UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2004

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 000-50744

NUVASIVE, INC.

(Exact name of registrant as specified in its charter)

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

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

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

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.001 per share

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

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $107.1 million as of the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing sale price on the Nasdaq National Market reported for such date. Shares of Common Stock held by each officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

There were 24,007,988 shares of the registrant's common stock issued and outstanding as of February 28, 2005.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference from the definitive proxy statement for the Annual Meeting of Stockholders to be held on July 27, 2005.

NuVasive , Inc.
Form 10-K for the Fiscal Year ended December 31, 2004

PART I

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 product portfolio is focused on applications in the over $2 billion U.S. spine fusion market. This market is expected to grow at an estimated annual rate of 18% through 2005. Our current principal product offering includes a minimally disruptive surgical platform that we call Maximum Access Surgery, or MAS, as well as classic fusion products. MAS combines three categories of our current product offerings—NeuroVision, a proprietary software-driven nerve avoidance system, MaXcess, a split blade-design minimally invasive surgical system and specialized implants—that collectively minimize soft tissue disruption during spine surgery. We believe our MAS platform provides a unique and comprehensive solution for safe and reproducible minimally disruptive surgical treatment of spine disorders. Our classic fusion portfolio is comprised of a range of products, including spine allografts, which are human bone that has been processed and precision shaped for transplant, and spine implants such as rods, plates and screws that are necessary for a variety of spine surgery procedures. The majority of our currently marketed products have been cleared by the FDA.

We believe our MAS platform, including its key components NeuroVision, MaXcess and implants, provides a surgeon with enhanced access to the spine in a manner that affords direct visibility and avoidance of critical nerves in addressing the spine pathology. Using our MAS platform, surgeons are able to perform minimally disruptive surgical procedures. In addition, our MAS platform has enabled procedures such as extreme lateral interbody fusion, or XLIF, which have significant benefits over other minimally invasive procedures. All of the procedures facilitated by our MAS platform provide benefits, including reduced operating time, trauma and blood loss to the patient and faster overall patient recovery time.

Our Strategy

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

- E*stablish our Integrated Surgical Systems as a Standard of Care.* We believe our MAS platform will become the standard of care for minimally invasive spine surgery as spine surgeons continue to adopt our products and recognize their benefits. We believe that our MAS platform has the potential to dramatically improve the clinical results of minimally invasive spine surgery. We dedicate significant efforts to educate spine surgeons regarding the multiple clinical benefits of our products. Importantly, we intend to capitalize on the increased patient demand for minimally disruptive surgical alternatives.

- *Expand Sales and Marketing Efforts.* We currently sell our products through a network of over 40 independent sales agencies with over 160 independent sales representatives that target approximately 4,000 surgeons that perform spine surgeries. We intend to expand the number of agencies selling our products in order to increase the market penetration of our products. We also intend to capitalize on broader market acceptance of our products to convert some of our relationships with these agencies into exclusive selling arrangements.

- *Continue to Introduce New Creative Products.* One of our core competencies is our ability to develop and commercialize creative spine surgery products. In 2004, we introduced new products and several product enhancements. We have several additional products currently under development, including total disc and nucleus replacement implants, MAS platform expansion and other implants to stabilize the spine. We believe that these additional complementary products will allow us to generate more revenue opportunities from each spine surgery procedure while improving patient care.

- *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 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 that allows us to rapidly manufacture product prototypes. We utilize our state-of-the-art cadaver operating theater to provide clinical training and to validate new ideas through prototype testing.

- *Selectively License or Acquire Complementary Spine Products and Technologies.* In addition to building our company though internal product development efforts, we intend to selectively license or acquire complementary products and technologies. By acquiring complementary products, we believe we can leverage our expertise at bringing new products to market and provide additional selling opportunities for our independent sales agencies.

Market Opportunity

Back pain is the number one cause of healthcare expenditures in the United States, with a direct cost of more than $50.0 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 $2.6 billion in 2004, and is anticipated to grow to over $2.9 billion by 2005.

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

- *Increased Use of Implants.* The use of implants has evolved into the standard of care in spine surgery. Over the past five years, there has been a significant increase in the percentage of spine fusion surgeries using implants and it is expected that over 95% of all spine fusion surgeries will involve implants by 2005.

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

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

Spine Anatomy and Disorders

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.

Current Treatments for Spine Disorders

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, and the number of spine surgery procedures is expected to grow to over 1.2 million per year by 2005. The most common spine surgery procedures are: discectomy, the removal of all or part of a damaged disc; laminectomy, the removal of all or part of a lamina, or thin layer of bone, to relieve pinching of the nerve and narrowing of the spinal canal; and fusion, where two or more adjoining vertebrae are fused together to provide stability. All three of these procedures require access to the spine. Traditional open surgical approaches require large incisions to be made in the back so that surgeons can see the spine and surrounding area. Most open procedures are invasive, lengthy and complex, and may result in significant blood loss, extensive dissection of tissue and lengthy hospitalization and rehabilitation.

Minimally Invasive Surgical Procedures

The benefits of minimally invasive surgery, or MIS, 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: (1) the limited or lack of access and visibility of the surgical anatomy, as well as, (2) 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.

Although a number of minimally invasive surgical approaches exist for spine surgery, virtually all have failed to gain widespread acceptance to date. The four primary minimally invasive surgical approaches are laparoscopic Anterior Lumbar Interbody Fusion, or Lap ALIF; MIS Posterior Lumbar Interbody Fusion, or MIS PLIF; and MIS Transforaminal Lumbar Iinterbody Fusion, or MIS TLIF and micro-decompression. In a Lap ALIF, the surgeon typically accesses the spine from an entry point on the patient's abdomen. This approach has not been widely accepted in part due to the need for a general surgeon to assist the spine surgeon in maneuvering past vascular structures and critical organs. In an MIS PLIF, the surgeon typically accesses the spine from an entry point on the patient's back. MIS TLIF is similar to MIS PLIF except that the surgeon retracts the back muscles to the side in order to avoid the spinal canal and nerves. MIS PLIF and MIS TLIF have not been widely accepted because of the difficulty in avoiding critical nerves.

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 surgery.

Our MAS platform combines 3 product categories: NeuroVision, MaXcess, and complementary implants. NeuroVision enables surgeons to avoid neural anatomy while MaXcess affords direct customized access to the spine

for implant delivery. MaXcess also allows surgeons to use well-established traditional instruments in a minimally disruptive and less traumatic manner. We also offer a variety of specialized implants that enable sufficient structural support while conforming to the anatomical requirements of the patient.

Our products facilitate minimally disruptive spine surgery procedures and enable superior applications of TLIF, PLIF, decompression and innovative procedures such as an XLIF™. The XLIF procedure, which the company developed with leading spine surgeons, allows surgeons to access the spine from the side rather than from the front or back, which results in less operating time and reduced patient trauma and blood loss. Notwithstanding these benefits, XLIFs have historically been viewed by most surgeons as too difficult to perform due to the number of critical nerves that must be avoided.

We believe procedures enabled by our MAS platform provide significant benefits, including reduced surgery times, reduced hospital stays, and less trauma and blood loss for the patient, resulting in faster overall patient recovery times. According to clinicians involved with one or more of the first 600 MAS procedures performed with our products, 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 70 minutes 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 Recovery Times.* Due to smaller incisions and less dissection, we believe that the pain and recovery times for patients following a MAS XLIF are significantly less than with an equivalent open procedure. In most cases, patients are walking the same day as surgery following a MAS XLIF.

MAS—NeuroVision

NeuroVision utilizes electromyography, or EMG, and proprietary software algorithms and graphical user interfaces to provide surgeons with an enhanced nerve avoidance system. Our system functions by monitoring changes in electrical signals across muscle groups, which allows us to detect underlying changes in nerve activity. We connect the instruments that surgeons use to a computer system that provides real time feedback during surgery. Our system analyzes and then translates complex neurophysiologic data into simple, useful information to assist the surgeon's clinical decision-making process. For example, during a pedicle screw test, in which the integrity of an implant 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 INS-1, was cleared by the FDA in November 2000 and commercially launched in 2001.

Surgeons can dynamically link familiar surgical instruments to NeuroVision, thus creating an interactive set of instruments that enable the safe navigation of neural anatomy. NeuroVision can be operated independently by the surgeon eliminating the need for additional technical support. 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.

MAS—MaXcess

Our MaXcess system consists of instrumentation and specialized implants that provide maximum access with minimal soft tissue disruption. MaXcess has a split blade design consisting of three blades that can be positioned to build the surgical exposure in the shape and size specific to the surgical requirements rather than the fixed tube design of other minimally invasive surgical systems. MaXcess' split blade design also provides expanded access to the spine, which allows surgeons to perform surgical procedures using instruments that are similar to those used in

open procedures but with a significantly smaller incision. The ability to use familiar instruments reduces the learning curve and facilitates the adoption of our products. Our system's illumination of the operative corridor aids in providing surgeons with direct visualization of the patient's anatomy, without the need for additional technology or other special equipment. During the fourth quarter of 2004, we introduced an extension of our MaXcess product with our MaXcess-Micro Access. This brings all of the benefits of minimally disruptive surgery to both the cervical spine for posterior application and the lumbar spine for decompression.

MaXcess allows surgeons to perform a wide range of conventional spine procedures through a minimally disruptive approach. MaXcess enables multiple applications designed for each of the following surgical approaches: TLIF, PLIF, XLIF and 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. We believe that MaXcess, in combination with NeuroVision and our specialized implants, will allow more surgeons to use the MAS platform to perform procedures which offer important clinical benefits. This includes the new and innovative lateral procedure, XLIF. The XLIF procedure significantly reduces the time of the surgery and also the patient tissue trauma and blood loss, resulting in faster overall patient recovery times. Previously, lateral surgery could only be performed by a handful of very highly skilled surgeons that needed to be accompanied by a general surgeon. Now, with our MAS solution, surgeons can successfully avoid critical nerves and access the spine with minimal soft tissue disruption.

We believe MaXcess provides the following key benefits compared to other existing minimally invasive surgical systems:

- *Maximizes Access.* The split-blade design enables surgeons to customize the surgical exposure to the patient and surgical requirement while maximizing the direct visualization of a patient's anatomy, without additional visualization tools such as endoscopes, cameras, and microscopes.

- *Uses Conventional Instruments.* MaXcess allows surgeons to use instruments similar to those used in open procedures and so requires minimal additional training.

- *Provides Benefits of MAS with Broad Application.* MaXcess enables surgeons to accomplish a wide range of surgical goals, such as neural decompression, disc height restoration and bony fusion, with MAS technology that minimizes operation time and expedites patient recovery and a return to activities of daily living.

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 posterior part of the spine. These implants include:

- SpheRx – our pedicle screw product

- CoRoent – for partial vertebral body replacement

- Allograft – precision-machined – for lumbar TLIF and PLIF application

Our implants are available in a variety of heights, widths and lengths to accommodate the anatomical requirements of the patient and the particular fusion procedure. Our implants are designed for insertion into the smallest possible space while maximizing surface area contact for fusion.

Our fixation systems have been uniquely designed to be delivered through our MaXcess system to provide stabilization of the posterior spine. These systems enable minimally disruptive placement of implants and are intended to reduce operating time and patient morbidity.

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

Classic Fusion

We have developed a suite of traditional spine surgery products, which we refer to as classic fusion, including a line of precision-machined cervical and PLIF 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 proprietary packaging process allows us to provide a ready-to-use structural graft eliminating the need for refrigeration and re-hydration. We package all of our allograft implants in a sterile saline solution. In addition, our allograft packaging and instrumentation are color-coded to assist the surgeon in selecting the proper size instrument for use with the chosen allograft implant.

Our classic fusion product offerings consist of the following:

- *Triad Cervical Allograft System.* A line of precision-machined cervical allograft implants and related instrumentation. Our cervical allograft is available in a variety of heights and widths.

- *Triad Lumbar Allograft Systems.* A line of precision-machined lumbar allograft implants and related instrumentation for PLIF surgical procedures. Our lumbar allografts are available in a variety of heights, widths and lengths.

- *Titanium Surgical Mesh System.* Titanium surgical mesh implant and related instrumentation used in the thoracic and lumbar regions of the spine to replace a diseased or damaged vertebrae caused by tumor or fracture, to restore the height of a collapsed vertebrae and to achieve decompression of the spinal cord and neural tissues. Our proprietary surgical mesh implant combines the strength of titanium with the ability to cut and shape the implant during surgery and is available in a wide range of diameters and heights.

Products Under Development

MAS Platform Expansion

We are developing additional complementary implant and instrument devices to expand our MAS platform. As with all of our implant and instrument development initiatives, it is important to create innovative products that assist the surgeon in providing better minimal access alternatives that enable a quicker recovery process for the patient. This goal has driven us to further development of our MaXcess retraction system that will offer expanded capabilities that incorporate new features based on surgeon feedback.

To further our desire for patient safety, we are continually improving the features and software capabilities of our NeuroVision neural avoidance system. This unique product remains the only surgeon directed nerve avoidance tool in the market. We believe that our continued improvements to our product platform and our development of new surgeon directed enhancements will ensure our continued leadership in this area.

The pipeline of near-term product releases are as follows:

- Cervical Plate – apply to both a rigid and dynamic mode

- Dual Ball Rod – extension of our pedicle screw product

- NeuroVision – improved electrode harness and an insulated spinal access needle

- MaXcess II – added features including an ALIF application

- CoRoent – new tapered design for easy insertion and other configurations for angled insertion

Motion Preservation—Total Disc Replacement Products

We are developing a proprietary total lateral lumbar disc replacement product and cervical disc replacement product. These products are intended to allow surgeons to address a patient's pain and dysfunction while maintaining normal range of motion and avoiding future adjacent level degeneration that often occurs after spine fusion. We believe that the ability to insert a lumbar total disc replacement from a lateral approach in a MAS procedure will be unique to us, but will require pre-market approval rather than 510(k) clearance. Our total disc replacement products are currently undergoing biomechanical testing. We have filed several patent applications on these products, two in the United States and one internationally. We plan to file for an Investigational Device Exemption with the FDA in 2005 with the possibility of commencing a clinical trial by year end for the cervical total disc replacement product.

Research and Development

Our research and development efforts are primarily focused in the near term on developing further enhancements to our existing products, launching as well as developing our total disc product. Our research and development staff consists of twenty-nine people, including one who holds a Ph.D. degree and three who hold other advanced degrees. Our research and development group has extensive experience in developing products to treat spine pathology, and 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

Our sales team is led by our sales vice president, national group sales director and eight regional directors who supervise over 40 independent sales agencies with over 160 independent sales representatives. We invoice products directly to hospitals, generally at list prices, and pay commissions to our sales agencies and representatives. We select our sales agencies and representatives based on their expertise in spine surgery medical device sales, reputation within the surgeon community and sales coverage. Each sales agency and representative is assigned a sales territory for some or all of our products and is subject to periodic performance reviews. These relationships typically provide the representative the exclusive right to sell our products within the sales territory. As our products become more broadly accepted in the market, we intend to convert some of these relationships into exclusive sales agency arrangements whereby the agent would sell only our products. We also require each sales agency and representative to attend periodic sales and product training programs. We also market our products at various industry conferences and through industry organized surgical training courses. In addition, we believe that as patients begin to realize the benefits of our technology, they will accelerate the demand for our products. Substantially all of our products are distributed within the United States.

As we launch new products and increase our marketing efforts with respect to existing products, we intend to expand the reach of our marketing and sales force. We plan to accomplish this by increasing the number of outside sales agencies and representatives. The establishment and development of a broader sales force will be expensive and time consuming.

We are planning to augment our marketing efforts with extensive sales training. Each sales agency will be sending their sales representatives to our seven day NuVasive sales school held at our corporate headquarters. In the fourth quarter of 2004, we hired a Director of Training to develop, manage and implement a first class curriculum.

Surgeon Training and Education

We devote significant resources to training and educating surgeons on the specialized skills involved in the proper use of our instruments and implants. We believe that the most effective way to introduce and build market demand for our products is by training spine surgeons in the use of our products. We maintain a state-of-the-art cadaver operating theater and training facility at our corporate headquarters to help drive adoption of our products. As of December 31, 2004, we had trained 202 spine surgeons in the use of our products. We intend to continue to focus on training both leading and community spine surgeons in the United States. We believe that a number of these surgeons will become advocates for our products and will be instrumental in generating valuable clinical data and demonstrating the benefits of our products to the medical community.

Manufacturing and Supply

We rely on third parties for the manufacture of our products and their components and servicing, and we do not currently maintain alternative manufacturing sources for NeuroVision, MaXcess or any other finished goods products. We have identified secondary sources for these products, however it would take time for these alternative vendors to scale-up production. Our outsourcing strategy is targeted at companies that meet FDA, International Organization for Standardization (ISO), and quality standards supported by internal policies and procedures. Supplier performance is maintained and managed through a corrective action program ensuring 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.

We are currently working with our third-party manufacturers to increase manufacturing capabilities as we increase our commercialization efforts. Manufacturers often experience difficulties in scaling-up production, including problems with production yields and quality control and assurance. If our third-party manufacturers are unable to manufacture our products to keep up with demand, we would not meet expectations for growth of our business.

Following the receipt of products or product components from our third-party manufacturers, we conduct inspection and packaging and labeling, as needed, at our headquarters facility. Under our existing contracts, we reserve the exclusive right to inspect and assure conformance of each product and product component to our specifications. We may consider manufacturing certain products or product components internally, if and when demand or quality requirements make it appropriate to do so.

In January 2004, we entered into a contract manufacturing agreement with Peak Industries, Inc., or Peak, as our exclusive supplier of NeuroVision systems and handpieces. The term of this agreement covers a five-year period and automatically renews for successive one-year periods.

We currently rely on Tissue Banks International, Inc. and Intermountain Tissue Center as our only suppliers of allograft implants. Each of these agreements automatically renew for successive one year terms unless otherwise terminated by either party in accordance with the terms of the respective agreement. Because implants are processed from human tissue, maintaining a steady supply is difficult.

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

Loaners

We seek to obtain inventory just in time to satisfy our customer obligations to meet surgery schedules. This strategy minimizes backlogs, while increasing inventory turns and maximizing cash flow. Our pool of MAS and Classic Fusion loaner equipment that we loan to or place with hospitals, significantly increased in 2004 as we expanded our distribution channels and increased market penetration of our products. This is important to the growth of our business and we anticipate subsequent investments in our operating budget.

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 employees, consultants and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationships with us. We also require our employees, 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, 2004 we had 31 issued U.S. patents and 102 pending patent applications, including 65 U.S. applications, 5 international (PCT) applications and 32 foreign national applications. The issued and pending patents cover, among other things:

- targeting systems;
- MAS surgical access and spine systems;
- implants and related instrumentation; and
- neurophysiology enabled instrumentation and methodology, including pedicle screw test systems, nerve root retraction systems and surgical access systems.

Our issued patents begin to expire in 2018. We have multiple patents covering unique aspects and improvements for many of our products. We do not believe that the expiration of any single patent is likely to significantly affect our intellectual property position.

We have undertaken to protect our neurophysiology platform, including NeuroVision, through a comprehensive strategy covering various important aspects of our neurophysiology-enabled instrumentation, including, screw test, nerve root retraction, surgical access and related methodology. Our NeuroVision patent portfolio includes 4 issued U.S. patents, 22 U.S. patent applications, including 16 U.S. utilities, 5 U.S. provisional, and 1 U.S. design, 3 international (PCT) patent applications, and 22 foreign national applications on this system and related instrumentation.

We obtained a US Patent with broad claims protecting our SpheRx™ pedicle screw system. In addition to this issued patent, we have several applications pending on the SpheRx pedicle screw system and related instrumentation, including 2 US utility applications, 2 US provisional applications, and 3 foreign national patent applications.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Patent litigation can involve complex factual and legal questions and its outcome is uncertain. Any claim relating to infringement of patents that is successfully asserted against us may require us to pay substantial damages. Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Our success will also depend in part on our not infringing patents issued to others, including our competitors and potential competitors. If our products are found to infringe the patents of others, our development, manufacture and sale of such potential products could be severely restricted or prohibited. In addition, our competitors may independently develop similar technologies. Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to protect our intellectual property rights.

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

competitors may assert that future products we may market infringe their patents.

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

Trademarks

We have 39 trademark registrations, both domestic and foreign, including the following US trademarks: NuVasive, NeuroVision, MaXcess, Creative Spine Technology, Triad, Spine Evolution Nucleus and SEN. We have 16 trademark applications pending, both domestic and foreign, for the following trademarks: MAS, SpheRx, DBR, CoRoent, XLIF, Absolute Responsiveness, I-PAS, and InStim.

Competition

We believe that the principal competitive factors in our markets include:

- improved outcomes for spine pathology procedures;
- acceptance by spine surgeons;
- ease of use and reliability;
- product price and qualification for reimbursement;
- technical leadership and superiority;
- effective marketing and distribution; and
- speed to market.

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 competitors 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.

MAS Platform

Our NeuroVision system competes with the conventional nerve monitoring systems offered by Nicolet

Biomedical and Axon Systems. We believe our system competes favorably with Nicolet's and Axon's systems on both price and ease of use for the spine surgeon. In addition, neither Nicolet's nor Axon's systems were designed to support surgeon directed applications. Sofamor Danek, a Medtronic company, announced the introduction of the NIM system for nerve monitoring. The NIM system is not surgeon directed and requires manual interpretation. Several companies offer products that compete with our MaXcess system, SpheRx pedicle screw system and implants including competitive offerings by DePuy Spine, Inc., a Johnson & Johnson company, and Medtronic Sofamor Danek.

Classic Fusion

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

Products Under Development (Motion Preservation)

Several companies have been developing total disc replacement products for both the lumbar and cervical spine including nucleus replacement products. During 2004 DePuy Spine, a Johnson and Johnson company, introduced the first total disc replacement for the lumbar spine to the market.

Government Regulation

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

- product design and development;
- product testing;
- product manufacturing;
- product labeling;
- product storage;
- premarket clearance or approval;
- advertising and promotion; and
- product sales and distribution.

FDA's Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either prior 510(k) clearance or prior premarket approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk are placed in either class I or II, which requires the manufacturer to submit to the FDA a premarket notification requesting permission for commercial distribution. This process is known as 510(k) clearance. Some low risk devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed

not substantially equivalent to a previously cleared 510(k) device are placed in class III, requiring premarket approval. Both premarket clearance and premarket approval applications are subject to the payment of user fees, paid at the time of submission for FDA review.

510(k) Clearance Pathway

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

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

Premarket Approval Pathway

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

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

Clinical Trials

A clinical trial is almost always required to support a premarket approval application and is sometimes required for a 510(k) premarket notification. These trials generally require submission of an application for an investigational device exemption to the FDA. The investigational device exemption application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The investigational device exemption application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated investigational device exemption requirements. Clinical trials for a significant risk device may begin once the investigational device exemption application is approved by the FDA and the appropriate institutional review boards at the clinical trial sites. Future clinical trials of our motion preservation designs and interbody implants will likely require that we obtain an investigational device exemption from the FDA prior to

commencing clinical trials. Our clinical trials must be conducted in accordance with FDA regulations and federal regulations concerning human subject protection and healthcare privacy. The results of our clinical testing may not support or may not be sufficient to obtain approval of our product.

Pervasive and Continuing FDA Regulation

After a device is placed on the market, numerous regulatory requirements apply. These include:

- quality system regulation, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- 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 inspections by the FDA and the Food and Drug Branch of the California Department of Health Services, and these inspections may include the manufacturing facilities of our subcontractors.

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 primary regulatory environment in Europe is that of the European Union, which consists of 25 countries encompassing most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directives 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 may consist of an

audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body in one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. In 2001, we were certified by TUV Product Service, a Notified Body, under the European Union Medical Device Directive allowing the CE conformity marking to be applied.

Third-Party Reimbursement

We expect that sales volumes and prices of our products will continue to be dependent in large part on the availability of reimbursement from third-party payors. Such payors include governmental programs, for example, Medicare and Medicaid, private insurance plans and managed care programs. These third-party payors may deny reimbursement if they determine that a device used in a procedure was not used in accordance with cost-effective treatment methods, as determined by the third-party payor, or was used for an unapproved indication. Also, third-party payors 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 payors, that reimbursement will be available or, if available, that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably.

Particularly in the United States, third-party payors 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 payors 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 payor coverage or reimbursement could have a material adverse effect on our business, operating results and financial condition.

Clinical Advisory Board

We have established a clinical advisory board led by Randal Betz, M.D. of Philadelphia, Pennsylvania that we call the Spine Evolution Nucleus, or SEN. This group consists of orthopedic and neurological spine surgeon thought leaders. The SEN consults with us on long-term product planning, research, development and marketing initiatives. Significant pioneering clinical developments have been contributed to us by Luiz Pimenta, M.D. from Sao Paulo, Brazil and other members of the SEN.

Employees

As of December 31, 2004, we had 105 employees, of which 11 were employed in operations, 29 in research and development, 6 in clinical regulatory, 19 in general and administrative and 40 in sales and marketing. None of our employees is represented by a labor union and we believe our employee relations are good.

Item 2. Properties.

Our headquarters were relocated in January 2005 to an approximately 63,000 square foot facility in San Diego, California that is leased to us until December, 2013. We believe that our existing facility is adequate for our current needs and anticipated expansion.

Item 3. Legal Proceedings.

Until recently, we have been involved in litigation with Medtronic Inc. regarding Medtronic's claims that we interfered with its contracts (including alleged interference with non-competition agreements and proprietary information and confidentiality agreements) by employing three former Medtronic employees, two of whom are current employees of ours and one of whom is a former member of our Board of Directors. This litigation also involved a suit filed by the three individuals in California seeking a judicial order that the contracts at issue were void under California law. We assumed responsibility for all costs associated with this litigation incurred by us and the three individuals.

We recently agreed with Medtronic to settle all related litigation. A settlement agreement to that effect has been signed and the actions have been dismissed. The financial terms of the settlement agreement were not material to our business.

We are not currently a party to any material legal proceedings.

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, 2004.

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 National Market under the symbol "NUVA." Our common stock began trading on the Nasdaq National Market on May 13, 2004, the date of our initial public offering. The following table presents, for the periods indicated, the high and low intra-day sale prices per share of our common stock during the periods indicated, as reported on NASDAQ.

Fiscal 2004:	High	Low
Second Quarter (from May 13, 2004)	$ 12.15	$ 10.29
Third Quarter	11.31	8.97
Fourth Quarter	11.60	8.74

We had approximately 307 stockholders of record as of December 31, 2004. 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."

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.

RECENT SALES OF UNREGISTERED SECURITIES

During 2004, we issued and sold the following securities that were not registered under the Securities Act, which issuances have not been previously disclosed in our Quarterly Reports on Form 10-Q or Current Reports on Form 8-K. The offers, sales, and issuances of these securities were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act, and/or Regulation D promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving a public offering or transactions under compensatory benefit plans and contracts relating to compensation as provided under such Rule 701. The recipients of securities in each such transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates and warrants issued in such transactions.

1. On March 12, 2004, pursuant to the exemption provided in Section 4(2) of the Securities Act, we issued a warrant to purchase 45,000 shares of our Series D-1 preferred stock at an exercise price of $4.30 per underlying share to Comerica Bank in consideration for providing us with an increase in an accounts receivable line of credit and loans to finance the purchase by us of capital equipment.

2. Between From January 1, 2004 and March 31, 2004, pursuant to exemptions from registration provided in Section 4(2) or Section 3(b) of the Securities Act or under Rule 701, we granted options to purchase an aggregate of 1,266,200 shares of our common stock to our directors, employees and consultants under our 1998 Plan at exercise prices ranging from $3.75 to $10.75 per share.

3. Between January 1, 2004 and March 31, 2004, pursuant to the exemptions provided in Section 4(2) of the Securities Act and Rule 701, we issued 539,868 shares of our common stock to our directors, employees and consultants upon exercise of options granted under our 1998 Plan in consideration for an aggregate purchase price of $405,666.

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	2,979,138	$ 5.02	410,828
Equity compensation plans not approved by security holders	—	—	
Total	2,979,138	$ 5.02	

Equity compensation plans approved by our stockholders include our 1998 Stock Option/Stock Issuance Plan, our 2004 Equity Incentive Plan and our 2004 Employee Stock Purchase Plan.

Use of Proceeds

The Registration Statement on Form S-1 (No. 333-113344) (the "Registration Statement") relating to our initial public offering of common stock was declared effective by the Securities and Exchange Commission on May 12, 2004. Pursuant to this Registration Statement, we raised aggregate proceeds of approximately $75.7 million. Of this amount, we paid approximately $5.3 million in underwriting fees and commissions, and approximately $2.3 million for offering-related expenses. This resulted in approximate aggregate net proceeds of $68.1 and total expenses of approximately $7.6 million. Arda Minocherhomjee, one of our directors, is a former principal of William Blair & Company, L.L.C. which was one of the underwriters of our initial public offering and received compensation for their services in connection therewith. Other than this affiliation, no offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of December 31, 2004, we had used approximately $315,000 of our public offering proceeds in connection with the acquisition of leased real estate facilities for our corporate offices, approximately $6.3 million for the repayment of outstanding indebtedness, and approximately $14.1 million to fund our operations. In addition, we have invested approximately $46.6 million in short-term marketable securities. The proceeds used to fund our operations included regular compensation for officers and directors. The use of proceeds does not represent a material change from the use of proceeds described in the prospectus relating to the Registration Statement.

Item 6. Selected Financial Data.

In the table below, we provide you with our historical selected consolidated financial data. We derived the consolidated statement of operations data for the years ended December 31, 2001 and 2000 and the consolidated

balance sheet data as of December 31, 2002, 2001, and 2000 from our audited consolidated financial statements for such periods and dates, which are not included in this Annual Report on Form 10-K. We derived the consolidated statement of operations data for the years ended December 31, 2004, 2003 and 2002 and the consolidated balance sheet data as of December 31, 2004 and 2003 from our audited consolidated financial statements for such periods and dates, which appear elsewhere in this Annual Report on Form 10-K. It is important that you read the selected consolidated financial data set forth below in conjunction with our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the operating results that may be expected in the future.

Consolidated Statement of Operations Data:

	(in thousands, except per share data)				
	2004	2003	2002	2001	2000
Revenues					
MAS	$ 28,135	$ 12,069	$ 5,269	$ 1,444	$ —
Classic fusion	10,268	10,586	6,991	1,120	52
Total revenues	38,403	22,655	12,260	2,564	52
Cost of goods sold	10,228	6,791	5,303	1,354	87
Gross profit	28,175	15,864	6,957	1,210	(35)
Operating expenses:					
Research and development	8,348	6,310	6,107	7,331	9,011
Selling and marketing	19,740	12,609	10,024	6,885	1,980
General and administrative	8,584	6,185	5,568	4,458	3,241
Stock-based compensation	6,143	743	113	22	—
Total operating expenses	42,815	25,847	21,812	18,696	14,232
Loss from operations	(14,640)	(9,983)	(14,855)	(17,486)	(14,267)
Interest and other (expense), net	430	(144)	(255)	(416)	117
Net loss	(14,210)	(10,127)	(15,110)	(17,902)	(14,150)
Beneficial conversion of convertible debt	—	—	—	(320)	—
Net loss attributable to common stockholders	$ (14,210)	$ (10,127)	$ (15,110)	$ (18,222)	$ (14,150)
Net loss per share					
Basic and diluted	$ (0.91)	$ (6.30)	$ (13.20)	$ (23.88)	$ (19.54)
Weighted average shares- basic and diluted	15,605	1,607	1,145	763	724

Consolidated Balance Sheet Data:

	As of December 31,				
	2004	2003	2002	2001	2000
	(in thousands)				
Cash, cash equivalents and short-term investments	$ 59,153	$ 9,648	$ 6,906	$ 9,658	$ 1,836
Working capital	62,656	6,139	7,251	8,415	297
Total assets	80,752	22,371	14,932	16,617	4,660
Long-term obligations, less current portion	13	1,224	329	1,795	2,901
Total stockholders' equity (deficit)	71,397	10,070	9,384	9,466	(720)

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

Overview

Background

We are a medical device company focused on the design, development and marketing of products for the surgical treatment of spine disorders. From our incorporation in 1997 through 2000, we devoted substantially all of our resources to research and development and start-up activities, consisting primarily of identification of potential products, recruiting qualified personnel and raising capital. Our current principal product offering includes a minimally disruptive surgical platform that we call maximum access surgery, or MAS, as well as classic fusion products. MAS combines NeuroVision, MaXcess, and other specialized implants including our SpheRx Pedicle Screw System, which was introduced in the third quarter of 2004. Our classic fusion portfolio is comprised of a range of products, including bone allografts, which are human bone that has been processed and precision shaped for transplant, and spine implants such as rods, plates and screws that are necessary for a variety of spine surgery procedures. Our products are designed to address the growing spine market with a focus on minimally disruptive spine surgery techniques. All of our currently marketed products have been cleared by the FDA. In 2001, we began to commercialize our nerve avoidance and classic fusion products. We began commercial distribution of MaXcess in the fourth quarter of 2003 and of our SpheRx Pedicle Screw product in the fourth quarter of 2004.

Since inception, we have been unprofitable. We incurred net losses of approximately $15.1 million in 2002, $10.1 million in 2003 and $14.2 million in 2004. As of December 31, 2004, we had an accumulated deficit of $78.5 million.

Revenues

From inception to December 31, 2004, we have recognized $75.9 million in revenue from sales of our products. As of December 31, 2004, we estimate that our products have been used in over 31,000 surgeries.

Our revenues are derived from the sale of medical products in two principal categories:

- *MAS Platform* . Our MAS revenues primarily consist of sales of disposable sets for use with our NeuroVision system, instruments and disposables used with MaXcess, and specialized implants used during surgery, such as SpheRx and Coroent.

- *Classic Fusion.* Our classic fusion revenues primarily consist of the sales of bone allograft and metal cage implants.

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. To date we have sold only 13 NeuroVision systems and have derived less than 5% of our revenues from the sale of such systems. We do not expect these sales to contribute significantly to our revenues in the future because we intend to continue to (i) loan these systems to hospitals and surgeons who purchase our disposables and implants for use in individual procedures or (ii) place these systems with hospitals for an extended period at no up-front cost to them provided they commit to minimum monthly purchases of our disposables and

implants. In the event that a hospital or surgeon does not meet its minimum monthly purchase commitments, our sole remedy is to remove our NeuroVision system.

Our implants, disposables and instruments are sold and shipped from inventories at our facility or from limited disposable inventories that are stored at our distributors' sites. We invoice hospitals a fee for using certain instruments and for any disposables or implants upon receiving notice of product use or implantation. For NeuroVision, we generally place the system in hospitals free of charge and allow it to remain on-site provided the hospital orders a minimum monthly quantity of our nerve avoidance disposable products. In addition, we have a program pursuant to which we loan, from a pool of fixed assets, NeuroVision systems to hospitals without charge to support individual surgical procedures. We derive revenue from the sales of disposables and/or implants used in these procedures.

Sales and Marketing

Substantially all of our operations are located in the United States and nearly all of our sales to date have been generated in the United States. We distribute our products through independent agencies. The independent agencies provide a delivery and consultative service to our surgeon and hospital customers and receive commissions based on sales and product placements in their territories. The commissions are reflected in our statement of operations within the selling and marketing expense line. We expect to continue to expand our distribution channel.

We expect to increase the amounts we spend on sales and marketing for the foreseeable future. These increased amounts will be directed towards hiring additional sales management and training personnel, expanding and training our distribution channels, promoting awareness of our products and providing training to surgeons. These amounts will also be used to compensate our independent sales agents related to sales of our products. To date, the majority of our revenues have been derived from the sale of disposables and implants. We expect this trend to continue in the near term.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States and regulations of the Securities and Exchange Commission. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an on-going basis, we evaluate our estimates including those related to product returns, bad debts, inventories and income taxes. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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 recognize revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, *Revenue Recognition,* which requires that four basic criteria must be met before revenues can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed and determinable; and (4) collectibility is reasonably assured. Specifically, revenue from the sale of our implants and disposables is recognized upon receipt of written acknowledgement that the product has been used in a surgical procedure or upon shipment to customers who immediately accept title. Revenue from the sale of our NeuroVision systems and instrument sets is recognized upon receipt of a purchase order and the subsequent shipment to customers who immediately accept title.

Allowance for Doubtful Accounts. We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. The allowance for doubtful accounts is reviewed quarterly and is estimated based on the aging of account balances, collection history and known trends with

current customers. As a result of this review the allowance is adjusted on a specific identification basis. Increases to the allowance for doubtful accounts result in a corresponding expense. We maintain a relatively large customer base that mitigates the risk of concentration with one customer. However, if the overall condition of the healthcare industry were to deteriorate, resulting in an impairment of our customers' ability to make payments, significant additional allowances could be required.

Excess and Obsolete Inventory. We calculate an inventory reserve for estimated obsolescence or excess inventory based upon historical turnover and assumptions about future demand for our products and market conditions. Our allograft implants have a four-year shelf life and are subject to demand fluctuations based on the availability and demand for alternative implant products. Our MAS inventory, which consists primarily of instruments, 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. Future product introductions and related inventories may require additional reserves based upon changes in market demand or introduction of competing technologies. Increases in the reserve for excess and obsolete inventory result in a corresponding expense to cost of goods sold.

Property, Plant and Equipment. Property, plant and equipment is carried at cost less accumulated depreciation. Depreciation is computed based on the estimated useful lives of two to seven years for machinery and equipment and three years for loaner equipment using the straight-line method. Maintenance and repairs are expensed as incurred. In accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, *"Accounting for the Impairment or Disposal of Long-Lived Assets,"* the Company reviews property, plant and equipment for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated future undiscounted cash flows relating to the asset are less than its carrying amount.

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, 2004 due to uncertainties related to our ability to utilize our deferred tax assets in the foreseeable future. These deferred tax assets primarily consist of certain net operating loss carryforwards and research and development tax credits.

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 accounting principles generally accepted in the United States. There are also areas in which our management's judgment in selecting any available alternative would not produce a materially different result. See our consolidated financial statements and notes thereto included in this Annual Report on Form 10-K, which contain accounting policies and other disclosures required by accounting principles generally accepted in the United States.

Results of Operations

The following table sets forth our results of operations expressed as a percentage of total revenues, for the years ended December 31, 2004, 2003 and 2002.

	2004	2003	2002
Revenues:			
MAS	73%	53%	43%
Classic fusion	27	47	57
Total revenues	100	100	100
Cost of goods sold	27	30	43
Gross profit	73	70	57
Operating expenses:			
Research and development	22	28	50
Selling and marketing	51	56	82
General and administrative	22	27	45
Stock-based compensation	16	3	1
Total operating expenses	111	114	178
Loss from operations	(38)	(44)	(121)
Interest and other (expense), net	1	(1)	(2)
Net loss	(37)%	(45)%	(123)%

Comparison of Years Ended December 31, 2004 and 2003

Revenues

Total revenues. Total revenues increased $15.7 million, or 70%, from $22.7 million in 2003 to $38.4 million in 2004.

MAS. MAS revenue increased $16.1 million, or 133%, from $12.1 million in 2003 to $28.1 million in 2004. The increase is attributable to continued market acceptance of our MAS products, including MaXcess and Neurovision disposables, and purchases of our MAS implants. MAS revenue accounted for 73% of total revenues in 2004 compared to 53% of total revenues in 2003. We expect our MAS products will continue to be a significant contributor of our total revenue for the foreseeable future, which is consistent with our strategy.

Classic Fusion. Classic fusion revenue decreased $318,000, or 3%, from $10.6 million in 2003 to $10.3 million in 2004. This decrease is attributable to a continued shift in market demand away from bone allograft and toward composite materials. We expect that demand for our allograft will continue at or near the present level, but the associated revenue will decrease as a relative percentage of our total revenues. Classic fusion revenue accounted for 27% of total revenues in 2004 compared to 47% of total revenues in 2003.

Cost of Goods Sold

Cost of goods sold increased $3.4 million, or 51%, from $6.8 million in 2003 to $10.2 million in 2004. Cost of goods sold consists of purchased goods and overhead costs. The increase is primarily due to increased product sales, specifically the related material costs. Cost of goods sold as a percentage of total revenues decreased from 30% in 2003 to 27% in 2004. The decrease is attributable to a shift in product mix to MAS products, which generally have lower material costs and therefore higher margins than our classic fusion products.

Gross Profit

Gross profit in 2004 was $28.2 million , or 73% of revenues, compared to $15.9 million, or 70% of revenues, in 2003. The improvement in gross margin was due primarily to the shift in product mix from classic fusion to MAS

products, which have significantly higher margins. For 2004, the gross margin for MAS was 79% and classic fusion was 59%. Our overall gross profit is subject to fluctuation based on the mix between MAS and classic fusion related products.

Operating Expenses

Research and Development. Research and development expenses increased $2.0 million, or 32%, from $6.3 million in 2003 to $8.3 million in 2004. Research and development expenses consist primarily of the cost of product research, product development, regulatory and clinical functions, and employee related expenses for personnel. The increase in research and development costs was largely due to an increase in employee related expenses of $1.4 million as a result of additional personnel hired to support development of our product pipeline, including the SpheRx Pedicle Screw product and Total Disc Replacement development and $459,000 in materials to support current product development. Research and development expense as a percentage of revenue decreased from 28% in 2003 to 22% in 2004.

Sales and Marketing. Sales and marketing expenses increased $7.1 million, or 57%, from $12.6 million in 2003 to $19.7 million in 2004. Sales and marketing expenses consist primarily of employee related expenses and commissions for personnel engaged in sales, marketing and customer support functions, along with advertising, tradeshow, and surgeon training expenses. The increase in sales and marketing expenses resulted from increased commissions, additional employee related costs of $5.1 million reflecting both increases in sales and number of sales representatives and an increase in shipping cost of $223,000. Additionally, the sales and marketing focus to market our MAS platform resulted in increased media expenses of $497,000 and increased expenses related to surgeon training of $714,000. Sales and marketing expense as a percentage of revenue decreased from 56% in 2003 to 51% in 2004.

General and Administrative. General and administrative expenses increased $2.4 million, or 39%, from $6.2 million in 2003 to $8.6 million in 2004. General and administrative expenses consist of employee related expenses for our administrative functions, third party professional service fees, facilities and insurance expenses. The increase in general and administrative expenses was due largely to insurance expenses of $484,000 for increased product liability and D + O premiums, legal expense of $235,000, public company expense of $123,000, audit and tax services expenses of $225,000 and employee related expenses of $601,000 to support anticipated expansion. General and administrative expense as a percentage of total revenue decreased from 27% in 2003 to 22% in 2004.

Interest and Other Income, Net

Interest and other income, net increased $574,000, or 399%, from ($144,000) in 2003 to $430,000 in 2004. The increase is primarily due to interest earned on the investment of proceeds received from our initial public offering.

Comparison of years ended December 31, 2002 and 2003

Revenues

Total revenue from our products increased from $12.3 million in 2002 to $22.7 million in 2003. These increases reflect an increased focus on commercializing our products. We released additional products in our MAS and classic fusion product lines during this time period which contributed to the increase in revenues.

The increase in revenues in 2003 over 2002 of $10.4 million resulted primarily from an additional $6.8 million in sales of our MAS products, principally our NeuroVision disposables, and an additional $3.6 million in sales of our classic fusion products, which included new product releases of additional implants in the second half of the year contributing $253,000. Our NeuroVision product software platform was upgraded during 2003 allowing us to add additional capabilities to our lumbar and cervical applications. During the fourth quarter of 2003, we launched our new minimally invasive spine surgery products under the product name MaXcess. MaXcess sales were not material to our MAS sales for 2003; however, we expect that through the usage of our MaXcess instrument systems, it will create the pull through of our specialized implants, resulting in significant contributions to our future MAS product

revenues.

Cost of Goods Sold

Cost of goods sold increased from $5.3 million in 2002 to $6.8 million in 2003. Cost of goods sold consists of purchased goods and overhead costs. The components of overhead cost are the depreciation on our instrument sets and NeuroVision systems, both of which we depreciate over three years, and the reserve for obsolescence. The increases in the cost of goods sold resulted primarily from increased sales of products, the additional depreciation associated with the purchases of additional NeuroVision and instrument sets, and the recording of an increased obsolescence reserve for our allograft inventory. Costs associated with increased sales of products consist largely of increased material costs. An increase in the obsolescence reserve of $900,000 was recorded in 2002 to account for the remaining shelf life on our allograft inventory, and in 2003 an increase in the reserve of $400,000 to recognize the early signs of a market transition from allograft to accepting alternative material. As a percentage of revenue, cost of goods sold decreased from 43% in 2002, to 30% in 2003, primarily as a result of favorable cost trends due to larger volume purchases of materials and increased sales of NeuroVision disposables which have higher margins.

Gross Margin

Gross margin was 57% of revenues in 2002 and 70% in 2003. The improvement in 2003 over 2002 primarily reflected the introduction of our NeuroVision nerve avoidance platform during the first quarter of 2003. This introduction resulted in shifting the mix of our MAS products to 53% versus 43% of our total revenue for the prior year, and our MAS products have significantly higher gross margins than our classic fusion products.

Operating Expenses

Research and Development Research and development expenses totaled $6.1 million in 2002 and $6.3 million in 2003. Research and development expenses consist of costs of product research, product development, regulatory and clinical functions and personnel. The increase in research and development expenses in 2003 over 2002 of $203,000 was due primarily to increased headcount cost of $948,000, lab and office costs of $77,000, patent and legal costs of $73,000 and travel costs totaling approximately $78,000. The increases for all of the above categories were attributable to supporting a ramp in our revenues. These costs were offset by a decrease in consulting fees of $973,000 as we transitioned from consultants to employees who were hired to support our released products. We expect research and development expenses to increase as we continue to develop new products to expand our product offerings.

Sales and Marketing Sales and marketing expenses totaled $10.0 million in 2002 and $12.6 million in 2003. The increase in expenses in 2003 over 2002 was primarily due to larger commissions paid to sales representatives of $2.3 million, increased marketing costs of $267,000, and increased travel costs of $387,000. These increases were offset by a decrease of $293,000 related to our German subsidiary in 2003. We expect sales and marketing expenses to continue to increase in the future as a result of continued growth in our sales infrastructure to support growth in our product sales.

General and Administrative General and administrative expenses totaled $5.6 million in 2002 and $6.2 million in 2003. The increase in expenses in 2003 over 2002 of $617,000 was primarily due to increased facility and office costs of $123,000 related to the space requirements to accommodate an expanding inventory, increased product liability insurance premiums of $304,000 related to higher revenues, and additional headcount of $257,000 to support a growing customer base.

Interest and Other Expense, Net

Interest and other expenses totaled $255,000 in 2002 and $144,000 in 2003. The decrease in 2003 over 2002 was primarily due to lower interest rates paid on our outstanding debt and a gain on the sale of intellectual property

totaling $125,000.

Deferred Stock-Based Compensation

We have accounted for options granted to employees and directors in accordance with Statement of Financial Accounting Standards ("SFAS") No. 123, *Accounting for Stock-Based Compensation,* and related interpretations. As such, compensation expense is recorded on stock option grants based on the fair value of the options granted, which is estimated on the date of grant using an option-pricing model and it is recognized on an accelerated basis over the vesting period (typically four years). Deferred stock-based compensation recorded through December 31, 2004, was approximately $8.6 million, with accumulated amortization of approximately $5.2 million. The remaining approximately $3.4 million will be amortized over the vesting periods of the options, generally four years from the date of grant. We expect to record amortization expense for deferred stock-based compensation as follows:

Fiscal year 2005	$ 2,121,000
Fiscal year 2006	1,017,000
Fiscal year 2007	303,000
Total	$ 3,441,000

We have accounted for stock options granted to non-employees on a fair-value basis in accordance with SFAS No. 123, Emerging Issues Task Force Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* , and Financial Accounting Standards Board Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans an Interpretation of APB Opinion No. 15 and 25* . As a result, the non-cash charge to operations for non-employee options with vesting or other performance criteria is affected each reporting period by changes in the fair value of our common stock. Compensation expense for options granted to non-employees amounted to $43,000, $458,000 and $925,000 for the years ended December 31, 2002, 2003, and 2004. The amount of compensation expense to be recorded in the future for options granted to non-employees is subject to change each reporting period based upon changes in the fair value of our common stock, estimated volatility and risk free interest rate until the non-employee completes performance under the option agreement.

Liquidity and Capital resources

Since our inception in 1997, we have incurred significant losses and as of December 31, 2004, we had an accumulated deficit of approximately $78.5 million. We have not yet achieved profitability, and anticipate that we will continue to incur net losses for the foreseeable future. We expect that our research and development, sales and marketing and general and administrative expenses will continue to grow and, as a result, we will need to generate significant net sales to achieve profitability. To date, our operations have been funded primarily with proceeds from the sale of our equity securities. Gross proceeds from our preferred stock sales, which occurred from inception through 2003, total $74.4 million to date. In May 2004, we closed our initial public offering, resulting in proceeds to us, net of underwriting fees and offering costs, of approximately $68.1 million.

Cash, cash equivalents and short-term investments was $59.2 million at December 31, 2004, $9.6 million at December 31, 2003, and $6.9 million at December 31, 2002. The increase in 2004 over 2003 was due to net proceeds of approximately $68.1 million from our initial public offering in May of 2004, offset by cash used to fund our operations of $8.6 million, proceeds from notes payable of $1.4 million, payment of notes payable of $6.1 million, proceeds from option and warrant exercises of $1.1 million, capital lease payments of $310,000 and purchases of fixed assets of $6.1 million. The increase in 2003 over 2002 was due primarily to $9.9 million of proceeds from the issuance of preferred stock in the second quarter of 2003 and an increase in notes payable of $4.7 million offset by the cash used to fund our 2003 operations of $6.0 million and capital expenditures of $4.5 million.

Net cash used in operating activities was $8.6 million in 2004 compared to $6.0 million in 2003 and $14.0 million in 2002. In 2004, the increase of net cash used in operating activities of $2.6 million was primarily due to an increase in inventory purchases of $3.2 million and an increase in cash used to fund operations of $14.1 million,

which are offset by increased cash receipts of $14.8 million. The decrease in net cash used in operating activities in 2003 over 2002 was primarily due to reductions in our net loss and partially offset by increases in inventory balances.

Net cash used in investing activities was $52.7 million in 2004 compared to $8.5 million in 2003 and $2.0 million in 2002. In 2004, the increase in cash used for investing activities is primarily due to the purchase of short-term investments with the proceeds of our initial public offering. Additionally, our investment in fixed assets has increased by $1.7 million with the overall increase in the size of our business. The increase in net cash used in investing activities from 2002 to 2003 was primarily due to purchases of property and equipment and the purchase of short term investments with the proceeds from our preferred stock financing.

Net cash provided by financing activities was $64.2 million in 2004 compared to $13.3 million in 2003 and $13.2 million in 2002. In 2004, the increase in net cash provided by financing activities was primarily due to cash received from our initial public offering and offset by repayment of our outstanding bank debt of $6.1 million. Net cash provided by financing activities from 2002 to 2003 remained constant due to borrowings in 2003 of $4.7 million and sale of preferred stock of $9.9 million.

We have operating lease commitments of $849,000 in 2005, $1.2 million in 2006, and $1.3 million each year thereafter until 2013. A significant majority of our operating lease commitments are related to our corporate headquarters lease, which was signed in December 2004. The rent expense related to our corporate headquarters lease will be recorded on a straight-line basis in accordance with generally accepted accounting principles.

The following summarizes our long-term contractual obligations as of December 31, 2004 *(in thousands)*:

	Total	Less than 1 Year	Payments Due by Period 1 to 3 Years	4 to 5 Years	After 5 Years
Capital leases	$ 18	$ 5	$ 13	$ —	$ —
Operating lease	9,535	849	2,484	2,627	3,575
Other contractual obligations (1)	3,419	563	901	714	1,241
Total	$ 12,972	$ 1,417	$ 3,398	$ 3,341	$ 4,816

(1) These amounts include a total of $720,000 to be paid as minimum royalties and the remainder is to be paid to clinical advisors.

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

RISK FACTORS

Set forth below and elsewhere in this report and in other documents we file with the Securities and Exchange Commission are risks and uncertainties that could cause our actual results to differ materially from the results contemplated by the forward-looking statements contained in this report and other public statements we make. If any of the following risks actually occurs, our business, financial condition, or results of operations could suffer. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business and Industry

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 that 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;
- 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 that 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 from 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.

If spine surgeons are unable to obtain sufficient reimbursement for procedures performed with our products, it is unlikely that our products will be widely used.

Successful sales of our products will depend on the availability of adequate reimbursement from third-party payors. Healthcare providers, such as hospitals and surgeons 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. Both public and private insurance reimbursement plans are central to new product acceptance. Spine surgeons are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of related procedures.

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 may not obtain international reimbursement approvals in a timely manner, if at all. Our failure to receive international reimbursement approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

We believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Third-party reimbursement and coverage may not be available or adequate in either the United States or 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.

Adverse changes in reimbursement procedures by payors may impact our ability to market and sell our products.

Even if the use of our products is reimbursed by private payors and Medicare, adverse changes in payors' policies toward reimbursement for our procedures would harm our ability to market and sell our products. We are unable to predict what changes will be made in the reimbursement methods used by payors. We cannot be certain that under prospective payment systems, in which healthcare providers may be reimbursed a set amount based on the type of procedure performed, such as those utilized by Medicare and in many privately managed care systems, the cost of our products will be justified and incorporated into the overall cost of the procedure.

To the extent we sell our products internationally, we will face similar risks relating to adverse changes in reimbursement procedures and policies. Reimbursement and healthcare payment systems vary significantly among international markets. Our inability to obtain international reimbursement approval, or any adverse changes in the reimbursement policies of foreign payors, could negatively affect our ability to sell our products.

We are in a highly competitive market segment, face competition from large, well-established medical device manufacturers with significant resources, and may not be able to compete effectively.

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, among others. With respect to MaXcess, our minimally disruptive surgical system, our largest competitors are Medtronic Sofamor Danek, DePuy Spine, a Johnson & Johnson company, and Synthes-Stratec. We compete with many of the same companies with respect to our other products. At any time, other companies may develop alternative treatments, products or procedures for the treatment of spine disorders that compete directly or indirectly with our products. If alternative treatments prove to be superior to our spine surgery products, adoption of our products could be negatively affected and our future revenues could suffer.

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

- significantly greater name recognition;
- established relations with spine surgeons;
- established distribution networks;
- products supported by long-term clinical data;
- greater experience in obtaining and maintaining United States Food and Drug Administration, or FDA, and other regulatory approvals for products and product enhancements;
- greater resources for product research and development; and
- greater experience in, and resources for, launching, marketing, distributing and selling products.

For these reasons, we may not be able to compete successfully against our current or potential future competitors and sales of our spine surgery products may decline.

We have limited sales and marketing experience and our sales and marketing efforts are largely dependent on third parties.

We currently have limited experience in marketing and selling our products. We have only been selling our products since 2001. We currently sell our products in the United States through distribution arrangements with a network of independent agents and sales representatives managed by our sales managers. As a result, we are dependent upon the sales and marketing efforts of our third-party sales agencies. We pay these agents and sales representatives a commission based on their product sales. To date, few of these agents or sales representatives are required to exclusively sell our products and may freely sell any other products, including products of our competitors.

As we launch new products and increase our marketing efforts with respect to existing products, we will need to expand the reach of our marketing and sales force. We plan to accomplish this by increasing our network of outside sales agencies. The establishment and development of a broader distribution network and sales force will be expensive and time consuming. Because of the intense competition for their services, we may be unable to identify additional qualified sales agencies and contract sales organizations. Further, we may not be able to enter into agreements with them on commercially reasonable terms, if at all. Even if we do enter into agreements with additional sales agencies and/or contract sales organizations, these parties may not commit the necessary resources to effectively market and sell our products and may not ultimately be successful in selling our products. Our financial condition and results of operations will be harmed if the marketing and sales efforts of our own employees, third-party sales agencies and contract sales organizations are unsuccessful.

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

We rely on third-party suppliers and manufacturers to manufacture and supply our products. To be successful, our contract manufacturers must be able to provide us with the products and components of our systems in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable cost and on a timely basis. Our anticipated growth could strain the ability of suppliers to deliver an increasingly large supply of products, materials and components. Manufacturers often experience difficulties in scaling up production, including problems with production yields and quality control and assurance. 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 products. 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.

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

Rapid growth of our business is likely to place a significant strain on our managerial, operational and financial resources and systems. While we anticipate hiring additional personnel to assist in the commercialization of our current products and the development of future products, there is no certainty that we will be able to successfully commercialize our products and meet our growth goals.

To execute our anticipated growth successfully, we must attract and retain qualified personnel and manage and train them effectively. We will be dependent on our personnel and third parties to effectively market our products to an increasing number of surgeons. We will also depend on our personnel to develop next generation technologies.

Further, our anticipated growth will place additional strain on our suppliers and manufacturers, resulting in increased need for us to carefully monitor for 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.

Our new facilities represent a significant increase in operating costs that could negatively affect our results of operations.

We recently relocated our operations to a different facility. Although this new facility allows for growth in our business and enables us to more effectively train surgeons in the use of our products, it has significantly increased our operating expenses. For example, our monthly lease payments have approximately doubled and we will also be required to pay increased maintenance costs for this facility. If we do not generate additional business opportunities, these additional expenses could negatively affect our results of operations.

We may not be able to timely develop new products or product enhancements that will be accepted by the market.

Our success will depend in part on our ability to develop and introduce new products and enhancements to our existing products. We cannot assure you that we will be able to successfully develop or market new products or that any of our future products will be accepted by the surgeons who use our products or the payors who financially support many of the procedures performed with our products. The success of any new product offering or enhancement to an existing product will depend on several factors, including our ability to:

- properly identify and anticipate surgeon and patient needs;
- develop new products or enhancements in a timely manner;
- obtain the necessary regulatory approvals for new products or product enhancements;
- provide adequate training to potential users of our products;
- receive adequate reimbursement notifications; and
- develop an effective 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 business will suffer.

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. 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. The process of obtaining regulatory approvals to market a medical device, particularly from the FDA, can be costly and time consuming, and there can be no assurance that such 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 510(k) clearance or is the subject of an approved premarket approval application, or PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. The PMA approval process is more costly, lengthy and uncertain than the 510(k) clearance process. Any products we develop that require regulatory clearance may be delayed. In addition, because we cannot assure you that any new products or any product enhancements we develop will be subject to the shorter 510(k) clearance process, the regulatory approval process for our products or product enhancements may take significantly longer than anticipated. There is no assurance that the FDA will not require that

a certain new product or product enhancement go through the lengthy and expensive PMA approval process. To date, all of our products have been cleared through the 510(k) process. We have no experience in obtaining PMA approval.

Further, pursuant to FDA regulations, we can only market our products for cleared or approved uses. Certain of our products may be used by physicians for indications other than those cleared or approved by the FDA, but we cannot promote the products for such off-label uses.

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

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

We obtained clearance to offer our MAS and certain Classic Fusion products 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 in the way of long-term clinical studies. 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 slow the adoption of our products by spine surgeons, significantly reduce our ability to achieve expected revenues and could prevent us from becoming profitable. Accordingly, 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 latent and costly product liability litigation.

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

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

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

We and our suppliers are required to comply with the FDA's quality system regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA enforces the quality system regulation through inspections. If we or one of our suppliers fail a quality system regulations inspection or if any corrective action plan is not sufficient, the manufacture of our products could be delayed. We underwent an FDA inspection in August 2003 regarding our allograft implant business, and another FDA inspection in April 2004 regarding our medical device activities. In connection with these inspections, the FDA requested minor corrective actions, which we believe we have taken, but

there can be no assurance the FDA will not subject us to further enforcement action. The FDA may impose additional inspections or audits at any time.

Any failure in our efforts to train spine surgeons could significantly reduce the market acceptance of our products.

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

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

We depend on a limited number of sources of human tissue for our allograft implants, and any failure to obtain tissue from these sources in a timely manner will interfere with our ability to effectively meet demand for our allograft implants.

Tissue Banks International, Inc. and U.S. Tissue and Cell (formerly Intermountain Tissue Center) collectively supplied us with all of our allograft implants, and will continue to be our only sources for the foreseeable future. The processing of human tissue into allograft implants is very labor intensive and it is therefore difficult to maintain a steady supply stream. In addition, due to seasonal changes in mortality rates, some scarce tissues used for our allograft implants are at times in particularly short supply. We cannot be certain that our supply of allograft implants from Tissue Banks International and U.S. Tissue and Cell will be available at current levels or will be sufficient to meet our needs. If we are no longer able to obtain allograft implants from these sources in amounts sufficient to meet our needs, we may not be able to locate and engage replacement sources of allograft implants on commercially reasonable terms, if at all. Any interruption of our business caused by the need to locate additional sources of allograft implants would significantly harm our revenues, which could cause the market price of our common stock to decline. We expect our revenues would continue to suffer at least until we are able to obtain a sufficient supply of allograft implants from a qualified new source.

Our allograft implants and technologies could become subject to significantly greater regulation by the FDA, which could disrupt our business.

Since 1997, the FDA has worked to establish a more comprehensive regulatory framework for allograft implants. The framework under FDA consideration could establish criteria for determining whether a particular human tissue-based product will be classified as human tissue, a medical device or a biologic drug. If the FDA decides to adopt and implement its proposed regulatory framework, one or more of our current allograft implants could be regulated to a much greater extent. For allograft implants regulated as medical devices, we may need to obtain clearance through the 510(k) process or approval through the PMA process if a grandfather approval clause is not adopted. For allograft implants regulated as biologics, we may need to obtain approval of a biologics license application.

To obtain the necessary approvals or clearances under the proposed regulatory framework, we could be required to perform clinical testing in support of required applications which would be time consuming and costly. In addition, the FDA could decide not to approve our applications. The FDA could also require us to stop marketing our current allograft implants pending their approval or clearance. The FDA may require post-market testing and surveillance to monitor the effects of approved allograft implants, may restrict the commercial applications of our allograft implants and may conduct periodic inspections of our facility and our suppliers' facilities. The FDA may

withdraw our product approvals or clearances if we do not comply with its regulatory standards or if we encounter problems after the initial marketing. If we encounter delays during the FDA approval process, the period during which we have the exclusive right to commercialize any allograft implants for which we have received patent protection would be shortened.

We are dependent on our senior management team, key clinical advisors and scientific personnel, and the loss of any of them could harm our business.

Our continued success depends in part upon the continued availability and contributions of our senior management team and the continued participation of our key clinical advisors. We have entered into employment agreements with Alexis V. Lukianov, Kevin C. O'Boyle, Keith Valentine, Patrick Miles, James J. Skinner, G. Bryan Cornwall and Jonathan D. Spangler, all members of our senior management team, but none of these agreements guarantees the services of the individual for a specified period of time. We also rely on the skills and talents of our scientific personnel because of the complexity of our products. The loss of members of our senior management, key clinical advisors or scientific personnel, or our inability to attract or retain other qualified personnel or advisors could have a material adverse effect on our results of operations and financial condition. We have not obtained and do not expect to obtain key man life insurance on any of our senior managers.

If we choose to acquire new and complementary businesses, products or technologies instead of developing them ourselves, we may be unable to complete these acquisitions or to successfully integrate them in a cost effective and non-disruptive manner.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and technologies. Accordingly, we may in the future pursue the acquisition of complementary businesses, products or technologies instead of developing them ourselves. We have no current commitments with respect to any acquisition or investment. We do not know if we will be able to successfully complete any acquisitions, or whether we will be able to successfully integrate any acquired business, product or technology or retain any key employees. Integrating any business, product or technology we acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. If we are unable to integrate any acquired businesses, products or technologies effectively, our business will suffer. In addition, any amortization or charges resulting from the costs of acquisitions could harm our business and operating results.

Risks Related to Our Financial Results and Need for Financing

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

We were incorporated in Delaware in 1997, and since that time have focused primarily on research and development and seeking regulatory clearances to market our products. We began commercial sales in 2001 and have several product offerings in both MAS and Classic Fusion. We have yet to demonstrate that we can generate sufficient sales of our products to become profitable. The extent of our future operating losses and the timing of profitability are highly uncertain, and we may never achieve profitability. At December 31, 2004, we had an accumulated deficit of approximately $78.5 million. It is possible that we will never generate sufficient revenues from product sales to achieve profitability. Even if we do achieve significant revenues from our product sales, we expect that increased operating expenses will result in significant operating losses in the near term as we, among other things:

- grow our internal and third-party sales and marketing forces to expand the penetration of our products in the United States;
- increase our research and development efforts to improve upon our existing products and develop new product candidates; and
- perform clinical research and trials on our existing products and product candidates.

As a result of these activities, we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

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

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

- our ability to introduce and quickly derive significant revenue from new products;
- surgeon and patient acceptance of our products;
- results of clinical research and trials on our existing products and products in development;
- demand and pricing of our products;
- the mix of our products sold (i.e., profit margins differ between our products);
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors
- our ability to establish and maintain a productive sales force;
- the ability of our suppliers to timely provide us with an adequate supply of materials and components;
- regulatory approvals and legislative changes affecting the products we may offer or those of our competitors;
- the effect of competing technological and market developments;
- our addition or termination of research programs or funding support;
- levels of third-party reimbursement for our products;
- interruption in the manufacturing or distribution of our products; and
- changes in our ability to obtain FDA approval or clearance for 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. 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.

Our future capital needs are uncertain and we may need to raise additional funds in the future, and such funds may not be available on acceptable terms or at all.

We believe that our current cash and cash equivalents, including the proceeds from our recent public offering, together with our short-term investments and the cash to be generated from expected product sales, will be sufficient to meet our projected operating requirements for at least the next 12 months. However, we may seek additional funds from public and private stock offerings, borrowings under lease lines or other sources. Our capital requirements will depend on many factors, including:

- the revenues generated by sales of our products;
- the costs associated with expanding our sales and marketing efforts;

- the expenses we incur in manufacturing and selling our products;
- the costs of developing new products or technologies;
- the cost of obtaining and maintaining FDA approval or clearance of our products and products in development;
- the number and timing of acquisitions and other strategic transactions;
- the costs associated with our expansion;
- the costs associated with increased capital expenditures; and
- unanticipated general and administrative expenses.

As a result of these factors, we may seek to raise additional funds, and such funds may not be available on favorable terms, or at all. Furthermore, if we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise funds on acceptable terms, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements. In these events, our ability to achieve our development and commercialization goals would be adversely affected.

Risks Related to Our Intellectual Property and Potential Litigation

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

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

In the event a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be difficult and time consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be extensive 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.

The medical device industry is characterized by patent litigation and we could become subject to litigation which could be costly, result in the diversion of management's time and efforts, negatively effect our ability to develop new or improved products, and require us to pay damages.

The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Our competitors may assert that our system, its components or the methods we employ in the use of our system are covered by U.S. or foreign patents held by them. In addition, they may claim that their patents have priority over ours because their patents issued first. Because patent applications can take many years to issue, there may be applications now pending of which we are unaware, which may later result in issued patents that our system may infringe. There could also be existing patents that one or more components of our system may inadvertently be infringing, of which we are unaware. As the number of participants in the market for spine disorder treatments grows, the possibility of patent infringement claims against us increases.

Any litigation or claims against us may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to infringe, we could be required to pay substantial damages and/or royalties and could be prevented from selling our products unless we could obtain a license or were able to redesign our system to avoid infringement. Any such license may not be available on reasonable terms, if at all. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may be unable to commercialize one or more of our products.

In addition, certain product categories, including pedicle screws, have been the subject of significant litigation in recent years. Since we sell pedicle screws and recently introduced our SpheRx Pedicle Screw System, any related litigation could harm our business.

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

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for spine surgery procedures. Spine surgery involves significant risk of serious complications, including bleeding, nerve injury, paralysis and even death. 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, we could have to pay an amount in excess of policy limits, which would have to be paid out of cash reserves. 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.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at universities or other medical device companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could severely harm our business.

Any claims relating to our improper handling, storage or disposal of biological, hazardous and radioactive materials could be time consuming and costly.

Our allograft implants and cadaver operating theater involve the controlled use of biological, hazardous and/or radioactive materials and waste. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, we could be held liable for damages or penalized with fines, and this liability could exceed our resources and any applicable insurance. We may have to incur significant costs to comply with future environmental laws and regulations.

Because allograft implants may entail a risk of injury to human recipients, we may be the subject of product liability claims regarding our allograft implants.

The development of allograft implants and technologies for human tissue repair and treatment may entail a risk of product liability claims because of the risk of injury and communicable disease to the human recipients, and substantial product liability claims may be asserted against us. Although we have not been the subject of any material product liability claims to date and have a $10 million insurance policy to cover potential claims, claims could arise in the future for which our insurance will not be adequate. Moreover, insurance covering our business may not always be available in the future on commercially reasonable terms, if at all. If our insurance proves to be inadequate to pay a damage award, we may not have sufficient funds to do so which would harm our financial condition. In addition, successful product liability claims made against one of our competitors could cause claims to be made against us or expose us to a perception that we are vulnerable to similar claims. Claims against us, regardless of their merit or potential outcome, may also hurt our reputation and ability to sell our products.

Our suppliers or we may be the subject of claims for non-compliance with FDA regulations in connection with the processing or distribution of allograft implants.

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

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

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

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

- volume and time 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;
- our ability to develop, obtain regulatory clearance for, and market, new and enhanced products on a timely basis;
- product liability claims or other litigation;

- 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 or applications;
- changes in the availability of third-party reimbursement in the United States or other countries;
- changes in earnings estimates or recommendations by securities analysts; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

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

Because of their significant stock ownership, our executive officers, directors and principal stockholders will be able to exert control over us and our significant corporate decisions.

Based on shares outstanding at December 31, 2004, our executive officers, directors, and stockholders holding more than 5% of our outstanding common stock and their affiliates, in the aggregate, beneficially own approximately 35% of our outstanding common stock. As a result, these persons, acting together, would have the ability to significantly influence (or determine) the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets. This concentration of ownership may harm the market price of our common stock by, among other things:

- delaying, deferring or preventing a change in control of our company;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- causing us to enter into transactions or agreements that are not in the best interests of all stockholders.

Future sales of our common stock may depress our stock price.

Our current stockholders hold a substantial number of shares of our common stock that they are able to sell in the public market in the near future. A significant portion of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares could significantly reduce the market price of our common stock. Moreover the holders of approximately 11,900,000 shares of our common stock, including shares issuable upon the exercise of warrants, have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

We have also registered all common stock that we may issue under our existing 1998 Stock Option/Stock Issuance Plan, and our 2004 Equity Incentive Plan and 2004 Employee Stock Purchase Plan. These shares can be freely sold in the public market upon issuance. If any of these holders cause a large number of securities to be sold in the public market, the sales could reduce the trading price of our common stock. These sales also could impede our ability to raise future capital.

We have and will continue to incur increased costs as a result of recently enacted and proposed changes in laws and regulations.

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules proposed by the Securities and Exchange Commission and by the Nasdaq Stock Market, could result in increased costs to us. These rules require, among other things, costly implementation and testing of systems regarding internal controls over financial reporting. The new rules could make it more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We are presently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs.

We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock market in general, the Nasdaq National Market and the market for medical device companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, the market prices of securities of medical device companies have been particularly volatile. These broad market and industry factors may materially harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could materially harm our financial condition and results of operations.

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 restated certificate of incorporation and restated 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;
- prohibiting our stockholders from making certain changes to our restated certificate of incorporation or restated bylaws except with 66 $^{2}/_{3}$% stockholder approval; and
- require advance written notice of stockholder proposals and director nominations.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our restated certificate of incorporation, restated 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 a stockholder's sole source of potential gain for the foreseeable future.

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

Our exposure to interest rate risk at December 31, 2004, is related to our investment portfolio and our borrowings which consist largely of debt instruments of the U.S. government and its agencies and in high quality corporate issuers. Due to the short-term nature of these investments, we have assessed that there is no material exposure to interest rate risk arising from our investments. Fixed rate investments and borrowings may have their fair market value adversely impacted from changes in interest rates.

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

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.

Not applicable

Item 9A. Controls and Procedures.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission'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 for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, the Company is engaged in an evaluation of the effectiveness of its internal controls over financial reporting. The Company's Section 404 project plan includes many time-critical milestones, and its actions during the remainder of this year will be critical to achieving these milestones and successfully completing the assessment of its internal controls. During the course of completing the Company's fiscal year 2004 audit, the Company identified control deficiencies relating to its tracking of field inventory that

it must correct prior to December 31, 2005. Remediation of these control deficiencies and any other deficiencies during the current year involve substantial work and, even though the Company has made the Section 404 project a top priority, there can be no assurances that all control deficiencies identified during this process will be remediated before the end of the fiscal year, or that the remaining unresolved control deficiencies will not rise to the level of significant deficiencies or material weaknesses.

Item 9B. Other Information.

None

PART III

Certain information required by Part III is omitted from this report because the Company will file a definitive proxy statement within 120 days after the end of its fiscal year pursuant to Regulation 14A (the "Proxy Statement") for its annual meeting of stockholders to be held on July 27, 2005, and certain information included in the Proxy Statement is incorporated herein by reference.

Item 10. Directors and Executive Officers of the Registrant.

The information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with the Annual Meeting of our Stockholders (the "Proxy Statement"), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2004, 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.

We have adopted a Code of Conduct and Ethics for all officers, directors and employees. We have posted the Code of Conduct and Ethics on our website located at www.nuvasive.com.

Item 12. Security Ownership of Certain Beneficial Owners and Management.

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

Item 13. Certain Relationships and Related Transactions.

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

Item 14. Principal Accounting 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 part of this report:

(1) Financial Statements and Report of Ernst & Young LLP

Index to Consolidated Financial Statements

Report of Independent Registered Public Accountants

Consolidated Financial Statements

Notes to Consolidated Financial Statements

(2) Financial Statement Schedule

(3) List of exhibits required by Item 601 of Regulation S-K. See part (b) below.

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

Exhibit Number	Description
3.1(1)	Restated Certificate of Incorporation
3.2(1)	Restated Bylaws
4.1(2)	Second Amended and Restated Investors' Rights Agreement, dated July 11, 2002, by and among us and the other parties named therein
4.2(2)	Amendment No. 1 to Second Amended and Restated Investors' Rights Agreement, dated June 19, 2003, by and among us and the other parties named therein
4.3(2)	Amendment No. 2 to Second Amended and Restated Investors' Rights Agreement, dated February 5, 2004, by and among us and the other parties named therein
4.4(2)	Specimen Common Stock Certificate
10.1(2)	Form of Warrant to purchase Series B Preferred Stock, dated October 13, 1999, between us and each of the persons listed on the Schedule of Warrant Holders attached thereto
10.2(2)	Warrant Agreement to Purchase Shares of Series A Preferred Stock, dated September 17, 1999, issued by us to Comdisco Ventures, Inc.
10.3(2)	Warrant Agreement to Purchase Shares of Series A Preferred Stock, dated September 17, 1999, issued by us to CNC Holdings I LLC
10.4(2)	Stock Subscription Warrant to Purchase Series B Preferred Stock, dated June 27, 2000, issued by us to TBCC Funding Trust II
10.5(2)	Form of Warrant to purchase Series D Preferred Stock used by us to issue warrants on February 14, 2001 and April 12, 2001 to each of the persons listed on the Schedule of Warrant Holders attached thereto
10.6(2)	Warrant to Purchase 22,530 Shares of Series D Preferred Stock, dated December 27, 2001, issued by us to GATX Ventures, Inc.
10.7(2)	Warrant to Purchase 1,186 Shares of Series D Preferred Stock, dated December 27, 2001, issued by us to GATX Ventures, Inc.
10.8(2)	Warrant to Purchase Common Stock, dated January 9, 2003, issued by us to Comerica Bank—California
10.9(2)	Warrant to Purchase Series D-1 Preferred Stock, dated January 9, 2003, issued by us to Comerica Bank—California
10.10(2)	Form of Warrant to purchase Common Stock used by us to issue warrants in connection with our sale of Series D-1 Preferred Stock to the persons listed on the Schedule of Warrant Holders attached thereto
10.11(2)#	1998 Stock Option/Stock Issuance Plan
10.12(2)#	Form of Notice of Grant of Stock Option under our 1998 Stock Option/Stock Issuance Plan
10.13(2)#	Form of Stock Option Agreement under our 1998 Stock Option/Stock Issuance Plan, and form of addendum thereto
10.14(2)#	Form of Stock Purchase Agreement under our 1998 Stock Option/Stock Issuance Plan
10.14.1(2)#	Form of Stock Issuance Agreement under our 1998 Stock Option/Stock Issuance Plan
10.14.2(2)#	Form of Stock Issuance Agreement issued to consultants and distributors, under our 1998 Stock Option/Stock Issuance Plan, on April 21, 2004, and May 4, 2004
10.15(2)#	2004 Equity Incentive Plan
10.16(2)#	Form of Stock Option Award Notice under 2004 Equity Incentive Plan
10.17(2)#	Form of Option Exercise and Stock Purchase Agreement under 2004 Equity Incentive Plan
10.18(2)#	Forms of Restricted Stock Grant Notice and Restricted Stock Agreement under 2004 Equity Incentive Plan
10.18.1(2)#	Form of Restricted Stock Unit Award Agreement under 2004 Equity Incentive Plan
10.19(2)#	2004 Employee Stock Purchase Plan
10.20(2)	Standard Industrial/Commercial Multi-Tenant Lease—Modified Net, dated July 13, 1999, between us and Michael L. Hightower

Exhibit Number	Description
10.21(2)	Addendum to Lease Between EUS Partners, the Successor to Michael L. Hightower, Lessor, and NuVasive, Inc. as Lessee, dated March 25, 2002
10.22(2)	Equipment Loan and Security Agreement, dated December 27, 2001, between us and GATX Ventures, Inc., Loan Agreement Supplement No. 1, dated December 31, 2001, and Loan Agreement Supplement No. 2, dated July 31, 2002
10.23(2)†	Patent Purchase Agreement, dated June 21, 2002, between us and Drs. Anthony Ross and Peter Guagliano
10.24(2)†	Intellectual Property Purchase Agreement, dated October 10, 2002, between us and Spine Partners, LLC
10.25(2)†	Development, Production and Marketing Services Agreement, dated December 30, 1999, as amended, by and among us and Tissue Banks International, Inc.
10.26(2)†	Supply Agreement, dated January 21, 2002, by and among us and Intermountain Tissue Center
10.27(2)#	Employment Letter Agreement, dated July 12, 1999, as amended on January 20, 2004, between us and Alexis V. Lukianov
10.28(2)#	Bonus Agreement, dated February 25, 2000, between us and Alexis V. Lukianov
10.29(2)#	Employment Agreement, dated December 20, 2002, as amended on January 20, 2004, between us and Kevin C. O'Boyle
10.30(2)#	Employment Agreement, dated January 20, 2004, between us and Keith Valentine
10.31(2)#	Employment Agreement, dated January 20, 2004, between us and G. Rogan Fry
10.32(2)#	Employment Agreement, dated January 20, 2004, between us and Patrick Miles
10.33(2)#	Employment Agreement, dated January 20, 2004, between us and James J. Skinner
10.34(2)#	Employment Agreement, dated January 20, 2004, between us and G. Bryan Cornwall
10.35(2)#	Employment Agreement, dated January 20, 2004, between us and Jonathan D. Spangler
10.36(2)	Form of Indemnification Agreement between us and our directors and officers
10.37(2)	Common Stock Purchase Warrant, dated January 16, 2002, issued by us to WWIP LLC
10.38(2)†	Clinical Advisor, Patent Purchase and Development Agreement, dated March 31, 2004, between us and James L. Chappuis
10.39(2)	Loan and Security Agreement, dated January 9, 2003, as amended, between us and Comerica Bank
10.40(2)	Warrant to Purchase Series D-1 Preferred Stock, dated March 12, 2004, issued by us to Comerica Bank
10.41(3)	Sublease between us and Gateway, Inc., dated October 12, 2004
10.42(4)+	Supply Agreement, dated January 14, 2005, between NuVasive, Inc. and Blood and Tissue Center of Central Texas
21.1(2)	List of our subsidiaries
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a/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/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) This exhibit was previously filed as an exhibit to our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 13, 2004, and is incorporated herein by reference.

(2) This exhibit was previously filed as an exhibit to our Registration Statement on Form S-1 (File No. 333-113344) originally filed with the Securities and Exchange Commission on March 5, 2004, as amended thereafter, and is incorporated herein by reference.

(3) This exhibit was previously filed as an exhibit to our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 15, 2004, and is incorporated herein by reference.

(4) This exhibit was previously filed as an exhibit to our Form 8-K filed with the Securities and Exchange Commission on January 21, 2005, and is incorporated herein by reference.

† NuVasive, Inc. has been granted confidential treatment with respect to certain portions of this exhibit (indicated by asterisks), which have been filed separately with the Securities and Exchange Commission.

+ Application has been made to the Securities and Exchange Commission to seek confidential treatment of certain provisions of this exhibit under Rule 406 of the Securities Act of 1933. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.

Indicates management contract or compensatory plan.

SUPPLEMENTAL INFORMATION

Copies of the Registrants Proxy Statement for the Annual Meeting of Stockholders to be held on July 27, 2005, 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.

SIGNATURES

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

NUVASIVE, INC.

Date: **March 31, 2005**

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

Date: **March 31, 2005**

By: /s/ Kevin C. O'Boyle
Kevin C. O'Boyle
Executive Vice President and Chief Financial Officer (Principal Financial Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Alexis V. Lukianov and 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 31, 2005
/s/ Kevin C. O'Boyle Kevin C. O'Boyle	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2005
/s/ Jack R. Blair Jack R. Blair	Director	March 31, 2005
/s/ James C. Blair James C. Blair	Director	March 31, 2005
/s/ Peter C. Farrell Peter C. Farrell	Director	March 31, 2005

/s/ Robert J. Hunt Robert J. Hunt	Director	March 31, 2005
/s/ Joseph S. Lacob Joseph S. Lacob	Director	March 31, 2005
/s/ Arda M. Minocherhomjee Arda M. Minocherhomjee	Director	March 31, 2005
/s/ Lesley H. Howe Lesley H. Howe	Director	March 31, 2005

EXHIBIT INDEX

Exhibit Number	Description
3.1(1)	Restated Certificate of Incorporation
3.2(1)	Restated Bylaws
4.1(2)	Second Amended and Restated Investors' Rights Agreement, dated July 11, 2002, by and among us and the other parties named therein
4.2(2)	Amendment No. 1 to Second Amended and Restated Investors' Rights Agreement, dated June 19, 2003, by and among us and the other parties named therein
4.3(2)	Amendment No. 2 to Second Amended and Restated Investors' Rights Agreement, dated February 5, 2004, by and among us and the other parties named therein
4.4(2)	Specimen Common Stock Certificate
10.1(2)	Form of Warrant to purchase Series B Preferred Stock, dated October 13, 1999, between us and each of the persons listed on the Schedule of Warrant Holders attached thereto
10.2(2)	Warrant Agreement to Purchase Shares of Series A Preferred Stock, dated September 17, 1999, issued by us to Comdisco Ventures, Inc.
10.3(2)	Warrant Agreement to Purchase Shares of Series A Preferred Stock, dated September 17, 1999, issued by us to CNC Holdings I LLC
10.4(2)	Stock Subscription Warrant to Purchase Series B Preferred Stock, dated June 27, 2000, issued by us to TBCC Funding Trust II
10.5(2)	Form of Warrant to purchase Series D Preferred Stock used by us to issue warrants on February 14, 2001 and April 12, 2001 to each of the persons listed on the Schedule of Warrant Holders attached thereto
10.6(2)	Warrant to Purchase 22,530 Shares of Series D Preferred Stock, dated December 27, 2001, issued by us to GATX Ventures, Inc.
10.7(2)	Warrant to Purchase 1,186 Shares of Series D Preferred Stock, dated December 27, 2001, issued by us to GATX Ventures, Inc.
10.8(2)	Warrant to Purchase Common Stock, dated January 9, 2003, issued by us to Comerica Bank—California
10.9(2)	Warrant to Purchase Series D-1 Preferred Stock, dated January 9, 2003, issued by us to Comerica Bank—California
10.10(2)	Form of Warrant to purchase Common Stock used by us to issue warrants in connection with our sale of Series D-1 Preferred Stock to the persons listed on the Schedule of Warrant Holders attached thereto
10.11(2)#	1998 Stock Option/Stock Issuance Plan
10.12(2)#	Form of Notice of Grant of Stock Option under our 1998 Stock Option/Stock Issuance Plan
10.13(2)#	Form of Stock Option Agreement under our 1998 Stock Option/Stock Issuance Plan, and form of addendum thereto
10.14(2)#	Form of Stock Purchase Agreement under our 1998 Stock Option/Stock Issuance Plan
10.14.1(2)#	Form of Stock Issuance Agreement under our 1998 Stock Option/Stock Issuance Plan
10.14.2(2)#	Form of Stock Issuance Agreement issued to consultants and distributors, under our 1998 Stock Option/Stock Issuance Plan, on April 21, 2004, and May 4, 2004
10.15(2)#	2004 Equity Incentive Plan
10.16(2)#	Form of Stock Option Award Notice under 2004 Equity Incentive Plan
10.17(2)#	Form of Option Exercise and Stock Purchase Agreement under 2004 Equity Incentive Plan
10.18(2)#	Forms of Restricted Stock Grant Notice and Restricted Stock Agreement under 2004 Equity Incentive Plan
10.18.1(2)#	Form of Restricted Stock Unit Award Agreement under 2004 Equity Incentive Plan
10.19(2)#	2004 Employee Stock Purchase Plan
10.20(2)	Standard Industrial/Commercial Multi-Tenant Lease—Modified Net, dated July 13, 1999, between us and Michael L. Hightower

Exhibit Number	Description
10.21(2)	Addendum to Lease Between EUS Partners, the Successor to Michael L. Hightower, Lessor, and NuVasive, Inc. as Lessee, dated March 25, 2002
10.22(2)	Equipment Loan and Security Agreement, dated December 27, 2001, between us and GATX Ventures, Inc., Loan Agreement Supplement No. 1, dated December 31, 2001, and Loan Agreement Supplement No. 2, dated July 31, 2002
10.23(2)†	Patent Purchase Agreement, dated June 21, 2002, between us and Drs. Anthony Ross and Peter Guagliano
10.24(2)†	Intellectual Property Purchase Agreement, dated October 10, 2002, between us and Spine Partners, LLC
10.25(2)†	Development, Production and Marketing Services Agreement, dated December 30, 1999, as amended, by and among us and Tissue Banks International, Inc.
10.26(2)†	Supply Agreement, dated January 21, 2002, by and among us and Intermountain Tissue Center
10.27(2)#	Employment Letter Agreement, dated July 12, 1999, as amended on January 20, 2004, between us and Alexis V. Lukianov
10.28(2)#	Bonus Agreement, dated February 25, 2000, between us and Alexis V. Lukianov
10.29(2)#	Employment Agreement, dated December 20, 2002, as amended on January 20, 2004, between us and Kevin C. O'Boyle
10.30(2)#	Employment Agreement, dated January 20, 2004, between us and Keith Valentine
10.31(2)#	Employment Agreement, dated January 20, 2004, between us and G. Rogan Fry
10.32(2)#	Employment Agreement, dated January 20, 2004, between us and Patrick Miles
10.33(2)#	Employment Agreement, dated January 20, 2004, between us and James J. Skinner
10.34(2)#	Employment Agreement, dated January 20, 2004, between us and G. Bryan Cornwall
10.35(2)#	Employment Agreement, dated January 20, 2004, between us and Jonathan D. Spangler
10.36(2)	Form of Indemnification Agreement between us and our directors and officers
10.37(2)	Common Stock Purchase Warrant, dated January 16, 2002, issued by us to WWIP LLC
10.38(2)†	Clinical Advisor, Patent Purchase and Development Agreement, dated March 31, 2004, between us and James L. Chappuis
10.39(2)	Loan and Security Agreement, dated January 9, 2003, as amended, between us and Comerica Bank
10.40(2)	Warrant to Purchase Series D-1 Preferred Stock, dated March 12, 2004, issued by us to Comerica Bank
10.41(3)	Sublease between us and Gateway, Inc., dated October 12, 2004
10.42(4)+	Supply Agreement, dated January 14, 2005, between NuVasive, Inc. and Blood and Tissue Center of Central Texas
21.1(2)	List of our subsidiaries
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a/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/15d-14(a of the Securities Exchange Act of 1934, as amended
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INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

NUVASIVE, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders
NuVasive, Inc.

We have audited the accompanying consolidated balance sheets of NuVasive, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, 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.

/s/ Ernst & Young LLP

San Diego, California
February 16, 2005

NUVASIVE, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except per share amounts)

	December 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,560	$ 5,631
Short-term investments	50,593	4,017
Accounts receivable, net of allowance of $255 and $320, respectively	6,770	3,728
Inventory, net	5,249	3,412
Prepaid expenses and other current assets	826	428
Total current assets	71,998	17,216
Property and equipment, net	8,725	5,026
Note receivable from related party	—	21
Other assets	29	108
Total assets	$ 80,752	$ 22,371
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 6,202	$ 5,036
Accrued payroll and related expenses	3,135	2,242
Current portion of notes payable	—	3,493
Current portion of obligations under capital leases	5	306
Total current liabilities	9,342	11,077
Notes payable, less current portion	—	1,202
Obligations under capital leases, less current portion	13	22
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, $.001 par value; 5,000 shares authorized, none and 31,586 issued and outstanding at December 31, 2004 and 2003, respectively	—	32
Common Stock, $.001 par value; 70,000 shares authorized, 23,951 and 1,717 issued and outstanding at December 31, 2004 and 2003, respectively	24	2
Additional paid-in capital	153,323	75,046
Notes receivable from related parties	—	(188)
Deferred compensation	(3,441)	(566)
Accumulated other comprehensive loss	(43)	—
Accumulated deficit	(78,466)	(64,256)
Total stockholders' equity	71,397	10,070
Total liabilities and stockholders' equity	$ 80,752	$ 22,371

See accompanying notes

NUVASIVE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Years ended December 31,		
	2004	2003	2002
Revenues:			
MAS	$ 28,135	$ 12,069	$ 5,269
Classic fusion	10,268	10,586	6,991
Total revenues	38,403	22,655	12,260
Cost of goods sold	10,228	6,791	5,303
Gross profit	28,175	15,864	6,957
Expenses:			
Research and development	8,348	6,310	6,107
Sales and marketing	19,740	12,609	10,024
General and administrative	8,584	6,185	5,568
Stock-based compensation	6,143	743	113
Total operating expenses	42,815	25,847	21,812
Interest income	694	138	197
Interest expense	(217)	(418)	(397)
Other income (expense), net	(47)	136	(55)
Net loss	$ (14,210)	$ (10,127)	$ (15,110)
Net loss per share:			
Basic and diluted	$ (0.91)	$ (6.30)	$ (13.20)
Weighted average shares- basic and diluted	15,605	1,607	1,145
Stock-based compensation is allocated as follows:			
Research and development	$ 2,216	$ 479	$ 31
Sales and marketing	1,909	148	—
General and administrative	2,018	116	82
Total stock-based compensation	$ 6,143	$ 743	$ 113

(1) As a result of the conversion of our preferred stock into 12,724,000 shares of our common stock upon completion of our initial public offering on May 13, 2004, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented above. Please reference Note 1 for an unaudited pro forma basic and diluted net loss per share calculation for the periods presented.

See accompanying notes.

NUVASIVE, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Preferred stock		Common stock		Additional Paid-in Capital	Notes Receivable From Stockholders	Deferred Compensation	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount						
Balance at December 31, 2001	21,688	$ 22	795	$ 1	$ 48,462	$ —	$ —	$ —	$ (39,019)	$ 9,466
Issuance of Series D-1 convertible preferred stock net of issuance costs of $262	5,949	6	—	—	14,809	—	—	—	—	14,815
Issuance of common stock to non-employees	—	—	4	—	2	—	—	—	—	2
Issuance of common stock for cash and notes to employees	—	—	991	1	534	(523)	—	—	—	12
Issuance of stock options and warrants to non-employees	—	—	—	—	70	—	—	—	—	70
Interest accrued on notes from stockholders	—	—	—	—	—	(15)	—	—	—	(15)
Forgiveness of notes and interest due from stockholders	—	—	—	—	—	103	—	—	—	103
Deferred compensation	—	—	—	—	121	—	(121)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	41	—	—	41
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	(15,110)	(15,110)
Balance at December 31, 2002	27,637	28	1,790	2	63,998	(435)	(80)	—	(54,129)	9,384
Issuance of Series D-1 convertible preferred stock	3,949	4	—	—	9,911	—	—	—	—	9,915
Redemption of common stock for intellectual property	—	—	(100)	—	(125)	—	—	—	—	(125)
Issuance of common stock for cash	—	—	113	—	57	—	—	—	—	57
Issuance of stock options and warrants to non-employees	—	—	—	—	33	—	—	—	—	33
Compensation expense related to issuance of stock options to consultants	—	—	—	—	458	—	—	—	—	458
Interest on notes from stockholders	—	—	—	—	—	(13)	—	—	—	(13)
Forgiveness of notes and interest due from stockholders	—	—	(86)	—	(57)	226	—	—	—	169
Payment received on note receivable from stockholder	—	—	—	—	—	34	—	—	—	34
Deferred stock-based compensation	—	—	—	—	771		(771)	—	—	—
Amortization of stock-based compensation	—	—	—	—	—	—	285	—	—	285
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	(10,127)	(10,127)
Balance at December 31, 2003	31,586	32	1,717	2	75,046	(188)	(566)	—	(64,256)	10,070
IPO proceeds net of offering costs of $7,627	—	—	6,883	7	68,085	—	—	—	—	68,092
Issuance of common stock for cash	—	—	2,575	2	887	—	—	—	—	889
Issuance of common stock for purchase plan	—	—	25	—	206	—	—	—	—	206
Issuance of restricted stock	—	—	27	—	292	—	—	—	—	292
Interest on notes from stockholders	—	—	—	—	72	—	—	—	—	72
Forgiveness of notes and interest due from stockholders'	—	—	—	—	—	188	—	—	—	188
Compensation expense related to issuance of stock options to non-employees	—	—	—	—	925	—	—	—	—	925
Deferred stock-based compensation	—	—	—	—	7,791	—	(7,791)	—	—	—
Amortization of stock-based compensation	—	—	—	—	—	—	4,916	—	—	4,916
Conversion of preferred to common stock	(31,586)	(32)	12,724	13	19	—	—	—	—	—
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(43)	—	(43)
Net loss	—	—	—	—	—	—	—	—	(14,210)	(14,210)
Balance at December 31, 2004	—	$ —	23,951	$ 24	$ 153,323	$ —	$ (3,441)	$ (43)	$ (78,466)	$ 71,397

See accompanying notes.

NUVASIVE, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years ended December 31,		
	2004	2003	2002
Operating activities:			
Net loss	$ (14,210)	$ (10,127)	$ (15,110)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,298	1,775	1,348
Amortization of loan fees	9	21	84
Stock-based compensation	4,916	285	41
Interest expense for warrants issued in conjuction with debt	72	—	—
Allowance for doubtful accounts	(65)	231	258
Allowance for excess and obsolete inventory	(343)	351	939
(Gain) loss on sale of fixed assets and stock transaction	142	(226)	55
Issuance of common stock and stock options to non-employees	1,217	458	43
Issuance of warrants	—	33	29
Interest accrued on notes from stockholders	—	(13)	(15)
Forgiveness of notes and interest due from related parties	209	295	228
Changes in operating assets and liabilities:			
Accounts receivable	(2,977)	(2,051)	(1,102)
Inventory	(1,494)	(1,303)	(529)
Prepaid expenses and other current assets	(398)	768	(282)
Accounts payable and accrued liabilities	1,166	3,122	(1,356)
Accrued payroll and related expenses	893	383	1,371
Net cash used in operating activities	(8,565)	(5,998)	(13,998)
Investing activities:			
Purchases of property and equipment	(6,139)	(4,465)	(1,259)
Proceeds from disposal of property and equipment	—	—	53
Purchase of short-term investments	(108,342)	(4,017)	—
Sales of short-term investments	61,723	—	—
Other assets	70	(48)	(757)
Net cash used in investing activities	(52,688)	(8,530)	(1,963)
Financing activities:			
Proceeds from notes payable	1,364	4,678	—
Payment of notes payable	(6,059)	(882)	(1,209)
Beneficial conversion of convertible debt			
Payment of capital leases	(310)	(549)	(507)
Proceeds from employee note	—	34	
Issuance of common stock	1,095	57	12
Net proceeds from initial public offering	68,092	—	—
Issuance of warrants	—	—	—
Net proceeds from issuance of convertible preferred stock	—	9,915	14,815
Proceeds from sale-leaseback of equipment	—	—	98
Net cash provided by financing activities	64,182	13,253	13,209
Increase (decrease) in cash and cash equivalents	2,929	(1,275)	(2,752)
Cash and cash equivalents at beginning of year	5,631	6,906	9,658
Cash and cash equivalents at end of year	$ 8,560	$ 5,631	$ 6,906
Supplemental schedule of cash flow information:			
Cash paid for interest	$ —	$ 193	$ 313
Supplemental schedule of noncash investing and financing activities:			
Repurchase of unvested common stock by reduction in notes receivable	$ —	$ 54	$ —

See accompanying notes.

(Notes in thousands, except share and per share amounts)

1. Organization and Significant Accounting Policies

Description of Business

NuVasive, Inc. (the Company or NuVasive) was incorporated in Delaware on July 21, 1997. The Company designs, develops and markets products for the surgical treatment of spine disorders and operates in one business segment. The Company began commercializing its products in 2001. Its current principal product offerings include a surgical platform called maximum access surgery, or MAS, and classic fusion products. MAS combines NeuroVision, a nerve avoidance system, MaXcess, a minimally invasive surgical system, SpheRx Pedicle Screw System and specialized implants. The Company places its NeuroVision systems in hospitals and allows them to remain on-site provided the hospital orders a minimum monthly quantity of the Company's nerve avoidance disposable products. MaXcess instruments are sold to hospitals for use in surgery. The classic fusion portfolio includes a range of spine allografts and spine implants such as rods, plates and screws. Classic fusion products are sold from implant sets shipped from the Company's facility. MAS disposable products are shipped from our inventory, some of which is stored at distributor sites.

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary NuVasive GmbH. All significant intercompany balances and transactions have been eliminated in consolidation. There has been no material activity by NuVasive GmbH during the year ended December 31, 2004.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

Reclassifications

Certain amounts in the prior year financial statements have been reclassified to conform to current year presentation.

Cash, Cash Equivalents and Short-term Investments

The Company considers all highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. Cash equivalents primarily represent funds invested in money market funds.

Short-term Investments

In accordance with Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities* , management determines the appropriate classification of debt securities at the time of purchase and reevaluates such designation periodically. Equity securities are classified as available-for-sale. Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Held-to-maturity securities are stated at amortized cost. The amortized cost of debt securities classified as held-to-maturity is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income.

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 allowance for a portion of receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices and 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 or their ability to make payments, an increase in the provision for doubtful accounts may be required.

Inventories

Inventories are stated at the lower of cost or market using the first-in, first-out (FIFO) method. The Company reviews the components of its inventory on a periodic basis for excess, obsolete and impaired inventory, and records a reserve for the identified items.

Fair Value of Financial Instruments

The carrying value of cash and cash equivalents, short-term investments, accounts receivable, accounts payable and accrued expenses and current portion of obligations under capital leases are considered to be representative of their respective fair values because of the short-term nature of those instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, management believes the fair value of the long-term debt and long-term portion of capital leases approximates their carrying values.

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, securities held to maturity 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 safety and maximize liquidity.

No single customer represented greater than 10 percent of sales for any of the periods presented.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation on computer equipment, furniture and fixtures, machinery and equipment, and loaner equipment. Depreciation is calculated using the straight-line method over the shorter of 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.

Impairment of Long-Lived Assets

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* , if indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through the undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the carrying value of the asset to the undiscounted cash flows associated with the use of the asset. The Company has not recognized any impairment losses through December 31, 2004.

Revenue Recognition

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

Research and Development

Research and development costs are expensed as incurred.

Product Shipment Costs

Product shipment costs are included in sales and marketing expense in the accompanying consolidated statements of operations and totaled approximately $609, $386 and $409 in 2004, 2003, 2002, respectively.

Patent Costs

Costs related to filing and pursuing patent applications are expensed to research and development as incurred as recoverability of such expenditures is uncertain.

(Notes in thousands, except share and per share amounts)

Marketing Costs

Marketing costs, including advertising expense, are expensed as incurred. Marketing expenses were $4,460, $2,283 and $1,946 for the years ended December 31, 2004, 2003 and 2002, respectively.

Stock-Based Compensation

The Company records compensation expense for employee stock options based upon their intrinsic value on the date of grant pursuant to Accounting Principles Board (APB) Opinion No. 25, " *Accounting for Stock Issued to Employees* ." The Company establishes the exercise price based on the fair value of the Company's stock at the date of grant as determined by the Board of Directors (the Board). In determining the fair value of the common stock, the Board considered (i) the advancement of the Company's technology, (ii) the Company's financial position and (iii) the fair value of the Company's preferred stock as determined in arm's-length transactions. Therefore, the options have no intrinsic value upon grant and no expense is recorded upon issuance. With respect to certain options granted during 2003 and 2004, the Company has recorded deferred stock-based compensation of $771 and $7,791, respectively, for the incremental difference at the grant date between the fair value per share determined by the Board and the deemed fair value per share determined solely for financial reporting purposes in conjunction with the Company's initial public offering. Deferred stock-based compensation is recognized and amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation (FIN) No. 28 *Accounting for Stock Appreciation Rights and Other Variable Stock Option Award Plans*, over the vesting period of the related options, generally four years.

Options or stock awards issued to non-employees are recorded at their fair value as determined in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation* , and are periodically remeasured in accordance with Emerging Issues Task Force (EITF) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring or in Conjunction with Selling Goods or Services* , and recognized as an expense over the related service period.

As required under SFAS No. 123, the pro forma effects of stock-based compensation on net loss are estimated at the date of grant using the Black-Scholes option-pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options. The fair value for these options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions for the years ended December 31, 2004, 2003 and 2002, respectively: risk-free interest rate of 3.7%, 3.2% and 3.0%; dividend yield of 0%; volatility of 63%, 60% and 60%; and an expected option life of five years. For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the vesting period of the related options.

The following table illustrates the effect on net losses if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based compensation:

	2004	2003	2002
Net loss	$ (14,210)	$ (10,127)	$ (15,110)
Add: Stock-based employee compensation expense included in net loss	4,916	285	41
Deduct: Stock-based employee compensation expense determined under fair value method for all awards	(7,640)	(324)	(204)
Pro forma net loss	$ (16,934)	$ (10,166)	$ (15,273)
Basic and diluted net loss per share as reported	$ (0.91)	$ (6.30)	$ (13.20)
Basic and diluted pro forma net loss per share	$ (1.09)	$ (6.33)	$ (13.34)

The pro forma effect on net loss for 2004, 2003 and 2002 may not be representative of the pro forma effect on reported net income or loss in future years because these amounts reflect less than four years of vesting and due to the uncertainty of stock option grant volume and potential change in assumptions driven by market factors.

Net Loss Per Share

The Company computes net loss per share in accordance with SFAS No. 128, *Earnings Per Share* , and SAB No. 98, *Earnings Per Share.* Under the provisions of SFAS No. 128 basic 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 and excluding the weighted average common shares subject to repurchase of 185,000, 141,000 and 125,000 shares at December 31, 2004, 2003 and 2002, respectively. Diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of common and common equivalent shares outstanding during the period.

The actual net loss per share amounts for 2004, 2003 and 2002 were computed based on the shares of common stock outstanding during the respective periods. The actual net loss per share for the year ended December 31, 2004 reflects the 6,883,000 shares of our common stock issued in our initial public offering on May 13, 2004 and the 12,724,000 shares of our common stock issued upon conversion of our preferred

(Notes in thousands, except share and per share amounts)

stock in conjunction with the initial public offering. As a result of the issuance of these common shares on May 13, 2004, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented below. In order to provide a more relevant measure of our operating results, the following unaudited pro forma net loss per share calculation has been provided. The shares used to compute unaudited pro forma basic and diluted net loss per share represent the weighted average common shares used to calculate actual basic and diluted net loss per share, increased to include the assumed conversion of all outstanding shares of preferred stock into shares of common stock using the as-if converted method as of the beginning of each year presented or the date of issuance, if later.

	2004	2003	2002
Actual:			
Numerator:			
Net loss	$ (14,210)	$ (10,127)	$ (15,110)
Denominator:			
Weighted average common shares	15,790,000	1,831,000	1,557,000
Weighted average unvested common shares subject to repurchase	(185,000)	(224,000)	(412,000)
Denominator for basic and diluted net loss per share	15,605,000	1,607,000	1,145,000
Basic and diluted net loss per share	$ (0.91)	$ (6.30)	$ (13.20)
Pro forma:			
Numerator:			
Net loss used above	$ (14,210)	$ (10,127)	$ (15,110)
Denominator:			
Shares used above	15,605,000	1,607,000	1,145,000
Pro forma adjustments to reflect assumed weighted average effect of conversion of preferred stock	4,659,000	12,725,000	11,145,000
	20,264,000	14,332,000	12,290,000
Pro forma basic and diluted net loss per share	$ (0.70)	$ (0.71)	$ (1.23)

The following table summarizes potential common stock equivalents that were excluded from historical basic and diluted earnings per share because of their anti-dilutive effect:

	Years Ended December 31,		
Common stock equivalents	**2004**	**2003**	**2002**
Options to purchase common stock	2,970,000	1,710,000	1,337,000
Warrants to purchase common stock	9,000	1,752,000	1,110,000
Warrants to purchase preferred stock	—	221,000	197,000
Common stock subject to repurchase	185,000	224,000	412,000
Convertible preferred stock	—	12,725,000	11,145,000
Total	3,164,000	16,632,000	14,201,000

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.

(Notes in thousands, except share and per share amounts)

Comprehensive Income (Loss)

SFAS No. 130, Reporting *Comprehensive Income,* requires that all components of comprehensive income, including net income, be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments, shall be reported, net of their related tax effect, to arrive at comprehensive income (loss). Comprehensive loss for the years ended December 31, 2004, 2003 and 2002, did not differ from reported net loss.

Segment Information

The Company adopted the provisions of SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information* . SFAS No. 131 requires public companies to report financial and descriptive information about their reportable operating segments. The Company identifies its operating segments based on how management internally evaluates separate financial information, business activities and management responsibility. The Company had determined that it operates in a single business segment and this standard did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Standards

In December 2004, the FASB issued SFAS No. 123(R), *Share Based Payments:* SFAS No. 123(R) will require companies to measure all stock- based compensation awards using a fair value method and record such expense in the consolidated financial statements, including grants of employee stock options. In addition, the adoption of SFAS No. 123(R) will require additional accounting related to the income tax effects and additional disclosure regarding the cash flow effects resulting from share-based payment arrangements. SFAS No. 123(R) is effective for public companies for interim and annual periods beginning after June 15, 2005. The adoption of SFAS No. 123(R), which is effective as of July 1, 2005, will have a significant impact on the Company's earnings, however the adoption will not significantly impact the Company's financial position or cashflows.

2. Balance Sheet Details

Short-term Investments

Short-term investments includes government bonds that are classified as held to maturity :

	December 31,	
	2004	2003
Amortized cost	$ —	$ 415
Gross unrealized loss	—	(8)
Estimated fair value	$ —	$ 407

Short-term investments also includes auction rate securities, commercial paper, government securities and corporate bonds that are classified as available-for-sale :

	December 31,	
	2004	2003
Cost	$ 50,636	$ 3,602
Gross unrealized loss	(43)	—
Estimated fair value	$ 50,593	$ 3,602

The estimated fair value of available for sale securities, by contractual maturity is as follows:

	2004		2003	
	Amortized Cost	Market Value	Amortized Cost	Market Value
Due in one year or less	$ 44,749	$ 44,721	$ 3,602	$ 3,602
Due in between one and two years	5,887	5,872	—	—

(Notes in thousands, except share and per share amounts)

Inventory

Inventories are stated at the lower of cost or market and consisted of the following :

	December 31,	
	2004	2003
Raw materials	$ 543	$ 2,465
Finished goods	5,550	2,134
	6,093	4,599
Less: Allowance for excess and obsolete inventory	(844)	(1,187)
	$ 5,249	$ 3,412

Property and Equipment

Property and equipment consisted of the following*:*

	December 31,	
	2004	2003
Loaner equipment	$ 9,057	$ 5,803
Machinery and equipment	1,243	1,166
Computer equipment	1,416	1,016
Leasehold improvements	654	450
Construction in progress	1,427	—
Furniture and fixtures	386	350
	14,183	8,785
Less: accumulated depreciation and amortization	(5,458)	(3,759)
	$ 8,725	$ 5,026

Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following :

	December 31,	
	2004	2003
Accounts payable	$ 1,598	$ 1,594
Accrued expense	4,225	3,376
Other	379	66
	$ 6,202	$ 5,036

(Notes in thousands, except share and per share amounts)

3. Notes Payable

In January 2003, the Company entered into a loan and security agreement (the Revised Credit Facility) and paid off the Original Credit Facility in full. The Revised Credit Facility provided for borrowings of up to $5,000, was collateralized by qualified accounts receivable and fixed assets of the Company and bears interest at the lender's prime rate (four percent at December 31, 2003) plus one and one-half percent per annum. Under the terms of the revised Credit Facility, the Company was required to maintain a minimum cash balance of the greater of $1,500 or 50% of the outstanding debt balance, as well as meet certain other financial and non-financial covenants.

On February 11, 2004, the Company received a commitment letter renewing the Revised Credit Facility entered into in January 2003 and increasing the amount it can borrow from $5,000 to $9,600. The interest rate is the lender's prime plus one-half of one percent per annum and the maturity dates are through 2008. Under the terms of the commitment, the Company was required to maintain a minimum cash balance of $2,500, as well as meet certain other financial and non-financial covenants.

In May of 2004 the Company paid off all amounts due under the Revised Credit Facility.

4. Commitments and Contingencies

The Company leases its facility under an operating lease, which expires on August 31, 2012. The minimum annual rent on the Company's facility is subject to increases based on stated rental adjustment terms of certain leases, taxes, insurance and operating costs. For financial reporting purposes, rent expense is recognized on a straight-line basis over the term of the lease. Accordingly, rent expense recognized in excess of rent paid is reflected as deferred rent and is included in accounts payable and accrued liabilities in the accompanying consolidated balance sheets. At December 31, 2004, the Company has obligations under capital leases, which total $18, of which $13 is due in 2005.

The Company's future minimum annual lease payments and long-term contractual obligations for years ending after December 31, 2004 are as follows :

	Capital leases	Operating lease	Other Contractual Obligations
2005	$ 5	$ 849	$ 563
2006	6	1,225	493
2007	6	1,259	408
2008	1	1,295	376
2009	—	1,332	338
Thereafter	—	3,575	1,241
Total minimum payments	18	$ 9,535	$ 3,419
Present value of net minimum lease payments	18		
Less: Current portion of capital lease obligations	(5)		
Long-term capital lease obligations	$ 13		

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

Rent expense was approximately $432, $300 and $300 for each of the years ended December 31, 2004, 2003 and 2002, respectively.

Property and equipment acquired through capital lease financing have a net book value of $18 and $284; which is net of accumulated depreciation of $5 and $1,600 at December 31, 2004, and 2003, respectively. Depreciation expense in the consolidated financial statements includes amortization expense related to assets acquired under capital leases.

The Company is party to certain claims and legal actions arising in the normal course of business.

5. Stockholders' Equity

Common Stock

In May 2004, the Company completed an initial public offering whereby 6,882,991 shares of the Company's common stock were sold at an offering price of $11 per share. All 6,882,991 shares were sold by the Company and there were no selling shareholders. The Company received net proceeds of approximately $68,100 in connection with the offering.

(Notes in thousands, except share and per share amounts)

Convertible Preferred Stock

All outstanding shares of convertible preferred stock converted to common in connection with the initial public offering on May 13, 2004. A summary of preferred stock issued and outstanding prior to the initial public offering is as follows:

	Shares issued and outstanding
Series A	1,820,000
Series B	1,847,000
Series C	428,000
Series D	4,670,000
Series D-1	3,960,000
	12,725,000

There are 5,000,000 shares of preferred stock authorized and none issued or outstanding at December 31, 2004.

Warrants

From 1999 to January of 2003, the Company issued warrants in connection with debt, sale-leaseback and private placement transactions. The Company recorded the fair value of the warrants as interest or consulting expense based on the terms of the transaction 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 SFAS 123.

All of the warrants were exercisable in connection with the initial underwriting of the Company's stock. As of December 31, 2004 warrants have been exercised on a net or cash basis resulting in the issuance of 1,763,145 shares of common stock. 9,486 warrants issued in 2001 in conjunction with a sale-leaseback agreement were outstanding at December 31, 2004.

Stock Options

In October 1998, the Company adopted the 1998 Stock Incentive Plan (the 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 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 terms of the stock option agreements, including vesting requirements. Options under the Plan have a 10-year term and normally vest over a term not to exceed four years from the date of grant. All options granted under the 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 Stock Incentive Plan with the 2004 Equity Incentive Plan (the "2004 Plan") under which 2,000,000 [plus shares left under the 1998 Plan] shares 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 (beginning in 2005) 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 or (ii) 10,000,000 shares or (iii) a number of shares determined by the Board of Directors.

The 2004 Plan provides for the grant of options to the Company's directors, officers, employees and consultants. The 2004 Plan provides for the grant of incentive and nonstatutory stock options and rights to purchase stock to employees, directors or 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.

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. Unvested common shares obtained through early exercise of options are subject to repurchase by the Company at the original issue price.

Also in April 2004 the board of directors approved the Employee Stock Purchase Plan (ESPP). The ESPP initially allowed for th issuance of up to 250,000 shares of our common stock, increasing annually on December 31 by the lesser of (i) 1,500,000 shares, (ii)1% of the outstanding shares of our common stock or (iii) a lesser amount determined by our board of directors. Under the terms of the ESPP, employees can elect to have up to 15% of their annual compensation withheld to purchase shares of our common stock. The purchase price of the common stock is equal to 85% of the lower of the fair market value per share of our common stock on the commencement date of the applicable offering period or the purchase date. In 2004, 25,799 shares were purchased under the ESPP and 224,201 remain available for issuance under the ESPP as of December 31, 2004.

In July 2002, certain executives exercised a total of 910,446 options, the consideration for which included cash of approximately $2 and promissory notes of approximately $523 payable to the Company. In March of 2004 these notes were forgiven by the Company or settled by payment.

In November 2003, the Company amended the 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. Under FIN 44, the modification to the Plan requires the Company to measure, based on the difference between the fair value of the common stock as of the date of the modification and the exercise price of each unvested option, the potential charge that would be recorded as additional compensation expense should the change in control provision be triggered prior to when the employees would have vested in the options under the original terms of the option grants. Based on the unvested employee options as of December 31, 2004, the maximum exposure to the Company related to the modification to the Plan is $2,900. The potential charge is reduced as employees continue to vest in their options over the normal four-year vesting period, thereby decreasing the unvested portion of the options on which the potential charge is based. Assuming the acceleration is not triggered, the potential exposure is reduced to zero by September 2007.

The Company recorded expense of $925, $458 and $43 and in 2004, 2003, 2002, respectively, related to the vesting of stock options granted to non-employees under consulting agreements, in accordance with EITF 96-18.

Following is a summary of stock option activity*:*

	Underlying Shares	Weighted Avg. Exercise Price
Outstanding at December 31, 2002	1,332,000	$ 0.60
Granted	684,000	$ 0.80
Exercised	(113,000)	$ 0.50
Cancelled	(192,000)	$ 0.63
Outstanding at December 31, 2003	1,711,000	$ 0.68
Granted	2,168,000	$ 6.85
Exercised	(811,000)	$ 0.84
Cancelled	(98,000)	$ 4.01
Outstanding at December 31, 2004	2,970,000	$ 5.02

The weighted average fair value of options granted during the years ended December 31, 2004, 2003 and 2002, was $10.36, $2.15 and $0.38 per share, respectively. At December 31, 2004, approximately 2,801,000 shares were vested under the Plan. The weighted average remaining contractual life of options outstanding at December 31, 2004 was approximately nine years.

At December 31, 2004 186,627 shares remain available for future issuance or grant under the Plan.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2004 *(in thousands, except per share data):*

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number of Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$0.25 to $0.25	64,000	6.93	$ 0.25	64,000	$ 0.25
$0.63 to $0.63	693,000	7.62	$ 0.63	693,000	$ 0.63
$0.70 to $1.88	131,000	8.01	$ 1.21	131,000	$ 1.21
$3.75 to $3.75	1,028,000	9.51	$ 3.75	1,028,000	$ 3.75
$9.27 to $11.63	1,054,000	9.27	$ 9.94	442,000	$ 10.21
	2,970,000	8.86	$ 5.03	2,358,000	$ 3.81

Common Stock Reserved for Future Issuance

The following table summarizes common shares reserved for issuance at December 31, 2004, on exercise or conversion of:

Convertible preferred stock warrants	9,000
Common stock options:	
Issued and outstanding	2,970,000
Available for future grant	187,000
Total shares reserved for future issuance	3,166,000

6. Related Party Transactions

In February 2000, the Company loaned $500 to an officer in exchange for a promissory note. The Company also agreed to pay all withholding obligations arising from the forgiveness of the loan. For the years ended December 31, 2004, 2003 and 2002, respectively, the Company has recognized compensation expense of $56, $619 and $454, and a liability of $26, $626and $461 for the payroll withholding obligations. In May of 2004 this loan was forgiven in full in conjunction with the initial public offering.

In July 2002, certain executives exercised stock options using non-recourse promissory notes payable to the Company totaling approximately $523. The notes bore interest at 6% per annum. The Company has recorded compensation expense related to the forgiveness of the notes and related interest for the years ended December 31, 2004, 2003 and 2002, respectively of approximately $188, $310, and $103. In July 2003, upon the resignation of two employees, the Company repurchased $54 of stock by adjusting the related notes receivable. Subsequently the Company received full payment of $34 from one employee and forgave the remaining balance of $28 for the other employee. In May 2004, the remaining notes were forgiven in full in conjunction with the initial public offering.

As a result of the modification of the original option grants to these executives, in order to provide for the forgiveness of the notes, there was deemed to be a new measurement date for the option grants. The resulting aggregate value of the options, based on the intrinsic value at the date of the modification of approximately $121, has been recorded as deferred compensation in the stockholders' equity section of the balance sheets and has been amortized to compensation expense over the term of the promissory notes. Total compensation expense recorded in 2003 and 2002 related to these options was approximately $76 and $41, respectively.

(Notes in thousands, except share and per share amounts)

7. Income Taxes

Due to the Company's net loss position for the years ended December 31, 2004, 2003 and 2002, and the Company's determination that realization of the deferred tax assets is not more likely than not, the Company has recorded a full valuation allowance against deferred tax assets. Accordingly, there was no provision or benefit for income taxes recorded. There were no components of current or deferred federal, state or foreign tax provisions for the years ended December 31, 2004, 2003, and 2002.

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, 2004 and 2003 are as follows:

	December 31,	
	2004	2003
Deferred Tax Assets:		
Allowances and reserves	$ 437	$ 580
Accrued expenses	173	119
Inventory	32	24
Deferred revenue	32	7
Stock based compensation	302	186
Property and equipment	105	24
Net operating loss carryforwards	25,122	22,320
Income tax credit carryforwards	3,427	2,749
Capitalized assets and other	1,218	873
	30,848	26,882
Valuation Allowance	(30,848)	(26,790)
Total deferred tax assets, net of valuation allowance	—	92
Deferred Tax Liabilities:		
Depreciation and amortization	—	(92)
Total deferred tax liabilities	—	(92)
Net deferred tax assets	$ —	$ —

The Company has established a valuation allowance against its deferred tax asset due to the uncertainty surrounding the realization of such assets. Management periodically evaluates the recoverability of the deferred tax asset. At such time as it is determined that it is more likely than not that the deferred tax assets are realizable, the valuation allowance will be reduced. The Company has recorded a valuation allowance of approximately $31,000 as of December 31, 2004 to reflect the estimated amount of deferred tax assets that may not be realized. The Company increased its valuation allowance by approximately $4,058 for the year ended December 31, 2004. The valuation allowance includes approximately $620 related to stock option deductions, the benefit of which will eventually be credited to equity.

At December 31, 2004, the Company had federal and California tax loss carryforwards of approximately $67,000 and $38,500, respectively. The federal and state net operating loss carryforwards begin to expire in 2018 and 2007, if unused. The Company also has losses attributable to its foreign subsidiary of approximately $551 at December 31, 2004. At December 31, 2004, the Company had federal and state tax credit carryforwards of approximately $2,300 and $1,700, respectively. The federal credits will begin to expire in 2012.

The utilization of net operating loss carryforwards and tax credit carryforwards is dependent on the future profitability of the Company. Furthermore, the Internal Revenue Code imposes substantial restriction on the utilization of net operating loss and tax credit carryforwards in the event of an "ownership change" of more than 50 percentage points during any three year period. Due to prior ownership changes as defined by IRC Section 382, a portion of the Company's net operating loss and tax credit carryforwards are limited in their annual utilization. It is currently estimated that annual limitations may result in the expiration of approximately $700 and $90 of the net operating loss and credit carryforwards, respectively.

(Notes in thousands, except share and per share amounts)

8. Employee Retirement Plan

The Company administers a retirement plan under Section 401(k) of the Internal Revenue Code for the benefit of all employees meeting minimum eligibility requirements. Under the plan, each employee may contribute up to 25% of his or her annual salary, not to exceed federal limits. The Company does not provide a matching contribution to the plan.

9. Quarterly Data

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:

	Year Ended December 31, 2004			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenues	$ 7,588	$ 8,809	$ 10,184	$ 11,822
Total operating expenses	9,531	10,783	10,565	11,936
Net loss	(4,227)	(4,466)	(2,756)	(2,761)
Basic and diluted net loss per common share (1)	(2.33)	(0.34)	(0.12)	(0.12)

	Year Ended December 31, 2003			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenues	$ 4,450	$ 5,495	$ 6,076	$ 6,634
Total operating expenses	5,520	5,849	6,337	$ 8,141
Net loss	(2,703)	(2,023)	(1,837)	$ (3,564)
Basic and diluted net loss per common share (1)	(1.67)	(1.26)	(0.45)	(2.27)

(1) Net loss per shares is computed independently for each of the quarters presented on an historical basis. The Company completed it's initial public offering of 6,882,991 shares in May 2004, these shares are included in the computation of loss per share from the date of the IPO forward. Therefore the sum of the quarterly loss per share is not comparable from quarter to quarter and will not equal the total loss per share for the year.

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

	Balance at Beginning of period	Additions (1)	Deductions (2)	Balance at the end of period
Year ended December 31, 2004				
Accounts Receivable Reserve	$ 320	287	352	$ 255
Year ended December 31, 2003				
Accounts Receivable Reserve	$ 105	231	16	$ 320
Year ended December 31, 2002				
Accounts Receivable Reserve	$ 123	258	276	$ 105

	Balance at Beginning of period	Additions (3)	Deductions (4)	Balance at the end of period
Year ended December 31, 2004				
Inventory Reserve	$ 1,187	98	441	$ 844
Year ended December 31, 2003				
Inventory Reserve	$ 800	588	201	$ 1,187
Year ended December 31, 2002				
Inventory Reserve	$ 119	920	239	$ 800

(1) Amount represents excess and obsolete reserve recorded as a contra-asset.

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

(3) Amount represents customer balances deemed uncollectible.

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-8 No. (333-116546) pertaining to the 1998 Stock Option/Stock Issuance Plan, 2004 Equity Incentive Plan and 2004 Employee Stock Purchase Plan of NuVasive, Inc. of our report dated February 16, 2004, with respect to the consolidated financial statements and schedule of NuVasive, Inc. included in the Annual Report (Form 10-K) for the year ended December 31, 2004.

/s/ ERNST & YOUNG LLP

San Diego, California
March 24, 2005

Exhibit 31.1

Form of Rule 13a-14(a) Certification (CEO)

CERTIFICATIONS

I, Alexis V. Lukianov, certify that:

1. I have reviewed this Annual Report on Form 10-K of NuVasive, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Paragraph omitted pursuant to SEC Release 33-8238.];

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

/s/ Alexis V. Lukianov

Alexis V. Lukianov
Chairman and Chief Executive Officer
March 31, 2005

Exhibit 31.2

Form of Rule 13a-14(a) Certification (CFO)

CERTIFICATIONS

I, Kevin C. O'Boyle, certify that:

1. I have reviewed this Annual Report on Form 10-K of NuVasive, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Paragraph omitted pursuant to SEC Release 33-8238.];

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

/s/ Kevin C. O'Boyle
Kevin C. O'Boyle
Executive Vice President and Chief Financial Officer
March 31, 2005

Exhibit 32.1

Form of Section 1350 Certification (CEO)

NuVasive, Inc.

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of NuVasive, Inc. (the "Company") on Form 10-K for the year ended December 31, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Alexis V. Lukianov, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Alexis V. Lukianov
Alexis V. Lukianov
Chief Executive Officer
March 31, 2005

Exhibit 32.2

Form of Section 1350 Certification (CFO)

NuVasive, Inc.

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of NuVasive, Inc. (the "Company") on Form 10-K for the year ended December 31, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kevin C. O'Boyle, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Kevin C. O'Boyle
Kevin C. O'Boyle
Chief Financial Officer
March 31, 2005