

NUVASIVE INC  
Form 424B4  
February 02, 2006  
Table of Contents

Filed Pursuant to Rule 424(b)(4)  
Registration No. 333-130354  
and Registration No. 333-131472

PROSPECTUS

7,500,000 Shares

## Common Stock

---

We are offering 6,704,120 shares of our common stock and the selling stockholders named in this prospectus, which are affiliates of William Blair & Company, an underwriter in this offering, are offering 795,880 shares of our common stock. We will not receive any proceeds from the sale of any shares of our common stock by the selling stockholders.

Our common stock is quoted on the Nasdaq National Market under the symbol NUVA.

*Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 7.*

	<u>Per Share</u>	<u>Total</u>
Public offering price	\$ 19.25	\$ 144,375,000
Underwriting discount and commissions	\$ 1.0106	\$ 7,579,500
Proceeds, before expenses, to NuVasive	\$ 18.2394	\$ 122,279,126
Proceeds, before expenses, to the selling stockholders	\$ 18.2394	\$ 14,516,374

We have granted the underwriters a 30-day option to purchase up to 1,125,000 additional shares of our common stock from us at the public offering price, less underwriting discounts and commissions.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

The underwriters expect to deliver the shares of common stock to investors on or about February 7, 2006.

---

**BANC OF AMERICA SECURITIES LLC**

**LEHMAN BROTHERS**

---

**THOMAS WEISEL PARTNERS LLC**

**WILLIAM BLAIR & COMPANY**

**STANFORD GROUP COMPANY**

February 1, 2006

**Table of Contents**

**Table of Contents**

**TABLE OF CONTENTS**

	<b>Page</b>
<u>Prospectus Summary</u>	1
<u>Risk Factors</u>	7
<u>Special Note Regarding Forward-Looking Statements</u>	21
<u>Use of Proceeds</u>	22
<u>Price Range of Our Common Stock</u>	23
<u>Dividend Policy</u>	23
<u>Capitalization</u>	24
<u>Dilution</u>	25
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	26
	<b>Page</b>
<u>Business</u>	35
<u>Management</u>	42
<u>Selling Stockholders</u>	46
<u>Underwriting</u>	47
<u>Legal Matters</u>	50
<u>Experts</u>	50
<u>Where You Can Find Additional Information</u>	50
<u>Information Incorporated by Reference</u>	51

---

**About This Prospectus**

You should rely only on the information contained or incorporated by reference in this prospectus. We and the selling stockholders have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We and the selling stockholders are not making offers to sell or seeking offers to buy these securities in any jurisdiction where the offer or sale is not permitted. You should assume the information contained or incorporated by reference in this prospectus is accurate as of the date on the front of this prospectus only. Our business, financial condition, results of operations and prospects may have changed since that date.

---

**Table of Contents**

**PROSPECTUS SUMMARY**

*This prospectus summary highlights information contained elsewhere in this prospectus and in documents we file with the Securities and Exchange Commission that are incorporated by reference in this prospectus. This summary is not complete and does not contain all of the information that you should consider before investing in our common stock. You should read the entire prospectus and the information incorporated by reference in this prospectus carefully, including Risk Factors and the consolidated financial statements and related notes thereto, before making an investment decision.*

**NuVasive, Inc.**

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 for lumbar and cervical spine fusion, a market estimated to exceed \$2.9 billion in the U.S. in 2005. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS, as well as classic fusion implants comprised of proprietary saline-packaged bone allografts and internal fixation products. Our products are used predominantly in spine fusion surgeries, both to enable access to the spine and to perform restorative and fusion procedures. As of December 31, 2005, we have trained 724 surgeons in the use of our products.

Our MAS platform combines three categories of our product offerings:

NeuroVision® a proprietary software-driven nerve avoidance system;

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

specialized implants, like our SpheRx® pedicle screw system, CoRoent® suite of implants and new ExtenSure dynamic stabilization and fusion system.

We believe our MAS platform provides a unique and comprehensive solution for safe and reproducible minimally disruptive surgical treatment of spine disorders by enabling surgeons to access the spine in a manner that affords direct visibility and avoidance of critical nerves. Our MAS platform enables a variety of spine surgery procedures and also uniquely enables an innovative procedure known as extreme lateral interbody fusion, or XLIF®, in which surgeons access the spine from the side of the patient's body, rather than from the front or back of the body. We believe our MAS platform enables procedures that deliver the following benefits to patients and care providers:

*Reduced Surgery Times.* XLIF procedures utilizing our MAS platform 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.

## Edgar Filing: NUVASIVE INC - Form 424B4

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

### **Developments Since Our Initial Public Offering**

Since our initial public offering, or IPO, in May 2004, we have undertaken multiple initiatives in product development and sales and marketing, and have relocated to a 62,000 square foot, state-of-the-art facility.

## Table of Contents

As a result of our internal product development and select strategic acquisitions, we have introduced twelve new products and product enhancements to our MAS platform since our IPO. These new products and product enhancements have resulted in increased revenue opportunities for each surgery performed using our products and include:

*SpheRx Dual Ball Rod (DBR)* a pedicle screw system that allows for instrument-free compression of the vertebrae.

*SpheRx Pedicle Screw System* a pedicle screw system designed for a posterior approach involving a minimally disruptive procedure.

*SmartPlate® Gradient CLP* a dynamic cervical plate that encompasses a gradient locking mechanism enabling the screws to be progressively resistant to axial compression.

*MaXcess Micro-Access System* the smallest, lightest version of our MaXcess retractor systems, designed to provide access during posterior lumbar and cervical decompression surgeries.

*MaXcess II* a second generation of our MaXcess retractor that incorporates NeuroVision within the posterior retraction blade and features superior and inferior blades that kick-out at an angle.

*ExtenSure* an interspinous dynamic stabilization and fusion system that utilizes an allograft implant to maintain decompression through a more natural restoration of the spinal anatomy.

*Insulated Pedicle Access System (I-PAS)* a surgical instrument used in conjunction with NeuroVision to determine the safe, percutaneous approach pathway of a pedicle screw prior to its implantation.

*CoRoent Large Tapered, CoRoent Large Contoured and CoRoent XLR* implants that offer superior anatomical fit, designed in response to demand from spine surgeons.

*NeuroVision Nerve Root Retractor* an instrument that combines stimulated and free run electromyography (EMG) to monitor spinal nerves and alert the surgeon of physiologic changes intraoperatively during nerve retraction.

*NeuroVision* we have made significant enhancements to our NeuroVision nerve avoidance system in the form of a software upgrade, improved nerve monitoring capabilities and a new harness and dual electrodes that are easier to apply.

In addition, we have a robust research and development pipeline and have filed for two Investigational Device Exemptions with respect to cervical spine devices currently under development. The first of these is NeoDisc, a nucleus-like cervical disc replacement device designed to preserve motion in the cervical region of the spine. The second is CerPass, our cervical total disc replacement device.

We also determined that we could increase productivity and revenue growth by creating a sales organization that is focused solely on our spine surgery products. This effort will result in our sales force being comprised of Area Business Managers, who are NuVasive employees, and exclusive independent distributors, who act as our sole representatives in specified territories. As of December 31, 2005, approximately 60% of our sales force exclusively sells our spine surgery products.

## Edgar Filing: NUVASIVE INC - Form 424B4

In January 2005, we relocated to our new state-of-the-art facility that has a six-suite cadaver operating theatre as well as warehousing and distribution capabilities. We believe our new facility positions us for continued momentum in surgeon training and adoption of our products.



## **Table of Contents**

### **Our Strategy**

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

*Establish our MAS Platform as a Standard of Care.* We believe that our MAS platform has the potential to become the standard of care for minimally invasive spine surgery as spine surgeons continue to adopt our products and recognize the benefits of the procedures they enable versus traditional open and other minimally invasive procedures. As of December 31, 2005, 724 surgeons have been trained on our MAS platform.

*Continue to Introduce New Creative Products.* We have introduced twelve new products and product enhancements since our IPO and have several additional products currently under development, including total disc and nucleus-like replacement devices, MAS platform expansion products and other implants designed to stabilize the spine.

*Establish Exclusive Sales Force with Broad Reach.* We believe that having a sales force dedicated to selling only our spine surgery products is critical to achieve continued growth across product lines, greater market penetration and increased sales.

*Provide Tailored Solutions in Response to Surgeon Needs.* Responding quickly to the needs of spine surgeons, which we refer to as Absolute Responsiveness, is central to our corporate culture, critical to our success and, we believe, differentiates us from our competition. We solicit information and feedback from our surgeon customers and clinical advisors regarding the utility of and potential improvements to our products and we utilize our state-of-the-art cadaver operating theatre to provide clinical training and validate new ideas through prototype testing.

*Selectively License or Acquire Complementary Spine Products and Technologies.* We believe we can leverage our expertise at bringing new products to market, provide a more complete product offering and improve the productivity of our sales force by acquiring or licensing complementary products. Since our IPO, we have acquired complementary and strategic assets, including cervical plate, surgical embroidery, and dynamic stabilization technologies.

### **Corporate Information**

Our business was incorporated in Delaware in July 1997. Our principal executive offices are located at 4545 Towne Centre Court, San Diego, California, 92121, and our telephone number is (858) 909-1800. Our website is located at [www.nuvasive.com](http://www.nuvasive.com). The information contained in, or that can be accessed through, our website is not part of this prospectus. Unless the context requires otherwise, as used in this prospectus the terms NuVasive, we, us, and our refer to NuVasive, Inc., a Delaware corporation.

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

This prospectus contains market data and industry forecasts that were obtained from industry publications. These publications generally state that the information contained therein has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed.



**Table of Contents**

**The Offering**

Common stock offered by NuVasive 6,704,120 shares

Common stock offered by the selling stockholders 795,880 shares

Common stock outstanding after this offering 31,810,070 shares

Use of proceeds We expect to use a majority of the net proceeds from this offering to expand our sales and marketing activities, fund research and development relating to potential new products, acquire or invest in complementary businesses, products or technologies, pay up to \$31.5 million of additional acquisition costs related to recently acquired assets and technology, and finance continued development costs related to recently acquired assets and technology. We also expect to use the net proceeds of this offering to finance regulatory approval activities and clinical trials, expand our operating facilities and for general corporate purposes.

We will not receive any of the proceeds from the selling stockholders' sale of 795,880 shares in this offering. The selling stockholders are affiliates of William Blair & Company, an underwriter in this offering.

Nasdaq National Market symbol NUVA

Risk Factors Investing in our common stock involves certain risks. You should carefully consider the risk factors discussed under the heading "Risk Factors" beginning on page 7 of this prospectus and other information contained or incorporated by reference in this prospectus before deciding to invest in our common stock.

The number of shares of our common stock to be outstanding immediately after this offering is based on 25,105,950 shares of our common stock outstanding as of December 31, 2005, and excludes:

9,486 shares of our common stock issuable upon the exercise of warrants outstanding as of December 31, 2005, at an exercise price of \$6.33 per share;

3,217,523 shares of our common stock issuable upon the exercise of options to purchase our common stock outstanding at December 31, 2005, at a weighted average exercise price of \$8.25 per share;

457,021 shares of our common stock reserved for future issuance under our 2004 Equity Incentive Plan as of December 31, 2005; and

166,925 shares of our common stock reserved for future issuance under our 2004 Employee Stock Purchase Plan as of December 31, 2005.

## Edgar Filing: NUVASIVE INC - Form 424B4

Unless otherwise indicated, all information in this prospectus assumes that the underwriters do not exercise their option to purchase up to 1,125,000 additional shares of our common stock in this offering.

**Table of Contents****Summary Consolidated Financial Data**

The following tables summarize our consolidated financial data for the periods presented. The summary consolidated financial data for the years ended December 31, 2002, 2003 and 2004 are derived from our audited consolidated financial statements. The financial data as of September 30, 2005, and for the nine months ended September 30, 2004 and 2005, are derived from our unaudited consolidated financial statements. You should read the following financial information together with the information under Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the notes to those consolidated financial statements incorporated by reference in this prospectus.

	Years Ended December 31,			Nine Months Ended September 30,	
	2002	2003	2004	2004	2005
	(unaudited)				
	(in thousands, except per share amounts)				
<b>Consolidated Statement of Operations Data:</b>					
Revenues:					
MAS	\$ 5,269	\$ 12,069	\$ 28,135	\$ 19,017	\$ 34,144
Classic Fusion	6,991	10,586	10,268	7,564	9,090
Total revenues	12,260	22,655	38,403	26,581	43,234
Cost of goods sold	5,303	6,791	10,228	7,309	9,107
Gross profit	6,957	15,864	28,175	19,272	34,127
Operating expenses:					
Research and development	6,107	6,310	8,348	4,855	7,511
Sales and marketing	10,024	12,609	19,740	13,906	26,382
General and administrative	5,568	6,185	8,584	6,874	11,972
Stock-based compensation	113	743	6,143	5,244	2,455
In-process research and development					12,897
Total operating expenses	21,812	25,847	42,815	30,879	61,217
Interest income (expense), net	(200)	(280)	477	170	949
Other expense, net	(55)	136	(47)	(12)	
Net loss	\$ (15,110)	\$ (10,127)	\$ (14,210)	\$ (11,449)	\$ (26,141)
Historical net loss per share(1):					
Basic and diluted	\$ (13.20)	\$ (6.30)	\$ (0.91)	\$ (0.89)	\$ (1.08)
Weighted average shares basic and diluted	1,145	1,607	15,605	12,859	24,263
Pro forma net loss per share(1):					
Basic and diluted	\$ (1.23)	\$ (0.71)	\$ (0.70)	\$ (0.60)	
Weighted average shares basic and diluted	12,290	14,332	20,264	19,082	

## Edgar Filing: NUVASIVE INC - Form 424B4

- (1) As a result of the issuance of 6,882,991 shares of our common stock in our IPO in May 2004, and the conversion of our preferred stock into 12,724,363 shares of our common stock upon completion of our IPO, there is a lack of comparability in the historical basic and diluted net loss per share amounts for the 2002, 2003 and 2004 years and the nine months ended September 30, 2004. In order to provide a more relevant measure of our operating results, a pro forma net loss per share calculation has been provided for these periods. The shares used to compute pro forma basic and diluted net loss per share represent the weighted average common shares used to calculate historical 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.

**Table of Contents**

	As of September 30, 2005	
	Actual	As Adjusted(1)
	(unaudited, in thousands)	
<b>Consolidated Balance Sheet Data:</b>		
Cash, cash equivalents and short-term investments	\$ 25,026	\$ 146,980
Working capital	37,454	159,408
Total assets	74,449	196,403
Long-term obligations, less current portion	1,660	1,660
Total stockholders' equity	61,044	182,998

- (1) The data in the as adjusted column gives effect to the sale by us of 6,704,120 shares of our common stock at the public offering price of \$19.25 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

**Table of Contents**

**RISK FACTORS**

*An investment in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below together with all other information contained or incorporated by reference in this prospectus before you decide to invest in our common stock. If any of the following risks actually occurs, our business, financial condition, results of operations and our future growth prospects would be materially and adversely affected. Under these circumstances, the trading price of our common stock could decline, and you may lose all or part of your investment.*

**Risks Related to Our Business and Industry**

**Our failure to build an effective and dedicated distribution network for our products could significantly impair our ability to increase sales of our products.**

We have only been selling our products since 2001. We currently sell a significant majority of 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. We are currently engaged in significant efforts to convince agents and sales representatives to exclusively sell our spine surgery products. We believe this is important in increasing our product sales as exclusivity brings greater focus from sales agents and a greater commitment to generate sales of our full product line. These efforts require us to offer higher commissions, sometimes for extended periods of time. As a result, these efforts can result in significantly increased expenses and may therefore negatively impact our results of operations. In addition, if we are unable to convince some of our established third-party sales agencies to exclusively sell our spine surgery products, we would have to try to transition this business to exclusive agents. There is a risk that sales revenue may be lost in connection with such a transition.

Our efforts to build a dedicated sales force also include initiatives to hire direct sales representatives who work directly for us. We have little experience in establishing a direct sales force, so there is a risk that this sales force will not succeed in growing sales of our products. Although we believe the cost of a direct sales force will be comparable to that of independent agents, there is also a risk that the cost may turn out to be higher.

The establishment and development of a broader and more dedicated 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 representatives and independent sales agencies. 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 representatives and/or independent sales agencies, these parties may not be successful in marketing and selling our products. Our business, financial condition and results of operations will be adversely affected if the marketing and sales efforts of our direct sales representatives and independent sales agencies are unsuccessful.

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



## Edgar Filing: NUVASIVE INC - Form 424B4

The market for spine surgery products is large and growing at a significant rate. This has attracted numerous new companies and technologies, and also encouraged more established companies to intensify competitive pressure. New entrants to our markets include companies owned partially by spine surgeons, who have significant market knowledge and access to the surgeons who use our products. As a result of this increased competition, we believe there will be growing pricing pressure in the near future. If competitive forces drive down the price we are able to charge for our products, our profit margins will shrink, which will hamper our ability to invest in and grow our business.

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

## Table of Contents

procedures performed with these devices. Spine surgeons are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of related procedures. We also believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for our existing products or our products currently under development and limit our ability to sell our products on a profitable basis.

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

**We are in a highly competitive market segment and face competition from large, well-established medical device manufacturers as well as new market entrants.**

The market for spine surgery products and procedures is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. With respect to NeuroVision, our nerve avoidance system, we compete with Medtronic Sofamor Danek, Inc., a wholly owned subsidiary of Medtronic, Inc., and Nicolet Biomedical, a VIASYS Healthcare company, both of which have significantly greater resources than us. With respect to MaXcess, our minimally disruptive surgical system, our largest competitors are Medtronic Sofamor Danek, Inc., DePuy Spine, Inc., a Johnson & Johnson company, and Synthes-Stratec, Inc. We compete with many of the same companies with respect to our other products. At any time, these companies may develop alternative treatments, products or procedures for the treatment of spine disorders that compete directly or indirectly with our products. Many of our larger competitors are either publicly traded or divisions or subsidiaries of publicly traded companies, and enjoy several competitive advantages over us, including:

significantly greater name recognition;

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

large and established distribution networks with significant international presence;

products supported by long-term clinical data;

greater experience in obtaining and maintaining United States Food and Drug Administration, or FDA, and other regulatory approvals or clearances for products and product enhancements;

more expansive portfolios of intellectual property rights; and

greater financial and other resources for product research and development, sales and marketing and litigation.

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

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

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

lack of experience with our products;

**Table of Contents**

lack of evidence supporting additional patient benefits;

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

limited availability of reimbursement within healthcare payment systems;

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

the time that must be dedicated for training.

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

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

It is important to our business that we continue to build a more complete product offering to surgeons and hospitals and to attract distributors. As such, our success will depend in part on our ability to develop and introduce new products and enhancements to our existing products to keep pace with the rapidly changing spine market. We cannot assure you that we will be able to successfully develop, obtain regulatory approval for or market new products or that any of our future products will be accepted by the surgeons who use our products or the payors who financially support many of the procedures performed with our products. The success of any new product offering or enhancement to an existing product will depend on several factors, including our ability to:

properly identify and anticipate surgeon and patient needs;

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

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

avoid infringing upon the intellectual property rights of third parties;

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

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

provide adequate training to potential users of our products;

receive adequate reimbursement notifications; and

develop an effective and dedicated marketing and distribution network.

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

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

We recently acquired assets from each of Pearsalls Limited, RSB Spine LLC, and RiverBend Design LLC, and may in the future acquire technology, products or businesses related to our current or future business. We have limited experience in acquisition activities and may have to devote substantial time and resources in order to complete any future acquisitions. Further, these past and potential acquisitions entail risks, uncertainties and potential disruptions to our business. For example, we may not be able to successfully integrate an acquired company's operations, technologies, products and services, information systems and personnel into our business. Further, products we acquire, such as the cervical plate we acquired from RSB Spine LLC and the ExtenSure product acquired from RiverBend Design LLC, may not provide the intended complementary fit with our

## Table of Contents

existing products. In addition, certain acquired technology, such as that acquired from Pearsalls Limited, requires significant additional development work and efforts to obtain regulatory clearance or approval. An acquisition may further strain our existing financial and managerial controls, and divert management's attention away from our other business concerns. In connection with in-process research and development activities, we would likely experience an increase in development expenses and capital expenditures. There may also be unanticipated costs and liabilities associated with an acquisition that could adversely affect our operating results.

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

We rely on third-party suppliers and manufacturers to manufacture and supply our products. To be successful, our contract manufacturers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable cost and on a timely basis. Our anticipated growth could strain the ability of suppliers to deliver an increasingly large supply of products, materials and components. Manufacturers often experience difficulties in scaling up production, including problems with production yields and quality control and assurance, especially with products such as allograft which is processed human tissue. If we are unable to obtain sufficient quantities of high quality components to meet customer demand on a timely basis, we could lose customers, our reputation may be harmed and our business could suffer.

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

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

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

## **Table of Contents**

### **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. This training process may take longer than expected and may therefore affect our ability to increase sales. Convincing surgeons to dedicate the time and energy necessary for adequate training is challenging, and we cannot assure you we will be successful in these efforts. If surgeons are not properly trained, they may misuse or ineffectively use our products. This may also result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us, any of which could have an adverse effect on our business.

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

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

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

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

The rapid growth of our business has placed a significant strain on our managerial, operational and financial resources and systems. To execute our anticipated growth successfully, we must attract and retain qualified personnel and manage and train them effectively. We 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 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.

We relocated our operations to a different facility in San Diego, California about one year ago. 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 are also 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.

**If we fail to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our future products or product enhancements, our ability to commercially distribute and market our products could suffer.**

Our medical devices are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device, particularly from the FDA, can be costly and time consuming, and there can be no assurance that such clearances or approvals will be granted on a timely basis, if at all. In particular, the FDA permits



## Table of Contents

commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved premarket approval application, or PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use.

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.

Any products we develop that require regulatory clearance may be delayed. In addition, any modification to our current products may require a new 510(k) clearance or, possibly, premarket approval, and we may be required to cease marketing or recall the modified product until we obtain clearance or approval. 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 process.

To date, all of our products, unless exempt, have been cleared through the 510(k) process. We have no experience in obtaining premarket approval. We expect that our total disc replacement devices currently under development, including CerPass, our investigational cervical total disc replacement device, and NeoDisc, our investigational nucleus-like cervical disc replacement device, will have to go through the PMA process. These devices have not yet reached the clinical trial stage and we cannot assure you whether successful clinical trials will be conducted or completed or regulatory approval will ultimately be obtained for these devices. Moreover, clinical trials typically have durations of several years and competing products may be introduced while our devices are undergoing clinical trials. This could reduce the potential demand for our products and negatively impact our business prospects. Our competitors' new products and technologies may be more effective or less expensive than our products or render our products obsolete.

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

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

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

## Edgar Filing: NUVASIVE INC - Form 424B4

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

## **Table of Contents**

treatment with our products does not improve patient outcomes. Such results would reduce demand for our products, significantly reduce our ability to achieve expected revenues and could prevent us from becoming profitable. Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to significant legal liability and harm to our business reputation. The spine medical device market has been particularly prone to latent and costly product liability litigation.

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

We and our suppliers are required to comply with the FDA's quality system regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA enforces the quality system regulation through inspections. If we or one of our suppliers fail a quality system regulations inspection or if any corrective action plan is not sufficient, the manufacture of our products could be delayed. We underwent an FDA inspection in August 2003 regarding our allograft implant business, and another FDA inspection in April 2004 regarding our medical device activities. In connection with these inspections, the FDA requested minor corrective actions, which we believe we have taken, but there can be no assurance the FDA will not subject us to further enforcement action. The FDA may impose additional inspections or audits at any time.

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

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

## **Risks Related to Our Financial Results and Need for Financing**

**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 our short-term investments and the cash to be generated from expected product sales, but excluding the proceeds from this offering, will be sufficient to meet our projected operating requirements for at least the next 12 months. However, continued expansion of our business will be expensive and we may seek, in addition to this offering, 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;

## Edgar Filing: NUVASIVE INC - Form 424B4

the costs associated with expanding our sales and marketing efforts, including efforts to establish a dedicated sales force;

the expenses we incur in developing and commercializing our products, including the cost of obtaining and maintaining FDA or other regulatory clearance and approval;

the number and timing of acquisitions and other strategic transactions;

the amount and timing of any milestone payments related to our asset acquisition transactions;

## **Table of Contents**

the costs associated with increased capital expenditures, including fixed asset purchases of instrument sets which we loan to hospitals to support surgeries; 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. Any of these events could adversely affect our ability to achieve our development and commercialization goals, which could have a material adverse effect on our business, financial condition and results of operations.

**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 have since focused primarily on research and development and on 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 September 30, 2005, we had an accumulated deficit of approximately \$104.6 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:

pay the acquisition costs (i.e., purchase price and related expenses) and continued development and regulatory costs related to our recent acquisition of assets and technology from each of RSB Spine LLC and Pearsalls Limited, especially with respect to the significant ongoing development and regulatory expenses associated with the assets acquired from Pearsalls Limited;

grow our internal and third-party sales and marketing forces to expand the penetration of our products in the United States, and expend significant sums in connection with our efforts to convince independent agents and sales representatives to exclusively sell our spine surgery products;

increase our research and development efforts to improve upon our existing products and develop new product candidates, such as the potential products resulting from the assets acquired from Pearsalls Limited; 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 drive increased sales of our products to hospitals and surgeons;

**Table of Contents**

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

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

results of clinical research and trials on our existing products and products in development;

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

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

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

the evolving product offerings of our competitors;

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

interruption in the manufacturing or distribution of our products;

the effect of competing technological and market developments; and

changes in our ability to obtain FDA clearance or approval 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 in the United States, and commercialization of them outside of the United States would likely require other regulatory approvals and import licenses. As a result, it will be difficult for us to forecast demand for these products with any degree of certainty. In addition, we will be increasing our operating expenses as we build our commercial capabilities. Accordingly, we may experience significant, unanticipated quarterly losses. Because of these factors, our operating results in one or more future quarters may fail to meet the expectations of securities analysts or investors.

**Risks Related to Our Intellectual Property and Potential Litigation**

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

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our pending U.S. and foreign patent applications may not issue as

## Edgar Filing: NUVASIVE INC - Form 424B4

patents in a form that will be advantageous to us or may issue and be subsequently successfully challenged by others and invalidated. In addition, our pending patent applications include claims to material aspects of our products and procedures that are not currently protected by issued patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Competitors may be able to design around our patents or develop products which provide outcomes which are comparable to ours. Although we have taken steps to protect our intellectual property and proprietary technology, including entering into confidentiality agreements and intellectual property assignment agreements with our officers, 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 costly, 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.



## **Table of Contents**

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.

### **We are subject to litigation regarding cadavers we purchased that originated from the University of California at Los Angeles.**

For a period of time, we purchased cadavers for surgeon training purposes from a broker who is now being investigated for his practices in obtaining those cadavers from the University of California, Los Angeles, or UCLA. We previously received inquiries and document requests from the FDA and the State of California regarding this investigation. Although we have been informed that we are not a subject of this investigation, we have been named as a defendant, along with the Regents of the University of California, The David Geffen School of Medicine at UCLA, Ernest V. Nelson, Henry G. Reid, and Johnson & Johnson, in multiple civil class action lawsuits relating to the underlying events. The lawsuits have been consolidated in a single court in the Superior Court of the State of California, County of Los Angeles. The lawsuits generally allege fraud, negligence and unfair business practices in connection with the use and distribution of the donated cadavers, and further allege that the cadavers were improperly sold. These lawsuits may result in significant legal fees and could be a diversion of management's time and other resources. If the claims contained in the lawsuit are successfully asserted against us, our financial performance and cash position could be negatively impacted and the market price of our shares may decline.

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

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for spine surgery procedures. Spine surgery involves significant risk of serious complications, including bleeding, nerve injury, paralysis and even death. In addition, we sell allograft implants, derived from cadaver bones, which pose the potential risk of biological contamination. If any such contamination is found to exist, sales of allograft products could decline.

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

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

We frequently engage spine surgeons as consultants to assist us with scientific research and development and to help us evaluate technologies. We are subject to federal and state laws and regulations governing our relationships with physicians and other health care providers. In April 2005, the United States Department of Justice expanded its investigation into the relationships between medical device companies and health care providers. The investigation originally appeared to focus on Medtronic Sofamor Danek, Inc., but the Department of Justice has since issued subpoenas to DePuy Spine, Inc., a Johnson & Johnson company, Biomet, Smith & Nephew, Stryker and Zimmer Holdings, all orthopedic device manufacturers, relating to the consulting process and procedures tied to fees that such companies have paid to physicians as consultants. Although we have not been contacted by the Department of Justice in respect of this investigation, we could become a subject of the investigation and be forced to incur significant costs as a result.

The regulations governing the interactions between medical device companies and health care providers continue to evolve. Compliance with these regulations is costly, especially as accepted methods of compliance

## **Table of Contents**

are developed. We expect to continue to incur costs related to compliance with these new measures, such as the requirement to comply with the new California Prescription Drug Marketing Act.

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

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

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

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

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

volume and timing of orders for our products;

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

disputes or other developments with respect to intellectual property rights;

our ability to develop, obtain regulatory clearance or approval 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;

## Edgar Filing: NUVASIVE INC - Form 424B4

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

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

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.

**We can provide no assurance regarding our, or our independent registered public accounting firm's, conclusions as of December 31, 2005 with respect to the effectiveness of our internal control over financial reporting.**

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to include an internal control report from management in our Annual Report on Form 10-K as of December 31, 2005 and each subsequent year end. The internal control report must include a statement:

about management's responsibility for establishing and maintaining adequate internal control over financial reporting;

## **Table of Contents**

identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting;

concerning management's assessment of the effectiveness of our internal control over financial reporting as of the end of the year covered by the Annual Report, including a statement as to whether or not internal control over financial reporting is effective; and

that our independent registered public accounting firm has issued an attestation report on management's assessment of internal control over financial reporting.

While we continue to expend significant resources in developing the necessary documentation and testing procedures required by Section 404, given the risks inherent in the operation of internal control over financial reporting, we can provide no assurance as to our, or our independent registered public accounting firm's, conclusions as of December 31, 2005 and each subsequent year end with respect to the effectiveness of our internal control over financial reporting. If we are unable to complete any assessment of our internal controls, or if our internal controls are not designed or operating effectively, our independent registered public accounting firm may either disclaim an opinion as it relates to management's assessment of the effectiveness of our internal controls or may issue a qualified opinion on the effectiveness of our internal controls. If this were to occur, investors could lose confidence in the reliability of our financial statements, which could cause the market price of our common stock to decline and which could affect our business and financial condition.

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

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 123R, pursuant to which we must measure all stock-based compensation awards, including grants of employee stock options, using a fair value-based method and record such expense in our consolidated financial statements. Currently, we disclose such expenses on a pro forma basis in the notes to our consolidated financial statements, but we do not record a charge for employee stock option expense in the financial statements. Once we begin to comply with SFAS No. 123R as of the beginning of fiscal year 2006, our reported earnings will decrease, which may affect our stock price.

**Our management team may invest or spend the proceeds of this offering in ways with which you may not agree or in ways which may not yield a return.**

Our management will have considerable discretion in the application of the net proceeds of this offering. We expect to use a majority of the net proceeds from this offering to expand our sales and marketing activities, fund research and development relating to potential new products, acquire or invest in complementary businesses, products or technologies, although we are not currently involved in any negotiations and have no commitments with respect to any such transactions, pay up to \$31.5 million to Pearsalls Limited for recently acquired assets and technology, and finance continued development costs related to assets and technology acquired from RSB Spine LLC, Pearsalls Limited and RiverBend Design LLC. We also expect to use the net proceeds of this offering to fund regulatory approval activities and clinical trials, expand our operating facilities and for general corporate purposes. We cannot specify with certainty how we will use the net proceeds of this offering or our existing cash balance. The net proceeds may be used for corporate purposes that do not increase our operating results or market value. Until the net proceeds are used, they may be placed in investments that do not produce income or that lose value.

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

## Edgar Filing: NUVASIVE INC - Form 424B4

Our current stockholders hold a substantial number of shares of our common stock, which they will be able to sell in the public market now and in the near future. After this offering, 31,810,070 shares of our common stock will be outstanding, based on the number of shares of our common stock outstanding as of December 31, 2005, but excluding shares issuable upon future exercises of outstanding warrants, upon future exercises of options granted under our 1998 Stock Option/Stock Issuance Plan and our 2004 Equity Incentive Plan and upon future purchases under our 2004 Employee Stock Purchase Plan. Substantially all of our outstanding shares will

## **Table of Contents**

be available for sale in the public market as of the date of this prospectus, subject to certain volume limitations applicable to certain of our stockholders and to our executive officers and directors. Sales of a substantial number of shares of our common stock within a short period of time after this offering could cause our stock price to fall.

**As a new investor, you will experience substantial dilution as a result of this offering and future equity issuances and, as a result, our stock price could decline.**

The public offering price of our common stock in this offering is considerably more than the net tangible book value per share of our outstanding common stock. As a result, investors purchasing common stock in this offering will pay a price per share that substantially exceeds the value of our assets after subtracting the liabilities and will incur substantial immediate dilution in pro forma net tangible book value per share of \$13.76 at the public offering price of \$19.25 per share. Investors who purchase shares of common stock in this offering will contribute approximately 46% of the total amount we have raised to fund our operations but will own only approximately 21% of our common stock, based upon the number of shares outstanding as of September 30, 2005. We believe that our current cash and cash equivalents, excluding the proceeds from this 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 twelve months. Because we may require additional funds to develop new products and continue to expand our business, we may conduct substantial future offerings of equity securities. The exercise of outstanding options and warrants and future equity issuances, including future public offerings or future private placements of equity securities and any additional shares issued in connection with acquisitions, will result in further dilution to investors.

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

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

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

## Edgar Filing: NUVASIVE INC - Form 424B4

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

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

require advance written notice of stockholder proposals and director nominations.



**Table of Contents**

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

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

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

**Table of Contents**

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and the documents incorporated by reference in this prospectus include forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including, but not limited to, statements regarding our future financial position, business strategy and plans and objectives of management for future operations. When used in this prospectus, the words believe, may, will, estimate, continue, anticipate, intend, expect and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to certain risks and uncertainties that could cause our actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this prospectus, and in particular, the risks discussed above and under the heading Risk Factors and those discussed in other documents we file with the Securities and Exchange Commission which are incorporated by reference in this prospectus. The following discussion should be read in conjunction with our Annual Report on Form 10-K and our quarterly reports on Form 10-Q, which are incorporated by reference in this prospectus, and the consolidated financial statements and notes thereto included in our annual and quarterly reports. Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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

**Table of Contents**

**USE OF PROCEEDS**

We estimate that the net proceeds from the sale of the 6,704,120 shares of common stock that we are selling in this offering will be approximately \$122.0 million, or approximately \$142.5 million if the underwriters exercise their option to purchase additional shares in full, based upon the offering price to the public of \$19.25 per share, and after deducting estimated underwriting discounts and commissions and estimated offering expenses.

We will not receive any of the proceeds from the sale of shares of our common stock offered by the selling stockholders. The selling stockholders are affiliates of William Blair & Company, an underwriter in this offering. See [Selling Stockholders](#) and [Underwriting Conflicts/Affiliates](#).

We expect to use a majority of the net proceeds from this offering to expand our sales and marketing activities, fund research and development relating to potential new products, acquire or invest in complementary businesses, products or technologies and finance continued development costs related to assets and technology recently acquired from RSB Spine LLC, Pearsalls Limited and RiverBend Design LLC. We also expect to use the net proceeds of this offering to finance regulatory approval activities and clinical trials, expand our operating facilities and for general corporate purposes. We currently have no commitments with respect to any additional acquisition or investment, and we are not involved in any negotiations with respect to any such transaction.

We expect to use up to an aggregate of \$31.5 million of the net proceeds of this offering to fund additional payments to Pearsalls Limited related to our acquisition of the investigational nucleus-like cervical disc replacement device called NeoDisc. These payments are contingent upon attainment of milestones toward approval by the FDA to market a product of ours that incorporates NeoDisc or other intellectual property acquired by us from Pearsalls Limited in August 2005. The first milestone, the attainment of which triggers a \$10.5 million payment to Pearsalls, relates to FDA approval of the Investigational Device Exemption application. The second milestone, the attainment of which triggers a \$6.0 million payment to Pearsalls, relates to enrollment by us of a sufficient number of patients for clinical trials. The final milestone is approval by the FDA to market the product, and upon attainment of this milestone we are obligated to make a \$15 million payment to Pearsalls. We have the option of satisfying a portion of each of the milestone payments with shares of our common stock rather than cash.

As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. The amounts and timing of our actual expenditures will depend on numerous factors, including the status of our product development efforts, sales and marketing activities, technological advances, amount of cash generated or used by our operations and competition. Accordingly, our management will have broad discretion in the application of the net proceeds and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering.

Pending the uses described above, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities.

**Table of Contents****PRICE RANGE OF OUR COMMON STOCK**

Our common stock has been trading on the Nasdaq National Market under the symbol NUVA since May 13, 2004. Prior to that time there was no public market for our stock. The following table lists quarterly information on the price range of our common stock based on the high and low intra-day sale prices per share of our common stock as reported by the Nasdaq National Market for the periods indicated below. These prices do not include retail markups, markdowns or commissions.

	<u>High</u>	<u>Low</u>
<b>Year Ended December 31, 2004:</b>		
Second Quarter (from May 13, 2004)	\$ 12.15	\$ 10.29
Third Quarter	\$ 11.31	\$ 8.97
Fourth Quarter	\$ 11.60	\$ 8.74
<b>Year Ended December 31, 2005:</b>		
First Quarter	\$ 14.17	\$ 9.86
Second Quarter	\$ 17.46	\$ 12.04
Third Quarter	\$ 21.08	\$ 16.05
Fourth Quarter	\$ 19.75	\$ 15.57

On February 1, 2006, the last reported sale price for our common stock on the Nasdaq National Market was \$19.36 per share. We estimate that there were approximately 250 holders of record of our common stock as of December 31, 2005.

**DIVIDEND POLICY**

We have never declared or paid any cash dividend on our capital stock. We currently intend to retain all available funds and any future earnings to support operations and finance the growth and development of our business and do not intend to pay cash dividends on our common stock in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

**Table of Contents****CAPITALIZATION**

The following table sets forth our cash, cash equivalents, short-term investments and capitalization as of September 30, 2005, as follows:

On an actual basis.

On an as adjusted basis to give effect to the sale of 6,704,120 shares of our common stock by us at the offering price of \$19.25 per share, after deducting underwriting discounts and commissions and estimated offering expenses.

You should read this table in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus and our financial statements and related notes which are incorporated by reference in this prospectus.

	As of September 30, 2005	
	Actual	As Adjusted
	(in thousands, except per share data)	
	(unaudited)	
Cash, cash equivalents and short-term investments	\$ 25,026	\$ 146,980
Long-term liabilities	1,660	1,660
Stockholders' equity:		
Common stock, \$0.001 par value; 70,000 shares authorized, 24,985 shares issued and outstanding, actual; 70,000 shares authorized, 31,689 shares issued and outstanding, as adjusted	25	32
Additional paid-in capital	167,252	289,199
Deferred compensation	(1,583)	(1,583)
Accumulated other comprehensive loss	(43)	(43)
Accumulated deficit	(104,607)	(104,607)
Total stockholders' equity	61,044	182,998
Total capitalization	\$ 62,704	\$ 184,658

The table above excludes the following shares:

9,486 shares of our common stock issuable upon the exercise of warrants outstanding as of September 30, 2005, at an exercise price of \$6.33 per share;

## Edgar Filing: NUVASIVE INC - Form 424B4

3,010,997 shares of our common stock issuable upon the exercise of options to purchase our common stock outstanding as of September 30, 2005, at a weighted average exercise price of \$7.01 per share;

735,719 shares of our common stock reserved for future issuance under our 2004 Equity Incentive Plan as of September 30, 2005;

195,149 shares of our common stock reserved for future issuance under our 2004 Employee Stock Purchase Plan as of September 30, 2005; and

1,125,000 shares of our common stock that may be purchased from us by the underwriters pursuant to their option to purchase additional shares.

**Table of Contents****DILUTION**

Our net tangible book value as of September 30, 2005 was approximately \$52.0 million, or approximately \$2.08 per share of our common stock. Net tangible book value per share is equal to the amount of our total tangible assets less the amount of our total liabilities, divided by the number of shares of our common stock outstanding at September 30, 2005. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of our common stock in this offering and the pro forma net tangible book value per share of our common stock immediately after this offering.

After giving effect to our sale of the 6,704,120 shares of our common stock in this offering at the public offering price of \$19.25 per share, and after deducting estimated underwriting discounts and commissions and our estimated offering expenses, our pro forma net tangible book value as of September 30, 2005 would have been approximately \$174.0 million, or approximately \$5.49 per share. This represents an immediate increase in net tangible book value of \$3.41 per share to our existing stockholders, and an immediate dilution in net tangible book value of \$13.76 per share to new investors. The following table illustrates this per share dilution:

Public offering price per share	\$ 19.25
Net tangible book value per share as of September 30, 2005	\$ 2.08
Increase in net tangible book value per share attributable to new investors	3.41
Pro forma net tangible book value per share after this offering	5.49
Dilution per share to new investors	\$ 13.76

If the underwriters exercise their option to purchase additional shares in full, the pro forma net tangible book value per share would increase to \$5.93 per share, and the pro forma dilution per share to new investors would be \$13.32.

The preceding discussion and table above assume no exercise of the following warrants and options outstanding as of September 30, 2005:

9,486 shares of our common stock issuable upon exercise of outstanding warrants at an exercise price of \$6.33 per share; and

3,010,997 shares of our common stock subject to outstanding options having a weighted average exercise price of \$7.01 per share.

Because the exercise prices of the majority of outstanding options and warrants are significantly below the public offering price, investors purchasing common stock in this offering will suffer additional dilution when and if these options and warrants are exercised. If the 9,486 warrants and 3,010,997 options were exercised prior to this offering, but assuming no exercise of the underwriters' option to purchase additional shares, our existing stockholders would, after this offering, own approximately 81% of the total number of outstanding shares of our common stock while contributing 57% of the total consideration for all shares, and our new investors would own approximately 19% of the total number of outstanding shares of our common stock while contributing 43% of the total consideration for all shares.





**Table of Contents**

**MANAGEMENT'S DISCUSSION AND ANALYSIS  
OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read the following discussion of our financial condition and results of operations in conjunction with the consolidated financial statements and the notes to those statements incorporated by reference in this prospectus. This discussion may contain forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, such as those set forth under Risk Factors, Special Note Regarding Forward-Looking Statements and elsewhere in this prospectus.*

**Overview**

*Background*

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 for lumbar and cervical spine fusion, a market estimated to exceed \$2.9 billion in the U.S. in 2005. Our principal product offering includes a minimally disruptive surgical platform we call Maximum Access Surgery, or MAS, as well as classic fusion implants. We also focus significant efforts on our research and development pipeline emphasizing both MAS and motion preservation products such as total disc replacement.

Our MAS platform offers advantages for both patients and surgeons such as reduced surgery and hospitalization time and faster recovery. Our MAS platform combines three categories of our product offerings NeuroVision, a proprietary software-driven nerve avoidance system, MaXcess and MaXcess II, a unique split-blade design retraction system, and specialized implants, like the SpheRx pedicle screw system, the CoRoent suite of implants and the ExtenSure dynamic stabilization and fusion system that collectively minimize soft tissue disruption during spine surgery while allowing maximum visualization, direct access to the spine and surgical reproducibility. Our classic fusion portfolio is comprised predominantly of proprietary saline-packaged bone allografts, metal mesh cage implants and fusion plates.

Since inception in 1997, 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 September 30, 2005, we had an accumulated deficit of \$104.6 million.

*Revenues*

From inception to September 30, 2005, we have recognized \$119.1 million in revenue from sales of our products. Our revenues are derived from the sale of medical products in two principal categories:

*MAS Platform.* Our MAS platform 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, CoRoent and

ExtenSure.

*Classic Fusion.* Our classic fusion revenues primarily consist of the sales of proprietary saline-packaged bone allografts, metal cage implants and fusion plates.

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 derived less than 5% of our total revenues from the sale of MAS instrument sets, MaXcess, and NeuroVision systems. We do not expect these sales to contribute significantly to our revenues in the future because we intend to continue to (i) loan NeuroVision, MaXcess and surgical instrument sets to hospitals and surgeons who purchase our disposables and implants for use in individual procedures or (ii) place NeuroVision, MaXcess and surgical instrument sets with hospitals for an extended period at no up-front cost to them provided they commit to minimum monthly purchases of our disposables and implants. In the event a hospital or surgeon does not meet its minimum monthly purchase commitments, our sole remedy is to remove our products.

Our implants and disposables are sold and shipped from our facility or from limited disposable inventories stored at our distributors sites. We invoice hospitals a fee for using certain instruments and for any disposables

## **Table of Contents**

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, MaXcess and surgical instrument sets to hospitals without charge to support individual surgical procedures. We derive revenue from the sales of disposables and/or implants used in these procedures often at a premium price when the system is loaned rather than purchased.

### *Sales and Marketing*

Substantially all of our operations are located in the United States and substantially all of our sales to date have been generated in the United States. We distribute our products through a sales force comprised of independent agencies and our own sales personnel. The members of our sales force 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 in the selling and marketing expense line. We expect to continue to expand our distribution channel. We have been engaged in a process to create a sales force that is exclusive to us with respect to the sale of spine products. These efforts are ongoing and we expect to incur increased sales and marketing expenses as we incentivize new and existing representatives to exclusively sell our spine surgery products.

### **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 (GAAP) and regulations of the Securities and Exchange Commission. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates including those related to bad debts, inventories, fixed assets and income taxes. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates.

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

*Revenue Recognition.* We recognize revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 104, *Revenue Recognition*, which requires four basic criteria 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 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 and excess inventory based upon historical turnover and assumptions about future demand for our products and market conditions. Our allograft implants have a four-year shelf life and are subject to demand fluctuations based on the

**Table of Contents**

availability and demand for alternative implant products. Our MAS platform 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 using the straight-line method based on the estimated useful lives of two to seven years for machinery and equipment and three years for loaner equipment. Maintenance and repairs are expensed as incurred. In accordance with Statement of Financial Accounting Standards No. 144,

*Accounting for the Impairment or Disposal of Long-Lived Assets,* we review property, plant and equipment for impairment whenever events or changes in circumstances indicate 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 September 30, 2005 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 GAAP. There are also areas in which 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 our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2005 and incorporated by reference in this prospectus, which contain accounting policies and other disclosures required by GAAP.

**Results of Operations****Revenues**

*Total revenues.* Total revenues for the seven-quarter period ending September 30, 2005, by revenue classification are summarized below.

	Q1-04		Q2-04		Q3-04		Q4-04	
	% of		% of		% of		% of	
	(000 s)	Rev	(000 s)	Rev	(000 s)	Rev	(000 s)	Rev
Revenues:								
MAS	\$ 4,804	63%	\$ 6,171	70%	\$ 8,042	79%	\$ 9,118	77%
Classic Fusion	2,784	37%	2,638	30%	2,142	21%	2,704	23%

Edgar Filing: NUVASIVE INC - Form 424B4

Total revenues	\$ 7,588	100%	\$ 8,809	100%	\$ 10,184	100%	\$ 11,822	100%
	<u>Q1-05</u>		<u>Q2-05</u>		<u>Q3-05</u>			
		<i>% of</i>		<i>% of</i>		<i>% of</i>		
	<u>(000 s)</u>	<u>Rev</u>	<u>(000 s)</u>	<u>Rev</u>	<u>(000 s)</u>	<u>Rev</u>		
<b>Revenues:</b>								
MAS	\$ 9,923	76%	\$ 12,557	84%	\$ 11,664	77%		
Classic Fusion	3,141	24%	2,479	16%	3,470	23%		
<b>Total revenues</b>	<b>\$ 13,064</b>	<b>100%</b>	<b>\$ 15,036</b>	<b>100%</b>	<b>\$ 15,134</b>	<b>100%</b>		

**Table of Contents***MAS Revenue.*

	<u>September 30,</u>		<u>\$ Change</u>	<u>% Change</u>
	<u>2005</u>	<u>2004</u>		
	(dollars in thousands)			
Nine months ended	\$ 34,144	\$ 19,017	\$ 15,127	80%
% of revenue	79%	72%		

MAS platform revenues increased during the nine-month period ended September 30, 2005, compared to the same period in 2004 due primarily to continued market acceptance of our MAS platform products, including MaXcess, MaXcess II and NeuroVision disposables, and purchases of our MAS platform implants. We expect our MAS platform products will continue to be a significant contributor to our total revenue for the foreseeable future, which is consistent with our strategy.

*Classic Fusion.*

	<u>September 30,</u>		<u>\$ Change</u>	<u>% Change</u>
	<u>2005</u>	<u>2004</u>		
	(dollars in thousands)			
Nine months ended	\$ 9,090	\$ 7,564	\$ 1,526	20%
% of revenue	21%	28%		

Classic fusion revenues increased during the nine-month period ended September 30, 2005, compared to the same period in 2004 due primarily to increased sales of lumbar allograft and to sales of our cervical plate, SmartPlate Gradient CLP. We currently expect demand for our classic fusion products will continue at or near the present level, but the associated revenue may decrease as a relative percentage of our total revenues.

*Cost of Goods Sold*

	<u>September 30,</u>		<u>\$ Change</u>	<u>% Change</u>
	<u>2005</u>	<u>2004</u>		
	(dollars in thousands)			
Nine months ended	\$ 9,107	\$ 7,309	\$ 1,798	25%
% of revenue	21%	27%		

Cost of goods sold consists of purchased goods and overhead costs. Cost of goods sold, as a percent of revenue, for our MAS platform products ranged from 20% to 25% in 2004 and 15% to 20% in 2005, calculated on a quarterly basis. Cost of goods sold, as a percent of revenue, for our

## Edgar Filing: NUVASIVE INC - Form 424B4

classic fusion products ranged from 35% to 40% in both 2004 and 2005, calculated on a quarterly basis.

The increase in cost of goods sold during the nine-month period ended September 30, 2005, compared to the same period in 2004 is due, in part, to increased product sales, specifically the related material costs. In addition, we recorded the following additional charges to cost of goods sold in 2005: (i) additional inventory reserves of approximately \$374,000 for excess and obsolete inventory in the third quarter of 2005; (ii) amortization of approximately \$77,000 in the third quarter of 2005 related to the revaluation of inventory acquired from RSB Spine LLC; and (iii) the write-off in connection with the acquisition of assets from RSB Spine LLC of approximately \$497,000 in the second quarter of 2005 related to our own cervical plate under development.

Cost of goods sold as a percentage of total revenues decreased during the nine-month period ended September 30, 2005, compared to the same period in 2004 due primarily to a shift in product mix to our MAS platform products which have a higher margin than our classic fusion products, offset by the additional charges noted above. Our overall cost of goods sold and gross profit are subject to fluctuation based on the mix between our MAS platform and classic fusion products.



**Table of Contents****Operating Expenses***Research and Development.*

	<b>September 30,</b>			
	<b>2005</b>	<b>2004</b>	<b>\$ Change</b>	<b>% Change</b>
	(dollars in thousands)			
Nine months ended	\$ 7,511	\$ 4,855	\$ 2,656	55%
% of revenue	17%	18%		

Research and development expenses consist primarily of product research and development, regulatory and clinical functions, and employee related expenses. During the nine-month period ended September 30, 2005, we released nine new or enhanced products, five of which were released in the third quarter. The increase in research and development costs is primarily due to (i) an increase in employee related and consulting expenses of \$1.5 million for the nine-month period ended September 30, 2005, compared to the same period in 2004. Additional personnel have been hired to support development of our product pipeline, including the SpheRx pedicle screw system, CerPass total disc replacement and NeoDisc investigational nucleus-like cervical disc replacement device. Expenses for materials to support current product development increased by \$1.1 million for the nine-month period ended September 30, 2005 compared to the same period in 2004. We expect research and development costs to continue to increase for the foreseeable future in support of our ongoing development activities and planned clinical trial activities.

*Sales and Marketing.*

	<b>September 30,</b>			
	<b>2005</b>	<b>2004</b>	<b>\$ Change</b>	<b>% Change</b>
	(dollars in thousands)			
Nine months ended	\$ 26,382	\$ 13,906	\$ 12,476	90%
% of revenue	61%	52%		

Sales and marketing expenses consist primarily of employee and distributor commissions and costs for personnel engaged in sales, marketing and customer support functions, along with advertising, tradeshow, and surgeon training expenses. In the second quarter of 2005, we implemented a program to transition our distributor network toward exclusivity. Exclusive distributor relationships are costly to implement and generally result in higher commissions as a percentage of revenue. It is expected that this trend will continue for the foreseeable future. The increase in sales and marketing expenses for the nine-month period ended September 30, 2005 compared to the same period in 2004 resulted primarily from (i) increased commissions of \$6.2 million, reflecting the increase in sales volume and, to a lesser extent, the higher commission rate; (ii) increased royalties of \$530,000, reflecting the increase in sales volume; (iii) additional employee related and consulting costs of \$2.8 million, attributable to the increase in sales volume and the number of sales representatives; (iv) increased promotional materials costs of \$365,000, attributable to the increase in sales volume and the number of sales representatives; (v) increased shipping costs of \$554,000, attributable to the increase in sales volume and the number of sales representatives; (vi) increased tradeshow and conference expenses of \$1.2 million, due in large part to the fact that our largest annual tradeshow occurred in the third quarter of 2005 and in the fourth quarter of 2004; and (vii) increased expenses related to surgeon training of \$696,000, reflecting the increase in the number of surgeons trained in 2005.

We expect to increase the amounts we spend on sales and marketing for the foreseeable future. These increased amounts will be directed towards hiring direct sales agents and additional sales management 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 sales force, including both independent and direct sales agents, related to sales of our products and to provide incentive for our independent sales agents to exclusively sell our spine surgery products.

**Table of Contents***General and Administrative.*

	<u>September 30,</u>			
	<u>2005</u>	<u>2004</u>	<u>\$ Change</u>	<u>% Change</u>
	(dollars in thousands)			
Nine months ended	\$ 11,972	\$ 6,874	\$ 5,098	74%
% of revenue	28%	26%		

General and administrative expenses consist primarily of employee related expenses for our administrative functions, third-party professional service fees, facilities and insurance expenses. The increases described below are primarily a result of growth in our overall business and the activities to support that growth. Specifically, we became a public company in May 2004 and incur certain expenses related to accounting, audit and tax services, insurance and certain other costs we did not incur as a private company. In particular, we have incurred additional consulting, audit and tax services expenses of \$1.3 million for the nine-month period ended September 30, 2005, primarily related to compliance with the Sarbanes-Oxley Act of 2002. In addition, to support increased business activity and personnel, we relocated our corporate headquarters to a larger facility in San Diego, California in January 2005.

For the comparative nine-month periods ended September 30, 2005 and 2004 the increase in general and administrative expenses was due primarily to the following increases: public company and corporate governance expenses of \$478,000; legal services expense of \$422,000; facilities rent and related expenses, including depreciation of \$1.7 million related to our larger corporate headquarters and company growth; consulting, audit and tax services of \$1.3 million; employee related expenses of \$818,000; and amortization expense related to purchased technology of \$171,000.

We expect general and administrative costs to continue to increase for the foreseeable future. These increased amounts will be directed towards hiring additional personnel and systems to support the planned growth of our company.

*Interest and Other Income, Net*

	<u>September 30,</u>			
	<u>2005</u>	<u>2004</u>	<u>\$ Change</u>	<u>% Change</u>
	(dollars in thousands)			
Nine months ended	\$ 949	\$ 158	\$ 791	501%
% of revenue	2%	1%		

Interest and other income, net consists primarily of interest income. The increase in net interest income for the nine-month period ended September 30, 2005 compared to the comparable period in 2004 is primarily due to interest earned on the investment of proceeds received from our initial public offering.

*Deferred Stock-Based Compensation*

We have accounted for options granted to employees, officers and directors in accordance with Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), 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 September 30, 2005 related to certain options outstanding as of the date of our IPO, was approximately \$8.4 million, net of terminations, with accumulated amortization of approximately \$6.8 million. The remaining approximately \$1.6 million, net of terminations, will be amortized over the remaining vesting periods of the options, generally four years from the date of grant. As of September 30, 2005, we expect to record amortization expense for deferred stock-based compensation as follows:

Remainder of fiscal year 2005	\$ 370,000
Fiscal year 2006	935,000
Fiscal year 2007	278,000
	<hr/>
Total	\$ 1,583,000
	<hr/>

**Table of Contents**

We have accounted for stock options granted to non-employees on a fair-value basis in accordance with SFAS 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 was \$771,000 and \$831,000 for the nine months ended September 30, 2005 and 2004, respectively. 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.

**Employee Stock Options**

As permitted by SFAS 123, we have elected to use the intrinsic value method prescribed by Accounting Principles Board Opinion No. 25 (APB 25), *Accounting for Stock Issued to Employees*, to measure compensation expense for stock-based awards to employees. Accordingly, we generally recognize no compensation expense with respect to stock-based awards to employees and directors as awards are generally issued with exercise prices equal to the fair value of the common stock on the grant date. Under APB 25, if the exercise price of our employee and director stock options is less than the estimated fair value of the underlying stock on the date of grant, we record deferred compensation for the difference. We report the pro forma information below regarding net loss and net loss per share as if we had accounted for employee stock awards under the fair value method as required by SFAS 123, as amended by Statement of Financial Accounting Standards No. 148 (SFAS 148), *Accounting for Stock-Based Compensation Transition and Disclosure*. The fair value of these stock-based awards to employees was estimated using the Black-Scholes option pricing model, assuming no expected dividends.

The following table illustrates the effect on net loss for the periods presented as if we had applied the fair value recognition provisions of SFAS 123 to its equity-based awards (*in thousands, except per share data*):

	Nine Months Ended	
	September 30,	
	2005	2004
Net loss attributable to common stockholders as reported	\$ (26,141)	\$ (11,449)
Add: Stock-based employee compensation expense included in net loss	1,684	4,099
Deduct: Stock-based employee compensation expense determined under fair value method for all awards	(3,006)	(5,149)
Pro-forma net loss attributable to common stockholders	\$ (27,463)	\$ (12,499)
Basic and diluted net loss per share as reported	\$ (1.08)	\$ (0.89)
Basic and diluted pro forma net loss per share	\$ (1.13)	\$ (0.97)

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123R, *Share-Based Compensation* (SFAS 123R), which supersedes APB 25 and its related implementation guidance. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services through share-based payment transactions. SFAS 123R requires a public entity to measure the cost of employee

## Edgar Filing: NUVASIVE INC - Form 424B4

services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The cost will be recognized over the period during which an employee is required to provide services in exchange for the award. We are currently evaluating the provisions of SFAS 123R and will adopt it in the first quarter of 2006, as required. The adoption of SFAS 123R will have a significant impact on our earnings; however, the adoption will not significantly impact our financial position or cash flows. The table above provides the pro forma net loss and net loss per share as if we had used a fair-value-based method similar to one of the methods permitted under SFAS 123R to measure the compensation expense for employee stock awards during the nine-month periods ended September 30, 2005 and 2004.

## **Table of Contents**

### ***Business Combination and Asset Acquisitions***

On June 3, 2005, we acquired intellectual property and related assets for cervical plate technology from RSB Spine LLC, a privately owned company focused on spine technology, providing us with cervical plate technology that received FDA 510(K) clearance and was first commercialized in 2004. We re-launched the cervical plate under our own product name (the SmartPlate Gradient CLP) in July 2005. On the closing date, we made a cash payment of \$3.8 million and issued 222,929 unregistered shares of our common stock valued at \$3.5 million. Those shares of common stock have since been registered for resale. This asset acquisition transaction and its impact to our consolidated statement of position and results of operations is fully described in Note 5 to the unaudited condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the period ended September 30, 2005, which is incorporated by reference in this prospectus.

On August 4, 2005, we acquired technology and assets from Pearsalls Limited, a privately-owned company based in the United Kingdom (Pearsalls). The acquired assets include an investigational cervical disc replacement device called NeoDisc. Also acquired was all of Pearsalls intellectual property related to embroidery technology for use in surgical implants. We made a closing payment of \$12 million, consisting of \$5 million in cash and \$7 million in unregistered common stock which has since been registered for resale. In addition, the transaction provides for us to make additional milestone payments totaling up to \$31.5 million as progress is made towards FDA approval for marketing of the NeoDisc investigational cervical disc replacement device. Finally, Pearsalls will receive a royalty of 5% on NeoDisc product sales. Additional payments made on attainment of milestones will be charged to research and development expense as incurred. Royalty payments will be charged to sales and marketing expense as incurred. This asset acquisition transaction and its impact to our consolidated statement of position and results of operations is fully described in Note 6 to the unaudited condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the period ended September 30, 2005, which is incorporated by reference in this prospectus.

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

### ***In-Process Research and Development***

We recorded an in-process research and development (IPRD) charge of \$12.9 million related to our acquisition of the technology assets of Pearsalls in the third quarter of 2005. At the date of the acquisition, the projects associated with the IPRD efforts had not yet reached technological feasibility and the research and development in process had no alternative future uses. Accordingly, the amounts were charged to expense on the acquisition date.

*Valuation of IPRD.* The value assigned to acquired in-process technology is determined by identifying products under development in areas for which technological feasibility had not been established. The value of the in-process technology was determined using a discounted cash flow model similar to the income approach, focusing on the income producing capabilities of the in-process technologies. Under this approach, the value is determined by estimating the revenue contribution generated by each of the identified technologies. Revenue estimates were based on (i) individual product revenues; (ii) anticipated growth rates; (iii) anticipated product development and introduction schedules; (iv) product sales cycles; and (v) the estimated life of a product's underlying technology. From the revenue estimates, operating expense estimates, including costs of sales, general and administrative, selling and marketing, and income taxes, were deducted to arrive at operating income. Revenue growth rates were estimated by management for the product by considering relevant market sizes and growth factors, expected industry trends, the anticipated nature and timing of new product introductions by us and our competitors, individual product sales cycles and the estimated life of the product's

underlying technology. Operating expense estimates reflect our historical expense ratios. Additionally, these projects will



## **Table of Contents**

require continued research and development after they have reached a state of technological and commercial feasibility. The resulting operating income stream was discounted to reflect its present value at the date of acquisition.

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

## **Liquidity and Capital Resources**

Since our inception in 1997, we have incurred significant losses and as of September 30, 2005, we had an accumulated deficit of approximately \$104.6 million. We have not yet achieved profitability, and anticipate we will continue to incur net losses for the foreseeable future. We expect 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. 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 \$25.0 million at September 30, 2005 and \$59.2 million at December 31, 2004. The decrease was due primarily to cash used (i) to fund our operations of \$17.1 million, (ii) for the acquisition of assets from RSB Spine LLC and the acquisition of assets from Pearsalls Limited of \$8.8 million in the aggregate, and (iii) for purchases of fixed assets of \$9.3 million.

Net cash used in operating activities was \$17.1 million in the first nine months of 2005 compared to \$8.3 million in the first nine months of 2004. The increase of net cash used in operating activities of \$8.8 million was primarily due to increased inventory purchases to support the launch of nine new or enhanced products in 2005 of \$8.2 million.

Net cash provided by investing activities was \$16.5 million in the first nine months of 2005 compared to \$43.3 million used in the first nine months of 2004. The increase in net cash provided by investing activities is primarily due to increased proceeds from the sale of short-term investments, net of purchases, of \$34.6 million, reduced by our increased investment in fixed assets of \$9.3 million and cash paid for the acquisition of assets from RSB Spine LLC of \$3.8 million and from Pearsalls Limited of \$5.0 million.

Net cash provided by financing activities was \$1.0 million in the first nine months of 2005 compared to \$64.2 million in the first nine months of 2004. The decrease in 2005 is primarily due to the net proceeds from the initial public offering of \$68.1 million offset by payments on notes payable of \$6.1 million, both in the 2004 period.

We believe our current cash and cash equivalents, excluding the proceeds from this 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.



## **Table of Contents**

### **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 for lumbar and cervical spine fusion, a market estimated to exceed \$2.9 billion in the U.S. in 2005. Our principal product offering includes a minimally disruptive surgical platform called Maximum Access Surgery, or MAS, as well as classic fusion implants. Our products are used predominantly in spine fusion surgeries, both to enable access to the spine and to perform restorative and fusion procedures. We also focus significant efforts on our research and development pipeline emphasizing both MAS and motion preservation products such as total disc replacement and nucleus-like cervical disc replacement. As of December 31, 2005, we have trained 724 surgeons in the use of our products.

Our MAS platform combines three categories of our product offerings:

NeuroVision a proprietary software-driven nerve avoidance system;

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

specialized implants, like our SpheRx pedicle screw system, CoRoent suite of implants and new ExtenSure dynamic stabilization and fusion system.

We believe our MAS platform provides a unique and comprehensive solution for safe and reproducible minimally disruptive surgical treatment of spine disorders by enabling surgeons to access the spine in a manner that affords direct visibility and avoidance of critical nerves. Our MAS platform enables a variety of spine surgery procedures and also uniquely enables an innovative procedure known as extreme lateral interbody fusion, or XLIF, in which surgeons access the spine from the side of the patient's body, rather than from the front or back of the body. Our MaXcess instruments provide access to the spine in a manner that affords direct visibility and our NeuroVision system allows surgeons to avoid critical nerves. We believe that the procedures facilitated by our MAS platform reduce operating times, decrease trauma and blood loss, and lead to faster overall patient recovery times.

Our classic fusion portfolio is comprised of a range of products, including proprietary saline-packaged bone allografts, which are human bone that has been processed and precision shaped for transplant. Our classic fusion portfolio also includes fusion plates such as our SmartPlate Gradient CLP.

In 2005, we relocated to a 62,000 square foot, state-of-the-art facility, which has a six-suite cadaver operating theatre as well as warehousing and distribution capabilities. We believe our new facility positions us for continued momentum in surgeon training and adoption of our products.

#### **Developments Since Our IPO**

Since our IPO, we have introduced twelve new products and product enhancements that have significantly upgraded our MAS platform and increased our revenue opportunities for each surgery performed using our products. We have also acquired complementary and strategic assets and technology. We believe that our NeuroVision and MaXcess products have generated significant surgeon interest and help to create pull-through of our newly-launched products, which include:

*SpheRx Dual Ball Rod (DBR)* a pedicle screw system that allows for instrument-free compression of the vertebrae, minimizes the incidence of tissue trauma associated with rod-overhang and effects secure rod placement with minimal rod migration.

*SpheRx Pedicle Screw System* a pedicle screw system designed for a posterior approach involving a minimally disruptive procedure.

## Table of Contents

*SmartPlate Gradient CLP* a dynamic cervical plate that encompasses a gradient locking mechanism enabling the screws to be progressively resistant to axial compression. This allows the plate to settle in concert with the eventual allograft implant settling that occurs within the disc space over time, offering a better anatomical fit.

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

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

*ExtenSure* an interspinous dynamic stabilization and fusion system. This device utilizes an allograft implant to maintain decompression through a more natural restoration of the spinal anatomy. ExtenSure was officially launched with limited availability in September 2005 and we anticipate a full launch in mid-2006.

*Insulated Pedicle Access System (I-PAS)* a surgical instrument used in conjunction with NeuroVision to determine the safe, percutaneous approach pathway of a pedicle screw prior to its implantation. I-PAS is the first percutaneous and dynamic neurophysiologic system on the market to continuously monitor and alleviate the risk of neurological injury during pedicle screw placement.

*CoRoent Large Tapered, CoRoent Large Contoured and CoRoent XLR* implants designed in response to the demand from spine surgeons for implants with superior anatomical fit that are simple to position and align. The CoRoent Large Tapered system is designed to be inserted using a patented Insert and Rotate technique, which minimizes damage to the surrounding bone. This procedure allows the surgeon to restore height and stability of the spine. Each of these CoRoent products are made of PEEK OPTIMA(R), a biocompatible polymer commonly used in implantable devices.

*NeuroVision Nerve Root Retractor* an instrument that combines stimulated and free run electromyography (EMG) to monitor spinal nerves and alert the surgeon of physiologic changes intraoperatively during nerve retraction.

*NeuroVision* we have made significant enhancements to our NeuroVision nerve avoidance system in the form of a software upgrade and improved nerve monitoring capabilities. The software upgrade incorporates a new graphical user interface that allows for greater ease of use by the surgical staff. NeuroVision has also been given a new harness and dual electrodes, or redesigned connectors, to streamline the application of surface electrodes that relay muscle activity to the monitoring system.

In addition, we filed for two Investigational Device Exemptions with respect to cervical spine devices currently under development. The first of these is NeoDisc, a nucleus-like cervical disc replacement device designed to preserve motion in the cervical region of the spine and fill the gap between pre-surgical treatment and total disc replacement (TDR) or spinal fusion. We believe that NeoDisc could be attractive for use in broad indications and pathologies because it is easily revisable and is intended to involve a relatively simple surgical placement procedure. The second is CerPass, our cervical TDR device, which incorporates a ceramic-on-ceramic design that we believe will achieve superior long-term wear characteristics compared to that of other bearing surfaces. CerPass also has a self-centering feature, designed to ensure proper placement.

## **Table of Contents**

### **Our Strategy**

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

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

*Continue to Introduce New Creative Products.* One of our core competencies is our ability to develop and commercialize creative spine surgery products. Since our IPO, we have introduced twelve new products and product enhancements. We have several additional products currently under development, including total disc and nucleus-like replacement devices, MAS platform expansion products and other implants designed to stabilize the spine. We believe that these additional products will allow us to generate, on average, greater revenues per spine surgery procedure while improving patient care.

*Establish Exclusive Sales Force with Broad Reach.* We believe that having a sales force dedicated to selling only our spine surgery products is critical to achieve continued growth across product lines, greater market penetration and increased sales. To that end, we have initiated a process to create an exclusive sales force comprised partially of Area Business Managers, or ABMs, who are NuVasive employees responsible for a defined territory. The remainder of the sales force will be exclusive independent distributors, each acting as our sole representative in a given territory.

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

*Selectively License or Acquire Complementary Spine Products and Technologies.* In addition to building our company through internal product development efforts, we intend to selectively license or acquire complementary products and technologies. By acquiring complementary products, we believe we can leverage our expertise at bringing new products to market and provide additional selling opportunities for our sales force. Since our IPO, we have acquired complementary and strategic assets, including cervical plate technology, which we re-launched as our SmartPlate Gradient CLP product, surgical embroidery technology, including an investigational nucleus-like cervical disc replacement device called NeoDisc, and dynamic stabilization technology, which we launched as our ExtenSure product.

### **Industry Background**

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 exceed \$2.9 billion by the end of 2005.

## Edgar Filing: NUVASIVE INC - Form 424B4

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,

## **Table of Contents**

trauma and tumors. The largest market and the focus of our business is degenerative conditions of the facet joints and disc space. These conditions can result in instability and pressure on the nerve roots as they exit the spinal column, causing back pain or radiating pain in the arms or legs.

The prescribed treatment for spine disorders depends on the severity and duration of the disorder. Initially, physicians will prescribe non-operative procedures including bed rest, medication, lifestyle modification, exercise, physical therapy, chiropractic care and steroid injections. In most cases, non-operative treatment options are effective; however, many patients require spine surgery. It is estimated that in excess of one million patients undergo spine surgery each year in the United States. The most common spine surgery procedures are: discectomy, the removal of all or part of a damaged disc; laminectomy, the removal of all or part of a lamina, or thin layer of bone, to relieve pinching of the nerve and narrowing of the spinal canal; and fusion, where two or more adjoining vertebrae are fused together to provide stability. All three of these procedures require access to the spine. Traditional open surgical approaches require large incisions to be made in the back so that surgeons can see the spine and surrounding area. Most open procedures are invasive, lengthy and complex, and may result in significant blood loss, extensive dissection of tissue and lengthy hospitalization and rehabilitation.

### **Minimally Invasive Surgical Procedures**

The benefits of minimally invasive surgery procedures in other areas of orthopedics have significantly contributed to the strong and growing demand for minimally invasive surgery of the spine. Surgeons and hospitals seek spine procedures that result in fewer operative complications, shorter surgery times and decreased hospitalization. At the same time, patients seek procedures that cause less trauma and allow for faster recovery times. Despite these benefits, the rate of adoption of minimally invasive surgical procedures has been relatively slow with respect to the spine.

We believe the two principal factors contributing to spine surgeons' slow adoption of minimally invasive alternatives are: (1) the limited or lack of direct access to 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.

### **The NuVasive Solution Maximum Access Surgery (MAS)**

Our MAS platform allows surgeons to perform a wide range of minimally disruptive procedures, while overcoming the shortcomings of alternative minimally invasive surgical techniques. We believe our products improve clinical results and have both the potential to expand the number of minimally disruptive procedures performed and become a standard of care in spine fusion and non-fusion surgery.

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



## Edgar Filing: NUVASIVE INC - Form 424B4

We believe procedures enabled by our MAS platform have 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. A study of 145 XLIF procedures performed in 2003 and 2004 supports our belief that our MAS platform provides the following benefits:

*Reduced Surgery Times.* XLIF procedures utilizing our MAS platform, which we refer to as MAS XLIF, have averaged about 70 minutes to perform which we believe is substantially shorter than it takes to perform an equivalent open procedure.

## **Table of Contents**

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

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

## **Development Projects**

We are developing proprietary total disc replacement devices for lateral lumbar spine applications and separately for cervical spine applications. These devices are intended to allow surgeons to address a patient's pain and dysfunction while maintaining normal range of motion and avoiding future adjacent level degeneration that often occurs after spine fusion. We believe that the ability to insert a lumbar total disc replacement device from a lateral approach in a MAS procedure will be unique to us, but will require premarket approval rather than 510(k) clearance. Our total disc replacement devices are currently undergoing biomechanical testing. We have filed several patent applications on these devices and we filed for an Investigational Device Exemption with the FDA with respect to our cervical total disc replacement investigational device called CerPass in June 2005.

We are also developing surgical embroidery technology that we acquired from Pearsalls Limited in August 2005, including an investigational nucleus-like cervical disc replacement device called NeoDisc that is designed to preserve motion in the cervical region of the spine and fill the gap between pre-surgical treatment and total disc replacement or spinal fusion. NeoDisc will also require pre-market approval from the FDA. In October 2005, we filed for an Investigational Device Exemption with respect to NeoDisc.

## **Sales and Marketing**

We currently sell our products through a combination of independent sales agencies and direct sales representatives employed by us. We historically sold our products through independent sales agencies that were also free to promote the sale of competitive products. We are in the process of creating a sales force that is entirely exclusive to us in the sale of spine surgery products. Our efforts will result in a sales force comprised partially of Area Business Managers, or ABMs, who are NuVasive employees responsible for a defined territory. The remainder of the sales force will be exclusive independent distributors, each acting as our sole representative in a given territory. The determination of whether to engage an ABM or exclusive distributor is made on a territory by territory basis, with a focus on the candidate who brings the best skills, experience and contacts. Our sales force is managed by a Senior Vice President of U.S. Sales and four Divisional Sales Directors, or DSDs. Each DSD is responsible for a portion of the United States and manages the ABMs and independent distributors engaged in that territory.

We believe the transition to an exclusive sales force is important to our continued growth as this effort will result in a focused sales force with incentives to sell our products across all product lines. As of December 31, 2005, approximately 60% of our sales force exclusively sells our spine surgery products.

## **Surgeon Training and Education**

## Edgar Filing: NUVASIVE INC - Form 424B4

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 theatre and training facility at our corporate headquarters to help promote adoption of our products. In 2005, we trained 422 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.

## **Table of Contents**

### **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 intended to ensure that all product requirements are met or exceeded. We believe these manufacturing relationships minimize our capital investment, help control costs, and allow us to compete with larger volume manufacturers of spine surgery products.

Following the receipt of products or product components from our third-party manufacturers, we conduct inspection and packaging and labeling, as needed, at 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.

### **Loaner Equipment**

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 platform and classic fusion loaner equipment that we loan to or place with hospitals continues to increase as we expand our distribution channels and increase market penetration of our products. These loaners are important to the growth of our business and we anticipate additional investments in our loaner inventory.

### **Competition**

We are aware of a number of major medical device companies that have developed or plan to develop products for minimally invasive spine surgery in each of our current and future product categories.

Our currently marketed products are, and any future products we commercialize will be, subject to intense competition. Many of our current and potential competitors have substantially greater financial, technical and marketing resources than we do, and they may succeed in developing products that would render our products obsolete or noncompetitive. In addition, many of these competitors have significantly greater operating history and reputations than we do in their respective fields. Our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, receive adequate reimbursement and are safer, less invasive and less expensive than alternatives available for the same purpose. Because of the size of the potential market, we anticipate that companies will dedicate significant resources to developing competing products. Below are our primary competitors grouped by our product categories.

Our NeuroVision system competes with the conventional nerve monitoring systems offered by Nicolet Biomedical and Axon Systems. We believe our system competes favorably with Nicolet's and Axon's systems on both price and ease of use for the spine surgeon. In addition, neither Nicolet's nor Axon's systems were designed to support surgeon directed applications. Sofamor Danek, a Medtronic company, has 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

## Edgar Filing: NUVASIVE INC - Form 424B4

by DePuy Spine, Inc., a Johnson & Johnson company, Medtronic Sofamor Danek and Stryker Spine.

Competition is intense in the fusion product market. We believe that our most significant competitors are Medtronic Sofamor Danek, DePuy Spine 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. Our differentiation in the market is based on packaging the allograft in a saline solution, which allows the product to be used immediately and does not require specialized handling.

## **Table of Contents**

We also face competition from a growing number of smaller companies with more limited product offerings and geographic reach. These companies, who represent intense competition in specified markets, include Abbott Spine, Inc. (an Abbott Laboratories company), Blackstone Medical, Inc., Alphatec Spine Inc., Scient x USA, Inc., OsteoTec Ltd, and others.

## **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.

For a discussion of the FDA regulations applicable to our business, please see our 2004 Annual Report on Form 10-K, which is incorporated by reference in this prospectus.

## **Legal Proceedings**

As described in our Quarterly Reports on Form 10-Q for the periods ending June 30, 2005 and September 30, 2005, we are involved in a series of related lawsuits involving families of decedents who donated their bodies through UCLA's willful body program. This litigation is still ongoing. The complaint alleges that the head of UCLA's willful body program, Henry G. Reid, and a third party, Ernest V. Nelson, improperly sold some of the donated cadavers to the defendants (including NuVasive). Plaintiffs allege the following causes of action: (i) breach of fiduciary duty, (ii) negligence, (iii) fraud, (iv) negligent misrepresentation, (v) negligent infliction of emotional distress, (vi) intentional infliction of emotional distress, (vii) intentional interference with human remains, (viii) negligent interference with human remains, (ix) violation of

## Edgar Filing: NUVASIVE INC - Form 424B4

California Business and Professions Code Section 17200 and (x) injunctive and declaratory relief.

Since the filing of our Quarterly Report on Form 10-Q for the period ended September 30, 2005, a hearing was held on December 13, 2005, at which the defendants (including NuVasive) challenged the plaintiff's master complaint. The court has not yet issued a ruling with respect to those challenges. Although the outcome of this lawsuit cannot be determined with certainty, we believe that we acted within the relevant law in procuring the cadavers for our clinical research and intend to vigorously defend ourselves against the claims contained in the complaint.

In addition, we are subject to certain legal actions that have arisen in connection with our transition to an exclusive sales force. One former independent distributor of our products, Synergy Orthopedic Products, LLC, has filed a claim for damages with respect to our termination of our business relationship with it. This case was filed on December 20, 2005, in the Superior Court of California, County of Orange. In addition, one potential distributor, nuSpine Medical Technologies, Inc., with whom we engaged in negotiations regarding a distributorship has filed a claim for damages. This case was filed on January 6, 2006, in the Franklin County Common Pleas Court, Columbus, Ohio. We intend to vigorously defend ourselves against the claims contained in these complaints and we believe that we acted within the relevant law in terminating our relationships and/or negotiations with the plaintiffs. Although the outcomes of these lawsuits cannot be determined with certainty, we believe that the ultimate outcomes will not have a significant adverse effect on our business, financial condition or results of operations.

**Table of Contents****MANAGEMENT**

Set forth below are the name, age, position, and a brief account of the business experience of each of our executive officers, significant employees and directors as of December 31, 2005.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Alexis V. Lukianov	50	Chairman of the Board and Chief Executive Officer
Keith Valentine	38	President
Kevin C. O Boyle	49	Executive Vice President and Chief Financial Officer
Patrick Miles	40	Senior Vice President of Marketing
Jeffrey P. Rydin	39	Senior Vice President of U.S. Sales
Jason M. Hannon	33	Vice President of Legal Affairs and Secretary
James J. Skinner	44	Vice President of Strategic Sales Development
Jonathan D. Spangler	38	Vice President and Chief Patent Counsel
G. Bryan Cornwall, Ph.D., P.Eng.	41	Vice President of Research and Development
Jack R. Blair(1)(3)	63	Director
James C. Blair, Ph.D.(2)(3)	66	Director
Peter C. Farrell, Ph.D., AM(3)	63	Director
Lesley H. Howe(1)	61	Director
Robert J. Hunt(1)(2)	56	Director
Hansen A. Yuan, M.D.(2)(3)	62	Director

- (1) Member of audit committee  
(2) Member of compensation committee  
(3) Member of nominating and corporate governance committee

*Alexis V. Lukianov* has served as our Chief Executive Officer, and as one of our directors since July 1999, and as Chairman of our board of directors since February 2004. Mr. Lukianov has over 25 years of experience in the orthopedic industry with 20 years in senior management. From April 1996 to April 1997, Mr. Lukianov was a founder of and served as Chairman of the Board and Chief Executive Officer of BackCare Group, Inc., a spine physician practice management company. From January 1990 to October 1995, Mr. Lukianov held various positions with Sofamor Danek USA, Inc., a developer and manufacturer of medical devices to treat disorders of the cranium and spine, and a subsidiary of Medtronic, Inc., a publicly traded medical technology company, and various of its predecessor entities, including as their Vice President, Marketing, Senior Vice President, Sales and Marketing, Executive Vice President, Global Corporate Development, and President. Mr. Lukianov also serves as a member of the board of directors of California Healthcare Institute, a non-profit public policy research organization.

*Keith Valentine* has served as our President since December 2004. Between January 2002 and December 2004 he served as our Executive Vice President. Prior to that, he served as our Vice President of Marketing from January 2001 to January 2002. From January 2000 to December 2000, Mr. Valentine served as Vice President of Marketing at ORATEC Interventions, Inc., a medical device company which was acquired by Smith & Nephew plc, also a medical device company, in 2002. From January 1992 to January 2000, Mr. Valentine served in various capacities at Medtronic Sofamor Danek USA, Inc., including Vice President of Marketing for the Rods Division and Group Director for the BMP Biologics program, the Interbody Sales Development effort and International Sales and Marketing. Mr. Valentine received a B.B.A. in Management and Biomedical Sciences from Western Michigan University.

*Kevin C. O Boyle* has served as our Executive Vice President since December 2004 and as our Chief Financial Officer since January 2003. From December 1996 to December 2002, Mr. O Boyle served in various positions at ChromaVision Medical Systems, Inc., a publicly traded medical device firm specializing in the oncology market, including as its Chief Financial Officer and Chief Operating Officer. From December



## Edgar Filing: NUVASIVE INC - Form 424B4

1989 to November 1996, Mr. O Boyle held various positions with Albert Fisher North America, Inc., a \$1 billion publicly traded international food company, including Chief Financial Officer and Senior Vice President of Operations. Mr. O Boyle is a CPA and received a B.S. in Accounting from the Rochester Institute of Technology

## **Table of Contents**

and successfully completed the Executive Management Program at the University of California at Los Angeles John E. Anderson Graduate Business School.

*Patrick Miles* has served as our Senior Vice President of Marketing since December 2004. Prior to that he served as our Vice President, Marketing from January 2001 to December 2004. From April 2000 to January 2001, Mr. Miles served as Director of Marketing for ORATEC Interventions, Inc., a medical device company. From June 1997 to March 2000, he served as Director of Marketing for Minimally Invasive Systems and Cervical Spine Systems for Medtronic Sofamor Danek USA, Inc. Mr. Miles received a B.S. in Finance from Mercer University.

*Jeffrey Rydin* has served as our Senior Vice President of U.S. Sales since December 2005. Prior to joining us, from January 2003 to December 2005, Mr. Rydin served as Area Vice President for DePuy Spine, Inc., a global designer, manufacturer and supplier of spinal devices and subsidiary of Johnson & Johnson, and as such he was responsible for building DePuy's Southeastern U.S. sales team. From December 2001 to January 2003, Mr. Rydin served as Vice President of Sales at Orquest, Inc., a developer of biologically-based implants for orthopaedics and spine surgery, which was acquired by DePuy in January 2003. From April 2000 to December 2001, Mr. Rydin served as Director of Sales at Symphonix Devices, Inc., a hearing technology company. From October 1996 to March 2000, he served as Director of Sales at General Surgical Innovations, Inc., a developer, manufacturer, and marketer of tissue dissection systems for minimally invasive surgical procedures, which was acquired by Tyco International Ltd. in November 1999. Mr. Rydin holds a B.A. in Social Ecology from the University of California, Irvine.

*Jason M. Hannon* has served as our Vice President of Legal Affairs and Secretary since June 2005. From February 2003 to April 2005, Mr. Hannon practiced corporate law at the law firm of Heller Ehrman LLP, specializing in mergers and acquisitions, public and private financing, licensing arrangements and corporate governance matters. From September 1999 to February 2003, Mr. Hannon practiced law at the law firm of Brobeck Phleger & Harrison LLP where he had a similar corporate practice. Mr. Hannon also served as a law clerk to the Honorable Jerome Farris of the U.S. Court of Appeals of the Ninth Circuit. Mr. Hannon is licensed to practice law in the State of California. Mr. Hannon received a B.A. degree from the University of California at Berkeley and a J.D. from Stanford Law School.

*James J. Skinner* has served as our Vice President of Strategic Sales Development since December 2005. Prior to that he served as our Vice President, Sales from January 2004 to December 2005. From August 2002 to December 2003, he served as Vice President of Sales for Surgicon, Inc., a medical device manufacturer. From November 2001 to July 2002, he served as Senior Director, Neurosurgery Applications at Stereotaxis, Inc., a medical technology company. From 1994 to April 2001, Mr. Skinner served in various capacities at Medtronic Sofamor Danek USA, Inc., including as a Regional Sales Director for Spinal Implants and Group Director of Sales of Surgical Navigation Technologies. Mr. Skinner received a B.S. in Biology from Northeastern Illinois University.

*Jonathan D. Spangler* has served as our Chief Patent Counsel since September 2001 and our Vice President since December 2004. From August 1999 to August 2001, he served as Chief Patent Counsel for A-Med Systems, Inc., a privately held medical technology company. From September 1997 to July 1999, Mr. Spangler practiced law at the law firm of Arnold White & Durkee, specializing in patent and trade secret litigation involving medical devices. From June 1995 to September 1997, Mr. Spangler practiced with the law firm of Haugen & Nikolai, specializing in patent prosecution involving medical devices. Mr. Spangler also worked at the U.S. Patent and Trademark Office as an entry level examiner. Mr. Spangler is licensed to practice law in the States of California and Minnesota and before the U.S. Patent and Trademark Office. Mr. Spangler received a B.S. degree in Biomedical Engineering from Marquette University and a J.D. from the University of Dayton School of Law.

*G. Bryan Cornwall, Ph.D., P.Eng.*, has served as our Vice President of Research and Development since January 2004. He also served in various capacities with us from April 1999 to February 2000, including as a Manager of Research and as a Project Engineer. Prior to re-joining us, from February 2000 to January 2004, Dr. Cornwall served in various capacities at MicroPore Biosurgery, Inc., a developer and manufacturer of medical devices and therapies, including as its Vice President of Research & Technology and as a Director of



## **Table of Contents**

Research. From February 1998 to April 1999, Dr. Cornwall served as Senior Product Engineer at DePuy ACE, Inc., a designer and manufacturer of orthopedic trauma devices and a subsidiary of Johnson & Johnson Corporation, a manufacturer of healthcare and hygiene products. Dr. Cornwall received a B.S. in Mechanical Engineering, a Masters of Applied Science in Material Science and a Ph.D. in Mechanical Engineering specializing in Orthopaedic Biomechanics from Queen's University, Ontario, Canada.

*Jack R. Blair* has served as a member of our board of directors since August 2001. From 1980 until his retirement in 1998, Mr. Blair served in various capacities with Smith & Nephew, Inc. and Richards Medical Company, which was acquired by Smith & Nephew in 1986, most recently as group president of its North and South America and Japan operations from 1986 to 1998. From 1982 to 1986, he held the position of President of Richards Medical Company. Mr. Blair currently serves as chairman of the board of directors of dj Orthopedics, Inc., a medical device company, as well as a privately-held orthopedic company and a privately-held specialty chemicals company. Mr. Blair also serves as a director/trustee of the open-end and closed-end funds in the Regions Morgan Keegan funds complex; three of these funds, RMK High Income Fund Inc., RMK Advantage Income Fund, Inc. and RMK Strategic Income Fund Inc., are publicly traded investment companies. Mr. Blair holds a B.A. in Government from Miami University and an M.B.A. from the University of California, Los Angeles.

*James C. Blair, Ph.D.* has served as a member of our board of directors since December 1999. Since 1985, he has served as a partner and managing member of Domain Associates, L.L.C., a venture capital management company focused on life sciences. Dr. Blair also serves on the board of directors of Pharmion Corporation, as well as several privately-held healthcare companies. Dr. Blair currently serves as an advisor to the Department of Molecular Biology at Princeton University and an advisor to the Department of Bioengineering at the University of Pennsylvania. He received a B.S.E. degree from Princeton University and an M.S.E. and Ph.D. degrees from the University of Pennsylvania.

*Peter C. Farrell, Ph.D., AM* has served as a member of our board of directors since January 2005. Dr. Farrell is founding Chairman and Chief Executive Officer of ResMed, Inc., a leading developer and manufacturer of medical equipment for the diagnosis and treatment of sleep-disordered breathing. Dr. Farrell holds bachelor and masters degrees in chemical engineering from the University of Sydney and the Massachusetts Institute of Technology, a Ph.D. in bioengineering from the University of Washington, Seattle and a Doctor of Science from the University of New South Wales for research related to dialysis and renal medicine.

*Lesley H. Howe* has served as a member of our board of directors since February 2004. Mr. Howe has over 35 years of experience in accounting, finance and business management within a variety of industries. From December 2001 to present, he has served as Chief Executive Officer of Consumer Networks LLC, a San Diego-based Internet marketing and promotions company. From 1997 to December 2001, Mr. Howe was an independent financial and business consultant advising clients on acquisition due diligence and negotiation strategies, as well as financing strategies. From 1974 to 1997, he was an audit partner of KPMG Peat Marwick LLP, an international accounting and auditing firm, and had been employed by KPMG since 1967. He served as area managing partner/managing partner of the Los Angeles office of KPMG from 1994 to 1997. Mr. Howe currently serves on the board of directors of P.F. Chang's China Bistro, Inc., an owner and operator of restaurants, and dj Orthopedics, Inc., a medical device company. Mr. Howe received a B.S. in business administration from the University of Arkansas.

*Robert J. Hunt* has served as a member of our board of directors since January 2005. Mr. Hunt is the co-founder of the Mercury Investment Group, an investment advisory firm established in 2002. Mr. Hunt also oversaw the finance team at AutoZone, Inc., for eight years, serving as Executive Vice President and Chief Financial Officer and Director prior to his retirement in 2002. Mr. Hunt previously held senior financial management positions at The Price Company, Malone & Hyde, Inc. and PepsiCo, Inc. He has also served as a director of SCB Computer Technology, Inc. Mr. Hunt holds bachelor and masters degrees from Columbia University and is a certified public accountant.

*Hansen Yuan, M.D.* has served as a member of our board of directors since September 2005. Dr. Yuan has been a Professor of Orthopedic and Neurological Surgery at the State University of New York, Upstate Medical University in Syracuse, New York since 1990. Dr. Yuan also served as President of the North American Spine



**Table of Contents**

Society (NASS) from 1995 to 1996 and Second Vice President of NASS from 1993 to 1995. Dr. Yuan has served on the Associate Editorial Board at The Spine Journal since 2002 and the Department of Health and Human Services Orthopedic and Rehabilitation Devices Panel since 1994. Dr. Yuan holds an M.D. from the University of Michigan Medical School.

**Table of Contents****SELLING STOCKHOLDERS**

The following table sets forth the names of the selling stockholders, the number of shares of common stock owned by the selling stockholders immediately prior to the date of this prospectus and the number of shares to be offered by the selling stockholders pursuant to this prospectus. The table also provides information regarding the beneficial ownership of our common stock by the selling stockholders as adjusted to reflect the assumed sale of all of the shares offered under this prospectus, excluding shares that may be sold to the underwriters upon exercise of their option to purchase additional shares. Percentage of beneficial ownership before this offering is based on 25,105,950 shares of our common stock outstanding as of December 31, 2005. Beneficial ownership is based on information furnished by the selling stockholders. Unless otherwise indicated and subject to community property laws where applicable, the selling stockholders named in the following table have, to our knowledge, sole voting and investment power with respect to the shares beneficially owned by them.

Selling Stockholders	Beneficial Ownership		Number of Shares Offered	Beneficial Ownership	
	Before Offering(1)			After Offering(1)	
	Number	Percent		Number	Percent
William Blair Capital Partners VII QP, L.P.(2)(3)	766,344	3.05%	766,344	*	
William Blair Capital Partners VII, L.P.(2)(3)	29,536	*	29,536	*	

\* Beneficial ownership is less than 1%.

- (1) Beneficial ownership and percentage ownership are determined in accordance with the rules of the Securities and Exchange Commission. In calculating the number of shares beneficially owned and the percentage ownership of a selling stockholder, shares underlying options held by the selling stockholder that are either currently exercisable or exercisable within 60 days from December 31, 2005 are deemed outstanding. These shares, however, are not deemed outstanding for the purpose of computing the percentage ownership of any other selling stockholder.
- (2) William Blair Capital Management VII, L.L.C. is the general partner of William Blair Capital Management VII, L.P., which is the general partner of William Blair Capital Partners VII QP, L.P. (WBCP VII QP) and William Blair Capital Partners VII, L.P. (WBCP VII). William Blair Capital Management VII, L.L.C., through a seven-person board of managers composed of certain of its members, has voting and dispositive authority over the shares held by WBCP VII QP and WBCP VII. Decisions of the board of managers are made by a majority vote of its members and, as a result, no single member of the board of managers has voting or dispositive authority over the shares. Arda M. Minocherhomjee, Ph.D., Robert D. Blank, Timothy Burke, David G. Chandler, John Ettelson, Robert P. Healy and Timothy M. Murray are the members of the board of managers and each disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein. Dr. Minocherhomjee served as a member of our board of directors from May 2001 to September 2005. His resignation from our board did not involve any disagreement with us.
- (3) This selling stockholder is an affiliate of a broker-dealer and purchased the shares being registered for resale in the ordinary course of business. At the time of the purchase of such shares, this selling stockholder had no agreements or understandings, directly or indirectly, with any person to distribute the shares.

**Table of Contents****UNDERWRITING**

We and the selling stockholders are offering the shares of common stock described in this prospectus through a number of underwriters. Banc of America Securities LLC, Lehman Brothers Inc., Thomas Weisel Partners LLC and William Blair & Company, L.L.C. are the representatives of the underwriters. We and the selling stockholders have entered into a firm commitment underwriting agreement with the representatives. Subject to the terms and conditions of the underwriting agreement, we and the selling stockholders have agreed to sell to the underwriters, and each underwriter has agreed to purchase, the number of shares of common stock listed next to its name in the following table:

<b><u>Underwriter</u></b>	<b><u>Number of Shares</u></b>
Banc of America Securities LLC	2,625,000
Lehman Brothers Inc.	2,625,000
Thomas Weisel Partners LLC	1,350,000
William Blair & Company, L.L.C.	750,000
Stanford Group Company	150,000
<b>Total</b>	<b>7,500,000</b>

The underwriting agreement is subject to a number of terms and conditions and provides that the underwriters must buy all of the shares if they buy any of them. The underwriters will sell the shares to the public when and if the underwriters buy the shares from us and the selling stockholders.

The underwriters initially will offer the shares to the public at the price specified on the cover page of this prospectus. The underwriters may allow a concession of not more than \$0.6064 per share to selected dealers. If all the shares are not sold at the public offering price, the underwriters may change the public offering price and the other selling terms. The common stock is offered subject to a number of conditions, including:

receipt and acceptance of the common stock by the underwriters; and

the underwriters' right to reject orders in whole or in part.

*Option to Purchase Additional Shares.* We have granted the underwriters an option to buy up to 1,125,000 additional shares of our common stock at the same price per share as they are paying for the shares shown in the table above. These additional shares would cover sales of shares by the underwriters which exceed the total number of shares shown in the table above. The underwriters may exercise this option at any time within 30 days after the date of this prospectus. To the extent that the underwriters exercise this option, each underwriter will purchase additional shares from us in approximately the same proportion as it purchased the shares shown in the table above. If purchased, the additional shares will be sold by the underwriters on the same terms as those on which the other shares are sold. We will pay the expenses associated with the exercise of this option.

*Discount and Commissions.* The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us and by the selling stockholders. These amounts are shown assuming no exercise and full exercise of the underwriters' option



Edgar Filing: NUVASIVE INC - Form 424B4

to purchase additional shares.

We estimate that the total expenses of the offering to be paid by us, not including underwriting discounts and commissions, will be approximately \$325,000.

	Paid by Us		Paid by the Selling Stockholders	
	No Exercise	Full Exercise	No Exercise	Full Exercise
Per Share	\$ 1.0106	\$ 1.0106	\$ 1.0106	\$ 1.0106
Total	\$ 6,775,184	\$ 7,912,109	\$ 804,316	\$ 804,316

*Listing.* Our common stock is quoted on the Nasdaq National Market under the symbol NUVA.

**Table of Contents**

*Stabilization.* In connection with this offering, the underwriters may engage in activities that stabilize, maintain or otherwise affect the price of our common stock, including:

stabilizing transactions;

short sales;

syndicate covering transactions;

imposition of penalty bids; and

purchases to cover positions created by short sales.

Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of our common stock while this offering is in progress. Stabilizing transactions may include making short sales of our common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock from us or on the open market to cover positions created by short sales. Short sales may be covered shorts, which are short positions in an amount not greater than the underwriters' option referred to above, or may be naked shorts, which are short positions in excess of that amount. Syndicate covering transactions involve purchases of our common stock in the open market after the distribution has been completed in order to cover syndicate short positions.

The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option.

A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchased in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The representatives also may impose a penalty bid on underwriters and dealers participating in the offering. This means that the representatives may reclaim from any syndicate members or other dealers participating in the offering the underwriting discount, commissions or selling concession on shares sold by them and purchased by the representatives in stabilizing or short covering transactions.

These activities may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result of these activities, the price of our common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence the activities, they may discontinue them at any time. The underwriters may carry out these transactions on the Nasdaq National Market, in the over-the-counter market or otherwise.

## Edgar Filing: NUVASIVE INC - Form 424B4

*Market Making.* In connection with this offering, some underwriters and any selling group members who are qualified market makers on the Nasdaq National Market may engage in passive market making transactions in our common stock on the Nasdaq National Market. Passive market making is allowed during the period when the SEC's rules would otherwise prohibit market activity by the underwriters and dealers who are participating in this offering. Passive market making may occur during the business day before the pricing of this offering, before the commencement of offers or sales of the common stock. A passive market maker must comply with applicable volume and price limitations and must be identified as a passive market maker. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for our common stock; but if all independent bids are lowered below the passive market maker's bid, the passive market maker must also lower its bid once it exceeds specified purchase limits. Net purchases by a passive market maker on each day are limited to a specified percentage of the passive market maker's average daily trading volume in our common stock during the specified period and must be discontinued when that limit is reached. Passive market making

## **Table of Contents**

may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of those transactions. The underwriters and dealers are not required to engage in a passive market making and may end passive market making activities at any time.

*Lock-up Agreements.* We, our directors and executive officers, and the selling stockholders have entered into lock-up agreements with the underwriters. Under these agreements, subject to exceptions (including an exception for periodic sales by our executive officers of shares of our common stock pursuant to Rule 10b5-1 trading plans adopted by such officers prior to the date of their respective lock-up agreement), we may not issue any new shares of common stock, and our directors and executive officers and the selling stockholders may not, directly or indirectly, offer, sell, contract to sell, pledge or otherwise dispose of or hedge any common stock or securities convertible into or exchangeable for shares of common stock, or publicly announce the intention to do any of the foregoing, without the prior written consent of Banc of America Securities LLC for a period of 90 days from the date of this prospectus. This consent may be given at any time without public notice. In addition, during this 90-day period, we have also agreed not to file any registration statement for, and each of our directors and executive officers and the selling stockholders have agreed not to make any demand for, or exercise any right of, the registration of, any shares of common stock or any securities convertible into or exchangeable for common stock without the prior written consent of Banc of America Securities LLC. This 90-day restrictive period may be extended if, during the last 17 days of the 90-day period, we issue an earnings release or material news or a material event relating to us occurs or, prior to the expiration of the 90-day period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 90-day period. In these cases, the restrictions described above will apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event. Banc of America Securities LLC has agreed that it will not, without the prior written consent of Lehman Brothers, exercise its consent to release shares from the lock-up agreements or allow the filing of (or demand for) a registration statement.

*Indemnification.* We and the selling stockholders will indemnify the underwriters against some liabilities, including liabilities under the Securities Act. If we and the selling stockholders are unable to provide this indemnification, we and the selling stockholders will contribute to payments the underwriters may be required to make in respect of those liabilities.

*Online Offering.* A prospectus in electronic format may be made available on the web sites maintained by one or more of the underwriters participating in this offering. Other than the prospectus in electronic format, the information on any such web site, or accessible through any such web site, is not part of the prospectus. The representatives may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters that will make internet distributions on the same basis as other allocations. In addition, shares may be sold by the underwriters to securities dealers who resell shares to online brokerage account holders.

*Conflicts/Affiliates.* The underwriters and their affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates and the selling stockholders for which services they have received, and may in the future receive, customary fees.

As of December 31, 2005, William Blair & Company, one of the underwriters in this offering to which we will pay a commission, and some of its affiliates collectively own in excess of 5% of the outstanding shares of our common stock. William Blair Capital Partners VII QP, L.P. and William Blair Capital Partners VII, L.P. are affiliates of William Blair & Company and are selling shares of common stock owned by them in this offering. This offering is being made in compliance with the applicable provisions of Rule 2710(h) of the Conduct Rules of the National Association of Securities Dealers, Inc., or the NASD. As a bona fide market exists for our common stock, the NASD does not require that we use a qualified independent underwriter for this offering.

**Table of Contents**

**LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon for us by Heller Ehrman LLP, San Diego, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Clifford Chance US LLP, New York, New York.

**EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements and schedule included in our Annual Report on Form 10-K for the year ended December 31, 2004, as set forth in their report, which is incorporated by reference in the registration statement. Our financial statements and schedule are incorporated by reference in this prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We are subject to the information reporting requirements of the Securities Exchange Act of 1934, as amended, and we file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission relating to our business, financial results and other matters. The reports, proxy statements and other information we file may be inspected and copied at prescribed rates at the Securities and Exchange Commission's Public Reference Room and via the Securities and Exchange Commission's website (see below for more information).

In connection with the common stock offered by this prospectus, we have filed a registration statement on Form S-3 under the Securities Act with the Securities and Exchange Commission. This prospectus, which constitutes a part of that registration statement, does not contain all of the information included in that registration statement and its accompanying exhibits and schedules. For further information with respect to our common stock and us you should refer to that registration statement and its accompanying exhibits and schedules.

You may inspect a copy of the registration statement of which this prospectus is a part and its accompanying exhibits and schedules, as well as the reports, proxy statements and other information we file with the Securities and Exchange Commission, without charge at the Securities and Exchange Commission's Public Reference Room, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, and you may obtain copies of all or any part of the registration statement from those offices for a fee. You may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission maintains a web site that contains reports, proxy and information statements and other information regarding registrants that file electronically, including us. The address of the site is <http://www.sec.gov>.

**Table of Contents**

**INFORMATION INCORPORATED BY REFERENCE**

The Securities and Exchange Commission allows us to incorporate by reference the information that we file with the Securities and Exchange Commission, which means that we can disclose important information to you by referring to those documents. The information incorporated by reference is an important part of this prospectus. The following documents filed by us with the Securities and Exchange Commission are incorporated by reference herein:

- (1) Annual Report on Form 10-K for the fiscal year ended December 31, 2004, as filed on March 31, 2005;
- (2) Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, as filed May 12, 2005;
- (3) Quarterly Report on Form 10-Q for the quarter ended June 30, 2005, as filed August 12, 2005;
- (4) Quarterly Report on Form 10-Q for the quarter ended September 30, 2005, as filed November 10, 2005;
- (5) Current Reports on Form 8-K, as filed on January 21, 2005, June 9, 2005, July 28, 2005 (but only as to Item 5.02), August 2, 2005, August 10, 2005, August 17, 2005, September 15, 2005, December 7, 2005, December 22, 2005 and January 9, 2006; and
- (6) the description of our common stock contained in our registration statement on Form S-1, filed March 5, 2004, under the caption "Description of Capital Stock - Common Stock", together with Amendments Nos. 1, 2, 3 and 4 on Form S-1/A filed with the Securities and Exchange Commission on April 8, 2004, April 26, 2004, May 5, 2004 and May 11, 2004, respectively, and in any report filed for the purpose of amending such description.

All documents subsequently filed by us with the Securities and Exchange Commission pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, and prior to the termination of this offering, shall be deemed to be incorporated by reference in this prospectus. Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained herein, or in any other subsequently filed document that also is or is deemed to be incorporated by reference herein, modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will provide, without charge, to each person, including any beneficial owner, to whom a copy of this prospectus is delivered, upon the written or oral request of such person, a copy of this prospectus and/or any or all of the documents that have been incorporated by reference herein, but are not delivered with this prospectus, other than exhibits to such documents (unless such exhibits are specifically incorporated by reference therein). Requests for such copies should be directed to:

NuVasive, Inc.

4545 Towne Centre Court

San Diego, California 92121

Attn: Chief Financial Officer

\* \* \* \* \*

**Table of Contents**



**Table of Contents**

**7,500,000 Shares**

**Common Stock**