

NUVASIVE INC
Form S-3/A
January 31, 2006
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As filed with the Securities and Exchange Commission on January 31, 2006

Commission File No. 333 -130354

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 2

to

FORM S-3

REGISTRATION STATEMENT UNDER

THE SECURITIES ACT OF 1933

NUVASIVE, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

3841
(Primary Standard Industrial
Classification Code Number)

33-0768598
(I.R.S. Employer
Identification Number)

4545 Towne Centre Court

San Diego, California 92121

(858) 909-1800

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Alexis V. Lukianov

Chairman and Chief Executive Officer

NuVasive, Inc.

4545 Towne Centre Court

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San Diego, California 92121

(858) 909-1800

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. "

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the Securities Act), other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. "

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. "

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. "

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JANUARY 31, 2006

PROSPECTUS

6,500,000 Shares

Common Stock

We are offering 5,704,120 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. The last reported sale price of our common stock on the Nasdaq National Market on January 26, 2006 was \$18.23 per share.

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	\$	\$
Underwriting discount and commissions	\$	\$
Proceeds, before expenses, to NuVasive	\$	\$
Proceeds, before expenses, to the selling stockholders	\$	\$

We have granted the underwriters a 30-day option to purchase up to 975,000 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 _____, 2006.

BANC OF AMERICA SECURITIES LLC

LEHMAN BROTHERS

THOMAS WEISEL PARTNERS LLC

WILLIAM BLAIR & COMPANY

STANFORD GROUP COMPANY

, 2006

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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.

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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.

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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.

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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.

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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.

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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. 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.

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The Offering

Common stock offered by NuVasive 5,704,120 shares

Common stock offered by the selling stockholders 795,880 shares

Common stock outstanding after this offering 30,810,070 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.

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Unless otherwise indicated, all information in this prospectus assumes that the underwriters do not exercise their option to purchase up to 975,000 additional shares of our common stock in this offering.

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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)				
Consolidated Statement of Operations Data:					
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	

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- (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.

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	As of September 30, 2005	
	Actual	As Adjusted(1)
	(unaudited, in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	\$ 25,026	\$ 123,228
Working capital	37,454	135,656
Total assets	74,449	172,651
Long-term obligations, less current portion	1,660	1,660
Total stockholders equity	61,044	159,246

- (1) The data in the as adjusted column gives effect to the sale by us of 5,704,120 shares of our common stock at an assumed public offering price of \$18.23 per share, the last reported sale price of our common stock on the Nasdaq National Market on January 26, 2006, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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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.

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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

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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;

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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

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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.

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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

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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.

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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

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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;

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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;

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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;

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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

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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.

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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

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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;

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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;

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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.

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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, 30,810,070 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

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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 \$13.34 at an assumed public offering price of \$18.23 per share, the last reported sale price of our common stock on the Nasdaq National Market on January 26, 2006. Investors who purchase shares of common stock in this offering will contribute approximately 41% of the total amount we have raised to fund our operations but will own only approximately 19% 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;

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

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

require advance written notice of stockholder proposals and director nominations.

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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.

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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.

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USE OF PROCEEDS

We estimate that the net proceeds from the sale of the 5,704,120 shares of common stock that we are selling in this offering will be approximately \$98.2 million, or approximately \$115.0 million if the underwriters exercise their option to purchase additional shares in full. This calculation is based upon an assumed offering price to the public of \$18.23 per share, the last reported sale price of our common stock on the Nasdaq National Market on January 26, 2006, 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.

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

On January 26, 2006, the last reported sale price for our common stock on the Nasdaq National Market was \$18.23 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.

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CAPITALIZATION