NUVASIVE INC
Form 10-K
March 02, 2009

Table of Contents

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

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2008

OR

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

Commission file number: 000-50744

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

Delaware	**33-0768598**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
7475 Lusk Boulevard, San Diego, California	**92121**
(Address of principal executive offices)	*(Zip Code)*

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

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

Title of Each Class:	**Name of Each Exchange on which Registered:**
Common Stock, par value $0.001 per share	**The NASDAQ Stock Market LLC (NASDAQ Global Select Market)**

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $1.4 billion as of the last business day of the registrant s most recently completed second fiscal quarter (i.e. June 30, 2008), based upon the closing sale price for the registrant s common stock on that day as reported by the NASDAQ Global Select Market. Shares of common stock held by each officer and director have been excluded in that such persons may be deemed to be affiliates.

There were 36,387,061 shares of the registrant s common stock issued and outstanding as of February 20, 2009.

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 21, 2009.

NuVasive, Inc.

Form 10-K for the Fiscal Year ended December 31, 2008

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 simila intended to identify forward-looking statements.

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

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

Item 1. *Business.*

Overview

We are a medical device company focused on the design, development and marketing of products for the surgical treatment of spine disorders. Our currently-marketed product portfolio is focused on applications for spine fusion surgery, a market estimated to exceed $4.6 billion in the United States in 2009. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS™, as well as a growing offering of cervical, biologics and motion preservation products. 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 to expand our MAS product platform, advance the applications of our unique technology to additional procedures, and develop motion preserving products such as total disc replacement and nucleus-like cervical disc replacement. We dedicate significant resources toward training spine surgeons on our unique technology and products. Currently, we are training approximately 400 to 500 surgeons annually.

Our MAS platform combines four categories of our product offerings:

NeuroVision® a proprietary software-driven nerve avoidance system;

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

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

Specialized implants includes our SpheRX® 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.

Table of Contents

Simply stated, the MAS platform does not force surgeons to reinvent approaches that add complexity and undermine safety, ease and efficacy. An important ongoing objective has been to maintain a leading position in access and nerve avoidance, as well as being the leader and pioneer in lateral surgery. Our MAS platform, with the unique advantages provided by NeuroVision, enables an innovative lateral procedure known as eXtreme Lateral Interbody Fusion, or XLIF®, in which surgeons access the spine for a fusion procedure from the side of the patient s body, rather than from the front or back. Our MaXcess instruments provide access to the spine in a manner that affords direct visibility and our NeuroVision system allows surgeons to avoid critical nerves. We believe that the procedures facilitated by our MAS platform reduce operating times, decrease trauma and blood loss, and lead to faster overall patient recovery times compared to open spine surgery.

In recent years we have significantly expanded our product offering relating to procedures in the cervical spine as well as in the area of biologics. Our cervical product offering now provides a full set of solutions for cervical fusion surgery, including both allograft and CoRoent implants, as well as cervical plating and posterior fixation products. Our biologic offering began in 2007 with the acquisition of rights to FormaGraft, a collagen synthetic product used to aid the fusion process. This offering expanded in 2008 with the acquisition of Osteocel from Osiris Therapeutics, an allograft cellular matrix containing viable mesenchymal stem cells, or MSCs, to aid in spinal fusion.

We also offer a suite of traditional spine surgery products, including certain products in our 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 140,000 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. Our primary distribution and warehousing operations are located in our facility in Memphis, Tennessee. Our business requires overnight delivery of products and surgical instruments for almost all surgeries involving our products. Because of its location and proximity to overnight third-party transporters, our Memphis facility has greatly enhanced our ability to meet demanding delivery schedules and provide a greater level of customer service.

Recent Product Introductions

In the last several years, we have introduced numerous new products and product enhancements that have significantly expanded our MAS platform, enhanced the applications of the XLIF procedure, expanded our offering of cervical products, and marked our entrance into the growing motion preservation market. We have also acquired complementary and strategic assets and technology, particularly in the area of biologics. Our newly-launched and acquired 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 are pedicle screw systems designed for a posterior approach, which have 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.

*XLP*tm *Lateral Plate* is a fixation plate designed to be placed through the same incision used in an XLIF procedure and 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 for spine surgery and the use of implants in the same safe and reproducible way XLIF has demonstrated in the lumbar spine.

Table of Contents

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 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.

Helix ACP™ and Helix Mini ACP™ are plates designed for the anterior approach in cervical surgeries. This combination of plates feature a one step canted coil locking mechanism for surgical ease and efficiency and provide multiple surgical options for cervical fixation.

VuePoint™ OCT is a posterior cervical fixation system comprised of rods, hooks, and screws. It is designed with full junctional capabilities, easily allowing occipito-cervical and cervico-thoracic junctional fixation.

CoRoent Family of Products are 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. In 2008, the following CoRoent products were introduced: CoRoent SLP (cervical), CoRoent LO (large oblique), CoRoent LI (large impacted), CoRoent XL-C (coronal tapered), CoRoent XL-W (extra-large wide), and CoRoent XL-60.

Affix™ is a plate that facilitates fusion between two spinous processes. It is often used with our next generation Extensure H2 product to stabilize and restore foraminal volume enabling nerves to pass freely.

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 to customers. Our offering of MaXcess retractors now provides access for surgery in all areas of the spine.

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

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

Full Spinal Cord Monitoring NeuroVision now incorporates multiple monitoring modalities, allowing monitoring of the entire spinal cord (MEP and SSEP).

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.

Navigated Guidance Guidance technology that enables precise pedicle screw placement replicated from pre-operation planning. This technology also potentially decreases the amount of radiation exposure to surgeons and patients during procedures.

System updates An 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 with redesigned connectors, to

Table of Contents

streamline the application of surface electrodes during patient preparation that relay muscle activity to the monitoring system.

Biologics We have expanded our product offerings in the last few years to include products in the biologics market. The biologics market in spine surgery has grown to approximately $1.5 billion and consists of autograft (autologous human tissue), allograft (donated human tissue), a varied offering of synthetic products, stem cell-based products, and growth factors. We made our initial entry into this market in 2007 by acquiring rights to FormaGraft, a collagen-based synthetic product. We expanded this offering in 2008 by acquiring Osteocel, an allograft cellular matrix containing viable MSCs to aid in fusion. Additionally, in early 2009 we made an investment in Progentix Orthobiology BV, a private company working to develop a novel synthetic. This investment includes options and obligations to buy Progentix Orthobiology BV over time as development milestones are achieved.

Our Strategy

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

Establish our MAS Platform as a Standard of Care. We believe our MAS platform has the potential to become the standard of care for minimally invasive spine surgery as spine surgeons continue to adopt our products and recognize their benefits. We also believe that our MAS platform has the potential to dramatically improve the clinical results of minimally invasive spine surgery. We dedicate significant resources to educating spine surgeons on the clinical benefits of our products, and we intend to capitalize on patient demand for minimally disruptive surgical alternatives.

Continue to Introduce New Creative Products. One of our core competencies is our ability to develop and commercialize creative spine surgery products. In the past three years, we have introduced more than 40 new products and product enhancements. We have several additional products currently under development that should expand our presence in fusion surgery as well as provide an entry into the motion preservation market segment. We intend to accomplish this with an unwavering commitment to our MAS platform and building on our core technology. We also intend to selectively acquire unique products or technologies that we believe will keep us on the forefront of innovation. 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 four Area Vice Presidents, each of whom is responsible for a geographic region of the country. Each Area Vice President is responsible for Sales Directors, who in turn are responsible for Area Business Managers, or ABMs, who are NuVasive shareowners (our employees) responsible for a defined territory. The remainder of the sales force are both direct (our shareowners) and exclusive independent sales representatives or exclusive distributor agents, each acting as our sole representative and selling only NuVasive spine products in a given territory.

Provide Tailored Solutions in Response to Surgeon Needs. Responding quickly to the needs of spine surgeons, which we refer to as Absolute Responsiveness®, is central to our corporate culture, critical to our success and, we believe, differentiates us from our competition. We solicit information and feedback from our surgeon

customers and clinical advisors regarding the utility of and potential improvements to our products. For example, we have an on-site machine shop to allow us to rapidly manufacture product prototypes and a state-of-the-art cadaver operating theatre to provide clinical training and validate new ideas through prototype testing.

Table of Contents

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; (iii) our FormaGraft bone graft biologic product and (iv) Osteocel, an allograft stem cell-based biologic product. 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 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, over $4.1 billion in 2008 and is estimated to grow to over $4.6 billion in 2009.

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 than prior generations.

Table of Contents

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

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

- Lumbar fusion procedures in which the surgeon approaches the spine through the patient s back or abdomen;
- Decompression, which is removal of a portion of bone over the nerve root or disc from under the nerve root to relieve pinching of the nerve; and
- Procedures designed to correct and/or stabilize the spine while simultaneously maintaining motion.

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

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 2008 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 one 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

Table of Contents

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 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 U.S Food and Drug Administration, or 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. With recent additions, the health and integrity of the spinal cord can also be assessed using motor evoked potentials (MEPs) and somatosensory evoked potentials (SSEPs). Both methods of intraoperative monitoring involve applying stimulation and recording the response that must travel along the motor or sensory aspect of the spinal cord. The data developed using NeuroVision can now be sent to health care professionals for additional interpretation of intraoperative information via networking capabilities and software that allows real-time assessment from remote locations.

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.

MaXcess II is 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.

MaXcess III is our most advanced retractor system. MaXcess III is a further enhancement of the previous MaXcess systems (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.

MaXcess-Micro Access System is a product that brings all of the benefits of minimally disruptive surgery to both the cervical spine for posterior application and the lumbar spine for decompression.

Table of Contents

Our MaXcess products have now 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 XLP Lateral Plate, our CoRoent family of unique implants for partial vertebral body replacement and interbody implants, precision-machined allograft implants, 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 implant 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.

We also made significant progress in the last couple years 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 is now complete.

Our motion preservation product development efforts include our mechanical lateral total disc replacement (XL TDR™). We filed with the FDA for Investigational Device Exemptions, or IDEs, on the mechanical lateral TDR as well as our ceramic-on-ceramic cervical TDR, CerPass™, in late 2007 and were granted these IDEs in 2008.

MAS Biologics

As part of our MAS offering, we have expanded our product offerings in the last couple years to include products in the biologics market. The biologics market in spine surgery has grown to approximately $1.5 billion and consists of autograft (autologous human tissue), allograft (donated human tissue), a varied offering of synthetic products, stem cell-based products, and growth factors. We made our initial entry into this market in 2007 by acquiring rights to FormaGraft, a collagen-based synthetic product. We expanded this offering in 2008 by acquiring Osteocel, an allograft cellular matrix containing viable MSCs to aid in fusion. Additionally, in early 2009 we made an investment

in Progentix Orthobiology BV, a private company working to develop a novel synthetic biologic. This investment includes options and obligations to buy Progentix Orthobiology BV over time as development milestones are achieved.

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

Table of Contents

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. 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 is now complete. NeoDisc is a nucleus-like cervical disc replacement device designed to preserve motion in the cervical region of the spine and provide an alternative to pre-surgical treatment and mechanical total disc replacement (TDR) or spinal fusion. Our motion preservation product development efforts include our mechanical lateral total disc replacement (XL TDR). We were granted IDEs on the mechanical lateral TDR as well as our ceramic-on-ceramic cervical TDR, CerPass, in 2008.

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.

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 22 shareowners, including seven who hold Ph.D. degrees and four 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 four Area Vice Presidents. Each Area Vice President is responsible for a portion of the United States and manages the directly-employed and independent sales agents engaged in that territory.

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.

NuVasive has also helped to establish SOLAS[tm], 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.

Table of Contents

Manufacturing and Supply

We rely on third parties for the manufacture of our products, their components and servicing. We currently maintain alternative manufacturing sources for some components of NeuroVision, MaXcess, and SpheRx, as well as some of our other finished goods products. We have and are in the process of identifying and qualifying additional suppliers for our highest volume products to maintain consistent supply to our customers. Our outsourcing strategy is targeted at companies that meet FDA, International Organization for Standardization, or ISO, and quality standards supported by internal policies and procedures. Supplier performance is maintained and managed through a 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 tissue 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. Like our relationships with our device manufacturing suppliers, we subject our tissue processing suppliers to the same quality criteria in terms of selection, qualification, and verification of processed tissue quality upon receipt of goods, as well as hold them accountable to compliance with FDA regulation, state requirements, as well as voluntary industry standards such as the American Association of Tissue Banks, or AATB.

We acquired NeoDisc, an investigational cervical disc replacement device, from Pearsalls Limited. NeoDisc is currently the subject of a clinical trial, and our supply of the product comes solely from Pearsalls Limited. We are in the process of determining whether to establish alternate suppliers.

We acquired certain rights to FormaGraft, a ceramic/collagen bone graft matrix used to promote spinal fusion, from Radius Medical, LLC. Our supply of the product comes solely from Maxigen Biotech. We are in the process of determining whether to establish alternate suppliers.

As part of the acquisition of the Osteocel Biologics Business from Osiris Therapeutics, Inc., Osiris will act as our exclusive supplier of Osteocel Plus for a period of 18 months from the close of the transaction. In that capacity, we will be highly dependent on Osiris for supply of Osteocel Plus and any failure on their part to process and supply such product will negatively impact our ability to meet projected sales and distribution of the product. Osteocel Plus is processed from allograft, which is donated human tissue.

We, and our third-party manufacturers, are subject to the FDA s quality system regulations, state regulations, such as the regulations promulgated by the California Department of Health Services, and regulations promulgated by the European Union. For tissue products, we are FDA registered and licensed in the States of California, New York, Florida, Maryland and Oregon. For our device implants and instruments, we are FDA registered, California licensed, CE marked and ISO certified. CE is an abbreviation for European Compliance. Our facility and the facilities of our third-party manufacturers are subject to periodic unannounced inspections by regulatory authorities, and may undergo compliance inspections conducted by the FDA and corresponding state agencies. The FDA may impose enforcement, inspections or audits at any time.

Loaner Equipment

We seek to deliver surgical instrument sets, including our NeuroVision systems, 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

Table of Contents

products. These loaners are important to the growth of our business and we anticipate additional investments in our loaner assets.

Intellectual Property

We rely on a combination of patent, trademark, copyright, trade secret and other intellectual property laws, nondisclosure agreements and other measures to protect our intellectual property rights. We believe that in order to have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. We require our shareowners, consultants and advisors to execute confidentiality agreements in connection with their 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, 2008, we had 53 issued U.S. patents, 36 foreign national patents, and 267 pending patent applications, including 198 U.S. applications, 11 international (PCT) applications and 58 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;

Biologics, including Osteocel and Formagraft;

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, 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 12 issued U.S. patents, 48 U.S. patent applications (including 41 U.S. utility patent applications, 6 U.S. provisional applications, and 1 U.S. design application), 10 issued foreign national patents, 2 international (PCT) patent applications, and 26 foreign national applications on this system and related instrumentation.

We have also undertaken to protect our XLIF 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 3 other issued U.S. Patents and 1 issued foreign patent, our XLIF patent portfolio includes 35 U.S. utility patent applications, 8 U.S. provisional patent applications, 2 international (PCT) patent applications, and 18 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 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 10 U.S. utility applications, 2 U.S. provisional applications, 1 issued foreign national patent, and 3 foreign national applications.

Table of Contents

Our biologics IP portfolio includes 4 US patent applications, 2 foreign applications, 1 International Application (PCT) owned outright by NuVasive. It also includes 4 US patents and 4 foreign patents exclusively licensed from Osiris Therapeutics. Collectively our biologics IP portfolio covers all aspects of Osteocel and Formagraft, including broad rights to Osteocel via the Osiris exclusive licence.

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 3 issued

Table of Contents

U.S. patents, 26 U.S. applications (including 20 U.S. utility applications and 6 U.S. provisional applications), 23 issued foreign national patents, 6 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. Our success will depend in part on our not infringing patents issued to others, including our competitors and potential competitors. As the number of entrants into our market increases, the possibility of 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. There are numerous risks associated with our intellectual property. For a complete discussion of these risks, please see the Risk Factors section of this Annual Report.

Trademarks

As of December 31, 2008, we had 73 trademark registrations, both domestic and foreign, including the following U.S. trademarks: NuVasive, NeuroVision, MAS, MaXcess, XLIF, SpheRx, DBR, CoRoent, SmartPlate, Creative Spine Technology, Triad, InStim, NeoDisc, ExtenSure, FormaGraft, Osteocel, Nerve Avoidance Leader and Absolute Responsiveness. We also had 21 trademark applications pending, both domestic and foreign, including the following trademarks: ExtenSure, CerPass, XLP, Halo, VuePoint, Embrace, Embody, Affix, ILIF, Magnitude, M5, NVM5, and XL TDR.

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, Cadwell, and Nicolet Biomedical. We believe our system competes favorably with these 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 with automated, real-time information. Medtronic s NIM-Eclipse neuromonitoring system, acquired from Axon, while surgeon directed, requires manual interpretation for neuromonitoring. Several companies offer products that compete with our MaXcess system, SpheRx pedicle screw system and implants, including competitive offerings by DePuy Spine, Inc., 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 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-though products along the entirety of the spine. However, with the introduction of competing lateral techniques we will face more competition in the market. Our allograft implants are 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 implant market.

Table of Contents

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.

While our recent acquisition of Osteocel and our investment in Progentix Orthobiology BV provide us with additional products to compete in the biologics market, competition is increasing. In addition to our larger competitors, which are investing in their biologics platforms, we face competition from smaller orthobiologics companies such as Osteotech.

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

Government Regulation

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

product design and development;

product testing;

product manufacturing;

product labeling;

product storage;

premarket clearance or approval;

advertising and promotion; and

product sales and distribution.

FDA s Premarket Clearance and Approval Requirements

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

510(k) Clearance Pathway

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

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

Table of Contents

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

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

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

Table of Contents

Clinical Trials

A clinical trial is almost always required to support a PMA application and is sometimes required for a 510(k) premarket notification. These trials generally require approval of a submitted application for an 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, our embroidery cervical disc replacement device, and have completed patient enrollment for this trial. We filed with the FDA for IDEs on the mechanical lateral TDR as well as our ceramic-on-ceramic TDR, CerPass, and were granted these IDEs in 2008. Our clinical trials must be conducted in accordance with FDA regulations and other federal regulations concerning human subject protection and privacy and must be publicly registered. The results of our clinical trials may not be sufficient to obtain approval of our product. There are numerous risks associated with conducting such a clinical trial, including the high costs and uncertain outcomes. For a complete discussion of these risks, please see the Risk Factors section of this Annual Report.

Pervasive and Continuing FDA Regulation

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

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

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

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

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

fines, injunctions, and civil penalties;

recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

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

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

criminal prosecution.

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

Table of Contents

Sales and Marketing Commercial Compliance

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

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

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

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

In addition to the anti-kickback law, federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Off-label promotion has been pursued as a violation of the federal false claims laws. Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although surgeons are permitted to use medical devices for indications other than those cleared or approved by the FDA based on their medical judgment, we are prohibited from promoting products for such off-label uses. Additionally, the majority of states in which we market our products have similar anti-kickback, false claims, anti-fee splitting and self-referral laws, imposing substantial penalties for violations.

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

Additionally, the commercial compliance environment is continually evolving in the healthcare industry as some states, including California and Massachusetts, with more states following suit, mandate implementation of commercial compliance programs, along with the tracking and reporting of gifts, compensation, and other remuneration to physicians. Federal legislation, pursuant to the Physician Payments Sunshine Act of 2009, has been proposed and is moving forward in Congress. This legislation would require public disclosure to the federal government of payments to physicians. These requirements all provide for penalties for non-compliance. The shifting commercial compliance environment, along with the requirement to comply with multiple jurisdictions with different compliance and/or reporting requirements, increases the possibility that a healthcare company may run afoul of one or more of the requirements.

International

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

The European Union, which consists of 27 countries in Europe, has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union

with respect to medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a Notified Body. This third-party assessment consists of an audit of the manufacturer s quality system and technical review of the manufacturer s product. We have now successfully passed several Notified Body audits since our original certification in 2001, granting us ISO registration and allowing the CE conformity marking to be applied to certain of our devices under

Table of Contents

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. The majority of states also have anti-kickback laws which establish similar prohibitions. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil penalties including, for example, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid.

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigations of health care providers, suppliers and manufacturers throughout the country for a wide variety of Medicare billing practices, and

has obtained multi-million and billion 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.

Table of Contents

Shareowners (our employees)

We refer to our employees as shareowners. As of December 31, 2008, we had 444 shareowners, of which 52 were employed in research and development, 38 in clinical and regulatory, 165 in general and administrative and operations and 189 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 7475 Lusk Boulevard, San Diego, California 92121, and our telephone number is (858) 909-1800. Our website is located at *www.nuvasive.com.*

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to those reports, electronically with the Securities and Exchange Commission (the Commission). We make these reports available free of charge on our website under the investor relations page as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Commission. All such reports were made available in this fashion during 2008.

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 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.

Table of Contents

To the extent we sell our products internationally, market acceptance may depend, in part, upon the availability of reimbursement within prevailing healthcare payment systems. 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 U.S. Food and Drug Administration, or FDA, and other regulatory approvals or clearances for products and product enhancements;
- more expansive portfolios of intellectual property rights; and
- greater financial and other resources for product research and development, sales and marketing and litigation.

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

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;

Table of Contents

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 Osiris Therapeutics, Inc., 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.

If our acquisitions are unsuccessful, our business may be harmed.

As part of our business strategy, we have acquired companies, technologies and product lines to maintain our objectives of developing or acquiring innovative technologies. Acquisitions involve numerous risks, including the following:

- the possibility that we will pay more than the value we derive from the acquisition, which could result in future non-cash impairment charges;

- difficulties in integration of the operations, technologies, and products of the acquired companies, which may require significant attention of our management that otherwise would be available for the ongoing development of our business;

- the assumption of certain known and unknown liabilities of the acquired companies; and

Table of Contents

difficulties in retaining key relationships with employees, customers, partners and suppliers of the acquired company.

Any of these factors could have a negative impact on our business, results of operations or financing position. Specifically, our recent Osteocel acquisition is the largest acquisition we have ever completed, with a potential total acquisition price of $85 million. If we failed to properly value that business, or fail to generate expected revenues or profits from operation of that business, our results of operations will suffer. Additionally, our investment in Progentix Orthobiology BV, a private company working to develop a novel synthetic biologic, includes options and obligations to buy Progentix Orthobiology BV over time as development milestones are achieved. If the Progentix products are not commercially successful or unable to meet expected commercial success, but certain development milestones are achieved, we may be obligated to purchase Progentix Orthobiology BV at a price greater than the value of the company.

Further, past and potential acquisitions entail risks, uncertainties and potential disruptions to our business, especially where we have little experience as a company developing or marketing a particular product or technology (as is the case with the Osteocel biologic product). For example, we may not be able to successfully integrate an acquired company s operations, technologies, products and services, information systems and personnel into our business, which will be required if we assume ownership of the Osteocel processing facility. Acquisitions may also further strain our existing financial and managerial controls, and divert management s attention away from our other business concerns.

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

We rely on third-party suppliers and manufacturers to 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 for our current product lines 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.

As part of the acquisition of the Osteocel® Biologics Business from Osiris Therapeutics, Inc., Osiris will act as our exclusive supplier of Osteocel Plus for a period of 18 months from the close of the transaction. In that capacity, we will be highly dependent on Osiris for supply of Osteocel Plus and any failure on their part to process and supply such product will negatively impact our ability to meet projected sales and distribution of the product. Osteocel Plus is processed from allograft, which is donated human tissue. Allograft is a supply-constrained material and there is ongoing risk that there will be insufficient supply to produce the necessary quantity of Osteocel Plus. Allograft also carries with it the possibility of disease transmission, which could result in negative patient outcomes and negative publicity for our company.

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 manage the complexities associated with a larger, faster growing and more geographically diverse organization;
- expand our clinical development resources to manage and execute increasingly global, larger and more complex clinical trials;

expand our sales and marketing resources for international expansion and to launch 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

Table of Contents

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 completed the implementation of our new enterprise resource planning, or ERP, software system in 2008 to support our increasingly complex business and business processes. After the initial implementation, we determined that additional consulting time was important for a successful transition and therefore incurred incremental expenses related to the on-going support costs for the implementation. These investments minimize the potential for transitional risk of moving to the new ERP system and will assist in driving expected efficiencies in 2009. We expect to move to a more traditional and leverageable on-going support model in 2009, without significant incremental costs.

Further, our anticipated growth, both internationally and domestically, will place additional strain on our suppliers and manufacturers, resulting in increased need for us to carefully monitor quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

Additionally, as the number of products we offer grows, it will become more difficult for our sales force to focus on selling each product and, thereby, possibly limiting the sales potential of certain products.

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 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.

Our NeoDisc® device is currently the subject of an Investigational Device Exemption clinical study. We have fully enrolled this clinical study and are in the follow-up period. Data is being collected from patients in the clinical study, and we will rely on that data to determine whether the device is safe and effective. There is no assurance that the NeoDisc device will be approved for sale in the United States by the FDA. The clinical study may prove that the device does not provide the intended benefit or that there are unintended negative side effects of the device that make it unsafe or not effective. In addition, the NeoDisc device includes embroidery technology, which has not been thoroughly studied for use as permanent implants in the spine. Any failure or delay in obtaining regulatory approval for NeoDisc will hamper our ability to commercialize the device in the United States.

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

Table of Contents

will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. Additionally, any modification to a 510(k)-cleared device that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, requires a new 510(k) clearance or, possibly, premarket approval. The FDA may not agree with any of our decisions regarding whether new clearances or approvals are necessary.

Our failure to comply with such regulations could lead to the imposition of injunctions, suspensions or loss of regulatory approvals, product recalls, termination of distribution, or product seizures. In the most egregious cases, criminal sanctions or closure of our manufacturing facilities are possible.

Pursuant to FDA regulations, we can only market our products for cleared or approved uses. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we market and sell our products in foreign countries, we may be subject to rigorous regulation in the future. In such circumstances, we would rely significantly on our foreign independent sales agencies to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

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

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

We and our suppliers are required to comply with the FDA s quality system regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA enforces the quality system regulation through inspections. If we or one of our suppliers fail a quality system regulations inspection or if any corrective action plan is not sufficient, the manufacture of our products could be delayed. We underwent an FDA inspection in April 2005 regarding our allograft implant business and another FDA inspection in June 2007 regarding our medical device activities. In connection with these inspections

as well as prior inspections, the FDA requested minor corrective actions, which we have taken to satisfy the corrective actions. There can be no assurance the FDA will not subject us to further enforcement action and the FDA may impose additional inspections at any time.

Additionally, we are the legal manufacturer of record for the products that are distributed and labeled by NuVasive, regardless of whether the products are manufactured by us or our suppliers. Thus, a failure by us or our

Table of Contents

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

fines, injunctions, and civil penalties;

recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

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

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

criminal prosecution.

Risks Related to Our Financial Results and Need for Financing

We have always incurred losses and have incurred significant total operating losses since our inception, and we cannot assure you that we will achieve profitability or that, if profitability is achieved, that we will be able to sustain profitability.

Since our inception in 1997, we have yet to generate ongoing sufficient sales of our products to achieve profits on an annual basis or to become profitable overall. Our net loss for the twelve months ended December 31, 2008 was approximately $27.5 million, as compared to approximately $11.3 million for the twelve months ended December 31, 2007. At December 31, 2008, we had an accumulated deficit of approximately $195.5 million, and cash, cash equivalents and short and long term investments totaling approximately $223.4 million. Even if we do achieve profitability as planned, we may not be able to sustain or increase profitability on an ongoing basis.

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

At December 31, 2008, we had $132.3 million in cash and cash equivalents and $91.0 million in investments in marketable securities. We have historically invested these amounts in U.S. treasuries and government agencies, corporate debt, money market funds, commercial paper and municipal bonds meeting certain criteria. Certain of these investments are subject to general credit, liquidity and other market risks. The general condition of the financial markets and the economy has exacerbated those risks and may affect the value of our current investments and restrict our ability to access the capital markets. Due to the continued downward yield trends on our cash, cash equivalents and marketable securities, our net interest income has progressively been reduced and, in the fourth quarter of 2008, it resulted in a net interest expense position. As our effective yield from our cash, cash equivalents and marketable securities is lower than our coupon rate, we will likely continue to record interest expense, net, through 2009. If there are further declines in the yield of our investment portfolio and we are unable to find alternative sources of liquidity, our results of operations, liquidity and financial condition may be adversely affected.

The liquidity of our customers and suppliers may also be affected by the current financial crisis. If our suppliers experience credit or liquidity problems important sources of raw materials or manufactured goods may be affected. If our customers liquidity and creditworthiness is negatively impacted by the current financial crisis and the condition of the economy, our ability to collect on our outstanding invoices and our collection cycles may be adversely affected.

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

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

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

Table of Contents

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.

We may not be able to sublease our former headquarters or receive rental income on any such sublease to cover our lease obligations.

We completed our relocation to the new facility, which serves as our current headquarters, in the third quarter of 2008. Subsequent to the relocation, we have attempted to sublease our former facility through August 2012, the date on which the related lease agreement expires. We have encountered and may continue to 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 date, we have incurred an additional $4.8 million in operating expenses for 2008. Continued difficulty in subleasing our former headquarters will cause us to incur further increases in operating expenses, which could cause us to exceed our planned expense levels and adversely affect our financial results. Furthermore, inability to sublease such facility may adversely affect our liquidity and capital resources.

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

In connection with our recent acquisitions, we may be obligated to make payments in the future upon the achievement of certain milestones. The likelihood of those milestones being achieved and the timing of such payments are uncertain and are subject to change over time. If we are required to make those payments, particularly at a time when

we are experiencing financial difficulty, our liquidity, financial results and financial condition may be adversely affected.

Table of Contents

Risks Related to Our Intellectual Property and Potential Litigation

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

On August 18, 2008, Medtronic Sofamor Danek USA, Inc. and its related entities (Medtronic) filed suit against NuVasive in the United States District Court for the Southern District of California, alleging that certain of our products infringe, or contribute to the infringement of, U.S. patents owned by Medtronic. Medtronic is a large, publicly-traded corporation with significantly greater financial resources than us.

Intellectual property litigation is expensive, complex and lengthy and its outcome is difficult to predict. We may also be subject to negative publicity due to the litigation. Pending or future patent litigation against us or any strategic partners or licensees may force us or any strategic partners or licensees to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party s intellectual property, unless that party grants us or any strategic partners or licensees rights to use its intellectual property, and may significantly divert the attention of our technical and management personnel. In the event that our right to market any of our products is successfully challenged, and if we fail to obtain a required license or are unable to design around a patent, our business, financial condition or results of operations could be materially adversely affected. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all and any licenses may require substantial royalties or other payments by us. Even if any strategic partners, licensees or we were able to obtain rights to the third party s intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Furthermore, if we are found to infringe patent claims of a third party, we may, among other things, be required to pay damages, including up to treble damages and attorney s fees and costs, which may be substantial.

An unfavorable outcome for us in this patent litigation could significantly harm our business if such outcome makes us unable to commercialize some of our current or potential products or cease some of our business operations. In addition, costs of defense and any damages resulting from the litigation may materially adversely affect our business and financial results. The litigation may also harm our relationships with existing customers and subject us to negative publicity, each of which could harm our business and financial results.

Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain.

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our pending U.S. and foreign patent applications may not issue as patents in a form that will be advantageous to us or may issue and be subsequently successfully challenged by others and invalidated. In addition, our pending patent applications include claims to material aspects of our products and procedures that are not currently protected by issued patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Competitors may be able to design around our patents or develop products which provide outcomes which are comparable to ours. Although we have taken steps to protect our intellectual property and proprietary technology, including entering into confidentiality agreements and intellectual property assignment agreements with our officers, shareowners, consultants and advisors, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary

information in the event of unauthorized use or disclosure or other breaches of the agreements. Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

In addition, there are numerous proposed changes to the patent laws and rules of the U.S. Patent and Trademark Office which, if enacted, may have a significant impact on our ability to protect our technology and enforce our

Table of Contents

intellectual property rights. For example, proposed changes to the patent rules of the U.S. 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 U.S. Patent and Trademark Office which served to stay the application of the proposed rules. The U.S. Court of Appeals for the Federal Circuit heard argument on the appeal of the case in early December 2008, and is expected to rule in the coming months. 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 U.S. patent laws, including (among other things) changing from a first to invent to a first inventor to file system, limiting the for a where a patentee may file a patent suit, requiring the apportionment of patent damages, and creating a post-grant opposition process to challenge patents after they have issued.

In the event a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult and time consuming. 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. Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to adequately protect our intellectual property rights.

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

A patent infringement suit brought against us or any of our strategic partners or licensees may force us or such strategic partners or licensees to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party s intellectual property, unless that party grants us or our strategic partners or licensees rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all and any licenses may require substantial royalties or other payments by us. Even if our strategic partners, licensees or we were able to obtain rights to the third party s intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could

severely harm our business.

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

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for spine surgery procedures. Spine surgery involves significant risk of serious

Table of Contents

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

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

Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of such prohibitions. In 2007, several medical device manufacturers entered into deferred prosecution agreements with the federal government and paid over $300 million, in aggregate, to the government over allegations that the companies had paid kickbacks to surgeons to reward and incentivize use of their surgical implant products. Additionally, the majority of states in which we market our products have similar anti-kickback, anti-fee splitting and self-referral laws, imposing substantial penalties for violations.

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

non-reimbursable, uses. Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although surgeons are permitted to use medical devices for indications other than those cleared or approved by the FDA based on their medical judgment, we are prohibited from promoting products for such off-label uses. We market our products and provide promotional materials and training programs to surgeons regarding the use of our products. Although we believe our marketing, promotional materials and training programs for surgeons do not constitute promotion of unapproved uses of our products, if it is determined that our marketing, promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in

Table of Contents

addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure and criminal penalty. To enforce compliance with federal laws, the U.S. Department of Justice, or DOJ, has increased its scrutiny of the interactions between healthcare companies and healthcare providers, which has led to an unprecedented level of investigations and settlements in the healthcare industry. Dealing with DOJ investigations can be time- and resource-consuming. Additionally, if a healthcare company settles an investigation with the DOJ, or other law enforcement agencies, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Further, the commercial compliance environment is continually evolving in the healthcare industry with certain states mandating implementation of commercial compliance programs and disclosure requirements while similar legislation has been proposed on the federal level.

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

The scope and enforcement of these laws is uncertain and subject to rapid change, especially in light of the lack of applicable precedent and regulations. There can be no assurance that federal or state regulatory authorities will not challenge or investigate our current or future activities under these laws. Any such challenge or investigation could have a material adverse effect on our business, financial condition and results of operations. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

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

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

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

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

The market price of our common stock is likely to be volatile and may fluctuate substantially due to many factors, including:

- general market conditions and other factors (such as the effect the recent financial crisis is having on stock markets as a whole), including factors unrelated to our operating performance or the operating performance of our competitors;
- volume and timing of orders for our products;
- the introduction of new products or product enhancements by us or our competitors;
- disputes or other developments with respect to intellectual property rights or other potential legal actions;

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

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

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

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

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

Table of Contents

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; and

changes in earnings estimates or recommendations by securities analysts.

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

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

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

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

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

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

prohibit our stockholders from making certain changes to our certificate of incorporation or bylaws except with 662/3% stockholder approval; and

require advance written notice of stockholder proposals and director nominations.

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

We do not intend to pay cash dividends.

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

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

None.

Item 2. ***Properties.***

Our current headquarters are located in an approximately 140,000 square foot facility in San Diego, California that is leased to us until August 2023. 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. We expect to be able to sublease

Table of Contents

our previous corporate headquarters through August 2012, the date on which our related lease agreement expires, however we expect that the space will remain vacant for approximately an additional 20 months from December 31, 2008 with no associated sublease income during that time. Upon moving the final phase of shareowners (employees) and operations to the new headquarters during August of 2008, we recorded a loss equal to the estimated present value of expected net future cash flows in the amount of $4.8 million. We have assumed, in performing the calculation of the loss, that the facility would remain vacant for approximately 24 months from the cease use date in August 2008 given the current market conditions. As of the date of this filing, we have not yet entered into a sublease agreement and cannot be assured that a sublease, if any, will provide the anticipated sublease income. In 2006, we purchased an approximately 100,000 square foot building in Memphis, Tennessee that we use as our primary distribution and warehouse facility.

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

We have been involved in a series of related lawsuits involving families of decedents who donated their bodies through UCLA s willed body program. The complaint alleges that the head of UCLA s willed body program, Henry G. Reid, and a third party, Ernest V. Nelson, improperly sold some of the donated cadavers to the defendants (including NuVasive). Plaintiffs allege the following causes of action: (i) breach of fiduciary duty, (ii) negligence, (iii) fraud, (iv)negligent misrepresentation, (v) negligent infliction of emotional distress, (vi) intentional infliction of emotional distress, (vii) intentional interference with human remains, (viii) negligent interference with human remains, (ix) violation of California Business and Professions Code Section 17200 and (x) injunctive and declaratory relief. We had been dismissed from these lawsuits by the trial court but the decision was appealed and in July 2008, the appellate court reversed the trial court s decision to dismiss us from these lawsuits. We are currently appealing the decision of the appellate court to the Supreme Court of California, which has agreed to hear our appeal.

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.

On August 18, 2008, Medtronic Sofamor Danek USA, Inc. and its related entities (Medtronic) filed suit against NuVasive in the United States District Court for the Southern District of California, alleging that certain of our products (the XLIF procedure, CoRoent XL, Gradiant, MaXcess, SpheRx Guide Assembly, SpheRx DBR, SpheRx DBR Guide, and Helix) infringe, or contribute to the infringement of, twelve U.S. patents: Nos. 5,860,973; 5,772,661; 6,936,051; 6,936,050; 6,916,320; 6,945,933; 7,008,422; 6,530,929; 6,235,028; 6,969,390; 6,428,542; 6,592,586 assigned or licensed to Medtronic (Medtronic Patents). Medtronic is seeking unspecified monetary damages and a court injunction against future infringement by NuVasive. On October 6, 2008, Medtronic filed an amended complaint dropping their claims of infringement relating to U.S. Patent Nos. 7,008,422; 6,530,929; 6,235,028. On October 13, 2008, we answered the complaint denying the allegations and filed counterclaims seeking dismissal of Medtronic s complaint and a declaration that we have not infringed and currently do not infringe any valid claim of the Medtronic Patents, including U.S. Patent Nos. 7,008,422; 6,530,929; 6,235,028 previously dropped by Medtronic. Additionally, we made counterclaims against Medtronic seeking the following relief: (i) Medtronic be permanently enjoined from charging that NuVasive has infringed or is infringing the Medtronic Patents; (ii) a declaration that the Medtronic Patents are invalid; (iii) a declaration that the 5,860,973 and 5,772,661 patents are unenforceable due to inequitable conduct; and (iv) costs and reasonable attorneys fees. On November 19, 2008, NuVasive and Medtronic agreed that U.S. Patent Nos. 7,008,422; 6,530,929; 6,235,028 would be dropped from the case pending the outcome of reexamination proceedings that the U.S. Patent Office on October 24 and 27, 2008, ordered to be conducted on two of those patents, upon requests for reexamination made by Globus Medical, Inc., who is not a party to our litigation with Medtronic. The case pending in the United States District Court on the remaining nine Medtronic patents in suit remains pending in the early stages of the proceedings. An order establishing a schedule for the case is expected within the next few months.

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, 2008.

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

	High	Low
2007:		
First Quarter	$ 25.84	$ 21.59
Second Quarter	28.76	23.47
Third Quarter	37.74	25.93
Fourth Quarter	44.96	34.80
2008:		
First Quarter	$ 43.85	$ 31.17
Second Quarter	46.06	34.48
Third Quarter	58.88	42.88
Fourth Quarter	51.17	29.27

We had approximately 149 stockholders of record as of January 31, 2009. 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, 2008, 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, 2008) 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 19 QUARTER CUMULATIVE TOTAL RETURN*
AMONG NUVASIVE, INC.,
THE NASDAQ COMPOSITE INDEX
AND THE NASDAQ MEDICAL EQUIPMENT INDEX

* $100 invested on 5/13/04 in stock & 4/30/04 in index-including reinvestment of dividends.
Fiscal year ending December 31.

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.

	2008	2007	2006	2005	2004
	(In thousands, except per share data)				
Statement of Operations Data:					
Total revenues	$ 250,082	$ 154,290	$ 98,091	$ 62,606	$ 39,090
Gross profit	205,781	126,908	79,063	50,214	28,862
Total operating expenses	233,641	144,160	133,289	81,708	43,502
Net loss	(27,528)	(11,265)	(47,910)	(30,339)	(14,210)
Net loss per share					
Basic and diluted	$ (0.77)	$ (0.32)	$ (1.47)	$ (1.24)	$ (0.91)
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 223,361	$ 89,698	$ 117,402	$ 19,490	$ 59,153
Working capital	256,491	118,188	136,236	32,829	62,656
Total assets	487,406	225,687	196,184	71,490	80,752
Convertible senior notes	230,000				
Other long-term liabilities	24,288	1,119	1,399	1,665	13
Total stockholders equity	$ 187,631	$ 196,578	$ 176,303	$ 58,136	$ 71,397

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

Forward-Looking Statements May Prove Inaccurate

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

Overview

We are a medical device company focused on the design, development and marketing of products for the surgical treatment of spine disorders. Our currently-marketed product portfolio is focused on applications for spine fusion surgery, a market estimated to exceed $4.6 billion in the United States in 2009. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS®, as well as a growing offering of biologics, cervical and motion preservation products. Our 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 to expand our MAS product platform, advance the applications of our unique technology to additional procedures and develop motion preserving products such as total disc replacement and nucleus-like cervical disc replacement. We dedicate significant resources to our sales and marketing efforts, including training spine surgeons on our unique technology and products.

Our MAS platform combines four categories of our product offerings:

NeuroVision® a proprietary software-driven nerve avoidance system;

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

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

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

Table of Contents

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.

In recent years we have significantly expanded our product offering relating to procedures in the cervical spine as well as the area of biologics. Our cervical product offering now provides a full set of solutions for cervical fusion surgery, including both allograft and CoRoent implants, as well as cervical plating and posterior fixation products. Our biologic offering began in 2007 with the acquisition of rights to FormaGraft , a collagen synthetic product used to aid the fusion process. This offering expanded in 2008 with the acquisition of Osteocel from Osiris Therapeutics, an allograft cellular matrix containing viable mesenchymal stem cells to aid in spinal fusion.

We also offer a suite of traditional spine surgery products, including certain products in our 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, 2008, we had an accumulated deficit of $195.5 million.

Revenues. The majority of our revenues are derived from the sale of disposables and implants and we expect this trend to continue in the near term. We loan our surgical instrument sets, including our NeuroVision systems, 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 primarily from our Memphis facility 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 2008, substantially all of our operations are located in the United States and substantially all of our sales to date have been generated in the United States. We sell our products through a sales force comprised of exclusive independent sales agencies and our own directly employed sales professionals; both selling only NuVasive spine surgery products. Our sales force provides a delivery and consultative service to our surgeon and hospital customers and is compensated based on sales and product placements in their territories. Sales force commissions are reflected in our statement of operations in the sales, marketing and administrative expense line. We expect to continue to expand our distribution channel. Beginning late in 2007 and continuing today, we are continuing our expansion in 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.

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

Table of Contents

evaluate our estimates including those related to bad debts, inventories, valuation of goodwill, intangibles and other long-term assets, income taxes, and stock compensation. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates.

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

Revenue Recognition. We follow the provisions of the Securities and Exchange Commission Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*, which sets forth guidelines for the timing of revenue recognition based upon factors such as passage of title, installation, payment and customer acceptance. We recognize revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured. Specifically, revenue from the sale of implants and disposables is recognized upon 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 and in the economy in general. As a result of this review, the allowance is adjusted on a specific identification basis. An increase to the allowance for doubtful accounts results in a corresponding charge to sales, marketing and administrative expense. We maintain a relatively large customer base that mitigates the risk of concentration with 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 provide an inventory reserve for estimated obsolescence and excess inventory based upon historical turnover and assumptions about future demand for our products and market conditions. Our allograft products have shelf lives ranging from two to four years and are subject to demand fluctuations based on the availability and demand for alternative products. Our inventory, which consists primarily of disposables and specialized implants, is at risk of obsolescence following the introduction and development of new or enhanced products. Our estimates and assumptions for excess and obsolete inventory are reviewed and updated on a quarterly basis. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our revenue forecasts. Increases in the reserve for excess and obsolete inventory result in a corresponding charge to cost of goods sold.

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

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, 2008 due to uncertainties related to our ability to utilize our deferred tax assets in the foreseeable future. Effective January 1, 2007,

we adopted FASB Interpretation (FIN) No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109* (FIN 48), which clarifies the accounting for uncertainty in tax positions. FIN 48 requires that we recognize the impact of a tax position in our financial statements only if that position is more likely than not of being sustained upon examination by taxing authorities, based on the technical merits of the position. Interest and penalties, if any, related to uncertain tax positions will be reflected in income tax expense.

Table of Contents

Valuation of Stock-Based Compensation. We apply the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) 123 (revised 2004), *Share-Based Payments* (SFAS 123(R)), which established 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. Option awards issued to non-employees (excluding non-employee directors) 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 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 expense and the actual factors which become known over time, specifically with respect to anticipated forfeitures, we may change the input factors used in determining stock-based compensation costs for future grants. These changes, if any, may materially impact our results of operations in the period such changes are made.

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

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

SFAS No. 142, *Goodwill and Other Intangible Assets* (SFAS 142), requires that goodwill and intangible assets be assessed for impairment using fair value measurement techniques on an annual basis or more frequently if facts and circumstance warrant such a review. For purposes of assessing the impairment of goodwill, the Company estimates the value of the reporting unit using its market capitalization as the best evidence of fair value. The Company determined that it is a single reporting unit for the purpose of goodwill impairment tests under SFAS 142. If the carrying amount of a reporting unit exceeds its fair value, then a goodwill impairment test is performed to measure the amount of the impairment loss, if any. We performed our annual test of goodwill during the fourth quarter of 2008, and have determined there has been no impairment of goodwill through December 31, 2008.

We evaluate our intangible assets for indications of impairment annually or whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Intangible assets consist of purchased technology, trademarks and trade names, customer relationships and agreements, manufacturing know-how and other intangibles and are amortized on a straight-line basis over their estimated useful lives of two to 20 years. Factors that could trigger an impairment review include significant under-performance relative to expected historical or projected future operating results, significant changes in the manner of our use of the acquired assets or the strategy for our

overall business or significant negative industry or economic trends. If this evaluation indicates that the value of the intangible asset may be impaired, we make an assessment of the recoverability of the net carrying value of the asset over its remaining useful life. If this assessment indicates that the intangible asset is not recoverable, based on the estimated undiscounted future cash flows of the technology over the remaining amortization period, we reduce the net carrying value of the related intangible asset to fair value and may adjust the remaining amortization period. Any such impairment charge could be significant and could have a material adverse

Table of Contents

effect on our reported financial results. We have not recognized any impairment charges on our intangible assets through December 31, 2008. As of December 31, 2008, the net carrying amount of our intangible assets was $57.1 million.

Property and equipment is carried at cost less accumulated depreciation. Depreciation is computed using the straight-line method based on 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 on all property and equipment are expensed as incurred.

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

Results of Operations

Revenue

	Year Ended December 31,			2007 to 2008		2006 to 2007	
	2008	2007	2006	$ Change	% Change	$ Change	% Change
Revenue	$ 250,082	$ 154,290	$ 98,091	$ 95,792	62%	$ 56,199	57%

Revenues have increased over time due primarily to continued market acceptance of our products within our MAS platform, including NeuroVision and MaXcess disposables, and our specialized implants such as our XLP™ lateral plate, SpheRx® pedicle screw systems, and CoRoent® suite of products. The continued adoption of minimally invasive procedures for spine has led to the continued expansion of our innovative lateral procedure known as eXtreme Lateral Interbody Fusion, or XLIF®, in which surgeons access the spine for a fusion procedure from the side of the patient s body, rather than from the front or back. The execution of our strategy of expanding our product offering for the lumbar region and addressing broader indications further up the spine in the thoracic and cervical regions through product introductions in 2008 and 2007 has contributed to revenue growth in each year. We expect revenue to continue to increase, which can be attributed to the continued adoption of our XLIF procedure and deeper penetration into existing accounts as our sales force executes on the strategy of selling the full mix of our products. In addition, the expansion of our biologics offering, including FormaGraft, acquired in January 2007, and Osteocel, acquired in July 2008, and our new product introductions and strategic business and asset acquisitions are expected to lead to continued revenue growth.

Cost of Goods Sold

	Year Ended December 31,			2007 to 2008		2006 to 2007	
	2008	2007	2006	$ Change	% Change	$ Change	% Change
Cost of Goods Sold	$ 44,301	$ 27,382	$ 19,028	$ 16,919	62%	$ 8,354	44%
% of total revenue	18%	18%	19%				

Cost of goods sold consists of costs of purchased goods and depreciation expense for surgical instrument sets.

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 2008 compared to 2007 and in 2007 compared to 2006 resulted primarily from (i) increased material costs of $12.0 million and $6.2 million, respectively, associated with the higher revenue in each year, as well as $5.6 million in costs related to sales of the Osteocel product in 2008; and (ii) increased depreciation expense of $2.9 million and $2.8 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 have launched several new products and enhancements over the last few years. In connection with the product launches, certain instruments and implants

Table of Contents

were rendered obsolete. As a result, we incurred an additional $119,000, $461,000 and $646,000 in 2008, 2007 and 2006, respectively, of expense related to inventory and instruments rendered obsolete. This expense is included in cost of goods sold in the accompanying consolidated statement of operations for the respective years.

Operating Expenses

Sales, Marketing and Administrative

	Year Ended December 31,			2007 to 2008		2006 to 2007	
	2008	2007	2006	$ Change	% Change	$ Change	% Change
Sales, Marketing and Administrative	$ 186,822	$ 119,579	$ 94,632	$ 67,243	56%	$ 24,947	26%
% of total revenue	75%	78%	96%				

Sales, marketing and administrative expenses consist primarily of compensation, commission and training costs for personnel engaged in sales, marketing and customer support functions; distributor commissions; surgeon training costs; shareowner (employee) related expenses for our administrative functions; third party professional service fees; amortization of acquired intangible assets; and facilities and insurance expenses.

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

Increases in costs based on revenue, such as sales force compensation and other direct costs related to the sales force, royalty expense, and shipping costs were $18.5 million, $11.7 million, and $20.2 million in 2008, 2007 and 2006, respectively, compared to the prior years. The increases are consistent with our increased revenue growth of approximately 62% in 2008 as compared to 2007 and an overall increase in sales force headcount of approximately 26%. Total costs related to our sales force, as a percent of revenue, were 31.3% 33.4%, and 47.2% in 2008, 2007 and 2006, respectively. The decrease in costs as a percentage of revenue from 2006 to 2007 was primarily attributable to certain costs associated with our transition to sales force exclusivity that were incurred in the 2006 but not incurred in 2007 or 2008.

We also experienced increased costs as a result of overall company growth and headcount additions in our marketing and administrative support functions, as well as costs related to the implementation of our new ERP system. Marketing and administrative compensation and personnel costs increased $19.6 million and $4.3 million in 2008 and 2007, respectively, compared to the prior years. Our marketing and administrative headcount increased over 30% during 2008. Stock-based compensation increased $6.4 million and $0.8 million in 2008 and 2007, respectively, compared to the prior years, primarily as a result of grants to new shareowners (employees) and valuation-related changes for all options granted in 2008, most significantly, the market value of our common stock. Facility, equipment and computer expenses increased by $5.9 million and $1.5 million in 2008 and 2007, respectively, compared to the prior years, primarily as a result of the move to our new corporate headquarters, as discussed below. We incurred other significant expenses in 2008 that are designed to increase the scalability of our business over time. We completed the implementation of our new enterprise resource planning, or ERP, software system in 2008. We incurred a total of $10.9 million in costs related to the ERP project through June 2008 which has been capitalized. We are amortizing the capitalized costs over a 7-year period beginning in July 2008. During the third quarter, we determined that additional consulting time was important for a successful transition and therefore incurred $2.6 million in the

third quarter of 2008 and $1.4 million in the fourth quarter of 2008 which were incremental non-capitalizable expenses related to the on-going support costs for the implementation. These third and fourth quarter investments minimize the potential for transitional risk of moving to the new ERP system and will assist in driving expected efficiencies in 2009. The total non-capitalizable costs of $4.0 million are included in sales, marketing and administrative expense in 2008. We expect to move to a more traditional and leverage-able on-going support model in 2009, without significant incremental costs.

In addition, we entered into a lease of a two-building campus-style headquarters complex in November 2007 to accommodate our continued growth. The relocation process to the new facility was achieved in stages that began in March 2008 and completed in August 2008. As a result, we began to incur increased facility costs beginning in

Table of Contents

March 2008. Specifically, we incurred approximately $3.4 million in incremental facility costs in 2008, including move-related costs, plus a charge of $4.8 million related to vacating our previous corporate headquarters, as discussed below.

We expect to be able to sublease our previous corporate headquarters through August 2012, the date on which our related lease agreement expires, however; we also expect that the space will remain vacant for approximately an additional 20 months from December 31, 2008 with no associated sublease income during that time. At the completion of moving the final phase of shareowners (employees) and operations from our previous facility to our new headquarters during August 2008, we recorded a loss equal to the present value of expected net future cash flows in the amount of $4.8 million. For purposes of estimating the loss on the lease, management has estimated, based on market conditions, that the facility would remain vacant for approximately 24 months beginning in September 2008. As of the date of this filing, we have not yet entered into a sublease agreement and cannot be assured that a sublease, if any, will provide the anticipated sublease income used to estimate the charge recorded.

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 continue to see the synergies of investments we have made.

Research and Development

	Year Ended December 31,			2007 to 2008		2006 to 2007	
	2008	2007	2006	$ Change	% Change	$ Change	% Change
Research and Development	$ 25,943	$ 24,581	$ 18,541	$ 1,362	6%	$ 6,040	33%
% of total revenue	10%	16%	19%				

Research and development expense consists primarily of product research and development, clinical trial costs, regulatory and clinical functions, and the related shareowner (employee) expenses.

In the last several years, we have introduced numerous new products and product enhancements that have significantly expanded our MAS platform, enhanced the applications of the XLIF procedure, expanded our offering of cervical products, and marked our entrance into the growing motion preservation market. We have also acquired complementary and strategic assets and technology, particularly in the area of biologics. In the third quarter of 2006, we commenced patient enrollment in our NeoDisc® clinical trial, resulting in increased research and development costs subsequent to this date. Enrollment in the NeoDisc clinical trial was completed in August 2008. The trial protocol requires a two-year follow-up period on all patients before submitting to the U.S. Food and Drug Administration, or FDA, for potential approval.

The year-over-year increases in research and development costs in 2008 compared to 2007 and in 2007 compared to 2006 are primarily due to (i) increases in compensation and other shareowner related expenses of $3.1 million and $4.4 million in 2008 and 2007, respectively, primarily due to increased headcount to support our product development and enhancement efforts; and (ii) decreased NeoDisc® trial costs of $0.6 million in 2008 compared to 2007 due to the trial becoming fully enrolled during August 2008, and an increase of $3.1 million in NeoDisc trial costs in 2007 compared to 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.

Interest and Other Income, Net

	Year Ended December 31,			2007 to 2008		2006 to 2007	
	2008	2007	2006	$ Change	% Change	$ Change	% Change
Interest and Other Income , net	$ 332	$ 5,987	$ 6,316	$ (5,655)	(94)%	$ (329)	(5)%
% of total revenue	0.1%	4%	6%				

Interest and other income, net, consists primarily of interest income earned on marketable securities offset by interest expense incurred related to the Company s convertible debt offering signed in March 2008. The decrease in net interest income in 2008 compared to 2007 is due to interest expense of $5.4 million incurred in 2008 related to the convertible debt issued in March 2008 and to lower yields available in the market for our investment portfolio. The decrease in net interest income in 2007 compared to 2006 is due to lower investment balances in 2007

Table of Contents

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.

Stock-Based Compensation

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

	Year Ended December 31,			2007 to 2008		2006 to 2007	
	2008	2007	2006	$ Change	% Change	$ Change	% Change
Stock-Based Compensation							
Sales, Marketing & Administrative	$ 17,837	$ 11,404	$ 10,581	$ 6,433	56%	$ 823	8%
Research & Development	3,110	2,217	2,764	893	40%	(547)	(20)%
Total Stock-Based Compensation	$ 20,947	$ 13,621	$ 13,345	$ 7,326	54%	$ 276	2%
% of total revenue	8%	9%	14%				

We apply the fair value recognition provisions of SFAS 123(R), which established 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.

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). The increase in stock-based compensation in 2008 of approximately $7.3 million as compared to 2007 and $0.3 million in 2007 as compared 2006, can be attributed to an increase in number of option grants due to increased headcount year over year for all years presented, and changes in valuation assumptions utilized in the Black-Scholes option pricing model, most significantly, the market value of our common stock. As of December 31, 2008, there was $16.2 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, 2008, there was $0.8 million of unrecognized compensation expense for shares expected to be issued under the Employee Stock Purchase Plan that will be recognized through April 2009.

Business Combinations and Asset Acquisitions

Acquisition of Osteocel® Biologics Business. On July 24, 2008, we completed the acquisition of certain assets of Osiris Therapeutics, Inc. (the Osteocel Biologics Business Acquisition). The transaction provides us with a comprehensive stem cell biologic platform with benefits similar to autograft, as well as rights to acquire the next generation cultured version of the product. Osteocel is a unique bone matrix product that provides the three beneficial properties similar to autograft: osteoconduction (provides a scaffold for bone growth), osteoinduction (bone formation stimulation) and osteogenesis (bone production). Osteocel allows surgeons to offer the benefits of these properties to patients without the discomfort and potential complications of autograft harvesting, in addition to eliminating the time spent on a secondary surgical procedure. Osteocel is produced for use in spinal applications through a proprietary processing method that preserves the native stem cell population that resides in marrow rich bone. The acquisition is

consistent with our objective of developing or acquiring innovative technologies. Of the total potential purchase price of up to $85 million, $35 million was paid to Osiris at closing (the Initial Purchase Price). Additional payments of up to $50 million include milestone-based contingent payments not to exceed $37.5 million and a non-contingent $12.5 million payment for the transfer of the manufacturing facility Osiris currently utilizes to manufacture the Osteocel product. Of the total initial purchase price, $16.7 million was allocated to in-process research and development, and recorded in expense in 2008, as the associated projects had not yet reached technological feasibility and had no alternative future uses.

Acquisition of Pedicle Screw Technology. On March 5, 2008, we completed a buy-out of royalty obligations on SpheRx® pedicle screw and related technology products and acquired new pedicle screw intellectual property totaling $6.3 million. Of the total purchase price, $2.1 million, representing the present value of the expected future cash flows associated with the terminated royalty obligations, was allocated to intangible assets to be amortized on a straight-line basis over a seven-year period. The remaining $4.2 million was allocated to in-process research and

Table of Contents

development, and recorded as expense in 2008, as the associated projects had not yet reached technological feasibility and had no alternative future uses.

Radius Medical LLC. 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 $7.0 million and issued 451,677 unregistered shares of our common stock, which were subsequently registered. As part of the acquisition, we also acquired certain rights and obligations under a supply agreement with Maxigen Biotech, Inc. (MBI) with respect to product manufacturing and distributor rights. MBI is a Taiwanese company 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 is included in other assets on the consolidated balance sheets.

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

In-Process Research and Development

In-process research and development (IPR&D) expense is comprised of in-process technologies of $16.7 million and $4.2 million associated with the acquisition of the Osteocel Biologics Business in the third quarter of 2008 and our acquisition of the pedicle screw technology during the first quarter of 2008, respectively, as described in more detail below. At the date of each acquisition, the projects associated with the IPR&D efforts had not yet reached technological feasibility and the research and development in process had no alternative future uses. Accordingly, these amounts were charged to expense on the respective acquisition date.

Valuation of IPR&D. 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 at the acquisition date. 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, marketing, general and administrative, 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.

Osteocel Bioglogics Business. On July 24, 2008, we completed the acquisition of the Osteocel Biologics Business from Osiris Therapeutics, Inc. The IPR&D expense related to this acquisition was $16.7 million and consisted of four primary projects in process at the time of the acquisition: a revised formulation of the current Osteocel Plus based upon various potential changes to the manufacturing processes and donor composition; a Putty formulation; a version combined with a synthetic carrier; and Osteceol XC, the next generation cultured version of

Table of Contents

the product for which we received rights to acquire. We expect completion of these projects to begin in approximately two years and continue over a period of approximately ten years.

Each of these projects will build upon the existing Osteocel family of research and development, or R&D, and related intellectual property. All four projects are in the early conceptual phase and have significant development and regulatory risk, making the specific launch dates difficult to predict. We have attempted to predict the timing of these inputs, estimated impact on cannibalization and revenue growth. The value of each potential product line extension s IPR&D value was based upon the R&D status, forward revenue and related R&D expense estimates at the time of acquisition.

Pedicle Screw Technology. In March 2008, we acquired new pedicle screw intellectual property totaling $4.2 million. The total purchase price of $4.2 million was allocated to in-process research and development, and consisted of three primary projects in process at the time of acquisition: DBR II pedicle screw system, Posted Pedicle Screw System, or PPS, and Deformity System. These projects will incorporate different facets of the design features of the technology acquired. The value of each potential project s IPR&D value was based upon the status, forward revenue and related R&D expense estimates at the time of acquisition, including headcount for engineering time going forward, as well as materials to be utilized for manufacture and testing. The three acquired projects were brought through the development processes through 2008 and are expected to be completed at different phases throughout 2009, beginning in approximately the second quarter.

Pearsalls Limited. On August 4, 2005, we completed the acquisition of 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®. The total purchase price of $20.1 million, including transaction costs, was recorded as technology development costs in the consolidated statement of operations in 2006 as the projects associated with the IPR&D 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.

In 2006, the Company began its first clinical trial in the United States for the NeoDisc® cervical disc replacement device, which completed enrollment in August 2008. The trial protocol requires a two-year follow-up period on all patients before submitting to the U.S. Food and Drug Administration, or FDA, for potential approval.

Liquidity and Capital Resources

Since our inception in 1997, we have incurred significant losses and as of December 31, 2008, we had an accumulated deficit of approximately $195.5 million. We have not yet achieved profitability, and may not be profitable in 2009. 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.

In March 2008, we issued $230.0 million principal amount of 2.25% Convertible Senior Notes due 2013 (the Notes). The net proceeds from the offering, after deducting the initial purchasers discount and costs directly related to the offering, were approximately $208.4 million. We will pay 2.25% interest per annum on the principal amount of the Notes, payable semi-annually in arrears in cash on March 15 and September 15 of each year. The Notes mature on March 15, 2013.

Cash, cash equivalents and marketable securities was $223.4 million at December 31, 2008 and $89.7 million at December 31, 2007. The increase is due primarily to the net proceeds from the Notes issued in March of 2008.

Net cash used in operating activities was $5.0 million in 2008 compared to $0.9 million in 2007. We spent an incremental $14.4 million during 2008 as compared to 2007 for inventory to support our increased operations and

growing business and in preparation for the introduction of NeuroVision M5, representing a significant upgrade to our core MAS platform, which was introduced at the beginning of the fourth quarter of 2008.

Net cash used by investing activities was $144.6 million in 2008 compared to net cash provided by investing activities of $14.3 million in 2007. The increase in net cash used by investing activities of $158.9 million is primarily due to the net change of $111.4 million in the activity in our investment portfolio, the net change of $34.3 million in cash used to fund the acquisitions of the Osteocel Biologics Business and the pedicle screw

Table of Contents

technology, and a $15.4 million increase in capital asset purchases. Included in the $15.4 million net increase of capital expenditures over the prior year, is approximately $9.5 million and $10.9 million of expenditures related to the new facility and for the implementation of our new ERP system, respectively. 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 $220.0 million in 2008 compared to $7.0 million in 2007. The increase in cash provided by financing activities of $213.0 million is primarily due to the receipt of net proceeds of $208.4 million from the issuance of the Notes in March 2008. In 2007, the proceeds from the sale of common stock under our equity plans increased by $4.5 million.

In 2006, we received and invested the proceeds of our secondary offering of $142.0 million.

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

Contractual Obligations and Commitments

Contractual obligations and commitments represent future cash commitments and liabilities under agreements with third parties, including our Convertible Senior Notes, operating leases and other contractual obligations. Our operating lease commitments are related to our current and previous corporate headquarters leases, leases for our United Kingdom (UK) facility and automobile leases. Our corporate headquarters leases continue through August 2012 (our previous headquarters) and June 2023 (our current headquarters). The rent expense related to our corporate headquarters leases will be recorded on a straight-line basis in accordance with U.S. generally accepted accounting principles (GAAP). We are in the process of soliciting bids for sublet of our previous corporate headquarters facility.

The following summarizes our long-term contractual obligations and commitments as of December 31, 2008 *(in thousands)*:

		Payments Due by Period			
	Total	Less Than 1 Year	1 to 3 Years	4 to 5 Years	After 5 Years
Convertible Senior Notes(1)	$ 253,288	$ 5,175	$ 10,350	$ 237,763	$
Operating leases	86,952	5,681	13,849	12,526	54,896
Royalty obligations	7,797	1,030	2,060	2,040	2,667
Clinical advisory agreements	1,982	585	810	427	160
Deferred consideration payments under acquisition agreements	300	300			
Total	$ 350,319	$ 12,771	$ 27,069	$ 252,756	$ 57,723

(1) The Convertible Senior Notes in the above table include the interest payments totaling 2.25% per annum. See Note 5 to the consolidated financial statements for further discussion of the terms of the Convertible Senior Notes.

In connection with the 2005 acquisition of RSB Spine LLC, we are contingently obligated to make additional consideration payments over a period of 12 years based upon sales of the products derived from Smart Plate® Gradient CLP™ and related technology. These payments are not included in the table above.

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. This annual payment is not included in the table above.

Table of Contents

In connection with our acquisition of Osteocel in July 2008, we are contingently obligated to make additional performance and sales based milestone payments of up to $37.5 million. As of December 31, 2008, Osteocel had achieved their first production based milestone, for which $5 million was accrued as of December 31, 2008 and payment was made in January 2009. These payments are not included in the table above. We have not yet paid any other of these contingent milestone payments.

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.***

Interest Rate Sensitivity and Risk. Our exposure to interest rate risk at December 31, 2008 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, 2008, we do not hold any material asset-backed investment securities and in 2008, we did not realize any losses related to asset-backed investment securities. Based upon our overall interest rate exposure as of December 31, 2008, a change of 10 percent in interest rates, assuming the amount of our investment portfolio remains constant, would not have a material effect on interest expense. Further, this analysis does not consider the effect of the change in the level of the overall economic activity that could exist in such an environment.

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

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

The following table presents the carrying value and related weighted-average rate of return for our investment portfolio as of December 31, 2008:

	Carrying Value	Weighted Average Rate of Return
Money market funds	$ 118,129	1.71%
Commercial paper	1,450	1.85%
Corporate notes	8,711	2.93%
Securities of government-sponsored entities	81,121	2.81%
Total interest bearing instruments	$ 209,411	

As of December 31, 2008, the stated maturities of our investments are $164.1 million within one year and $45.3 million from one to three years. These investments are recorded on the balance sheet at fair market value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income.

Market Price Sensitive Instruments. In order to reduce the potential equity dilution, we entered into convertible note hedge transactions (the Hedge) entitling us to purchase up to 5.1 million shares of our common stock at an initial stock price of $44.74 per share, each of which is subject to adjustment. Upon conversion of our Convertible Senior Notes, the Hedge is expected to reduce the equity dilution if the daily volume-weighted average price per share of our common stock exceeds the strike price of the Hedge. We also entered into warrant transactions

Table of Contents

with the counterparties of the Hedge entitling them to acquire up to 5.1 million shares of our common stock, subject to adjustment, at an initial strike price of $49.13 per share, subject to adjustment. The warrant transactions could have a dilutive effect on our earnings per share to the extent that the price of our common stock during a given measurement period (the quarter or year to date period) at maturity of the warrants exceeds the strike price of the warrants.

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

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

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

None

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

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of the Company s disclosure controls and procedures (as such term is defined in SEC Rules 13a 15(e) and 15d 15(e)) as of December 31, 2008. Based on such evaluation, our management has concluded as of December 31, 2008, the Company s disclosure controls and procedures are effective.

Management s Report on Internal Control over Financial Reporting. Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance 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, 2008. Ernst & Young LLP, the Company s independent registered public accounting firm, has issued an attestation report on the Company s internal control over financial reporting which is included herein.

Changes in Internal Control over Financial Reporting. We are involved in ongoing evaluations of internal controls. In anticipation of the filing of this Form 10-K, our Chief Executive Officer and Chief Financial Officer, with the assistance of other members of our management, performed an evaluation of any change in internal control over financial reporting that occurred during our last fiscal quarter that has materially affected, or is likely to materially

affect, our internal controls over financial reporting. During the third quarter of 2008, we implemented an Enterprise Resource Planning, or ERP, system which is expected to improve and enhance internal controls over financial reporting. This ongoing implementation has materially changed how transactions are being processed and has also changed the structure and operation of some internal controls. While the ERP changes materially affected

Table of Contents

our internal control over financial reporting during the third quarter, the implementation has proceeded to date without material adverse effects on our internal control over financial reporting.

Except for the ERP implementation described above, there have been no other changes in our internal control over financial reporting during the year ended December 31, 2008 that have materially affected, or are 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, 2008, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). NuVasive, Inc. s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

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

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

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

In our opinion, NuVasive, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, 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, 2008 and 2007, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2008 of NuVasive, Inc. and our report dated February 27, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 27, 2009

Table of Contents

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

Compensatory Arrangements with Certain Officers

Fiscal 2009 Bonus Plan

On February 26, 2009, the Compensation Committee of the Board of Directors (the Committee) of the Company adopted metrics pursuant to which performance bonuses for fiscal year 2009 may be awarded to certain of the Company s key employees, including each of the Company s named executive officers (as defined in Item 402(a)(3) of Regulation S-K).

The named executive officers will be eligible for the following target performance bonuses upon the Company s achievement of the specified performance milestones:

Name	Position	Target Bonus as a Percentage of Salary
Alexis V. Lukianov	Chairman and Chief Executive Officer	75%
Keith C. Valentine	President and Chief Operating Officer	75%
Kevin C. O Boyle	Executive Vice President and Chief Financial Officer	50%
Patrick Miles	Executive Vice President, Product Marketing and Development	75%
Jeffrey Rydin	Senior Vice President, U.S. Sales	75%

The Committee will have the discretion, based on personal and/or Company performance, to (i) award performance bonuses even if the Company does not achieve the specified performance milestones or (ii) award performance bonuses in excess of the target performance bonus if the specified performance milestones are achieved or surpassed.

Fiscal 2008 Bonus Awards

In addition, the Committee awarded the following performance bonuses, in accordance with the metrics previously adopted by the Committee, to the Company s named executive officers with respect to fiscal 2008:

Name	Position	Fiscal 2008 Bonus
Alexis V. Lukianov	Chairman and Chief Executive Officer	$ 750,000
Keith C. Valentine	President and Chief Operating Officer	$ 500,000
Kevin C. O Boyle	Executive Vice President and Chief Financial Officer	$ 200,000
Patrick Miles	Executive Vice President, Product Marketing and Development	$ 400,000
Jeffrey Rydin	Senior Vice President, U.S. Sales	$ 450,000

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 21, 2009, and certain information included in the Proxy Statement is incorporated herein by reference.

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

PART IV

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

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

(1) Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2008 and 2007

Consolidated Statements of Operations for the years ended December 31, 2008, 2007 and 2006

Consolidated Statements of Stockholders Equity for the years ended December 31, 2008, 2007 and 2006

Consolidated Statements of Cash Flows for the years ended December 31, 2008, 2007 and 2006

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules: Schedule II Valuation Accounts

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

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

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

Exhibit Number	Description
2.1(1)	Asset Purchase Agreement, dated as of June 3, 2005, by and between NuVasive, Inc. and RSB Spine LLC
2.2(2)	Agreement, dated as of January 3, 2007, by and between NuVasive, Inc. and RSB Spine LLC
2.3(3)	Asset Purchase Agreement, dated as of August 4, 2005, by and among NuVasive, Inc., Pearsalls Limited and American Medical Instruments Holdings, Inc.

Table of Contents

Exhibit Number	Description
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)	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
2.7(22)	Asset Purchase Agreement, dated May 8, 2008, by and between the Company and Osiris Therapeutics, Inc.
2.8(24)	Amendment to Asset Purchase Agreement, dated September 30, 2008, by and between the Company and Osiris Therapeutics, Inc.
3.1(6)	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(23)	Indenture, dated March 7, 2008, between the NuVasive Inc. and U.S. Bank National Association, as Trustee
4.7(23)	Form of 2.25% Convertible Senior Note due 2013
4.8(23)	Registration Rights Agreement, dated March 7, 2007, among NuVasive, Inc. and Goldman, Sachs & Co., and J.P. Morgan Securities Inc., related to the 2.25% Convertible Senior Notes due 2013
4.9(18)	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(24)#	Amendment No. 1 to 2004 Employee Stock Purchase Plan
10.14(11)#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Alexis V. Lukianov
10.15(22)#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Keith C. Valentine

10.16(22)#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Kevin C. O Boyle
10.17(22)#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Patrick Miles

Table of Contents

Exhibit Number	Description
10.18(22)#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Jeffrey P. Rydin
10.19#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Jason M. Hannon
10.20#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Alexis V. Lukianov
10.21#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Keith C. Valentine
10.22#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Kevin C. O Boyle
10.23#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Patrick Miles
10.24#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Jeffrey P. Rydin
10.25#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Jason M. Hannon
10.26(8)#	Form of Indemnification Agreement between NuVasive, Inc. and each of our directors and officers
10.27(13)	Sublease, dated October 12, 2004, by and between NuVasive, Inc. and Gateway, Inc.
10.28(14)#	Description of 2007 annual salaries for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
10.29(15)#	Description of 2008 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(17)#	Summary of the 2008 bonus payments to our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
10.32(19)	Customer Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation.
10.33(19)	IBM Global Services Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation.
10.34(20)	Lease Agreement for Sorrento Summit, entered into as of November 6, 2007, between the Company and HCPI/Sorrento, LLC.
10.35(21)#	Description of 2008 annual salaries and annual stock grant for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
10.36(23)	Purchase Agreement, dated March 3, 2008, among NuVasive, Inc. and Goldman, Sachs & Co., and J.P. Morgan Securities Inc., related to the 2.25% Convertible Senior Notes due 2013
10.37(23)	Confirmation of Call Option Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013
10.38(23)	Confirmation of Call Option Transaction, dated March 3, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013
10.39(23)	Confirmation of Warrant Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013
10.40(23)	Confirmation of Warrant Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013
10.41(23)	Amendment to the Confirmation of Call Option Transaction, dated March 11, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013
10.42(23)	

	Amendment to the Confirmation of Call Option Transaction, dated March 11, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013
10.43(23)	Amendment to the Confirmation of Warrant Transaction, dated March 11, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013

Table of Contents

Exhibit Number	Description
10.44(23)	Amendment to the Confirmation of Warrant Transaction, dated March 11, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013
10.45(22)	Form of Voting Agreement, dated May 8, 2008, by and among each of Peter Friedli, Venturetec, Inc., U.S. Venture 05, Inc., Joyce, Ltd. and C Randal Mills, Ph.D, and the Company
10.46(22)	Manufacturing Agreement, dated July 24, 2008 by and between the Company and Osiris Therapeutics, Inc.
10.47(24)	Amendment to Manufacturing Agreement, dated September 30, 2008, by and between the Company and Osiris Therapeutics, Inc.
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 January 25, 2006.

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

(7) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on December 15, 2008.

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

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

(10)

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

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

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

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

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

(15) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 11, 2008.

Table of Contents

(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 Current Report on Form 8-K filed with the Commission on February 29, 2008.

(18) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 16, 2006.

(19) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on August 8, 2007.

(20) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on November 8, 2007.

(21) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 11, 2008.

(22) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 8, 2008.

(23) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008.

(24) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on November 7, 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 21, 2009, and copies of the form of proxy to be used for such Annual Meeting, will be furnished to the SEC prior to the time they are distributed to the Registrant s Stockholders.

Table of Contents

SIGNATURES

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

NUVASIVE, INC.

By: /s/ Alexis V. Lukianov

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

Date: March 2, 2009

By: /s/ Kevin C. O Boyle

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

Date: March 2, 2009

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Alexis V. Lukianov Alexis V. Lukianov	Chairman and Chief Executive Officer (Principal Executive Officer)	March 2, 2009
/s/ Kevin C. O Boyle Kevin C. O Boyle	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 2, 2009
/s/ Jack R. Blair	Director	March 2, 2009

Jack R. Blair		
/s/ Peter C. Farrell	Director	March 2, 2009
Peter C. Farrell		

Table of Contents

Signature	Title	Date
/s/ Robert J. Hunt Robert J. Hunt	Director	March 2, 2009
/s/ Lesley H. Howe Lesley H. Howe	Director	March 2, 2009
/s/ Hansen Yuan Hansen Yuan	Director	March 2, 2009
/s/ Eileen M. More Eileen M. More	Director	March 2, 2009

NUVASIVE, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
NuVasive, Inc.

We have audited the accompanying consolidated balance sheets of NuVasive, Inc. as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2008. 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, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), NuVasive, Inc. s internal control over financial reporting as of December 31, 2008, 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 27, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 27, 2009

Table of Contents

NUVASIVE, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2008	2007
	(In thousands, except par value)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 132,318	$ 61,915
Short-term marketable securities	45,738	19,247
Accounts receivable, net of allowance of $1,952 and $926, respectively	51,622	27,496
Inventory, net	68,834	36,280
Prepaid expenses and other current assets	3,466	1,240
Total current assets	301,978	146,178
Property and equipment, net	73,686	43,538
Long-term marketable securities	45,305	8,536
Intangible assets, net	57,099	24,496
Other assets	9,338	2,939
Total assets	$ 487,406	$ 225,687
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 26,633	$ 13,839
Royalties payable	1,722	2,076
Accrued payroll and related expenses	17,132	12,075
Total current liabilities	45,487	27,990
Senior convertible notes	230,000	
Other long-term liabilities	24,288	1,119
Commitments and contingencies		
Stockholders equity:		
Common stock, $0.001 par value; 70,000 shares authorized, 36,310 and 35,330 issued and outstanding at December 31, 2008 and 2007, respectively	36	35
Additional paid-in capital	383,293	364,469
Accumulated other comprehensive (loss) income	(190)	54
Accumulated deficit	(195,508)	(167,980)
Total stockholders equity	187,631	196,578
Total liabilities and stockholders equity	$ 487,406	$ 225,687

See accompanying notes to consolidated financial statements.

Table of Contents

NUVASIVE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2008	2007	2006
	(In thousands, except per share amounts)		
Revenue	$ 250,082	$ 154,290	$ 98,091
Cost of goods sold	44,301	27,382	19,028
Gross profit	205,781	126,908	79,063
Operating expenses:			
Sales, marketing and administrative	186,822	119,579	94,632
Research and development	25,943	24,581	18,541
In-process research and development	20,876		
NeoDisc technology costs			20,116
Total operating expenses	233,641	144,160	133,289
Interest and other income, net	332	5,987	6,316
Net loss	$ (27,528)	$ (11,265)	$ (47,910)
Net loss per share:			
Basic and diluted	$ (0.77)	$ (0.32)	$ (1.47)
Weighted-average shares basic and diluted	35,807	34,782	32,501

See accompanying notes to consolidated financial statements.

Table of Contents

NUVASIVE, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Common stock		Additional Paid-in	Deferred	Accumulated Other Comprehensive	Accumulated	Total Stockholders
	Shares	Amount	Capital	Compensation	Income (Loss)	Deficit	Equity
				(In thousands)			
Balance at December 31, 2005	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)
Balance at December 31, 2006	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)
Balance at December 31, 2007	35,330	35	364,469		54	(167,980)	196,578
Issuance of common stock under employee and director stock option and purchase plans	980	1	11,849				11,850
Convertible Note hedge, net of warrants			(13,972)				(13,972)
Stock-based compensation expense			20,947				20,947
Comprehensive loss:							
Unrealized gain on marketable securities, net					519		519
Foreign currency translation					(763)		(763)
Net loss						(27,528)	(27,528)
Comprehensive loss							(27,772)
Balance at December 31, 2008	36,310	$ 36	$ 383,293	$	$ (190)	$ (195,508)	$ 187,631

See accompanying notes to consolidated financial statements.

Table of Contents

NUVASIVE, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2008	2007	2006
	(In thousands)		
Operating activities:			
Net loss	$ (27,528)	$ (11,265)	$ (47,910)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	23,105	12,952	8,350
In-process research and development	20,876		
Stock-based compensation	20,947	13,621	13,345
Leasehold abandonment	4,403		
NeoDisc technology costs			8,060
Allowance for doubtful accounts, net of write-offs	1,026	189	124
Allowance for excess and obsolete inventory, net	(836)	514	1,768
Other	179	109	388
Changes in operating assets and liabilities, net of effects from acquisitions:			
Accounts receivable	(25,152)	(8,725)	(7,422)
Inventory	(32,451)	(18,026)	(8,877)
Prepaid expenses and other current assets	274	349	(220)
Accounts payable and accrued liabilities	5,098	5,719	3,987
Accrued payroll and related expenses	5,057	3,676	2,802
Net cash used in operating activities	(5,002)	(887)	(25,605)
Investing activities:			
Cash paid for acquisitions	(41,256)	(6,970)	
Purchases of property and equipment	(39,795)	(24,403)	(20,396)
Purchases of short-term marketable securities	(90,150)	(75,135)	(130,510)
Sales of short-term marketable securities	63,659	129,818	63,525
Purchases of long-term marketable securities	(69,036)	(23,540)	(1,996)
Sales of long-term marketable securities	32,267	17,000	
Other assets	(304)	(2,483)	(452)
Net cash (used in) provided by investing activities	(144,615)	14,287	(89,829)
Financing activities:			
Payments of long-term liabilities	(300)	(300)	(300)
Issuance of convertible debt, net of costs	222,442		
Purchase of convertible note hedges	(45,758)		
Sale of warrants	31,786		
Issuance of common stock	11,850	7,339	144,665
Net cash provided by financing activities	220,020	7,039	144,365

Increase in cash and cash equivalents	70,403	20,439	28,931
Cash and cash equivalents at beginning of year	61,915	41,476	12,545
Cash and cash equivalents at end of year	$ 132,318	$ 61,915	$ 41,476
Supplemental disclosure of non-cash transactions:			
Landlord paid tenant improvements	$ 7,309	$	$
Issuance of common stock for NeoDisc technology costs	$	$	$ 8,060
Issuance of common stock in connection with acquisitions	$	$ 10,501	$

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 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®, as well as a growing offering of biologics, cervical and motion preservation products. 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 products 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 sells a small quantity of MAS instrument sets, 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.

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.

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.

Concentration of Credit Risk and Significant Customers. Financial instruments, which potentially subject the Company to concentrations of credit risk, consist primarily of cash and cash equivalents, short-term and long-term

marketable securities and accounts receivable. The Company limits its exposure to credit loss by placing its cash and investments with high credit quality financial institutions. Additionally, the Company has established guidelines regarding diversification of its investments and their maturities, which are designed to maintain principal and maximize liquidity. No single customer represented greater than 10 percent of sales for any of the years presented.

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Fair Value of Financial Instruments. The Company s financial instruments consist principally of cash and cash equivalents, short-term and long-term marketable securities, accounts receivable, accounts payable, accrued expenses and Convertible Senior Notes (See Note 5). Marketable securities consist of available-for-sale securities that are reported at fair value with the related unrealized gains and losses included in accumulated other comprehensive income (loss), a component of shareholders equity. Effective January 1, 2008, the Company adopted Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements* (SFAS 157), which defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 requires disclosure that establishes a framework for measuring fair value and expands disclosure about fair value measurements. The statement requires fair value measurement be classified and disclosed in one of the following three categories:

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

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

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

The Company adopted SFAS 157 on January 1, 2008 related to financial assets and liabilities. This did not have a material impact on the consolidated financial statements.

The Company measures available-for-sale securities at fair value on a recurring basis. Pursuant to SFAS 157, the fair value of cash equivalents and marketable securities is determined based on Level 1 inputs, which consist of quoted prices in active markets for identical assets. The Company believes that the recorded values of all other financial instruments approximate their current fair values because of their nature and respective maturity dates or durations.

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

Marketable Securities. The Company defines marketable securities as income yielding securities that can be readily converted into cash. Examples of marketable securities include U.S. Treasury and agency obligations, commercial paper and corporate notes and bonds.

The Company accounts for investments in debt and equity instruments under SFAS, No. 115, *Accounting for Certain Investments in Debt and Equity Securities* (SFAS 115) and FASB Staff Position No. 115-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments* (FSP 115-1). Management determines the appropriate classification of such securities at the time of purchase and re-evaluates such classification as of each balance sheet date. All of the Company s marketable securities are classified as available-for-sale and are reported at fair value with the related unrealized gains and losses included in accumulated other comprehensive income (loss), a component of shareholders equity. The Company follows the guidance provided by FSP 115-1, to assess whether their investments with unrealized loss positions are other than temporarily impaired. Realized gains and losses and declines in value judged to be other than temporary are determined based on the specific identification method and are reported in other income (expense), net in the consolidated statements of income. Realized gains and losses are immaterial in

all periods presented. See Note 4.

In February 2008, the FASB also issued FSP No. 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2), which delays the effective date of SFAS 157 for non-financial assets and liabilities to fiscal years beginning after November 15, 2008. In October 2008, the FASB issued FSP No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active* (FSP 157-3), which clarifies how management s internal assumptions should be considered in measuring fair value when (i) observable data are not present, (ii) observable

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

market information from an inactive market should be taken into account, and (iii) the use of broker quotes or pricing services should be considered in assessing the relevance of observable and unobservable data to measure fair value. The fair value of the Company s cash equivalents and marketable securities are determined based on Level 1, or observable data, and therefore FSP No. 157-3 did not have a material impact on the Company s consolidated financial statements.

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 cost. The Company reviews the components of its inventory on a periodic basis for excess, obsolete or impaired inventory, and records a reserve for the identified items. At December 31, 2008 and 2007, the balance of the allowance for excess and obsolete inventory is $2.8 million and $3.6 million, respectively.

Goodwill and Intangible Assets. Goodwill represents the excess of the aggregate purchase price over the fair value of the tangible and identifiable intangible assets acquired by the Company. The goodwill recorded as a result of the business combinations in the years presented is not deductible for tax purposes. Goodwill is not amortized. In accordance with SFAS No. 142, *Goodwill and Other Intangible Assets* (SFAS 142), the Company assesses goodwill and intangible assets for impairment using fair value measurement techniques on an annual basis or more frequently if facts and circumstance warrant such a review. For purposes of assessing the impairment of goodwill, the Company estimates the value of the reporting unit using its market capitalization as the best evidence of fair value. The Company determined that it is a single reporting unit for the purpose of goodwill impairment tests under SFAS 142. If the carrying amount of a reporting unit exceeds its fair value, then a goodwill impairment test is performed to measure the amount of the impairment loss, if any. During the years ending December 31, 2008, 2007 and 2006, the Company did not record any impairment charges related to their goodwill.

The Company accounts for intangible assets in accordance with SFAS 142. Intangible assets are initially measured at their fair value, determined either by the fair value of the consideration exchanged for the intangible asset, or the estimated discounted cash flows expected to be generated from the intangible asset. Intangible assets, such as acquired technology, manufacturing know-how, licensed technology, supply agreements and certain trade names and trademarks, are amortized on a straight-line basis over their estimated useful life, ranging from two to twenty years. In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144), intangible assets with a finite life are tested for impairment whenever events or circumstances indicate that the carrying amount may not be recoverable.

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

Property, Plant and Equipment. Property and equipment are carried at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, ranging from 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. Maintenance and repairs are expensed as incurred. In accordance with SFAS 144, we review

property, plant and equipment for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated future undiscounted cash flows relating to the asset are less than its carrying amount. An impairment loss is measured as the amount by which the carrying amount of an asset exceeds its fair value.

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® implants. In connection with these launches, certain instruments were rendered obsolete

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

as of the launch date. As a result, the Company reduced the useful life of such instruments to end on the respective launch dates of the new products and incurred additional depreciation expense of $119,000, $461,000 and $646,000 in 2008, 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, 2008.

Revenue Recognition. The Company follows the provisions of the Securities and Exchange Commission s Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition,* which sets forth guidelines for the timing of revenue recognition based upon factors such as passage of title, installation, payment and customer acceptance. The Company recognizes revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured. Specifically, revenue from the sale of implants and disposables is recognized upon 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. Amounts billed to customers for shipping and handling of products are reflected in revenues and are not significant for any period presented. Product shipment costs are included in sales, marketing and administrative expense in the accompanying consolidated statements of operations and were $9.3 million, $6.1 million, and $3.8 million for the years ended December 31, 2008, 2007, and 2006, respectively.

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. The total stock options excluded from historical diluted loss per share, as of the end of each year, for 2008, 2007, and 2006, totaled 5.2 million, 4.4 million and 3.9 million, respectively. 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.

The warrants sold to the initial purchasers of the Convertible Senior Notes (See Note 5) and/or their affiliates to acquire up to 5.1 million shares of the Company s common stock, subject to adjustment, were excluded from the calculation of diluted net loss per share for the year ended December 31, 2008 since the fair market value as of the end of any reporting period during the year was below the strike price of $49.13 per share. In addition, the Convertible Senior Notes are convertible into shares of the Company s common stock, based on an initial conversion rate, subject to adjustment, of 22.3515 shares per $1,000 principal amount of the Notes (which

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

represents an initial conversion price of approximately $44.74 per share), which have been excluded from the diluted net loss per share calculation for the year ended December 31, 2008 as their effect is anti-dilutive.

	Years Ended December 31,		
	2008	2007	2006
	(In thousands, except per share data)		
Numerator:			
Reported net loss	$ (27,528)	$ (11,265)	$ (47,910)
Denominator for basic and diluted net loss per share:			
Weighted-average common shares	35,807	34,782	32,501
Basic and diluted net loss per share	$ (0.77)	$ (0.32)	$ (1.47)

Stock-Based Compensation. The Company applies the fair value recognition provisions of SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), which establishes accounting for share-based awards exchanged for shareowner (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.

Comprehensive Income (Loss). The Company records comprehensive income (loss) in accordance with SFAS No. 130, *Reporting Comprehensive Income,* which establishes standards for reporting and displaying comprehensive income (loss) and its components, including net income, 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 income (loss) includes unrealized gains or losses on the Company s available-for-sale securities, changes in the fair value of derivatives designated as effective cash flow hedges, and foreign currency translation adjustments. The Company has disclosed Comprehensive income (loss) as a component of stockholders equity.

Accumulated other comprehensive income (loss), consists of the following for the year ended December 31, 2008 (*in thousands*):

Net loss	$ (27,528)
Other comprehensive income (loss):	
Unrealized gain on marketable securities	519
Translation adjustments	(763)
Total comprehensive loss	$ (27,772)

The components of accumulated other comprehensive income (loss) in 2007 and 2006 are insignificant.

2. Business Combinations

Osteocel Biologics Business Acquisition.

On July 24, 2008, NuVasive completed the acquisition of certain assets of Osiris Therapeutics, Inc. (Osiris) (the Osteocel® Biologics Business Acquisition) for $35.0 million in cash paid at closing pursuant to the Asset Purchase Agreement, as amended. The completion date of this transaction is referred to as the Technology Closing Date. At the Technology Closing Date, the Company also entered into a Manufacturing Agreement, as amended (collectively with the Asset Purchase Agreement, the Agreements) with Osiris.

Under the terms of the Agreements, NuVasive will make additional payments of up to $50 million, including milestone-based contingent payments not to exceed $37.5 million and a non-contingent $12.5 million payment for the transfer of the manufacturing facility Osiris currently utilizes to manufacture the Osteocel product. Both the

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

contingent and non-contingent payments are payable in either cash or a combination of cash and stock, at the Company s election. The contingent payments are based on meeting a combination of specific product delivery milestones and a sales performance milestone and are not included in the preliminary estimate of the purchase price of the Osteocel Biologics Business. During the year ended December 31, 2008, $5.0 million of contingent consideration was earned and subsequently paid in January 2009.

Pursuant to the Agreements, as amended, Osiris will supply, and the Company will purchase, specified quantities of Osteocel product and Osiris will meet certain performance criteria for a period not to exceed 18 months. At the conclusion of this period, NuVasive will make the non-contingent payment for the manufacturing facility and will be assigned the lease agreement for the manufacturing facility. Title to the manufacturing related assets, leasehold improvements and all other tangible assets, as defined in the Agreements, will pass to NuVasive on this date.

Pursuant to the Agreements, as amended, the sales price per cubic centimeter (cc) of the Osteocel product transferred to NuVasive was reduced for the first approximate 40,000 ccs delivered after the Technology Closing Date. NuVasive recorded a short-term asset of $2.5 million representing the value of the discounted purchase price contract. The $2.5 million was fully amortized to cost of sales as of December 31, 2008.

Reason for the Osteocel Acquisition. The transaction provides NuVasive with a comprehensive stem cell biologic platform with benefits similar to autograft, as well as rights to acquire the next generation cultured version of the product. Osteocel is a unique bone matrix product that provides the three beneficial properties similar to autograft: osteoconduction (provides a scaffold for bone growth), osteoinduction (bone formation stimulation) and osteogenesis (bone production). Osteocel allows surgeons to offer the benefits of these properties to patients without the discomfort and potential complications of autograft harvesting, in addition to eliminating the time spent on a secondary surgical procedure. Osteocel is produced for use in spinal applications through a proprietary processing method that preserves the native stem cell population that resides in marrow rich bone.

Purchase Price. The estimated purchase price has been allocated to the tangible and intangible assets acquired based on their respective fair values as of the Technology Closing Date. The preliminary allocation of the estimated purchase price resulted in an excess of the fair value of net tangible and intangible assets acquired over the total purchase price by approximately $3.7 million which has been recorded as a long-term liability in accordance with Statement of Financial Accounting Standards No. 141, *Business Combinations.*

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

Cash paid on Technology Closing Date	$ 35,000
Present value of long-term deferred consideration liability, due on Manufacturing Closing Date	11,965
Estimated transaction costs and other	544
Total estimated initial purchase price	$ 47,509

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Estimated Fair Value	Estimated Useful Life
Manufacturing know-how and trade secrets	$ 19,800	13 years
Developed technology	7,200	10 years
Discounted price purchase contract	2,500	0.5 years
Trade name and trademarks	4,700	15 years
Customer contracts and relationships	330	0.5-2 years
In-process research and development	16,700	
	51,230	
Long-term liability	(3,721)	
Total estimated initial purchase price allocation	$ 47,509	

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

The Company s purchase price allocation was updated in the fourth quarter of 2008 due to the achievement of a performance milestone in the amount of $5 million. As a result, the Company decreased the $3.7 million long-term liability to zero and recorded the excess as goodwill as of December 31, 2008. Goodwill represents the excess of the purchase price over the fair value of tangible and identifiable intangible assets acquired. Should the contingent milestones continue to be earned, the goodwill balance has the potential to increase over time, will not be amortized and is not deductible for tax purposes.

The following unaudited pro forma information shows the results of the Company s operations for the specified reporting periods as through the acquisition had occurred as of the beginning of that period (*in thousands, except per share data*):

	Year Ended December 31	
	2008	2007
Revenue	$ 269,086	$ 169,530
Net loss	$ (21,379)	$ (12,010)
Net loss per share, basic and diluted	$ (0.60)	$ (0.35)

The proforma results have been prepared for comparative purposes only and are not necessarily indicative of the actual results of operations had the acquisition taken place as of the beginning of the periods presented, or the results that may occur in the future. The proforma results exclude the $16.7 million non-cash acquired IPR&D charge recorded upon the closing of the acquisition during the third quarter of 2008. The Company s consolidated financial statements include the operating results of Osteocel from the date of acquisition.

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. In connection with

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the transaction, Radius received net cash payments of approximately $5.0 million and 451,677 unregistered shares of NuVasive common stock. 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®, 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.

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 FormaGraft. 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 on a non-exclusive basis). NuVasive is required to purchase a minimum of $0.9 million of product from MBI per calendar year. In 2008 and 2007, NuVasive purchased a total of $1.5 million and $1.9 million of product from MBI, respectively. 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

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

on the consolidated balance sheet. As of December 31, 2008, there have been no indicators of impairment of the Company s investment in MBI.

3. Asset Acquisitions

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

On August 4, 2005, NuVasive completed the acquisition of 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. The total purchase price at closing was $13.0 million. 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.

In June 2006, the Company received conditional FDA approval of the Investigational Device Exemption to begin clinical trial enrollment for the NeoDisc cervical disc replacement device. This FDA approval was a development milestone under the Pearsall s agreement, and resulted in a payment obligation by the Company of $10.5 million which occured 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 IPR&D 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)

4. Balance Sheet Details

Cash Equivalents and Marketable Securities. Marketable securities include commercial paper, government-sponsored entity securities and corporate bonds that are classified as available-for-sale. A summary of the Company s cash equivalents and marketable securities, including the gross unrealized gains and losses and fair values for those marketable securities, are as follows:

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(In thousands)		
December 31, 2008				
Classified as current assets				
Money market funds	$ 118,129	$	$	$ 118,129
Commercial paper with initial maturities of 90 days or less	1,452		(2)	1,450
Corporate notes with initial maturities of greater than 90 days	4,283	4	(6)	4,281
Securities of government-sponsored entities	40,054	197	(5)	40,246
	163,918	201	(13)	164,106
Less cash equivalents	(118,368)			(118,368)
Short-term marketable securities	45,550	201	(13)	45,738
Classified as non-current assets				
Corporate notes	4,467	15	(52)	4,430
Securities of government-sponsored entities	40,495	380		40,875
Total marketable securities at December 31, 2008	$ 90,512	$ 596	$ (65)	$ 91,043
December 31, 2007				
Classified as current assets				
Money market funds	$ 52,469	$	$	$ 52,469
Commercial paper	9,261		(10)	9,251
Corporate notes	9,987	9		9,996
	71,717	9	(10)	71,716
Less cash equivalents	(52,469)			(52,469)
Short-term marketable securities	19,248	9	(10)	19,247
Classified as non-current assets Corporate notes	1,501			1,501
Securities of government-sponsored entities	7,022	13		7,035

Total marketable securities at December 31, 2007	$ 27,771	$ 22	$ (10)	$ 27,783

As of December 31, 2008, the stated maturities of our marketable securities are $164.1 million within one year and $45.3 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.

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As of December 31, 2008 we had three investments that were in an unrealized loss position. The gross unrealized losses related to these investments of approximately $52,000 were due to changes in interest rates. We have determined that the gross unrealized losses on these investments at December 31, 2008 are temporary in nature. We review our investments to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, and our intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. We maintain an investment portfolio of various holdings, types and maturities. We do not use derivative financial instruments. We place our cash investments in instruments that meet high credit quality standards, as specified in our investment policy guidelines. These guidelines also limit the amount of credit exposure to any one issue, issuer or type of instrument.

Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense. The Company recorded a net realized loss for securities sold of $126,000 for the year ended December 31, 2008. Realized gains and losses for securities sold were immaterial for the year ended December 31, 2007. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

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

	Useful Life in Years	December 31, 2008	2007
Loaner equipment	3	$ 62,376	$ 42,292
Machinery and equipment	5	10,077	7,879
Computer equipment and software	3	16,190	8,128
Leasehold improvements	1 to 15	15,470	3,861
Furniture and Fixtures	3 to 7	3,583	1,422
Land, building and improvements	20	5,333	4,896
		113,029	68,478
Less: accumulated depreciation amortization		(39,343)	(24,940)
		$ 73,686	$ 43,538

Depreciation expense was $17.0 million, $11.4 million, and $7.8 million for the years ended December 31, 2008, 2007 and 2006, respectively.

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

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Goodwill and intangible assets as of December 31, 2008 consisted of the following *(in thousands):*

	Weighted Average Amortization Period In Years	Gross Assets	Accumulated Amortization	Net Assets
Goodwill		$ 2,331	$	$ 2,331
Purchased Technology	13	18,730	2,474	16,256
Licensed Technology	20	7,145	691	6,454
Manufacturing Know-how and Trade Secrets	13	19,800	647	19,153
Supply Agreement	14	9,400	1,298	8,102
Trade Name and Trademarks	15	4,700	133	4,567
Customer Contracts and Relationships	2	330	94	236
Total		$ 62,436	$ 5,337	$ 57,099

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

	Gross Assets	Accumulated Amortization	Net Assets
Goodwill	$ 1,100	$	$ 1,100
Purchased Technology	9,200	1,388	7,812
Licensed Technology	7,145	334	6,811
Supply Agreement	9,400	627	8,773
Total	$ 26,845	$ 2,349	$ 24,496

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

	Year Ended December 31,		
	2008	2007	2006
Purchased Technology	$ 1,086	$ 541	$ 541
Licensed Technology	357	627	
Manufacturing Know-how and Trade Secrets	647		
Supply Agreement	672	334	

Trade Name and Trademarks	133		
Customer Contracts and Relationships	94		
Other		15	12
Total	$ 2,989	$ 1,517	$ 553

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Amortization Expense
2009	$ 4,600
2010	4,528
2011	4,441
2012	4,441
2013	4,441
Thereafter through 2027	32,317
Total Future Amortization Expense	$ 54,768

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

	December 31, 2008	2007
Accounts payable	$ 15,656	$ 1,680
Accrued expense	10,669	6,085
Other	308	6,074
	$ 26,633	$ 13,839

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

	December 31, 2008	2007
Osteocel non-contingent payment (Note 2)	$ 12,111	$
Deferred rent	9,256	
Other	2,921	1,119
	$ 24,288	$ 1,119

In 2005, the Company acquired certain assets from RSB Spine LLC (RSB). 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 was recorded as a long-term liability in accordance with Statement of Financial Accounting Standards No. 141, Business Combinations. Under the purchase agreements, 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 arrangement will first be applied to reduce the long-term liability and then will be recorded as goodwill when incurred. As of December 31, 2008, the remaining long-term liability is $500,000 and is included in other long-term liabilities. In addition, in connection with that transaction, the Company is obligated to make a payment of $50,000 in June 2009.

5. Convertible Senior Notes

In March 2008, the Company issued $230.0 million principal amount of 2.25% Convertible Senior Notes (the Notes), which includes the subsequent exercise of the initial purchasers option to purchase an additional $30.0 million aggregate principal amount of the Notes. The net proceeds from the offering, after deducting the initial purchasers discount and costs directly related to the offering, were approximately $208.4 million. The Company will pay 2.25% interest per annum on the principal amount of the Notes, payable semi-annually in arrears

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

in cash on March 15 and September 15 of each year. The Notes mature on March 15, 2013 (the Maturity Date). The Company made an interest payment of approximately $2.7 million in September 2008.

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

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

6. Commitments and Contingencies

On November 6, 2007, the Company entered into a 15-year lease agreement for the purpose of relocating the Company s corporate headquarters to an approximately 140,000 square foot two-building campus style complex in San Diego. Rental payments consist of base rent that escalates at an annual rate of three percent over the 15-year period of the lease, plus building related expenses paid to the landlord. 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 issued a $3.1 million irrevocable transferable letter of credit. Relocation to the new facility began in March 2008 and was completed during August 2008.

The Company expects to sublease its previous corporate headquarters through August 2012, the date on which the related lease agreement expires, however the Company also expects that the space will remain vacant for approximately an additional 20 months from December 31, 2008 with no associated sublease income during that time. Upon moving the final phase of shareowners (employees) and operations to the new headquarters during August of 2008, the Company recorded a loss equal to the estimated present value of expected net future cash flows in the amount of $4.8 million. The Company has assumed, in performing the calculation of the loss, that the facility would remain vacant for approximately 24 months from the cease use date in August 2008 given the current market conditions. As of the date of this filing, the Company has not yet entered into a sublease agreement and cannot be assured that a sublease, if any, will provide the anticipated sublease income used to calculate the above charge. The

charge related to the estimated fair value of expected net future cash flows is reflected in the consolidated statement of operations as sales, marketing and administrative expense.

For financial reporting purposes, rent expense is recognized on a straight-line basis over the term of the lease. Accordingly, rent expense recognized in excess of rent paid is reflected as a liability in the accompanying consolidated balance sheets.

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2008 are as follows *(in thousands):*

	Operating Leases	Other Contractual Obligations
2009	$ 5,681	$ 1,915
2010	6,853	1,500
2011	6,996	1,370
2012	6,702	1,272
2013	5,824	1,195
Thereafter	54,896	2,827
Total minimum payments	$ 86,952	$ 10,079

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

In connection with the acquisition of Osteocel as described in Note 2, the Company is contingently obligated to make additional performance and sales based milestone payments of up to $37.5 million. The Company has not paid any of these payments as of December 31, 2008.

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 Smart Plate® Gradient CLP™ and related technology. Through December 31, 2008, 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 $4.4 million for the year ended December 31, 2008 and $1.8 million for each of the years ended December 31, 2007 and 2006.

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.

7. Stockholders Equity

There are 5,000,000 shares of preferred stock authorized and none issued or outstanding at December 31, 2008 and 2007.

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 by the Company. The board of directors determines the terms of the stock option agreements, including vesting

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 2008, 2007, and 2006, 131,916, 113,494, and 106,258 shares, respectively, were purchased under the ESPP and approximately 848,000 remain available for issuance under the ESPP as of December 31, 2008.

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, 2008, substantially all of the options affected by the modification are vested.

Stock-Based Compensation. The Company follows the fair value recognition provisions of Statement of Financial Accounting Standards (SFAS) 123 (revised 2004), *Share-Based Payments* (SFAS 123(R)), which establishes accounting for share-based awards exchanged for shareowner (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.

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.

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 is based on awards ultimately expected to vest and is reduced for estimated forfeitures.

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:

	Year Ended December 31,		
	2008	**2007**	**2006**
Stock Options			
Volatility	42% to 45%	50%	65%
Expected term (years)	4.0 to 4.5	2.5 to 4.5	2.5 to 4.5
Risk free interest rate	1.6% to 3.4%	3.4% to 4.9%	4.4% to 5.1%
Expected dividend yield	0.0%	0.0%	0.0%
ESPP			
Volatility	42%	50%	65%
Expected term (years)	0.5 to 2.0	0.5 to 2.0	0.5 to 2.0
Risk free interest rate	1.5% to 3.0%	4.4% to 4.9%	4.4% to 5.0%
Expected dividend yield	0.0%	0.0%	0.0%

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

	Years Ended December 31,		
	2008	**2007**	**2006**
	(In thousands, except per share amounts)		
Sales, marketing and administrative expense	$ 17,837	$ 11,404	$ 10,581
Research and development expense	3,110	2,217	2,764
Stock based compensation expense	$ 20,947	$ 13,621	$ 13,345

Effect on basic and diluted net loss per share	$ (0.58)	$ (0.39)	$ (0.41)

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, 2008, there was $16.2 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, 2008, there was $0.8 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 2009. The total intrinsic value of options exercised was $28.1 million, $20.2 million and $8.0 million, respectively, the years ended December 31, 2008, 2007 and 2006.

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Following is a summary of stock option activity through December 31, 2008 under all stock option plans:

	Underlying Shares	Weighted Avg. Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value as of December 31, 2008
		(In thousands, except per share data)		
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		
Granted	1,833	$ 39.92		
Exercised	(854)	$ 10.28		
Cancelled	(136)	$ 26.00		
Outstanding at December 31, 2008	5,205	$ 25.92	7.74	$ 55,322
Exercisable at December 31, 2008	2,366	$ 16.94	6.74	$ 42,093
Vested or Expected to Vest at December 31, 2008	4,679	$ 25.25	7.66	$ 52,279

The weighted-average fair value of options granted in the years ended December 31, 2008, 2007, and 2006, was $14.46, $10.81, and $9.68 per share, respectively. The aggregate intrinsic value of options at December 31, 2008 is based on the Company s closing stock price on December 31, 2008 of $34.65. The Company received $8.8 million, $5.4 million and $1.5 million in proceeds from the exercise of stock options during the years ended December 31, 2008, 2007 and 2006, respectively.

Common Stock Reserved for Future Issuance. The following table summarizes common shares reserved for issuance at December 31, 2008 on exercise or conversion of *(in thousands)*:

Common stock options:	
Issued and outstanding	5,205
Available for future grant	85
Available for issuance under the Employee Stock Purchase Plan	848
Reserved for issuance in connection with conversion of convertible senior note warrants	5,141
Total shares reserved for future issuance	11,279

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company recorded expense of $28,000, $476,000 and $785,000 in 2008, 2007 and 2006, respectively, related to the vesting of stock options granted to non-employees under consulting agreements, in accordance with EITF 96-18.

8. Income Taxes

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, 2008 and December 31, 2007 are as follows:

	Year Ended December 31,	
	2008	2007
	(In thousands)	
Deferred Tax Assets:		
Capitalized assets	$ 21,201	$ 12,384
Stock based compensation	9,939	6,062
Original issue discount	15,097	
Other	2,351	1,345
Net operating loss carry-forwards	31,854	35,446
General business credit carry-forwards	4,974	
Gross deferred tax assets	85,416	55,237
Net valuation allowance	(85,416)	(55,237)
Net deferred tax (assets)/liabilities	$	$

At December 31, 2008, the Company had net deferred tax assets of $85.4 million. Due to uncertainties surrounding the Company s ability to generate future taxable income to realize such assets, a full valuation allowance has been established.

Included in the Company s net deferred tax asset balance on December 31, 2008 is an $15.1 million deferred tax asset pertaining to future tax deductions of original issue discount related to the Company s 2008 convertible note hedge transaction. For tax purposes the convertible senior notes and convertible note hedge were treated as a single synthetic debt instrument per Treasury Regulation 1.1275-6. As a result of this treatment, a future tax benefit will be created as the call premium is amortized over the life of the synthetic debt instrument. Since the convertible note hedge was treated as an equity adjustment in accordance with FAS 150 and EITF 00-19, the related tax benefit was also established as an equity adjustment. This deferred tax asset and corresponding valuation allowance were recorded with an offset to stockholders equity (paid in capital). If and when the Company s valuation allowance is removed, the corresponding benefit will be recognized as an increase to stockholders equity (paid in capital).

At December 31, 2008, the Company has US federal, state and foreign continuing operations net operating loss carryovers of $84 million, $50 million and $1.2 million, respectively. Deferred tax assets corresponding to such net operating losses are offset by a full valuation allowance. In addition, the Company has $39 million of excess tax benefit carryovers related stock option deduction windfalls that will be realized in APIC following utilization of all continuing operations tax attributes.

During 2008, NuVasive recognized federal and state taxable income before application of excess tax benefits attributable to stock option exercises. As such, NuVasive elected the *with and without method* *direct effects only*, prescribed under EITF D-32, with respect to recognition of stock option excess tax benefits within stockholders equity (paid in capital) and will utilize continuing operations net operating losses to offset

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

aforementioned taxable income. Accordingly, during 2008, NuVasive is utilizing approximately $11 million and $9 million of federal and state continuing operations net operating loss carry forwards, respectively. Utilization of continuing operations net operating losses is for FAS 109 purposes only, as for tax return purposes the Company s 2008 windfall tax benefit will offset net income included on federal and state income tax returns.

At December 31, 2008, the Company has U.S. federal and California research and experimental (R&E) credit carry-forwards of $3.2 million and $2.7 million, respectively. The deferred tax assets corresponding to such credit carry forwards are offset by a full valuation allowance. During 2008, a formal review of such credits was performed, as discussed below.

The future utilization of the Company s net operating loss carry-forwards and R&E credit carry forwards may be subject to an annual limitation pursuant to Internal Revenue Code § 382 and § 383 as a result of Company ownership changes. Although the Company determined that an ownership change has not occurred through the period ended December 31, 2006, a formal study has yet to be completed for subsequent periods.

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 de-recognition, 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 its liability for unrecognized tax benefits.

During 2008, NuVasive obtained a formal review of its federal and California R&E credit carry forwards and qualified research expense associated with each. It was determined that a portion of the Company s R&E credit carry forwards did not meet the more likely than not , threshold prescribed by FIN 48. As such, the Company s R&E credit deferred tax asset has been reduced by a FIN 48 reserve. Such adjustment had no rate impact as NuVasive maintains a full valuation allowance and has not utilized any of its R&E credit carry forwards, as the Company has generated net operating losses since inception.

In 2008, the Company increased its unrecognized tax benefits by $1.0 million related to current and prior year tax positions. This amount remains unrecognized at December 31, 2008.

The Company s policy is to recognize interest and penalties related to income tax matters in income tax expense. Because NuVasive has generated net operating losses since inception for both state and federal purposes, no additional tax liability, penalties or interest has been recognized for balance sheet or income statement purposes as of and for the period ended December, 31, 2008.

Of the Company s total unrecognized tax benefits, $637,000 would increase the Company s tax rate in the event they removed their valuation allowance position. In addition, the Company does not anticipate there will be a significant change in unrecognized tax benefits within the next 12 months.

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

9. Impact of Recently Issued Accounting Standards.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*, or SFAS 141R. SFAS 141R establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. The statement also provides guidance for recognizing and measuring the goodwill acquired in the business combination and determines what information to disclose to enable users of financial statements to evaluate the

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

nature and financial effects of the business combination. SFAS 141R is effective for financial statements issued for fiscal years beginning after December 15, 2008. Accordingly, any business combinations we engaged in were recorded and disclosed according to SFAS 141 through December 31, 2008. The Company expects SFAS No. 141R will have an impact on the consolidated financial statements, but the nature and magnitude of the specific effects will depend upon the nature, terms and size of the acquisitions consummated after the effective date of January 1, 2009.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of Accounting Research Bulletin No. 51*, or SFAS 160. SFAS 160 addresses the accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent s ownership interest, and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the impact of SFAS 160, but do not expect the adoption to have a material impact on the consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133,* or SFAS 161. SFAS 161 applies to all derivative instruments and related hedged items accounted for under SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, or SFAS 133. SFAS 161 requires entities to provide greater transparency about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS 133 and its related interpretations, and how derivative instruments and related hedged items affect an entity s financial position, results of operations and cash flows. SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The Company does not expect the adoption of SFAS 161 to have a material effect on its consolidated results of operations and financial condition.

In April 2008, the FASB issued FSP No. 142-3, *Determination of the Useful Life of Intangible Assets*, or FSP 142-3, which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142. This pronouncement requires enhanced disclosures concerning a company s treatment of costs incurred to renew or extend the term of a recognized intangible asset. FSP 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008. The Company is currently evaluating the impact of FSP 142-3, but do not expect the adoption to have a material impact on the consolidated financial statements.

In May 2008, the FASB issued Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). FSP APB 14-1 requires that the liability and equity components of convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) be separately accounted for in a manner that reflects an issuer s nonconvertible debt borrowing rate. The resulting debt discount is amortized over the period the convertible debt is expected to be outstanding as additional non-cash interest expense. FSP APB 14-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The provisions of FSP APB 14-1 are required to be applied retrospectively to all periods presented. The Company is required to adopt FSP APB 14-1 beginning in the first quarter of 2009. The Company does not expect FSP APB 14-1 to have a material impact on the consolidated financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles,* or SFAS 162. SFAS 162 identifies the sources of accounting principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles, or GAAP, in the U.S. SFAS 162 is effective 60 days following the SEC approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with*

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Generally Accepted Accounting Principles. The Company currently adheres to the hierarchy of GAAP as presented in SFAS 162, and adoption is not expected to have a material impact on the consolidated financial statements.

In November 2008, the FASB ratified EITF Issue No. 08-7, *Accounting for Defensive Intangible Assets*, or EITF 08-7. EITF 08-7 applies to defensive intangible assets, which are acquired intangible assets that the acquirer does not intend to actively use but intends to hold to prevent its competitors from obtaining access to them. As these assets are separately identifiable, EITF 08-7 requires an acquiring entity to account for defensive intangible assets as a separate unit of accounting which should be amortized to expense over the period the asset diminished in value. Defensive intangible assets must be recognized at fair value in accordance with SFAS 141R and SFAS 157. EITF 08-7 is effective for financial statements issued for fiscal years beginning after December 15, 2008. The Company expects EITF 08-7 will have an impact on the consolidated financial statements when effective, but the nature and magnitude of the specific effects will depend upon the nature, terms and value of the intangible assets purchased after the effective date.

10. Legal Proceedings

UCLA Litigation

The Company has been involved in a series of related lawsuits involving families of decedents who donated their bodies through UCLA s willed body program. The complaint alleges that the head of UCLA s willed body program, Henry G. Reid, and a third party, Ernest V. Nelson, improperly sold some of the donated cadavers to the defendants (including NuVasive). Plaintiffs allege the following causes of action: (i) breach of fiduciary duty, (ii) negligence, (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. NuVasive been dismissed from these lawsuits by the trial court but the decision was appealed and in July 2008, the appellate court reversed the trial court s decision to dismiss the Company from these lawsuits. The Company is currently appealing the decision of the appellate court to the Supreme Court of California, which has agreed to hear their appeal.

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

Medtronic Sofamor Danek USA, Inc. Litigation

On August 18, 2008, Medtronic Sofamor Danek USA, Inc. and its related entities (Medtronic) filed suit against NuVasive in the United States District Court for the Southern District of California, alleging that certain of the Company s products infringe, or contribute to the infringement of twelve U.S. patents owned by Medtronic (Medtronic Patents). Medtronic is seeking unspecified monetary damages and a court injunction against future infringement by NuVasive. On October 6, 2008, Medtronic filed an amended complaint dropping their claims of infringement relating to three of the named U.S. Patents. On October 13, 2008, the Company answered the complaint denying the allegations and filed counterclaims seeking dismissal of Medtronic s complaint and a declaration that NuVasive has not infringed and currently does not infringe any valid claim of the Medtronic Patents, including those previously

dropped by Medtronic. As of December 31, 2008, the probability of an outcome cannot be reasonably determined, nor can the Company reasonably estimate a potential loss, therefore, in accordance with SFAS 5, the Company has not recorded an accrual related to this litigation.

Table of Contents

NUVASIVE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. 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):*

	Year Ended December 31, 2008			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenues	$ 51,184	$ 57,417	$ 66,915	$ 74,566
Gross profit	42,089	47,846	54,720	61,126
Total operating expenses	50,469	48,525	77,653	56,994
Net income (loss)	$ (7,654)	$ (495)	$ (23,079)	$ 3,700
Basic and diluted net loss per common share	$ (0.22)	$ (0.01)	$ (0.64)	$ 0.10

	Year Ended December 31, 2007			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
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)

12. Subsequent Event

On January 13, 2009, the Company completed the purchase of forty percent (40%) of the capital stock of Progentix Orthobiology, B.V., a company organized under the laws of the Netherlands (Progentix), from existing shareholders pursuant to a Preferred Stock Agreement for $10 million in cash. NuVasive and Progentix additionally entered into a Senior Secured Facility Agreement dated January 13, 2009 (the Facility Agreement) whereby Progentix may borrow up to $5 million from NuVasive to fund ongoing clinical and regulatory efforts (the Loan). The Loan accrues interest at a rate of six percent (6%) per year. Additionally, NuVasive, Progentix and the shareholders of Progentix entered into an Option Purchase Agreement dated January 13, 2009 (the Option Agreement), whereby NuVasive may be obligated, upon the achievement of certain milestones by Progentix within two years, to purchase the remaining sixty percent (60%) of capital stock of Progentix for $45 million, subject to certain adjustments (the Remaining Shares). NuVasive may also be obligated in the event that Progentix achieves the milestones contemplated above within the requisite two year period to make additional payments to Progentix of up to an aggregate total of $25 million upon completion of additional milestones and dependent on NuVasive s sales success. NuVasive also has the right under the Option Agreement to purchase the Remaining Shares at any time between the second anniversary of the Option Agreement and the Fourth Anniversary of the Option Agreement (the Option Period) for $35 million, and in certain

circumstances where NuVasive achieves in excess of a certain annual sales run rate on Progentix products during the Option Period, NuVasive may be required to purchase the Remaining Shares for $35 million. Under the Option Agreement, ten percent (10%) of the purchase price plus an amount equal to $1.5 million is set aside in escrow. NuVasive and Progentix also entered into a Distribution Agreement dated January 13, 2009, whereby Progentix appointed NuVasive as its exclusive distributor for certain Progentix products. The Distribution Agreement shall remain in effect for a term of ten years unless earlier terminated in accordance with its terms.

Table of Contents

NuVasive, Inc.

Schedule II: Valuation Accounts

	Balance at Beginning of Period	Additions(1)	Deductions(2)	Balance at End of Period
		(In thousands)		
Accounts Receivable Reserve				
Year ended December 31, 2008	$ 926	$ 1,393	$ 367	$ 1,952
Year ended December 31, 2007	$ 737	$ 991	$ 802	$ 926
Year ended December 31, 2006	$ 613	$ 495	$ 371	$ 737

	Balance at Beginning of Period	Additions(3)	Deductions(4)	Balance at End of Period
Inventory Reserve				
Year ended December 31, 2008	$ 3,614	$ 3,208	$ 4,044	$ 2,778
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

(1) Amount represents customer balances deemed uncollectible.

(2) Uncollectible accounts written-off.

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

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

Table of Contents

Exhibit Number	Description
2.1(1)	Asset Purchase Agreement, dated as of June 3, 2005, by and between NuVasive, Inc. and RSB Spine LLC
2.2(2)	Agreement, dated as of January 3, 2007, by and between NuVasive, Inc. and RSB Spine LLC
2.3(3)	Asset Purchase Agreement, dated as of August 4, 2005, by and among NuVasive, Inc., Pearsalls Limited and American Medical Instruments Holdings, Inc.
2.4(4)	Amendment No. 1 to Asset Purchase Agreement, dated as of September 26, 2006, by and among NuVasive, Inc., Pearsalls Limited and American Medical Instruments Holdings, Inc.
2.5(5)	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
2.7(22)	Asset Purchase Agreement, dated May 8, 2008, by and between the Company and Osiris Therapeutics, Inc.
2.8(24)	Amendment to Asset Purchase Agreement, dated September 30, 2008, by and between the Company and Osiris Therapeutics, Inc.
3.1(6)	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(23)	Indenture, dated March 7, 2008, between the NuVasive Inc. and U.S. Bank National Association, as Trustee
4.7(23)	Form of 2.25% Convertible Senior Note due 2013
4.8(23)	Registration Rights Agreement, dated March 7, 2007, among NuVasive, Inc. and Goldman, Sachs & Co., and J.P. Morgan Securities Inc., related to the 2.25% Convertible Senior Notes due 2013
4.9(18)	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(24)#	Amendment No. 1 to 2004 Employee Stock Purchase Plan
10.14(11)#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Alexis V. Lukianov
10.15(22)#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Keith C. Valentine
10.16(22)#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Kevin C. O Boyle
10.17(22)#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Patrick Miles

Table of Contents

Exhibit Number	Description
10.18(22)#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Jeffrey P. Rydin
10.19#	Compensation Letter Agreement, dated August 5, 2008, between NuVasive, Inc. and Jason M. Hannon
10.20#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Alexis V. Lukianov
10.21#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Keith C. Valentine
10.22#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Kevin C. O Boyle
10.23#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Patrick Miles
10.24#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Jeffrey P. Rydin
10.25#	Amendment to Compensation Letter Agreement, dated December 10, 2008, between NuVasive, Inc. and Jason M. Hannon
10.26(8)#	Form of Indemnification Agreement between NuVasive, Inc. and each of our directors and officers
10.27(13)	Sublease, dated October 12, 2004, by and between NuVasive, Inc. and Gateway, Inc.
10.28(14)#	Description of 2007 annual salaries for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
10.29(15)#	Description of 2008 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(17)#	Summary of the 2008 bonus payments to our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
10.32(19)	Customer Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation.
10.33(19)	IBM Global Services Agreement, dated as of June 27, 2007, by and between NuVasive, Inc. and International Business Machines Corporation.
10.34(20)	Lease Agreement for Sorrento Summit, entered into as of November 6, 2007, between the Company and HCPI/Sorrento, LLC.
10.35(21)#	Description of 2008 annual salaries and annual stock grant for our Chief Executive Officer, our Chief Financial Officer and our other named executive officers
10.36(23)	Purchase Agreement, dated March 3, 2008, among NuVasive, Inc. and Goldman, Sachs & Co., and J.P. Morgan Securities Inc., related to the 2.25% Convertible Senior Notes due 2013
10.37(23)	Confirmation of Call Option Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013
10.38(23)	Confirmation of Call Option Transaction, dated March 3, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013
10.39(23)	Confirmation of Warrant Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013
10.40(23)	Confirmation of Warrant Transaction, dated March 3, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013
10.41(23)	

	Amendment to the Confirmation of Call Option Transaction, dated March 11, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013
10.42(23)	Amendment to the Confirmation of Call Option Transaction, dated March 11, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013
10.43(23)	Amendment to the Confirmation of Warrant Transaction, dated March 11, 2008, to NuVasive, Inc. from Goldman, Sachs & Co. related to the 2.25% Convertible Senior Notes due 2013
10.44(23)	Amendment to the Confirmation of Warrant Transaction, dated March 11, 2008, to NuVasive, Inc. from JPMorgan Chase Bank related to the 2.25% Convertible Senior Notes due 2013
10.45(22)	Form of Voting Agreement, dated May 8, 2008, by and among each of Peter Friedli, Venturetec, Inc., U.S. Venture 05, Inc., Joyce, Ltd. and C Randal Mills, Ph.D, and the Company

Table of Contents

Exhibit Number	Description
10.46(22)	Manufacturing Agreement, dated July 24, 2008 by and between the Company and Osiris Therapeutics, Inc.
10.47(24)	Amendment to Manufacturing Agreement, dated September 30, 2008, by and between the Company and Osiris Therapeutics, Inc.
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 January 25, 2006.

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

(7) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on December 15, 2008.

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

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

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

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

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

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

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

(15) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 11, 2008.

(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 Current Report on Form 8-K filed with the Commission on February 29, 2008.

(18) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 16, 2006.

(19) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on August 8, 2007.

Table of Contents

(20) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on November 8, 2007.

(21) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 11, 2008.

(22) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 8, 2008.

(23) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008.

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