed an IDE for our CerPass device, 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 and must be publicly registered. The results of our clinical trials may not be sufficient to obtain approval of our product. There are numerous risks associated with conducting such a clinical trial, including the high costs and uncertain outcomes. For a complete discussion of these risks, please see the **Risk Factors** section of this Annual Report.

### ***Pervasive and Continuing FDA Regulation***

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

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

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

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

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

- fines, injunctions, and civil penalties;

- recall or seizure of our products;

- operating restrictions, partial suspension or total shutdown of production;

- refusing our request for 510(k) clearance or premarket approval of new products;

- withdrawing 510(k) clearance or premarket approvals that are already granted; and

criminal prosecution.

We are subject to unannounced device inspections by the FDA and the California Food and Drug Branch, as well as other regulatory agencies overseeing the implementation and adherence of applicable state and federal tissue licensing regulations. These inspections may include our subcontractors' facilities.



## **Table of Contents**

### ***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. We have now successfully passed several Notified Body audits since our original certification in 2001, granting us ISO registration and allowing the CE conformity marking to be applied to certain of our devices under the European Union Medical Device Directive. We have expanded our certification scope and are now working with two different Notified Bodies overseeing our currently released, as well as forthcoming, product development projects.

### **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.

### **Healthcare Fraud and Abuse**

Healthcare fraud and abuse laws apply to our business if a customer submits a claim for an item or service that is reimbursed under Medicare, Medicaid or most other federally-funded health care programs. The federal Anti-Kickback Law prohibits unlawful inducements for the referral of business reimbursable under federally-funded health care programs, such as remuneration provided to physicians to induce them to use certain tissue products or medical devices reimbursable by Medicare or Medicaid. The Anti-Kickback Law is subject to evolving interpretations. Some states also have anti-kickback laws which establish similar prohibitions. If a governmental authority

## **Table of Contents**

were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil penalties including, for example, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid.

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

### **Shareowners (our employees)**

We refer to our employees as shareowners. As of December 31, 2007, we had 345 shareowners, of which 35 were employed in research and development, 34 in clinical and regulatory, 128 in general and administrative and operations and 148 in sales and marketing. None of our shareowners are 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](http://www.nuvasive.com).

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to those reports, electronically with the Securities and Exchange Commission (the Commission ). We make these reports available free of charge on our website under the investor relations page as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Commission. All such reports were made available in this fashion during 2007.

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

### **Item 1A. Risk Factors**

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

### **Risks Related to Our Business and Industry**

***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

**Table of Contents**

products. As a result of this increased competition, we believe there will be growing pricing pressure in the near future. If competitive forces drive down the price we are able to charge for our products, our profit margins will shrink, which will hamper our ability to invest in and grow our business and achieve profitability.

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 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., and Nicolet Biomedical, a VIASYS Healthcare company, both of which have significantly greater resources than we do, as well as numerous regional nerve monitoring companies. With respect to MaXcess, our minimally disruptive surgical system, our largest competitors are Medtronic Sofamor Danek, Inc., DePuy Spine, Inc., a Johnson & Johnson company, and Synthes-Stratec, Inc. We compete with many of the same companies with respect to our other products. We also compete with numerous smaller companies with respect to our implant products, many of whom have a significant regional market presence. At any time, these companies may develop alternative treatments, products or procedures for the treatment of spine disorders that compete directly or indirectly with our products.

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

significantly greater name recognition;

established relations with a greater number of spine surgeons, hospitals, other healthcare providers and third-party payors;

larger and more well 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.

**Table of Contents**

***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
- 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 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, and enhance the products we currently offer. 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 or enhancements 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 acquired from Pearsalls Limited and RSB Spine 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 may suffer.



**Table of Contents**

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

We 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 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 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, may require 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. We may also fail to retain the employees that are critical to the success of the acquired business. There may also be unanticipated costs and liabilities associated with an acquisition that could adversely affect our operating results.

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

We rely on third-party suppliers and manufacturers to 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. If we are unable to obtain sufficient quantities of high quality components to meet customer demand on a timely basis, we could lose customers, our reputation may be harmed and our business could suffer.

We currently use one or two manufacturers for each of our devices or components. Our dependence on one or two manufacturers involves several risks, including limited control over pricing, availability, quality and delivery schedules. If any one or more of our manufacturers cease to provide us with sufficient quantities of our components in a timely manner or on terms acceptable to us, or cease to manufacture components of acceptable quality, we would have to seek alternative sources of manufacturing. We could incur delays while we locate and engage alternative qualified suppliers and we might be unable to engage alternative suppliers on favorable terms. Any such disruption or increased expenses could harm our commercialization efforts and adversely affect our ability to generate revenue.

Invibio, Inc. is our exclusive supplier of polyetheretherketone, which comprises our PEEK partial vertebral body product called CoRoent. We have a supply agreement with Invibio, pursuant to which we have agreed to purchase our entire supply of polyetheretherketone from Invibio. We also have an exclusive supply arrangement with Peak Industries, Inc., pursuant to which Peak Industries is our exclusive supplier of NeuroVision systems. In the event we experience delays, shortages, or stoppages of supply with either supplier, we would be forced to locate a suitable alternative supplier which could take significant time and result in significant expense. Any inability to meet our customers' demands for these products could lead to decreased sales, harm our reputation and result in the loss of customers to our competitors, which could cause the market price of our common stock to decline.

Maxigen Biotech, Inc., or MBI, is our exclusive supplier of our FormaGraft product. We are party to a supply agreement with MBI, pursuant to which we have agreed to purchase our entire supply of FormaGraft from MBI. We will require that 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

**Table of Contents**

MBI we may not be able to secure an adequate source of supply of FormaGraft, 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 AlloSource, Inc. will be available at current levels or will be sufficient to meet our needs. If we are no longer able to obtain allograft 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 reduce our revenues.

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

Our continued success depends in part upon the continued service of Alexis V. Lukianov, our Chairman and Chief Executive Officer, and Keith Valentine, our President and Chief Operating Officer, who are critical to the overall management of NuVasive as well as to the development of our technology, our culture and our strategic direction. We have entered into employment agreements with Messrs. Lukianov and Valentine, but neither of these agreements guarantees the service of the individual for a specified period of time. The loss of either Messr. Lukianov or Valentine could have a material adverse effect on our business, results of operations and financial condition. We have not obtained and do not expect to obtain any key-person life insurance policies.

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

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

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

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

assimilate new staff members and we will need to manage complexities associated with a larger, faster growing and more geographically diverse organization ;

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

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

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

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

We are implementing an enterprise resource planning system to support our increasingly complex business and business processes and such implementation is costly and carries substantial operations risk, including loss of data or information, unanticipated increases in costs, disruption of operations or business interruption.

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.

**Table of Contents**

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

Several investigational devices in our development pipeline, including our NeoDisc cervical disc replacement device, 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.

***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.

**Table of Contents**

***The safety of our products is not yet supported by long-term clinical data and our products may therefore prove to be less safe and effective than initially thought.***

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

***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 April 2005 regarding our allograft implant business and another FDA inspection in June 2007 regarding our medical device activities. 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 have taken to satisfy the corrective actions. There can be no assurance the FDA will not subject us to further enforcement action and the FDA may impose additional inspections 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, harm to our reputation and loss of customers 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 multiple products. We have yet to demonstrate that we can generate ongoing sufficient sales of our products to become profitable. The extent of our future operating losses and the timing of profitability, if at all, are difficult to predict. At December 31, 2007, we had an accumulated deficit of approximately \$168.0 million, and cash, cash equivalents and short and long



**Table of Contents**

term investments totaling approximately \$89.7 million, compared to approximately \$117.4 million as of December 31, 2006. Our net loss for the twelve months ended December 31, 2007 was approximately \$11.3 million. Even if we do achieve profitability as planned, we may not be able to sustain or increase profitability on an ongoing basis.

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

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

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

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

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

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

the mix of our products sold (i.e., profit margins differ between our products);

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

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

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

regulatory approvals and legislative and reimbursement policy 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.

***After we relocate to our new headquarters, we may not be able to sublease our current headquarters or receive rental income on any such sublease to cover our lease obligations.***

In November 2007, we entered into a 15 year lease of a two-building campus style complex in San Diego, California to serve as our new headquarters. Relocation to the new facility is expected to be completed in phases in the second and third quarters of 2008. Subsequent to the relocation dates, we expect to sublease our current facility through

August 2012, the date on which the related lease agreement expires. We may encounter significant difficulties or delays in subleasing our current headquarters and may not be able to sublease it for rents equal to or greater than those which we are obligated to pay. To the extent that we are unable to sublease our current headquarters at an amount equal to our rent obligations for that facility or to the extent sublessees fail to perform their obligations to pay rent, we could incur greater operating expenses than we have planned. Such increases in operating expenses in a period could cause us to exceed our planned expense levels and adversely affect our financial results for that period. Furthermore, inability to sublease such facility may adversely affect our liquidity and capital resources.

**Table of Contents**

**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 addition, there are numerous proposed changes to the patent laws and rules of the US Patent and Trademark Office which, if enacted, may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, proposed changes to the patent rules of the US Patent and Trademark Office were scheduled to take effect on November 1, 2007 which would have significantly limited the right to pursue continuation applications. On October 31, 2007, a temporary injunction was granted in a lawsuit against the US Patent and Trademark Office which served to stay the application of the proposed rules. However, the court has yet to rule on whether to make the injunction permanent. If the injunction is lifted, the proposed rules may take effect and may adversely impact our ability to prevent others from designing around our existing patents. Moreover, Congress is considering several significant changes to the US patent laws, including (among other things) changing from a first to invent to a first inventor to file system, requiring that patent lawsuits be brought in the forum of the defendant, requiring the apportionment of patent damages, and creating a post-grant opposition process to challenge patents after they have issued.

In the event a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time consuming. 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 II 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. It is not unusual for parties to exchange letters surrounding allegations of intellectual property infringement and licensing arrangements. Patent litigation can involve complex factual and legal questions and its outcome is uncertain. Any claim relating to infringement of patents that is successfully asserted

against us may require us to pay substantial damages, including treble damages in some cases. Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Our success will also depend in part on our not infringing patents issued to others, including our competitors and potential competitors. If our products are found to infringe the patents of others, our development, manufacture and sale of such potential products could be severely restricted or prohibited. In addition, our competitors may independently develop technologies similar to ours.

## **Table of Contents**

Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to adequately protect our intellectual property rights.

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

A patent infringement suit brought against us or any 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 and any licenses may require substantial royalties or other payments by us. Even if any strategic partners, licensees or we were able to obtain rights to the third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. 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 and our reputation would be harmed.

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

***Any claims relating to 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 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

## **Table of Contents**

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 Accountability Act of 1996, which protects the privacy of individually identifiable healthcare information; and the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections. 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 or investigate our current or future activities under these laws. Any such challenge or investigation could have a material adverse effect on our business, financial condition and results of operations. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

***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.

## **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;



**Table of Contents**

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 businesses, products, assets or technology;

litigation, including intellectual property litigation;

announcements of actions by the FDA or other regulatory agencies;

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.

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

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

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

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

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

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

require advance written notice of stockholder proposals and director nominations.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, our bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our

then-current board of directors, including delay or impede a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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

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

**Table of Contents**

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

None.

**Item 2. *Properties.***

Our current headquarters are located in 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. In November 2007, we entered into a 15 year lease of an approximate 140,000 square foot two-building campus style complex in San Diego, California. Relocation to the new facility is expected to be completed in phases in the second and third quarters of 2008. Under the master lease agreement, through options to acquire additional space in the project and to require the construction of an additional building on the campus, the agreement provides for facility expansion rights to an aggregate of more than 300,000 leased square feet. Subsequent to the relocation dates, we currently expect to sublease our current facility through August 2012, the date on which the related lease agreement expires, and expect lease income to approximate lease expense on the current facility.

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

We have been involved in a series of related lawsuits involving families of decedents who donated their bodies through UCLA's willed body program. We have been dismissed from these lawsuits 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.

**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, 2007.

**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.

	<b>High</b>	<b>Low</b>
<b>2006:</b>		
First Quarter	\$ 21.57	\$ 17.19
Second Quarter	20.21	15.14
Third Quarter	21.38	15.21
Fourth Quarter	25.29	19.35
<b>2007:</b>		
First Quarter	\$ 25.84	\$ 21.59
Second Quarter	28.76	23.47
Third Quarter	37.74	25.93
Fourth Quarter	44.96	34.80

We had approximately 171 stockholders of record as of January 31, 2008. 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, 2007, 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, 2007) for the Company's common stock since May 13, 2004 (the date on which the Company's common stock was first registered under Section 12 of the Exchange Act) to the cumulative return over such period of (i) The NASDAQ Stock Market Composite Index, and (ii) NASDAQ Medical Equipment Index. The graph assumes that \$100 was invested on the date on which the Company completed the initial public offering of its common stock, in the common stock and in each of the comparative indices. The graph further assumes that such amount was initially invested in the Common Stock of the Company at the price to which such stock was first offered to the public by the Company on the date of its initial public offering. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

**COMPARISON OF 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.

	2007	2006	2005	2004	2003
	(In thousands, except per share data)				
Statement of Operations Data:					
Total revenues	\$ 154,290	\$ 98,091	\$ 62,606	\$ 39,090	\$ 23,029
Gross profit	126,908	79,063	50,214	28,862	16,238
Total operating expenses	144,160	133,289	81,708	43,502	25,473
Net loss	(11,265)	(47,910)	(30,339)	(14,210)	(10,127)
Net loss per share					
Basic and diluted	\$ (0.32)	\$ (1.47)	\$ (1.24)	\$ (0.91)	\$ (6.30)
Balance Sheet Data:					
Working capital	\$ 118,188	\$ 136,236	\$ 32,829	\$ 62,656	\$ 6,139
Total assets	225,687	196,184	71,490	80,752	22,371
Long-term liabilities	1,119	1,399	1,665	13	1,224
Total stockholders' equity	\$ 196,578	\$ 176,303	\$ 58,136	\$ 71,397	\$ 10,070

**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 primarily on applications for spine fusion surgery, a market estimated to exceed \$4.2 billion in the United States in 2008. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS<sup>™</sup>, as well as a growing offering of 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 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 initiatives 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.

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 including our SpheR® pedicle screw system and CoRoent® suite of implants.

## **Table of Contents**

We also offer a suite of traditional spine surgery products, including certain CoRoent® suite of implants, a titanium surgical mesh system, a line of precision-machined cervical and lumbar allograft implants, and related instrumentation. Our Triad® and Extensure™ lines of bone allograft, in our patented saline packaging, is human bone that has been processed and precision shaped for transplant. We also offer fusion fixation products that offer unique technological benefits such as our Gradient Plus™ Cervical Plate and SpheRx pedicle screw system.

We 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 and are actively seeking to initiate clinical trials with other potential products.

Since inception, we have been unprofitable. As of December 31, 2007, we had an accumulated deficit of \$168.0 million.

*Revenues.* From inception to December 31, 2007, we have recognized \$392.0 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 other MAS 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 represent approximately 20% 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 independent sales agents' sites. We recognize revenue for disposables or implants used upon receiving a purchase order from the hospital indicating product use or implantation. Additionally, 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.* Through 2007, 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 exclusive sales agents and our own directly employed sales professionals. Our sales force provides a delivery and consultative service to our surgeon and hospital customers and is compensated based on sales and product placements in their territories. Sales force commissions are reflected in our statement of operations in the sales, marketing and administrative expense line. We expect to continue to expand our distribution channel. 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. Late in 2007 and continuing in 2008, we commenced international sales efforts with the initial focus on European markets. We expect our international sales force to be made up of a combination of distributors and direct sales personnel.

*Acquisition of Radius Medical LLC.* On January 23, 2007, NuVasive and Radius Medical, LLC (Radius), along with certain members and managers of Radius, entered into an Asset Purchase Agreement (the Purchase Agreement) providing for the acquisition by us of substantially all of Radius' right, title and interest in and to the assets used by 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. The transaction allows us to sell and market a biologic product, FormaGraft®, a synthetic bone void filler designed to aid in bone growth with fusion procedures, and a platform for future development. FormaGraft received 510(k) clearance from the Food and Drug Administration (FDA) in May 2005. The acquisition is consistent with our objective of developing or acquiring innovative technologies.



### **Critical Accounting Policies**

Our discussion and analysis of our financial condition and results of operations is based upon our audited consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates including those related to bad debts, inventories, long-term assets, income taxes, and stock

## **Table of Contents**

compensation. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates.

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

*Revenue Recognition.* We follow the provisions of the Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*, which sets forth guidelines for the timing of revenue recognition based upon factors such as passage of title, installation, payment and customer acceptance. We recognize revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) 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 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 charge to the sales, marketing and administrative expense line. 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 accurately 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 inventory, which consists primarily of disposables and specialized implants, is at risk of obsolescence following the introduction and development of new or enhanced products. Our estimates and assumptions for excess and obsolete inventory are reviewed and updated on a quarterly basis. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our revenue forecasts. Increases in the reserve for excess and obsolete inventory result in a corresponding charge to cost of goods sold.

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

*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 being depreciated over a period of 20 years. Maintenance and repairs are expensed as incurred. Intangible assets, consisting of purchased and licensed technology and a supply agreement, are amortized on a straight-line basis over their estimated useful lives of 14 to 20 years.

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

**Table of Contents**

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, 2007.

*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, 2007 due to uncertainties related to our ability to utilize our deferred tax assets in the foreseeable future.

*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 or future grants. 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 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,			2006 to 2007		2005 to 2006	
2007	2006	2005	\$ Change	% Change	\$ Change	% Change

Revenue	\$ 154,290	\$ 98,091	\$ 62,606	\$ 56,199	57%	\$ 35,485	57%
---------	------------	-----------	-----------	-----------	-----	-----------	-----

Revenues have increased over time due primarily to continued market acceptance of our products within our MAS<sup>®</sup> platform, including NeuroVision<sup>®</sup>, MaXcess<sup>®</sup> disposables, and our specialized implants such as our XLP lateral plate, SpheRx<sup>®</sup> pedicle screw system and CoRoent<sup>®</sup> suite of products. The execution of our strategy of expanding our product offering for the lumbar region and addressing broader indications further up the spine in the thoracic and cervical regions through product introductions in 2006 and 2007 have significantly contributed to revenue growth. Additionally, the completion of our transition to an exclusive sales force in mid-2006 has increased the effort focused on selling our products as well as the overall market penetration.

**Table of Contents****Cost of Goods Sold**

	Year Ended December 31,			2006 to 2007		2005 to 2006	
	2007	2006	2005	\$ Change	% Change	\$ Change	% Change
Cost of Goods Sold	\$ 27,382	\$ 19,028	\$ 12,392	\$ 8,354	44%	\$ 6,636	54%
% of total revenue	18%	19%	20%				

Cost of goods sold consists of purchased goods and depreciation expense for instruments.

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 and volume. The year-over-year increase in cost of goods sold in total dollars in 2007 compared to 2006 and in 2006 compared to 2005 resulted primarily from (i) increased material costs of \$6.2 million and \$4.2 million, respectively, associated with the higher revenue in each year; and (ii) increased depreciation expense of \$2.8 million and \$2.9 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.

Consistent with our philosophy of obsoleting our own products, we launched several new products and enhancements in 2006 and 2007. In connection with the product 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 \$61,000 and \$646,000 in 2007 and 2006, respectively. This depreciation expense is included in cost of goods sold in the accompanying statement of operations for the respective years.

**Operating Expenses***Sales, Marketing and Administrative*

	Year Ended December 31,			2006 to 2007		2005 to 2006	
	2007	2006	2005	\$ Change	% Change	\$ Change	% Change
Sales, Marketing and Administrative	\$ 119,579	\$ 94,632	\$ 56,515	\$ 24,947	26%	38,117	67%
% of total revenue	78%	96%	90%				

Sales, marketing and administrative expenses consist primarily of compensation, commission and training costs for personnel engaged in sales, marketing and customer support functions; independent sales agents commissions; surgeon training costs; shareowner (employee) related expenses for our administrative functions; third party professional service fees; and facilities and insurance expenses. In addition, we classify the amortization expense related to purchased technology in this expense category.

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.

The increases in sales, marketing and administrative expense principally result from growth in our product sales and the overall growth in the Company, including headcount increases in 2006 and 2007.

Increases in costs based on additional product sales, such as sales force compensation and other direct costs related to the sales force, royalty expense, and shipping costs were \$11.7 million and \$20.2 million in 2007 and 2006, respectively, compared to the prior years. The significant increase in total dollars in these aggregated categories in 2006 compared to 2005 relates primarily to the transition to an exclusive sales force. Total costs related to our sales force, as a percent of revenue, were 33.4%, 47.2%, and 43.6% in 2007, 2006 and 2005, respectively. The year-over year fluctuations are the result of the costs associated with our transition to an exclusive sales force; increasing in 2006 compared to 2005 and decreasing in 2007 compared to 2006 as a result of completing the transition in mid-2006. Going forward, we expect the total costs related to the sales force as a percent of revenue will decrease.

**Table of Contents**

We also experienced increased costs as a result of overall company growth and headcount additions in our marketing and administrative support functions. Marketing and administrative compensation and personnel costs increased \$4.3 million and \$5.8 million in 2007 and 2006, respectively, compared to the prior years. Stock-based compensation increased \$0.8 million and \$8.9 million in 2007 and 2006, respectively, compared to the prior years. The increase in 2006 is due primarily to the recognition of compensation expense related to stock options required under SFAS 123R (adopted on January 1, 2006). Facility, equipment and computer expenses increased by \$1.5 million and \$1.4 million in 2007 and 2006 respectively, compared to the prior years. Amortization expense related to acquired intangible assets increased by \$1.0 million and \$0.2 million in 2007 and 2006 respectively, compared to the prior years, as a result of acquisition activity in 2007.

On a long-term basis, as a percentage of revenue, we expect total sales, marketing and administrative costs to continue to decrease over time as we begin to see the synergies of investments we have made (such as our sales force exclusivity transition). However, we have other significant expenses planned that are designed to increase the scalability of our business. For example, we purchased and began the implementation of a new enterprise resource planning software system, or ERP system, in 2007. We will capitalize the majority of the aggregate \$7.2 million anticipated cost of the ERP project and amortize them over a 7 year period. We have incurred \$4.8 million related to the ERP project through December 31, 2007. These costs have been capitalized and amortization will commence when the system is placed in service (which is expected to occur in the second half of 2008). In addition, we entered into a lease of a two-building campus-style headquarters complex in November 2007 to accommodate our Company growth. Relocation to the new facility is expected to be in phases in the second and third quarters of 2008, and as a result, we will incur increased facility costs beginning on the relocation dates. In addition, the lease term for our current facility continues through August 2012, which requires us to either find a new tenant for our current headquarters or otherwise exit the lease. If we have difficulty finding a new tenant or exiting the lease, we could be required to continue paying rent and related costs on this facility through August 2012.

*Research and Development*

	Year Ended December 31,			2006 to 2007		2005 to 2006	
	2007	2006	2005	\$ Change	% Change	\$ Change	% Change
Research & Development	\$ 24,581	\$ 18,541	12,296	\$ 6,040	33%	\$ 6,245	51%
% of total revenue	16%	19%	20%				

Research and development expense consists primarily of product research and development, regulatory and clinical functions, and shareowner (employee) related expenses. During 2007, 2006 and 2005, we launched a number of products and product enhancements, including in 2007, the SpheRx II and DBR II Pedicle Screw Systems, the XLP Lateral Plate, Gradient Plus cervical plate and an expanded line of CoRoent implants. In 2006, we launched our next generation instrument sets for spine fusion procedures, the MaXcess<sup>®</sup> III retractor system, and CoRoent<sup>®</sup> implant line extensions, and in 2005 we launched, NeuroVision updates, SpheRx<sup>®</sup> DBR and CoRoent line extensions. In the third quarter of 2006, we commenced patient enrollment in our NeoDisc<sup>®</sup> clinical trial, resulting in increased research and development costs subsequent to this date.

The year-over-year increases in research and development costs in 2007 compared to 2006 and in 2006 compared to 2005 are primarily due to (i) increases in compensation and other shareowner related expenses of \$4.4 million and \$1.8 million in 2007 and 2006, respectively, primarily due to increased headcount to support our product development and enhancement efforts; (ii) increased NeoDisc<sup>®</sup> trial cost of \$3.1 million and \$1.7 million in 2007 and 2006 respectively; and (iii) a decrease in stock-based compensation expense of \$0.5 million in 2007 compared to 2006 and



an increase in stock-based compensation expense of \$1.4 million in 2006 compared to 2005. The increase in 2006 is due primarily to the recognition of compensation expense related to stock options required under SFAS 123R (adopted on January 1, 2006).

We expect research and development costs to continue to increase in absolute dollars for the foreseeable future in support of our ongoing development activities and planned clinical trial activities; however, as a percentage of revenue, these costs are expected to decrease moderately over time.

**Table of Contents****Interest and Other Income, Net**

	Year Ended December 31,			2006 to 2007		2005 to 2006	
	2007	2006	2005	\$ Change	% Change	\$ Change	% Change
Interest and Other Income , net	\$ 5,987	\$ 6,316	\$ 1,155	\$ (329)	(5)%	\$ 5,161	447%
% of total revenue	4%	6%	2%				

Interest and other income, net consists primarily of interest income. The decrease in net interest income in 2007 compared to 2006 is due to lower investment balances in 2007 compared to 2006 as a result of cash used to operate our business and to lower yields available in the market for our investment portfolio. The increase in net interest income in 2006 compared to 2005 is due primarily to interest earned on the investment of proceeds of \$142.0 million received from our secondary public offering completed in February 2006.

**Stock-Based Compensation**

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

	Year Ended December 31,			2006 to 2007		2005 to 2006	
	2007	2006	2005	\$ Change	% Change	\$ Change	% Change
Stock-Based Compensation							
Sales, Marketing & Administrative	\$ 11,404	\$ 10,581	\$ 1,635	\$ 823	8%	\$ 8,946	547%
Research & Development	2,217	2,764	1,405	\$ (547)	(20)%	1,359	97%
Total Stock-Based Compensation	\$ 13,621	\$ 13,345	\$ 3,040	\$ 276	2%	\$ 10,305	339%
% of total revenue	9%	14%	5%				

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 (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 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 total deferred stock-based compensation for certain options granted during 2003 and 2004, of \$8.6 million 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. 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 has been included as a component of stock-based compensation in our statements of operations.

We 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*

**Table of Contents**

*Rights and Other Variable Stock Option Award Plans* (FIN 28). As of December 31, 2007, there was \$10.6 million of unrecognized compensation expense for stock options which is expected to be recognized over a weighted-average period of approximately 1.1 years. In addition, as of December 31, 2007, there was \$0.9 million of unrecognized compensation expense for shares expected to be issued under the Employee Stock Purchase Plan that will be recognized through April 2008.

***Business Combinations and Asset Acquisitions***

*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. In connection with the transaction, we made net cash payments totaling \$5.0 million and issued 451,677 unregistered shares of our common stock, which were subsequently registered. We also funded at closing \$2.0 million in cash into an escrow account for the benefit of Radius, which will be maintained for a period of 18 months. As part of the acquisition, we also acquired certain rights and obligations under a supply agreement with Maxigen Biotech, Inc. (MBI) with respect to product manufacture and distributor rights. MBI is a Taiwanese company who manufactures FormaGraft and owns a portion of the core technology.

In connection with the acquisition of Radius, we made a separate \$2.0 million equity investment in MBI. On May 1, 2007, the equity investment in MBI was completed resulting in NuVasive ownership of approximately 9% of MBI. We account for this investment at cost and included in other assets on the consolidated balance sheet.

*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.

*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<sup>™</sup>. Also acquired was all of Pearsalls' 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 common stock. In addition, the original transaction provided for us to make additional milestone 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 the second quarter of 2006, we recorded a payment obligation by us of \$10.5 million related to an achieved milestone. In September 2006, we entered into an agreement with Pearsalls Limited, 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 up to \$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 additional common stock. The total charge recorded in 2006 was \$20.1 million, including transaction costs.

*RSB Spine LLC.* On June 3, 2005, we acquired intellectual property and related assets for cervical plate technology from RSB Spine LLC, or RSB,. We made a closing payment of \$7.3 million, consisting of \$3.8 million in cash and \$3.5 million in common stock. 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.

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

## **Table of Contents**

### ***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 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, 2007, we had an accumulated deficit of approximately \$168.0 million. We have not yet achieved profitability, but do expect to be marginally profitable in 2008. To date, our operations have been funded primarily with proceeds from the sale of our equity securities which total \$284.5 million since inception, including \$210.1 million sold in the public markets.

Cash, cash equivalents and marketable securities was \$89.7 million at December 31, 2007 and \$117.4 million at December 31, 2006. The decrease was due primarily to the cash used to fund our operations, to acquire capital assets and surgical instrument sets to support products launched in 2007, for the acquisition of Radius Medical LLC and for our \$2.0 million investment in MBI.

Net cash used in operating activities was \$0.9 million in 2007 compared to \$25.6 million in 2006. The decrease of net cash used in operating activities of \$24.7 million was primarily due to our improved operating results in the period.

Net cash provided by investing activities was \$14.3 million in 2007 compared to net cash used by investing activities of \$89.8 million in 2006. In 2006, we received and invested the proceeds of our secondary offering of \$142.0 million, offset by cash used to acquire property and equipment and to support the business operations. In 2007, investing

activity decreased significantly as cash was used to (i) acquire Radius Medical LLC, (ii) invest in MBI and (iii) support the business operations.

Net cash provided by financing activities was \$7.0 million in 2007 compared to \$144.4 million in 2006. In 2006, we completed an offering of our common stock in the public markets, resulting in proceeds of \$142.0 million. In 2007, the proceeds from the sale of common stock under our equity plans increased by \$4.7 million.

**Table of Contents**

We believe our current cash and cash equivalents together with our short-term marketable securities 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 both our current and future corporate headquarters leases and two automobiles. Our corporate headquarters leases continue through August 2012 and June 2023, respectively. The rent expense related to our corporate headquarters leases will be recorded on a straight-line basis in accordance with GAAP. We are in the process of soliciting bids for sublet of our current corporate headquarters facility.

The following summarizes our long-term contractual obligations and commitments as of December 31, 2007 (*in thousands*):

	Total	Less Than 1 Year	Payments Due by Period		
			1 to 3 Years	4 to 5 Years	After 5 Years
Operating leases	\$ 122,011	\$ 4,244	\$ 24,912	\$ 15,328	\$ 77,527
Deferred consideration payments under acquisition agreements	650	300	350		
Royalty obligations	12,262	1,829	4,631	2,630	3,172
Total	\$ 134,923	\$ 6,373	\$ 29,893	\$ 17,958	\$ 80,699

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 Smart Plate® Gradient CLP™ and related 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, 2007 is related to our investment portfolio which consists largely of debt instruments of high quality corporate issuers and the U.S. government and its agencies. Due to the short-term nature of these investments, we have assessed that there is no material exposure to interest rate risk arising from our investments. Fixed rate investments and borrowings may have their fair market value adversely impacted from



changes in interest rates. At December 31, 2007, we do not hold any material asset-backed investment securities and in 2007, we did not realize any losses related to asset-backed investment securities.

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.

**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, 2007:

	<b>Carrying Value (In thousands)</b>	<b>Weighted Average Rate of Return</b>
Classified as Current Assets:		
Money Market Funds	\$ 52,469	4.43%
Commercial Paper with initial maturities of 90 days or less	9,251	4.80%
Corporate Notes with initial maturities of greater than 90 days	9,996	5.27%
	71,716	
Less cash equivalents	(52,469)	
	19,247	
Classified as Non-Current Assets:		
Debt securities issued by the U.S. Treasury and other U.S. government agencies	7,035	4.83%
Corporate Notes	1,501	4.60%
	8,536	
Total interest bearing instruments	\$ 27,783	

As of December 31, 2007, the stated maturities of our investments are \$71.7 million within one year and \$8.5 million within one to three years. These investments are recorded on the balance sheet at fair market value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income.

**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, 2007. Based on such evaluation, our management has concluded as of December 31, 2007, 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

**Table of Contents**

Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States.

Management has used the framework set forth in the report entitled *Internal Control – Integrated Framework* published by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission to evaluate the effectiveness of the Company’s internal control over financial reporting. Management has concluded that the Company’s internal control over financial reporting was effective as of December 31, 2007. Ernst & Young LLP, the Company’s independent registered public accounting firm, has issued an attestation report on the Company’s internal control over financial reporting which is included herein.

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

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
NuVasive, Inc.

We have audited NuVasive, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). NuVasive, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the 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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, NuVasive, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, 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, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2007 of NuVasive, Inc. and our report dated February 25, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

February 25, 2008

San Diego, California

**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 22, 2008, 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](http://www.nuvasive.com), and in our filings with the Securities and Exchange Commission. We intend to disclose future amendments to, or waivers from, provisions of our Code of Conduct and Ethics that apply to our Principal Executive Officer, Principal Financial Officer, Principal Accounting Officer, or controller, or persons performing similar functions, within four business days of such amendment or waiver.

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

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

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

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

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

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

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, 2007 and 2006

Consolidated Statements of Operations for the years ended December 31, 2007, 2006 and 2005

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2007, 2006 and 2005

Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005



**Table of Contents**

## Notes to Consolidated Financial Statements

## (2) Financial Statement Schedules: Schedule II Valuation Accounts

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

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

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

<b>Exhibit Number</b>	<b>Description</b>
2.1(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(17)	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

Edgar Filing: NUVASIVE INC - Form 10-K

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
10.12(10)#	2004 Employee Stock Purchase Plan

**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
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(8)	Intellectual Property Purchase Agreement, dated October 10, 2002, between NuVasive, Inc. and Spine Partners, LLC
10.25(5)	Intellectual Property Purchase Agreement Addendum, dated as of August 12, 2005, by and between NuVasive, Inc. and Spine Partners, LLC
10.26(13)	Sublease, dated October 12, 2004, by and between NuVasive, Inc. and Gateway, Inc.
10.27(11)	Earnest Money Contract and Agreement, dated May 26, 2006, between NuVasive, Inc. and New York Life Insurance Company
10.28(14)#	Description of 2006 performance bonus arrangements for our executive officers
10.29(15)#	Description of 2007 annual salaries for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
10.30(16)#	Summary of the 2007 bonus payments to our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
10.31(18)	Customer Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation.
10.32(18)	IBM Global Services Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation.
10.33(19)	Lease Agreement for Sorrento Summit, entered into as of November 6, 2007, between the Company and HCPI/Sorrento, LLC.
10.34(20)#	Description of 2008 annual salaries and annual stock grant for 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
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.

**Table of Contents**

- (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 March 13, 2006.
- (15) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 22, 2007.
- (16) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on February 23, 2007.
- (17) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 16, 2006.
- (18) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on August 8, 2007.
- (19) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on November 8, 2007.
- (20) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 11, 2008.

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 22, 2008, 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: February 29, 2008

By: /s/ Kevin C. O Boyle

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

Date: February 29, 2008

**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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Alexis V. Lukianov Alexis V. Lukianov	Chairman and Chief Executive Officer (Principal Executive Officer)	February 29, 2008
/s/ Kevin C. O Boyle Kevin C. O Boyle	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 29, 2008
/s/ Jack R. Blair	Director	February 29, 2008



Jack R. Blair

/s/ Peter C. Farrell

Director

February 29, 2008

Peter C. Farrell

**Table of Contents**

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Robert J. Hunt Robert J. Hunt	Director	February 29, 2008
/s/ Lesley H. Howe Lesley H. Howe	Director	February 29, 2008
/s/ Hansen Yuan Hansen Yuan	Director	February 29, 2008
/s/ Eileen M. More Eileen M. More	Director	February 29, 2008

**Table of Contents**

**NUVASIVE, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

<u>Report of Independent Registered Public Accounting Firm</u>	53
<u>Consolidated Balance Sheets as of December 31, 2007 and 2006</u>	54
<u>Consolidated Statements of Operations for the years ended December 31, 2007, 2006 and 2005</u>	55
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2007, 2006 and 2005</u>	56
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005</u>	57
<u>Notes to Consolidated Financial Statements</u>	58

**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, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2007. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of NuVasive, Inc. at December 31, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 1 to the consolidated financial statements, NuVasive, Inc. changed its method of accounting for Share-Based Payments in accordance with Statement of Financial Accounting Standards No. 123 (revised 2004) on January 1, 2006.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of NuVasive, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 25, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California  
February 25, 2008

**Table of Contents****NUVASIVE, INC.****CONSOLIDATED BALANCE SHEETS**

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In thousands, except par value)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 61,915	\$ 41,476
Short-term marketable securities	19,247	73,930
Accounts receivable, net of allowance of \$926 and \$737, respectively	27,496	18,960
Inventory, net	36,280	18,636
Prepaid expenses and other current assets	1,240	1,716
Total current assets	146,178	154,718
Property and equipment, net of accumulated depreciation	43,538	30,573
Long-term marketable securities	8,536	1,996
Intangible assets, net of accumulated amortization	24,496	8,441
Other assets	2,939	456
Total assets	\$ 225,687	\$ 196,184
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 13,839	\$ 8,938
Royalties payable	2,076	1,068
Accrued payroll and related expenses	12,075	8,476
Total current liabilities	27,990	18,482
Long-term liabilities	1,119	1,399
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, \$.001 par value; 5,000 shares authorized, no shares issued and outstanding at December 31, 2007 and 2006		
Common Stock, \$.001 par value; 70,000 shares authorized 35,330 and 33,929 issued and outstanding at December 31, 2007 and 2006, respectively	35	34
Additional paid-in capital	364,469	333,009
Accumulated other comprehensive income (loss)	54	(25)
Accumulated deficit	(167,980)	(156,715)
Total stockholders' equity	196,578	176,303
Total liabilities and stockholders' equity	\$ 225,687	\$ 196,184

See accompanying notes to consolidated financial statements.

**Table of Contents****NUVASIVE, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands, except per share amounts)</b>		
Revenue	\$ 154,290	\$ 98,091	\$ 62,606
Cost of goods sold	27,382	19,028	12,392
Gross profit	126,908	79,063	50,214
Operating expenses:			
Sales, marketing and administrative	119,579	94,632	56,515
Research and development	24,581	18,541	12,296
In-process research and development			12,897
NeoDisc technology costs		20,116	
Total operating expenses	144,160	133,289	81,708
Interest and other income (expense), net	5,987	6,316	1,155
Net loss	\$ (11,265)	\$ (47,910)	\$ (30,339)
Net loss per share:			
Basic and diluted	\$ (0.32)	\$ (1.47)	\$ (1.24)
Weighted-average shares basic and diluted	34,782	32,501	24,473

See accompanying notes to consolidated financial statements.

Table of Contents

## NUVASIVE, INC.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Common stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount	Capital	Compensation	(Loss)	Deficit	Equity
	(In thousands)						
<b>Balance at December 31, 2004</b>	23,951	\$ 24	\$ 153,323	\$ (3,441)	\$ (43)	\$ (78,466)	\$ 71,397
Issuance of common stock under employee and director stock option and purchase plans	485		1,757				1,757
Issuance of common stock for acquisitions	670	1	12,269				12,270
Compensation expense related to issuance of stock options to non- employees			988				988
Amortization of stock-based compensation			(194)	2,246			2,052
Unrealized loss on marketable securities and foreign currency translation					11		11
Net loss						(30,339)	(30,339)
<b>Balance at December 31, 2005</b>	25,106	25	168,143	(1,195)	(32)	(108,805)	58,136
Issuance of common stock under employee and director stock option and purchase plans	592	1	2,618				2,619
Issuance of common stock for NeoDisc technology costs	402		8,060				8,060
Issuance of common stock in secondary offering	7,829	8	142,038				142,046
Elimination of unamortized deferred compensation balance			(1,195)	1,195			



Stock based compensation expense			13,345				13,345
Unrealized loss on marketable securities and foreign currency translation				7			7
Net loss					(47,910)		(47,910)
<b>Balance at December 31, 2006</b>	33,929	34	333,009	(25)	(156,715)		176,303
Issuance of common stock under employee and director stock option and purchase plans	949	1	7,338				7,339
Issuance of common stock for acquisitions	452		10,501				10,501
Stock-based compensation expense			13,621				13,621
Unrealized loss on marketable securities and foreign currency translation				79			79
Net loss					(11,265)		(11,265)
<b>Balance at December 31, 2007</b>	35,330	\$ 35	\$ 364,469	\$	\$ 54	\$ (167,980)	\$ 196,578

See accompanying notes to consolidated financial statements.

**Table of Contents****NUVASIVE, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands)</b>		
<b>Operating activities:</b>			
Net loss	\$ (11,265)	\$ (47,910)	\$ (30,339)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	12,952	8,350	4,359
In-process research and development			12,897
Stock-based compensation	13,621	13,345	3,040
NeoDisc technology costs		8,060	
Reserve recorded for obsolete inventory in connection with planned 2006 product introductions and enhancements		343	
Allowance for doubtful accounts	882	124	443
Allowance for excess and obsolete inventory	827	1,769	535
Other	187	53	539
Changes in operating assets and liabilities:			
Accounts receivable	(9,418)	(7,422)	(5,219)
Inventory	(18,339)	(8,878)	(6,864)
Prepaid expenses and other current assets	349	(220)	(370)
Accounts payable and accrued liabilities	5,719	3,987	(1,303)
Accrued payroll and related expenses	3,598	2,794	2,427
Net cash used in operating activities	(887)	(25,605)	(19,855)
<b>Investing activities:</b>			
Cash paid for acquisition	(6,970)		(8,800)
Purchases of property and equipment	(24,403)	(20,396)	(12,675)
Purchases of short-term marketable securities	(75,135)	(130,510)	(44,918)
Sales of short-term marketable securities	129,818	63,525	88,566
Purchases of long-term marketable securities	(23,540)	(1,996)	
Sales of long-term marketable securities	17,000		
Other assets	(2,483)	(452)	(75)
Net cash provided by (used in) investing activities	14,287	(89,829)	22,098
<b>Financing activities:</b>			
Payments of long-term liabilities	(300)	(300)	(18)
Issuance of common stock	7,339	144,665	1,760
Net cash provided by financing activities	7,039	144,365	1,742
Increase in cash and cash equivalents	20,439	28,931	3,985
Cash and cash equivalents at beginning of year	41,476	12,545	8,560

Edgar Filing: NUVASIVE INC - Form 10-K

Cash and cash equivalents at end of year	\$ 61,915	\$ 41,476	\$ 12,545
<b>Supplemental disclosure of non-cash transactions:</b>			
Issuance of common stock for NeoDisc technology costs	\$	\$ 8,060	\$
Issuance of common stock in connection with acquisitions	\$ 10,501	\$	\$ 12,270

See accompanying notes to consolidated financial statements.

**Table of Contents**

**NUVASIVE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Significant Accounting Policies**

*Description of Business.* NuVasive, Inc. (the Company or NuVasive) was incorporated in Delaware on July 21, 1997. The Company designs, develops and markets products for the surgical treatment of spine disorders and operates in one business segment. The Company began commercializing its products in 2001. Its current product portfolio is focused primarily on applications for spine fusion surgery. Its principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS<sup>tm</sup>, as well as a growing offering of cervical and motion preservation initiatives. Currently-marketed products are used predominantly in spine fusion surgeries, both to enable access to the spine and to perform restorative and fusion procedures. The Company also focuses significant research and development efforts on 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 initiatives such as total disc replacement and nucleus-like cervical disc replacement. The Company dedicates significant resources to sales and marketing efforts, including training spine surgeons on its unique technology and products.

The Company loans its MAS systems to surgeons and hospitals who purchase disposables and implants for use in individual procedures. In addition, NeuroVision, MaXcess and surgical instrument sets are placed with hospitals for an extended period at no up-front cost to them provided they commit to minimum monthly purchases of disposables and implants. The Company also sells a small quantity of MAS instrument sets, and MaXcess and NeuroVision systems to hospitals. The Company also offers a range of bone allograft in patented saline packaging and spine implants such as rods, plates and screws. Implants and disposables are shipped from the Company's facilities or from limited disposable inventories stored at independent sales agents' sites.

In 2006, the Company began its first clinical trial in the United States for the NeoDisc cervical disc replacement device.

*Basis of Presentation and Principles of Consolidation.* The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, NuVasive Europe GmbH and NuVasive UK Limited. All significant intercompany balances and transactions have been eliminated in consolidation. There has been no material activity by the Company's subsidiaries during the years presented.

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

*Reclassification.* Certain reclassifications to prior period information have been made for consistent presentation. Specifically, in 2006 and 2005 the Company classified all bonus expense in sales, marketing and administrative expense in the statement of operations. Beginning in 2007, such expense is classified according to employee function. Expense of \$0.8 million and \$0.5 million in 2006 and 2005, respectively, has been reclassified from sales, marketing and administrative expense to research and development expense to conform to this presentation change.

*Cash, Cash Equivalents and Short-term Marketable Securities.* The Company classifies investments with original maturities of 90 days or less when acquired as cash equivalents. All of the Company's short-term marketable securities are classified as available-for-sale and are reported at fair value, with unrealized gains and losses included in

stockholders' equity as a component of accumulated other comprehensive loss. Any unrealized gains or losses deemed other than temporary will be reflected in interest and other income (expense), net. The cost of securities sold is based on the specific identification method and realized gains and losses are included in interest and other income (expense), net. The Company has cash equivalents and investments with various high quality institutions and, by policy, limits the amount of credit exposure to any one institution.

**Table of Contents**

**NUVASIVE, INC.**

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

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

The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for specific receivables if and when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices as well as a review of the overall quality and age of those invoices not specifically reviewed. In determining the provision for invoices not specifically reviewed, the Company analyzes historical collection experience and current economic trends. If the historical data used to calculate the allowance provided for doubtful accounts does not reflect the Company's future ability to collect outstanding receivables or if the financial condition of customers were to deteriorate, resulting in impairment of their ability to make payments, an increase in the provision for doubtful accounts may be required.

*Fair Value of Financial Instruments.* The carrying value of cash and cash equivalents, accounts receivable, and accounts payable and accrued expenses are considered to be representative of their respective fair values because of the short-term nature of those instruments.

*Concentration of Credit Risk and Significant Customers.* Financial instruments, which potentially subject the Company to concentrations of credit risk, consist primarily of cash and cash equivalents, short-term marketable securities and accounts receivable. The Company limits its exposure to credit loss by placing its cash and investments with high credit quality financial institutions. Additionally, the Company has established guidelines regarding diversification of its investments and their maturities, which are designed to maintain principal and maximize liquidity. No single customer represented greater than 10 percent of sales for any of the years presented.

*Inventory.* Inventory is stated at the lower of cost or market and is recorded in cost of goods sold based on a method that approximates specific identification. The Company reviews the components of its inventory on a periodic basis for excess, obsolete and impaired inventory, and records a reserve for the identified items. At December 31, 2007 and 2006, the balance of the allowance for excess and obsolete inventory is \$3.6 million and \$2.9 million, respectively.

*Long-Term Assets.* Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets (ranging from two to seven years). Leasehold improvements are amortized using the straight-line method over the estimated useful life of the asset or the lease term, whichever is shorter. Building and improvements are depreciated over a period of 20 years. Intangible assets, consisting of purchased and licensed technology and a supply agreement, are amortized on a straight-line basis over their estimated useful lives of 14 to 20 years. The Company evaluates its 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, the Company makes 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, the Company reduces the net carrying value of the related asset to fair value and may adjust the remaining depreciation or amortization period. If indicators of impairment are present, the initial evaluation of intangible assets is based on the estimated undiscounted future cash flows of the technology over the remaining amortization period.

In the third quarter of 2006, the Company 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<sup>®</sup> implants. In connection with these launches, certain instruments were rendered obsolete as of the launch date. As a result, the Company reduced the useful life of such instruments to end on the respective launch dates and incurred additional depreciation expense of \$61,000 and \$646,000 in 2007 and 2006, respectively. This depreciation expense is included in cost of goods sold in the accompanying statement of operations.

The Company has not recognized any other impairment losses on its long-term assets through December 31, 2007.

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

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

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

*Product Shipment Costs.* Product shipment costs are included in sales, marketing and administrative expense in the accompanying consolidated statements of operations.

*Income Taxes.* In accordance with SFAS No. 109, *Accounting for Income Taxes*, a deferred tax asset or liability is determined based on the difference between the financial statement and tax basis of assets and liabilities as measured by the enacted tax rates which will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized.

*Net Loss Per Share.* The Company computes net loss per share using the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss for the period by the weighted-average number of common shares outstanding during the period. Due to the net loss reported in all periods, the effect of stock options is anti-dilutive and is therefore excluded. Although these options are currently not included in the net loss per share calculation, they could be dilutive when, and if, the Company reports future earnings.

	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands, except per share data)</b>		
Numerator:			
Reported net loss	\$ (11,265)	\$ (47,910)	\$ (30,339)
Denominator for basic and diluted net loss per share:			
Weighted-average common shares	34,782	32,501	24,473
Basic and diluted net loss per share	\$ (0.32)	\$ (1.47)	\$ (1.24)

In 2007, 2006, and 2005, potential common stock equivalents, as of the end of the year, excluded from historical diluted loss per share because of their anti-dilutive effect totaled 4.4 million, 3.9 million and 3.3 million shares,



respectively.

*Stock-Based Compensation.* On January 1, 2006, the Company 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 the Company to expense the estimated fair value of these awards over the requisite service period. The Company has no awards with market or performance conditions. In March 2005, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) 107, which provided supplemental implementation guidance for SFAS 123(R). The Company has applied the provisions of SAB 107 in the adoption of SFAS 123(R). Prior to January 1, 2006, the Company accounted for its share-based awards to employees and directors using the

**Table of Contents**

**NUVASIVE, INC.**

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

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.

The Company 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 employees 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 employees 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).

*Comprehensive Income (Loss)*. SFAS No. 130, *Reporting Comprehensive Income*, requires that all components of comprehensive income, including net income, be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss which includes the unrealized gain (loss) on short-term marketable securities and foreign currency translation adjustments for the years ended December 31, 2007, 2006 and 2005, did not differ significantly from the reported net loss.

**2. Business Combinations**

*Radius Acquisition*. On January 23, 2007, NuVasive and Radius Medical, LLC (Radius), along with certain members and managers of Radius, entered into an Asset Purchase Agreement (the Purchase Agreement) providing for the acquisition by NuVasive of substantially all of Radius' right, title and interest in and to the assets used by 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. The Company has included the results of the acquired Radius operations in its statement of operations from the date of the acquisition. The Company does not consider the Radius acquisition material to its results of operations or financial position, and therefore is not presenting pro forma information.

*Reasons for the Radius Acquisition*. The transaction provides NuVasive with a biologic product, FormaGraft<sup>®</sup>, a synthetic bone void filler designed to aid in bone growth with fusion procedures, and a platform for future development. FormaGraft received 510(k) clearance from the Food and Drug Administration (FDA) in May 2005. The acquisition is consistent with the Company's objectives of developing or acquiring innovative technologies.

In connection with the transaction, Radius received net cash payments of approximately \$5.0 million and 451,677 unregistered shares of NuVasive common stock, which were subsequently registered. NuVasive also funded at closing \$2 million in cash into an escrow account, which will be maintained for a period of eighteen months from the acquisition date to secure the indemnification obligations of Radius and its members under the Purchase Agreement. At the end of this eighteen month period, the funds held in escrow that are not subject to pending indemnification claims will be disbursed to Radius.

As part of the acquisition, NuVasive also acquired, as of January 23, 2007, all of Radius' right, title and interest in and to that certain Supply Agreement dated November 4, 2004, by and between Maxigen Biotech, Inc. (MBI) and Radius, as amended to date (the MBI Supply Agreement). MBI is a Taiwanese company that manufactures FormaGraft and

owns a portion of the core technology underlying FormGraft. Under the MBI Supply Agreement and following NuVasive's succession to Radius' interest therein, MBI has agreed to exclusively sell to NuVasive (and NuVasive has agreed to exclusively purchase from MBI) such quantities as NuVasive may order of all current and future products manufactured by MBI for use as synthetic bone graft substitutes consisting of certain collagens or ceramics, and grants exclusive distributor rights to NuVasive for North America, EU countries, South American and Central American countries, Australia, New Zealand and their respective territories (with additional territories

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

on a non-exclusive basis). NuVasive is required to purchase a minimum of \$0.9 million of product from MBI per calendar year. In 2007, NuVasive purchased a total of \$1.9 million of product from MBI. MBI has also granted to NuVasive an exclusive, perpetual, royalty-free license to use all such MBI products, and all related proprietary rights and proprietary information relating thereto, including without limitation, rights to conduct research and development, develop modifications, improvements or additional products and to use and sell such improvements and additional products. Radius was required to pay MBI a one-time license fee in consideration for the above described license, which obligation was satisfied by Radius.

*Purchase Price.* The total purchase consideration consisted of (*in thousands, except share and per share data*):

Net cash paid to Radius	\$ 4,970
NuVasive common stock issued on the closing date (451,667 shares at \$23.25 per share)	10,501
Cash deposited in escrow	2,000
Acquisition-related costs, consisting primarily of professional fees	306
 Total purchase price	 \$ 17,777

The Company has allocated the total purchase consideration to the assets acquired based on their respective fair values at the acquisition date. The following table summarizes the preliminary allocation of the purchase price (*in thousands*).

MBI Supply Agreement	\$ 9,400
Licensed technology	7,145
Inventory	132
Goodwill	1,100
 Total purchase price	 \$ 17,777

In connection with the acquisition of Radius, NuVasive made a separate \$2.0 million equity investment in MBI. On May 1, 2007, the equity investment in MBI was completed resulting in NuVasive ownership of approximately 9% of MBI. The Company accounts for this investment at cost and includes it in other assets on the consolidated balance sheet.

*RSB Acquisition.* On June 3, 2005, the Company acquired the intellectual property and related assets for cervical plate technology from RSB Spine LLC (RSB), a privately owned company focused on spine technology (the RSB Acquisition), in a purchase business combination transaction. The Company has included the results of the acquired RSB operations in its statement of operations from the date of the acquisition. The Company does not consider the RSB Acquisition material to its results of operations or financial position, and therefore is not presenting pro forma information.

The total purchase consideration of \$8.5 million consisted of cash paid of \$4.0 million, including professional fees, common stock issued valued at \$3.5 million for accounting purposes and deferred consideration payable of \$1.1 million.

The allocation of the purchase consideration to the assets and liabilities acquired resulted in an excess of the fair value of net tangible and intangible assets acquired over the total purchase price of approximately \$874,000 which has been recorded as a long-term liability in accordance with Statement of Financial Accounting Standards No. 141, *Business Combinations*.

Under the acquisition agreement, RSB will receive four annual non-contingent deferred purchase consideration payments of \$300,000 through June 2009. In addition, RSB will receive annual payments over a period of 12 years based upon sales of the products derived from the cervical plate technology. Any amounts paid under this

**Table of Contents**

**NUVASIVE, INC.**

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

arrangement will first be applied to reduce the long-term liability and then will be recorded as goodwill when incurred. The recorded values of the long-term liability and the shares issued have been reduced to reflect this adjustment.

In exchange for contingent cash payments totaling \$500,000 through June 2009, the purchase agreement granted NuVasive the right of first refusal on all additional existing technologies and any future technology that may be developed by RSB in the five years following the closing date. Through December 31, 2007, a total of \$200,000 has been paid under this term of the agreement. In January 2007, an additional agreement was entered into with RSB under which the Company relinquished its right of first refusal to certain technologies that may be developed by RSB and eliminated its contingent obligation to make the additional \$300,000 in cash payments and agreed to make one additional non-contingent cash payment of \$50,000 in June 2009.

In connection with the original transaction with RSB, NuVasive has written off assets, consisting primarily of inventory, totaling approximately \$497,000 for the initial alpha/beta testing of the Company's own cervical plate under development. The charge is recorded in cost of goods sold in the accompanying consolidated statement of operations for the year ended December 31, 2005.

**3. Asset Acquisitions**

On August 4, 2005, NuVasive acquired technology and assets from Pearsalls Limited, a privately-owned company based in the United Kingdom (Pearsalls). The acquired assets include an investigational nucleus-like cervical disc replacement device called NeoDisc®. Also acquired was all of Pearsall's intellectual property related to embroidery technology for use in surgical implants. NuVasive 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 subsequently been registered. In addition, the transaction provided for NuVasive to make additional payments totaling up to \$31.5 million as progress is made towards FDA approval for marketing of the NeoDisc product. Finally, the agreement called for Pearsalls to receive a royalty of 5% on NeoDisc product sales. No royalties will be due on other products based on the acquired technology, except for a limited royalty on products for non-spine applications.

The total purchase consideration of \$13.0 million consisted of cash paid of \$5.3 million, including professional fees, and common stock issued valued at \$7.7 million for accounting purposes.

The purchase price has been allocated to the fair value of the assets acquired at the date of the acquisition consisting of fixed assets of \$113,500. The remaining purchase price of \$12.9 million has been allocated to in-process research and development (IPRD) because 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 \$12.9 million was charged to expense on the acquisition date.

In June 2006, the Company received conditional FDA approval of the Investigational Device Exemption to begin clinical trial enrollment for our NeoDisc cervical disc replacement device. This FDA approval was a development milestone under the Pearsall's agreement, and resulted in a payment obligation by us of \$10.5 million which accrued in the second quarter of 2006. In September 2006, the Company entered into an additional agreement with Pearsalls, 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 up to \$21.0 million; and (iii) certain future contingent

royalty payments; all of which relate to NeoDisc and related technology. The terms of the additional agreement also render the manufacturing relationship for NeoDisc non-exclusive, giving NuVasive control over the manufacturing of NeoDisc, and effects the transfer of intellectual property rights to NuVasive. The \$20 million total payment consisted of \$12 million in cash and \$8 million in NuVasive stock and is recorded as technology development costs in the consolidated statement of operations. The total charge recorded in 2006 was \$20.1 million, including transaction costs, and has been charged to expense in 2006 because the projects associated with the IPRD efforts, as of the date of the 2006 transaction, had still not yet reached technological feasibility and the continuing research and development in process had no alternative future uses.

**Table of Contents**

**NUVASIVE, INC.**

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

On August 12, 2005, NuVasive acquired assets and intellectual property from RiverBend Design LLC (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. NuVasive made a closing payment to RiverBend of 51,308 unregistered shares of common stock which have subsequently been registered. In addition, NuVasive 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 on a straight-line basis over the estimated useful life of 17 years.

At the same time as the transaction with RiverBend, NuVasive executed an Intellectual Property Purchase Agreement Addendum (the Addendum) with Spine Partners LLC (Spine Partners), a company affiliated with RiverBend. The Addendum amended the terms of the Intellectual Property Purchase Agreement dated October 10, 2002, between NuVasive and Spine Partners. The Addendum adjusts the royalty payments due to Spine Partners for the NuVasive SpheRx multi-axial pedicle screws. The Addendum also effects the transfer to NuVasive of multiple patent applications and related technology and know-how relating to pedicle-based dynamic stabilization systems.



Table of Contents

## NUVASIVE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**4. Balance Sheet Details**

*Cash Equivalents and Marketable Securities.* Short-term marketable securities include auction rate securities, commercial paper, government securities and corporate bonds that are classified as available-for-sale as follows:

	<b>Cost</b>	<b>Estimated Fair Value</b>
	<b>(In thousands )</b>	
December 31, 2007		
Classified as current assets		
Money market funds	\$ 52,469	\$ 52,469
Commercial paper	9,261	9,251
Corporate notes	9,987	9,996
	71,717	71,716
Less cash equivalents	(52,469)	(52,469)
Short-term marketable securities		
Classified as non-current assets		
Corporate notes	1,501	1,501
Debt securities issued by the U.S. Treasury and other U.S. government agencies	7,022	7,035
Total marketable securities at December 31, 2007	\$ 27,771	\$ 27,783
December 31, 2006		
Classified as current assets		
Money market funds	\$ 8,910	\$ 8,910
Commercial paper	66,733	66,708
Auction rate securities	26,600	26,600
	102,243	102,218
Less cash equivalents	(28,288)	(28,288)
Short-term marketable securities		
Classified as non-current assets Debt securities issued by the U.S. Treasury and other U.S. government agencies		
	2,000	1,996
Total marketable securities at December 31, 2006	\$ 75,955	\$ 75,926

As of December 31, 2007, the stated maturities of our investments are \$71.7 million within one year and 8.5 million within one to three years. These investments are recorded on the balance sheet at fair market value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income. There are no material unrealized gains or losses at December 31, 2007.

Table of Contents

## NUVASIVE, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
Loaner equipment	\$ 42,292	\$ 28,725
Machinery and equipment	7,879	6,267
Computer equipment and software	8,128	2,232
Leasehold improvements	3,861	2,884
Furniture and fixtures	1,422	1,239
Land, building and improvements	4,896	4,840
	68,478	46,187
Less: accumulated depreciation and amortization	(24,940)	(15,614)
	\$ 43,538	\$ 30,573

*Goodwill and Intangible Assets.* Goodwill and intangible assets were acquired in connection with the business combination and asset acquisitions discussed in Notes 2 and 3. Goodwill represents the excess of the aggregate purchase price over the fair value of the tangible and identifiable intangible assets acquired by the Company. The goodwill recorded as a result of the business combinations in the years presented is not deductible for tax purposes. Goodwill is not amortized, but rather is tested for impairment at least annually in accordance with Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* (SFAS 142). The Company has determined that it is a single reporting unit for the purpose of goodwill impairment tests under SFAS 142. During the year ended December 31, 2007 there was no impairment to goodwill. As of December 31, 2007, the carrying amount of goodwill was \$1.1 million.

Goodwill and intangible assets as of December 31, 2007 consisted of the following (*in thousands*):

	<b>Weighted Average Amortization Period in Years</b>	<b>Gross Assets</b>	<b>Accumulated Amortization</b>	<b>Net Assets</b>
Goodwill		\$ 1,100	\$	\$ 1,100
Purchased Technology	17	9,200	1,388	7,812
Licensed Technology	14	7,145	334	6,811
Supply Agreement	20	9,400	627	8,773
Total		\$ 26,845	\$ 2,349	\$ 24,496

Intangible assets as of December 31, 2006 consisted of the following (*in thousands*):

	<b>Gross Assets</b>	<b>Accumulated Amortization</b>	<b>Net Assets</b>
Other	\$ 100	\$ 12	\$ 88
Purchased Technology	9,200	847	8,353
Total	\$ 9,300	\$ 859	\$ 8,441

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

Total amortization expense related to intangible assets is set forth in the table below (*in thousands*):

	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
Purchased Technology	\$ 541	\$ 541	\$ 306
Supply Agreement	334		
Licensed Technology	627		
Other	15	12	
<b>Total</b>	<b>\$ 1,517</b>	<b>\$ 553</b>	<b>\$ 306</b>

The estimated future amortization of intangible assets on an annual basis is \$1.5 million per year for each of the next five years, with the balance of \$15.8 million to be expensed through 2027.

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

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
Accounts payable	\$ 1,680	\$ 3,543
Accrued expense	6,085	3,566
Other	6,074	1,829
	<b>\$ 13,839</b>	<b>\$ 8,938</b>

**5. Commitments and Contingencies**

The Company leases its corporate headquarters under an operating lease, which expires on August 31, 2012. The minimum annual rent on the Company's facility is subject to increases based on stated rental adjustment terms of certain leases, taxes, insurance and operating costs. For financial reporting purposes, rent expense is recognized on a straight-line basis over the term of the lease. Accordingly, rent expense recognized in excess of rent paid is reflected as deferred rent and is included in accounts payable and accrued liabilities in the accompanying consolidated balance sheets.

On November 6, 2007, the Company entered into a 15-year operating lease agreement for the purpose of relocating its corporate headquarters to an approximately 140,000 square foot two-building campus style complex. Rental payments will consist of base rent of \$2.43 per square foot per month, escalating at an annual rate of three percent over the 15-year period of the lease, plus related operating expenses. The lease provides an allowance of \$6.0 million for tenant

improvements and certain rent abatements through November 2008. Relocation to the new facility is expected to be completed in phases in the second and third quarters of 2008. In addition, through options to acquire additional space in the project and to require the construction of an additional building on the campus, the agreement provides for facility expansion rights to an aggregate of more than 300,000 leased square feet. In connection with the lease, the Company has issued a \$3.1 million irrevocable transferrable letter of credit secured by a cash investment.

Subsequent to the relocation date, the Company expects to sublease the current facility through August 2012, the date on which the related lease agreement expires, and expects lease income to approximate lease expense on the current facility.

In 2007, NuVasive entered into various contracts for improvements and furnishings related to the lease of a larger corporate headquarters facility as discussed above. Total tenant improvements and related purchases to be paid by NuVasive are estimated to be \$8.4 million. NuVasive has entered into contractual agreements related to

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

these tenant improvements and related purchases of which \$5.8 million remains committed as of December 31, 2007.

During 2007, NuVasive entered into contracts relative to installation, modification and maintenance of an enterprise reporting system. Total remaining commitments total \$1.3 million at December 31, 2007.

The Company's future minimum annual lease payments, including payments for costs directly associated with the facility leases, and long-term contractual obligations for years ending after December 31, 2007 are as follows (*in thousands*):

	<b>Operating Leases</b>	<b>Other Contractual Obligations</b>
2008	\$ 4,244	\$ 2,129
2009	7,995	2,015
2010	8,327	1,566
2011	8,590	1,370
2012	8,218	1,400
Thereafter	84,637	4,432
Total minimum payments	\$ 122,011	\$ 12,912

Other contractual obligations consist of certain intellectual property purchase and consulting agreements for which the Company is required to make annual payments.

In connection with the acquisition of RSB described in Note 2, the Company is contingently obligated to make additional annual payments over a period of 12 years based upon sales of the products derived from the cervical plate technology. Through December 31, 2007, these amounts have not been significant.

As a result of the acquisition of Radius Medical LLC in January 2007, the Company is 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 goods or 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.

Rent expense, including expenses directly associated with the facility leases, was approximately \$1.8 million for each of the years ended December 31, 2007, 2006 and 2005.

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

## **6. Stockholders Equity**

There are 5,000,000 shares of preferred stock authorized and none issued or outstanding at December 31, 2007 and 2006.

*Stock Options.* In October 1998, the Company adopted the 1998 Stock Incentive Plan (the 1998 Plan) to grant options to purchase common stock to eligible employees, non-employee members of the board of directors, consultants and other independent advisors who provide services to the Company. Under the 1998 Plan, 3,922,800 shares of common stock, as amended, were reserved for issuance upon exercise of options granted



**Table of Contents**

**NUVASIVE, INC.**

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

by the Company. The board of directors determines the terms of the stock option agreements, including vesting requirements. Options under the 1998 Plan have a 10-year term and generally vest over a period not to exceed four years from the date of grant. All options granted under the 1998 Plan allow for early exercise prior to the option becoming fully vested. Unvested common shares obtained upon early exercise of options are subject to repurchase by the Company at the original issue price.

In April 2004, the board of directors replaced the 1998 Plan with the 2004 Equity Incentive Plan (the 2004 Plan) under which 800,000 shares (plus the remaining shares available for grant under the 1998 Plan) of the Company's common stock are authorized for future issuance, and reserved for purchase upon exercise of options granted. In addition, the 2004 Plan provides for automatic annual increases in the number of shares reserved for issuance thereunder equal to the lesser of (i) 4% of the Company's outstanding shares on the last business day in December of the calendar year immediately preceding; (ii) 4,000,000 shares; or (iii) a number of shares determined by the board of directors.

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

Also in April 2004, the board of directors approved the Employee Stock Purchase Plan (ESPP). The ESPP initially allowed for the issuance of up to 100,000 shares of NuVasive common stock, increasing annually on December 31 by the lesser of (i) 600,000 shares; (ii) 1% of the outstanding shares of NuVasive common stock; or (iii) a lesser amount determined by the board of directors. Under the terms of the ESPP, employees can elect to have up to 15% of their annual compensation, up to a maximum of \$25,000 per year withheld to purchase shares of NuVasive common stock. The purchase price of the common stock is equal to 85% of the lower of the fair market value per share of the common stock on the commencement date of the two-year offering period or the end of each semi-annual purchase period. In 2007, 2006, and 2005, 113,494, 106,258, and 57,276 shares, respectively, were purchased under the ESPP and 626,227 remain available for issuance under the ESPP as of December 31, 2007.

In November 2003, the Company amended the 1998 Plan to provide for the acceleration of 50% of the unvested options of all employees upon a change in control and the vesting of the remaining unvested options for those employees that are involuntarily terminated within a year of the change in control. As of December 31, 2007, substantially all of the options affected by the modification are vested.

Through December 31, 2005, the Company had recorded total deferred stock-based compensation for certain options granted during 2003 and 2004 of 8.6 million 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 the Company's initial public offering. Deferred stock-based compensation was 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), over the vesting period of the related options, generally four years. Amortization of deferred stock-based compensation through December 31, 2005, net of terminations, was \$7.2 million. 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 the Company's consolidated balance sheet. Compensation expense in 2006 and subsequent years, calculated in accordance with SFAS 123(R), related to these options is included as a component of the related expense category within operating expenses.

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

*Stock-Based Compensation.* On January 1, 2006, the Company 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 the Company to expense the estimated fair value of these awards over the requisite employee service period. The Company has no awards with market or performance conditions. In March 2005, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) 107, which provided supplemental implementation guidance for SFAS 123(R). The Company has applied the provisions of SAB 107 in the adoption of SFAS 123(R). Prior to January 1, 2006, the Company accounted for its share-based awards to employees and directors 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 or stock awards issued to non-employees are recorded at their fair value as determined in accordance with SFAS 123, *Accounting for Stock-Based Compensation*, and 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 under SFAS 123(R), the Company estimates the fair value of stock options and shares issued under the Employee Stock Purchase Plan using a Black-Scholes option-pricing model which is consistent with the model used for pro forma disclosures under SFAS 123 prior to the adoption of SFAS 123(R). 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. The expected volatility is based on the historical volatility of the Company's common stock over the most recent period commensurate with the estimated expected term of the Company's stock options. The expected term of the Company's stock options is based on historical experience. In addition, in accordance with SFAS 123(R) share-based compensation expense recognized in the statement of operations in 2006 for award grants after January 1, 2006 is based on awards ultimately expected to vest and is reduced for estimated forfeitures. In the Company's pro forma information required under SFAS 123 for the periods prior to 2006, the Company accounted for forfeitures as they occurred.

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

	<b>Year Ended December 31,</b>		
	<b>2007 Actual</b>	<b>2006 Actual</b>	<b>2005 Pro Forma</b>
<b>Stock Options</b>			
Volatility	50%	65%	60%
Expected term (years)	2.5 to 4.5	2.5 to 4.5	5.0
Risk free interest rate	3.4% to 4.9%	4.4% to 5.1%	4.1%
Expected dividend yield	0.0%	0.0%	0.0%

**ESPP(1)**

Volatility	50%	65%	N/A
Expected term (years)	0.5	0.5	
Risk free interest rate	4.4% to 4.9%	4.4% to 5.0%	
Expected dividend yield	0.0%	0.0%	

(1) Shares issued under the ESPP were insignificant in periods prior to 2006.

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

The compensation cost that has been included in the statement of operations for all share-based compensation arrangements was as follows for the three years ended December 31, 2007, 2006 and 2005:

	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands, except per share amounts)</b>		
Sales, marketing and administrative expense	\$ 11,404	\$ 10,581	\$ 1,635
Research and development expense	2,217	2,764	1,405
Stock based compensation expense	\$ 13,621	\$ 13,345	\$ 3,040
Effect on basic and diluted net loss per share	\$ (0.39)	\$ (0.41)	\$ (0.12)

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, 2007, there was \$10.6 million of unrecognized compensation expense for stock options which is expected to be recognized over a weighted-average period of approximately 1.1 years. In addition, as of December 31, 2007, there was \$0.9 million of unrecognized compensation expense for shares expected to be issued under the Employee Stock Purchase Plan which is expected to be recognized through April 2008. The total intrinsic value of options exercised was \$20.2 million, \$8.0 million and \$5.4 million, respectively, the years ended December 31, 2007, 2006 and 2005.

The following table illustrates the effect on net losses as if the Company had applied the fair value recognition provisions of SFAS 123 to determine stock-based compensation in 2005:

	<b>Year Ended December 31, 2005</b>	
	<b>(In thousands, except per share amounts)</b>	
Net loss as reported	\$	(30,339)
Add: Stock-based compensation included in net loss		2,052
Deduct: Stock-based employee and director compensation expense determined under fair value method for all awards		(5,209)
Pro forma net loss	\$	(33,496)
Basic and diluted net loss per share as reported	\$	(1.24)

Basic and diluted pro forma net loss per share	\$	(1.37)
------------------------------------------------	----	--------

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

Following is a summary of stock option activity through December 31, 2007 under all stock option plans:

	<b>Underlying Shares</b>	<b>Weighted Avg. Exercise Price</b>	<b>Weighted-Average Remaining Contractual Term (years)</b>	<b>Aggregate Intrinsic Value as of December 31, 2007</b>
				<b>(In thousands, except per share data)</b>
Outstanding at December 31, 2004	2,970	\$ 5.02		
Granted	1,043	\$ 15.70		
Exercised	(427)	\$ 3.02		
Cancelled	(316)	\$ 9.37		
Outstanding at December 31, 2005	3,270	\$ 8.27		
Granted	1,331	\$ 18.41		
Exercised	(485)	\$ 2.99		
Cancelled	(205)	\$ 13.70		
Outstanding at December 31, 2006	3,911	\$ 12.07		
Granted	1,394	\$ 24.61		
Exercised	(830)	\$ 6.45		
Cancelled	(113)	\$ 17.85		
Outstanding at December 31, 2007	4,362	\$ 16.97	7.74	\$ 98,480
Exercisable at December 31, 2007	2,101	\$ 12.11	6.93	\$ 57,578
Vested or Expected to Vest at December 31, 2007	4,234	\$ 17.99	7.87	\$ 96,355

The weighted-average fair value of options granted in the years ended December 31, 2007, 2006 and 2005, was \$10.81, \$9.68 and \$8.64 per share, respectively. The aggregate intrinsic value of options at December 31, 2007 is based on the Company's closing stock price on December 31, 2007 of \$39.52. The Company received \$5.4 million, \$1.5 million and \$1.3 million in proceeds from the exercise of stock options during the years ended December 31, 2007, 2006 and 2005, respectively.

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

The following table summarizes information about stock options outstanding and exercisable at December 31, 2007:

Range of Exercise Prices	Number of Shares	Options Outstanding		Options Exercisable	
		Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price  (Shares in thousands)	Number of Shares	Weighted Average Exercise Price
\$0.25 to \$3.75	444	5.52	\$ 2.93	443	\$ 2.93
\$9.41 to \$9.50	536	6.82	\$ 9.50	490	\$ 9.50
\$9.86 to \$16.62	566	7.10	\$ 13.04	418	\$ 12.76
\$16.63 to \$19.27	1,310	7.74	\$ 18.21	642	\$ 18.23
\$19.28 to \$43.20	1,240	8.91	\$ 22.87	63	\$ 19.72
\$24.59 to \$35.85	213	9.12	\$ 27.61	40	\$ 25.57
\$36.11 to \$43.20	53	9.87	\$ 41.15	5	\$ 36.64
\$0.25 to \$43.20	4,362	7.74	\$ 16.97	2,101	\$ 12.11

*Common Stock Reserved for Future Issuance.* The following table summarizes common shares reserved for issuance at December 31, 2007 on exercise or conversion of (*in thousands*):

Common stock options:	
Issued and outstanding	4,362
Available for future grant	387
Available for issuance under the Employee Stock Purchase Plan	626
Total shares reserved for future issuance	5,375

The Company recorded expense of \$476,000, \$785,000 and \$988,000 and in 2007, 2006, and 2005, respectively, related to the vesting of stock options granted to non-employees under consulting agreements, in accordance with EITF 96-18.

**7. Income Taxes**

On July 13, 2006, the FASB issued FIN 48. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50%



likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company adopted the provisions of FIN 48 on January 1, 2007. There were no unrecognized tax benefits as of the date of adoption. As a result of the implementation of FIN 48, the Company did not recognize an increase in the liability for unrecognized tax benefits. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company's balance sheets at December 31, 2007 and 2006, and has not recognized interest and/or penalties in the statement of operations for the year ended December 31, 2007.

The Company is subject to taxation in the United States and various state jurisdictions. All of the Company's tax years are subject to examination by the United States and California tax authorities due to the carry forward of unutilized net operating losses and R&D credits.

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

The adoption of FIN 48 did not impact the Company's financial condition, results of operations or cash flows. At December 31, 2007, the Company had net deferred tax assets of \$55.2 million. Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation has been established to offset the net deferred tax asset. Additionally, the future utilization of the Company's net operating loss and research and development credit carry forwards to offset future taxable income may be subject to an annual limitation, pursuant to Internal Revenue Code Sections 382 and 383, as a result of ownership changes that may have occurred previously or that could occur in the future. Although the Company determined that an ownership change had not occurred through December 31, 2006, it is possible that an ownership change occurred subsequent to that date.

The Company is analyzing its research and development costs and has not yet completed the analysis. Until this analysis is completed, the Company has removed the deferred tax assets for research and development credits of \$6.4 million generated through 2007 from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its unrecognized tax benefits under FIN 48. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities at December 31, 2007 and 2006 are as follows:

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
Deferred tax assets:		
Net operating loss carryforwards	\$ 35,446	\$ 35,556
Income tax credit carryforwards		4,720
Capitalized assets and other	12,384	11,398
Other	7,407	6,965
	55,237	58,639
Valuation allowance	(55,237)	(58,639)
Total deferred tax assets, net of valuation allowance	\$	\$

**8. Impact of Recently Issued Accounting Standards.**

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS 157). SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 applies whenever other standards required (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after

November 15, 2007. The Company is currently evaluating the effect that the adoption of SFAS 157 will have on its consolidated results of operations and financial condition and is not yet in a position to determine such effects.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115 (SFAS 159). SFAS 159 expands the use of fair value accounting but does not affect existing standards that require assets or liabilities to be carried at fair value. Under SFAS 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be

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

recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred, such as debt issuance costs. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS 159, changes in fair value are recognized in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and is required to be adopted by the Company in the first quarter of fiscal 2008. The Company is currently determining whether fair value accounting is appropriate for any of the eligible items and cannot estimate the impact, if any, that SFAS 159 will have on the Company's consolidated results of operations and financial condition.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* (SFAS 141R). SFAS 141R requires the use of full fair value to record all the identifiable assets, liabilities, noncontrolling interests and goodwill acquired in a business combination. SFAS 141R is effective for fiscal years beginning on or after December 15, 2008.

**9. Quarterly Data (unaudited)**

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

	<b>Year Ended December 31, 2007</b>			
	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
Total revenues	\$ 33,220	\$ 35,618	\$ 38,522	\$ 46,930
Gross profit	27,513	28,908	31,597	38,890
Total operating expenses	33,792	33,952	35,182	41,234
Net loss	\$ (4,420)	\$ (3,416)	\$ (2,283)	\$ (1,146)
Basic and diluted net loss per common share	\$ (0.13)	\$ (0.10)	\$ (0.07)	\$ (0.03)

	<b>Year Ended December 31, 2006</b>			
	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
Total revenues	\$ 19,685	\$ 22,724	\$ 25,194	\$ 30,488
Gross profit	15,805	17,637	20,289	25,332
Total operating expenses	25,009	37,944	40,809	29,527
Net loss	\$ (8,106)	\$ (18,470)	\$ (18,651)	\$ (2,683)
Basic and diluted net loss per common share	\$ (0.27)	\$ (0.56)	\$ (0.56)	\$ (0.08)



**Table of Contents****NuVasive, Inc.****Schedule II: Valuation Accounts**

	<b>Balance at Beginning of Period</b>	<b>Additions(1)</b>	<b>Deductions(2)</b>	<b>Balance at End of Period</b>
	<b>(In thousands)</b>			
Accounts Receivable Reserve				
Year ended December 31, 2007	\$ 737	\$ 991	\$ 802	\$ 926
Year ended December 31, 2006	\$ 613	\$ 495	\$ 371	\$ 737
Year ended December 31, 2005	\$ 255	\$ 443	\$ 85	\$ 613

	<b>Balance at Beginning of Period</b>	<b>Additions(3)</b>	<b>Deductions(4)</b>	<b>Balance at End of Period</b>
Inventory Reserve				
Year ended December 31, 2007	\$ 3,100	\$ 3,551	\$ 3,037	\$ 3,614
Year ended December 31, 2006	\$ 1,332	\$ 2,685	\$ 917	\$ 3,100
Year ended December 31, 2005	\$ 844	\$ 1,019	\$ 531	\$ 1,332

(1) Amount represents customer balances deemed uncollectible.

(2) Uncollectible accounts written-off, net of recoveries.

(3) Amount represents excess and obsolete reserve recorded to cost of sales. In 2006, this amount includes a reserve of approximately \$343,000 recorded in connection with planned 2006 product introductions and enhancements. In 2005, this amount includes an approximately \$484,000 write-off of cervical plate inventory in connection with the acquisition of RSB Spine LLC.

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

**Table of Contents****Index to Exhibits**

<b>Exhibit Number</b>	<b>Description</b>
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(17)	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
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)#	

Edgar Filing: NUVASIVE INC - Form 10-K

- 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



**Table of Contents**

<b>Exhibit Number</b>	<b>Description</b>
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(8)	Intellectual Property Purchase Agreement, dated October 10, 2002, between NuVasive, Inc. and Spine Partners, LLC
10.25(5)	Intellectual Property Purchase Agreement Addendum, dated as of August 12, 2005, by and between NuVasive, Inc. and Spine Partners, LLC
10.26(13)	Sublease, dated October 12, 2004, by and between NuVasive, Inc. and Gateway, Inc.
10.27(11)	Earnest Money Contract and Agreement, dated May 26, 2006, between NuVasive, Inc. and New York Life Insurance Company
10.28(14)#	Description of 2006 performance bonus arrangements for our executive officers
10.29(15)#	Description of 2007 annual salaries for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
10.30(16)#	Summary of the 2007 bonus payments to our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
10.31(18)	Customer Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation.
10.32(18)	IBM Global Services Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation.
10.33(19)	Lease Agreement for Sorrento Summit, entered into as of November 6, 2007, between the Company and HCPI/Sorrento, LLC.
10.34(20)#	Description of 2008 annual salaries and annual stock grant for 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
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.

**Table of Contents**

- (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 March 13, 2006.
- (15) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 22, 2007.
- (16) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on February 23, 2007.
- (17) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 16, 2006.
- (18) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on August 8, 2007.
- (19) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on November 8, 2007.
- (20) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 11, 2008.

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.