NUVASIVE INC
Form S-3
August 17, 2005

As filed with the Securities and Exchange Commission on August 17, 2005

Commission File No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

NUVASIVE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**3841**	**33-0768598**
(State of jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

4545 Towne Centre Court
San Diego, California 92121
(858) 909-1800
(Address and telephone number of registrant s principal executive offices and principal place of business)

Alexis V. Lukianov
Chairman and Chief Executive Officer
NuVasive, Inc.
4545 Towne Centre Court
San Diego, California 92121
(858) 909-1800
(Name, address and telephone number of agent for service)

Copy to:

Michael S. Kagnoff, Esq.
Heller Ehrman LLP
4350 La Jolla Village Drive
Seventh Floor
San Diego, California 92122
(858) 450-8400

Approximate date of proposed sale to the public: From time to time after this Registration Statement becomes effective as determined by the selling stockholders.

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

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. ý

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. o

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. o

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Share(1)	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee
Common Stock, par value $.001 per share (2)	274,237	$19.32	$5,298,259	$624

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) of the Securities Act, based upon the average of the high and low sales prices of the Registrant s common stock, as reported on The Nasdaq National Market, on August 12, 2005.

(2) Represents shares of common stock held by the selling stockholders.

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.

The information in this prospectus is not complete and may be changed. These securities may not be sold 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 offers to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED AUGUST 17, 2005.

PROSPECTUS

274,237 Shares

Common Stock

The selling stockholders identified in this prospectus may sell up to 274,237 shares of our common stock. 222,929 of such shares of common stock were originally issued by us in connection with our acquisition of assets from RSB Spine LLC and 51,308 of such shares were originally issued by us in connection with our acquisition of assets from RiverBend Design LLC. The selling stockholders may offer and sell their shares in public or private transactions, or both. These sales may occur at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market prices, or at negotiated prices.

The selling stockholders may sell shares to or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the selling stockholders, the purchasers of the shares, or both. See Plan of Distribution for a more complete description of the ways in which the shares may be sold. We will not receive any of the proceeds from the sale of the shares by the selling stockholders.

Our common stock is quoted on The Nasdaq National Market under the symbol NUVA. The high and low prices for our common stock on The Nasdaq National Market were $19.93 and $19.31 on August 16, 2005.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 2 of this prospectus.

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 date of this prospectus is August , 2005.

ABOUT THIS PROSPECTUS

This prospectus relates to the resale of up to 274,237 shares of common stock held by the selling stockholders. 222,929 of such shares were issued to RSB Spine LLC pursuant to the terms of an Asset Purchase Agreement dated June 3, 2005, which was executed in connection with our recent asset purchase from RSB Spine. The remaining 51,308 shares were issued to RiverBend Design LLC pursuant to the terms of an Intellectual Property Purchase Agreement dated August 12, 2005, which was executed in connection with our recent asset purchase from RiverBend Design. We will not receive any proceeds from the potential sale of the shares offered by the selling stockholders.

This prospectus constitutes part of the registration statement on Form S-3 filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended, utilizing a shelf registration or continuous offering process. It omits some of the information contained in the registration statement and reference is made to the registration statement for further information with respect to us and the securities being offered by the selling stockholders. Any statement contained in the prospectus concerning the provisions of any document filed as an exhibit to the registration statement or otherwise filed with the Securities and Exchange Commission is not necessarily complete, and in each instance, reference is made to the copy of the document filed.

You should rely only on information contained in or incorporated by reference in this prospectus. We have not authorized anyone to provide you with information that is different. If anyone provides you with different or inconsistent information, you should not rely on it. These securities will not be sold in any jurisdiction where such sale is not permitted. The information contained in this prospectus is accurate only as of the date of this prospectus or earlier dates as specified herein. Our business, financial condition, results of operations and prospects may have changed since those dates.

This prospectus provides you with a general description of the common stock that will be sold pursuant to this prospectus. The registration statement filed with the Securities and Exchange Commission includes exhibits that provide more details about the matters discussed in this prospectus. You should read this prospectus and the related exhibits filed with the Securities and Exchange Commission, together with the additional information described under Where You Can Find More 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.

RISK FACTORS

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

Risks Related to Our Business and Industry

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

It is important to our business that we continue to 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 new products or enhancements in a timely manner;

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

avoid infringing upon the intellectual property rights of third parties;

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

provide adequate training to potential users of our products;

receive adequate reimbursement notifications; and

develop an effective marketing and distribution network.

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

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

Successful sales of our products will depend on the availability of adequate reimbursement from third-party payors. Healthcare providers, such as hospitals that purchase medical devices for treatment of their patients, generally rely on third-party payors to reimburse all or part of the costs and fees associated with the procedures performed with these devices. Both public and private insurance reimbursement plans are central to new product acceptance. Spine surgeons are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of related procedures.

To the extent we sell our products internationally, market acceptance may depend, in part, upon the availability of reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance. We may not obtain international reimbursement approvals in a timely manner, if at all. Our failure to receive international reimbursement approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

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

or reimbursement policies of third-party payors may adversely affect the demand for our existing products or our products currently under development and limit our ability to sell our products on a profitable basis.

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

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

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

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, our products provide benefits or an attractive alternative to conventional modalities of treating spine disorders. Surgeons may be slow to change their medical treatment practices for the following reasons, among others:

lack of experience with our products;

lack of evidence supporting additional patient benefits;

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

availability of reimbursement within healthcare payment systems;

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

the time that must be dedicated for training.

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

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

We recently acquired assets from each of RSB Spine LLC and Pearsalls Limited, 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 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, may not provide the intended complementary fit with our 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. 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 in a highly competitive market segment, face competition from large, well-established medical device manufacturers with significant resources, and may not be able to compete effectively.

The market for spine surgery products and procedures is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. With respect to NeuroVision, our nerve avoidance system, we compete with Medtronic Sofamor Danek, Inc., a wholly owned subsidiary of Medtronic, Inc., and Nicolet Biomedical, a VIASYS Healthcare company, among others. With respect to MaXcess, our minimally disruptive surgical system, our largest competitors are Medtronic Sofamor Danek, DePuy Spine, a Johnson & Johnson company, and Synthes-Stratec. We compete with many of the same companies with respect to our other products. At any time, other companies may develop alternative treatments, products or procedures for the treatment of spine disorders that compete directly or indirectly with our products. If alternative treatments prove

to be superior to our spine surgery products, adoption of our products could be negatively affected and our future revenues could suffer.

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

- significantly greater name recognition;
- established relations with spine surgeons;
- established distribution networks;
- products supported by long-term clinical data;
- greater experience in obtaining and maintaining United States Food and Drug Administration, or FDA, and other regulatory approvals for products and product enhancements;
- more expansive portfolios of intellectual property rights;
- contractually preferred or exclusive relationships with hospitals;
- greater resources for product research and development; and
- greater experience in, and resources for, launching, marketing, distributing and selling products.

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

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

We currently have limited experience in marketing and selling our products. We have only been selling our products since 2001. We currently sell our products in the United States through distribution arrangements with a network of independent agents and sales representatives managed by our sales managers. As a result, we are dependent upon the sales and marketing efforts of our third-party sales agencies. We pay these agents and sales representatives a commission based on their product sales. To date, few of these agents or sales representatives are required to exclusively sell our products and may freely sell any other products, including products of our competitors. We are currently engaged in significant efforts to convince agents and sales representatives to exclusively sell our products. These efforts require us to offer higher commissions to these parties, 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, no assurance can be given that we will ultimately succeed in convincing agents and sales representatives to exclusively sell our products.

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

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

We rely on third-party suppliers and manufacturers to manufacture and supply our products. To be successful, our contract manufacturers must be able to provide us with 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 products. If any one or more of our manufacturers cease to provide us with sufficient quantities of our components in a timely manner or on terms acceptable to us, or cease to manufacture components of acceptable quality, we would have to seek alternative sources of manufacturing. We could incur delays while we locate and engage alternative qualified suppliers and we might be unable to engage alternative suppliers on favorable terms. Any such disruption or increased expenses could harm our commercialization efforts and adversely affect our ability to generate revenue.

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.

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

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

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

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

We recently relocated our operations to a different facility. Although this new facility allows for growth in our business and enables us to more effectively train surgeons in the use of our products, it has significantly increased our operating expenses. For example, our monthly lease payments have approximately doubled and we will also be

required to pay increased maintenance costs for this facility. If we do not generate additional business opportunities, these additional expenses could negatively affect our results of operations.

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

Our medical devices are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. Our failure to comply with such regulations could lead to the imposition of injunctions, suspensions or loss of regulatory approvals, product recalls, termination of distribution or product seizures. In the most egregious cases, criminal sanctions or closure of our manufacturing facilities are possible. The process of obtaining regulatory approvals to market a medical device, particularly from the FDA, can be costly and time consuming, and there can be no assurance that such approvals will be granted on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received 510(k) clearance or is the subject of an approved premarket approval application, or PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. The PMA approval process is more costly, lengthy and uncertain than the 510(k) clearance process. Any products we develop that require regulatory clearance may be delayed. In addition, because we cannot assure you that any new products or any product enhancements we develop will be subject to the shorter 510(k) clearance process, the regulatory approval process for our products or product enhancements may take significantly longer than anticipated. There is no assurance that the FDA will not require that a certain new product or product enhancement go through the lengthy and expensive PMA approval process. To date, all of our products have been cleared through the 510(k) process. We have no experience in obtaining PMA approval.

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

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

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

We obtained clearance to offer our MAS and certain Classic Fusion products through the FDA s 510(k) clearance process. The FDA s 510(k) clearance process is less rigorous than the PMA process and requires less in the way of long-term clinical studies. As a result, we currently lack the breadth of published long-term clinical data supporting the safety of our products and the benefits they offer that might have been generated in connection with the PMA process. For these reasons, spine surgeons may be slow to adopt our products, we may not have comparative data that our competitors have or are generating and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes. Such results would slow the adoption of our products by spine surgeons, significantly reduce our ability to achieve expected revenues and could prevent us from becoming profitable. Accordingly, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to significant legal liability and harm to our business reputation. The spine medical device market has been particularly prone to latent and costly product liability litigation.

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

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or, possibly, premarket approval.

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

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

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

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

Tissue Banks International, Inc. and U.S. Tissue and Cell (formerly Intermountain Tissue Center) collectively 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 would significantly harm our revenues, which could cause the market price of our common stock to decline. We expect our revenues would continue to suffer at least until we are able to obtain a sufficient supply of allograft implants from a qualified new source.

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

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

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

surveillance to monitor the effects of approved allograft implants, may restrict the commercial applications of our allograft implants and may conduct periodic inspections of our facility and our suppliers facilities. The FDA may withdraw our product approvals or clearances if we do not comply with its regulatory standards or if we encounter problems after the initial marketing. If we encounter delays during the FDA approval process, the period during which we have the exclusive right to commercialize any allograft implants for which we have received patent protection would be shortened.

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

Our continued success depends in part upon the continued availability and contributions of our senior management team and the continued participation of our key clinical advisors. We have entered into employment agreements with each member of our senior management team, but none of these agreements guarantees the services of the individual for a specified period of time. We also rely on the skills and talents of our scientific personnel because of the complexity of our products. The loss of members of our senior management, key clinical advisors or scientific personnel, or our inability to attract or retain other qualified personnel or advisors could have a material adverse effect on our results of operations and financial condition. We have not obtained and do not expect to obtain key man life insurance on any of our senior managers.

Risks Related to Our Financial Results and Need for Financing

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

We were incorporated in Delaware in 1997, and since that time have focused primarily on research and development and seeking regulatory clearances to market our products. We began commercial sales in 2001 and have several product offerings in both MAS and Classic Fusion. We have yet to demonstrate that we can generate sufficient sales of our products to become profitable. The extent of our future operating losses and the timing of profitability are highly uncertain, and we may never achieve profitability. At June 30, 2005, we had an accumulated deficit of approximately $86.1 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 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 expenses associated with the assets acquired from Pearsalls;

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 independents agents and sales representatives to exclusively sell our 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 introduce and quickly derive significant revenue from new products;

surgeon and patient acceptance of our products;

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

demand and pricing of our products;

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

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

our ability to establish and maintain a productive sales force;

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

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

the effect of competing technological and market developments;

our addition or termination of research programs or funding support;

levels of third-party reimbursement for our products;

interruption in the manufacturing or distribution of our products; and

changes in our ability to obtain FDA approval or clearance for our products.

Many of the products we may seek to develop and introduce in the future will require FDA approval or clearance, without which we cannot begin to commercialize them. As a result, it will be difficult for us to forecast demand for these products with any degree of certainty. In addition, we will be increasing our operating expenses as we build our commercial capabilities. Accordingly, we may experience significant, unanticipated quarterly losses. Because of these factors, our operating results in one or more future quarters may fail to meet the expectations of securities analysts or investors.

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

We believe that our current cash and cash equivalents, including the proceeds from our public offering in May 2004, together with our short-term investments and the cash to be generated from expected product sales, will be sufficient to meet our projected operating requirements for at least the next 12 months. However, we may seek additional funds from public and private stock offerings, borrowings under lease lines or other sources. Our capital requirements will depend on many factors, including:

the revenues generated by sales of our products;

the costs associated with expanding our sales and marketing efforts;

the expenses we incur in manufacturing and selling our products;

the costs of developing new products or technologies;

the cost of obtaining and maintaining FDA approval or clearance of our products and products in development;

the number and timing of acquisitions and other strategic transactions;

the costs associated with our expansion;

the costs associated with increased capital expenditures; and

unanticipated general and administrative expenses.

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

Risks Related to Our Intellectual Property and Potential Litigation

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

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

intellectual property assignment agreements with our 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 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.

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 from a broker who is now being investigated for his practices in obtaining those cadavers from U.C.L.A. 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.

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

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

Any litigation or claims against us may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to infringe, we could be required to pay substantial damages and/or royalties and could be prevented from selling our products unless we could obtain a license or were able to redesign our system to avoid infringement. Any such license may not be available on reasonable terms, if at all. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may be unable to commercialize one or more of our products. As an example, Medtronic Inc. has reportedly agreed to pay orthopedic surgeon Gary Michelson $1.35 billion in order to settle an ongoing lawsuit and acquire certain technology relating to spine surgery.

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

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

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for spine surgery procedures. Spine surgery involves significant risk of serious complications, including bleeding, nerve injury, paralysis and even death. Currently, we maintain product liability insurance in the amount of $10 million. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, we could have to pay an amount in excess of policy limits, which would have to be paid out of cash reserves, if such reserves are sufficient. 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 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, but the Department of Justice has now issued subpoenas as to DePuy, 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 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 may be subject to damages resulting from claims that we or our officers or employees have wrongfully used or disclosed alleged trade secrets of their former employers.

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

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

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

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

The development of allograft implants and technologies for human tissue repair and treatment may entail a risk of product liability claims because of the risk of injury and communicable disease to the human recipients, and substantial product liability claims may be asserted against us. Although we have not been the subject of any material product liability claims to date and have a $10 million insurance policy to cover potential claims, claims could arise in the future for which our insurance will not be adequate. Moreover, insurance covering our business may

not always be available in the future on commercially reasonable terms, if at all. If our insurance proves to be inadequate to pay a damage award, we may not have sufficient funds to do so which would harm our financial condition. In addition, successful product liability claims made against one of our competitors could cause claims to be made against us or expose us to a perception that we are vulnerable to similar claims. Claims against us, regardless of their merit or potential outcome, may also hurt our reputation and ability to sell our products.

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

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

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

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

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

volume and time of orders for our products;

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

disputes or other developments with respect to intellectual property rights;

our ability to develop, obtain regulatory clearance 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;

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

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

changes in earnings estimates or recommendations by securities analysts; and

general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

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

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;

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 have 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 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.

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

Based on shares outstanding at June 30, 2005, our executive officers, directors, and stockholders holding more than 5% of our outstanding common stock and their affiliates, in the aggregate, beneficially own approximately 26% of our outstanding common stock. As a result, these persons, acting together, would have the ability to significantly influence (or determine) the outcome of all matters submitted to our stockholders

for approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets. This concentration of ownership may harm the market price of our common stock by, among other things:

delaying, deferring or preventing a change in control of our company;

impeding a merger, consolidation, takeover or other business combination involving our company; or

causing us to enter into transactions or agreements that are not in the best interests of all stockholders.

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

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules proposed by the Securities and Exchange Commission and by the Nasdaq Stock Market, have resulted in significant new costs. These rules require, among other things, significant

changes to our system of corporate governance, costly implementation and testing of systems regarding internal control over financial reporting. The new rules could make it more difficult or more costly for us to obtain certain types of insurance, including directors and officers liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We are presently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs. Any unanticipated costs will impair our results of operations.

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

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

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

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

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

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

require advance written notice of stockholder proposals and director nominations.

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

We do not intend to pay cash dividends.

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains 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, that involve risks, uncertainties, assumptions and other factors which, if they do not materialize or prove correct, could cause our results to differ materially from historical results or those expressed or implied by such forward-looking statements. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements. The potential risks

and uncertainties that could cause actual growth and results to differ materially include, but are not limited to, the risk that we will not successfully integrate the assets from RSB Spine LLC and RiverBend Design LLC into our business or that we may not successfully commercialize the products derived from those assets, the rapidly changing and competitive nature of the medical device industry, our ability to convince surgeons to use our products, the ability of patients to obtain third-party reimbursement for surgical procedures employing our products, risks related to government regulation of medical devices, risks related to our ability to effectively manage the growth of our business, risks related to ownership and enforcement of intellectual property rights, our ability to successfully develop new products, and other risks and uncertainties more fully described above under Risk Factors and in other documents we file with the Securities and Exchange Commission. Our public filings with the Securities and Exchange Commission are available at www.sec.gov. We assume no obligation to update any forward-looking statement to reflect events or circumstances arising after the date on which it was made.

USE OF PROCEEDS

All shares of our common stock offered by this prospectus are being registered for the account of the selling stockholders. We will not receive any of the proceeds from the sale of these shares.

SELLING STOCKHOLDERS

All of the shares of common stock registered for sale pursuant to this prospectus are owned by the selling stockholders. 222,929 of the shares offered hereby were acquired by RSB Spine LLC in connection with our acquisition of assets from that entity pursuant to an Asset Purchase Agreement, dated as of June 3, 2005, between us and RSB Spine LLC. The remaining 51,308 shares offered hereby were acquired by RiverBend Design LLC in connection with our acquisition of assets from that entity pursuant to an Intellectual Property Purchase Agreement, dated August 12, 2005. The selling stockholders do not have a material relationship with us.

The following table provides information regarding the beneficial ownership of the outstanding shares of our common stock by the selling stockholders both before this offering and as adjusted to reflect the assumed sale of all of the shares offered under this prospectus. Percentage of beneficial ownership before this offering is based on 24,423,481 shares of our common stock outstanding as of July 29, 2005. The selling stockholders may offer the shares for sale from time to time in whole or in part. Except where otherwise noted, each selling stockholder named in the following table has, to our knowledge, sole voting and investment power with respect to the shares beneficially owned by it.

	Beneficial Ownership Before Offering			Beneficial Ownership After Offering
	Number of Shares	Percent	Number of Shares Being Registered	
RSB Spine LLC	222,929	*	222,929	*
RiverBend Design LLC	51,308	*	51,308	*

* Less than 1%.

The selling stockholders provided us with information with respect to their respective share ownership. Because the selling stockholders may sell all, part or none of their shares, we are unable to estimate the number of shares that will be held by the selling stockholders upon resale of shares of common stock being registered hereby. We have, therefore, assumed for the purposes of the registration statement related to this

prospectus that the selling stockholders will sell all of their shares. See Plan of Distribution.

PLAN OF DISTRIBUTION

The selling stockholders and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or

trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales;

broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or

any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts relating to its sales of shares to exceed what is customary in the types of transactions involved.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out its short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The selling stockholders have informed us that they do not have any agreement or understanding, directly or indirectly, with any person to distribute the common stock.

Because the selling stockholders may be deemed to be underwriters within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act. In addition, any securities

covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriter or broker-dealer regarding the sale of the resale shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling stockholders.

The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Securities Exchange Act of 1934, as amended, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to our common stock for a period of two business days prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of our common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

We will not receive any proceeds from the sale of the shares by the selling stockholders.

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 this prospectus and elsewhere in the registration statement. Our financial statements and schedule are incorporated by reference in reliance on Ernst & Young LLP s report, given on their authority as experts in accounting and auditing.

LEGAL MATTERS

The validity of the issuance of the shares of common stock offered hereby and certain other legal matters in connection therewith have been passed upon for us by Heller Ehrman LLP, San Diego, California.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the information reporting requirements of the Securities Exchange Act of 1934, as amended, and we file periodic 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, filed as 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, 450 Fifth Street, N.W., 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.

DOCUMENTS INCORPORATED BY REFERENCE

The Securities and Exchange Commission allows us to incorporate by reference information in this prospectus and other 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 herein by reference:

(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) Current Reports on Form 8-K, as filed on April 26, 2005, June 9, 2005, July 28, 2005, August 2, 2005, August 10, 2005 and August 17, 2005; and

(5) 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 any or all of the documents that have been incorporated herein by reference, 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

You should rely only on the information contained in this prospectus. We have not authorized any person to provide you with information different from that contained in this prospectus. This prospectus may be used only where it is legal to sell the common stock of NuVasive, Inc. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the date of delivery of this prospectus or of any sale of the common stock of NuVasive, Inc.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

The following table sets forth the costs and expenses payable by us in connection with the issuance and distribution of the securities being registered, other than underwriting discounts (all amounts except the Securities and Exchange Commission filing fee are estimated):

	Amount to be paid
SEC registration fee	$ 631
Legal fees and disbursements	10,000
Accounting fees and disbursements	10,000
Miscellaneous	4,369
Total expenses	25,000

Item 15. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation s board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities (including reimbursement for expenses incurred) arising under the Securities Act of 1933, as amended (the Securities Act).

As permitted by the Delaware General Corporation Law, our restated certificate of incorporation includes a provision that eliminates the personal liability of our directors for monetary damages for breach of fiduciary duty as a director, except for liability (1) for any breach of the director s duty of loyalty to us or our stockholders, (2) for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, (3) under Section 174 of the Delaware General Corporation Law (regarding unlawful dividends and stock purchases) or (4) for any transaction from which the director derived an improper personal benefit.

As permitted by the Delaware General Corporation Law, our restated bylaws provide that (1) we are required to indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, subject to certain very limited exceptions, (2) we may indemnify our other employees and agents as set forth in the Delaware General Corporation Law, (3) we are required to advance expenses, as incurred, to our directors and executive officers in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to certain very limited exceptions and (4) the rights conferred in the restated bylaws are not exclusive.

We have entered into indemnification agreements with each of our directors and executive officers to give such directors and officers additional contractual assurances regarding the scope of the indemnification set forth in our restated certificate of incorporation and to provide additional procedural protections. We also intend to enter into indemnification agreements with any new directors and

executive officers in the future. At present, there is no pending litigation or proceeding involving any of our directors, officers, employees, or agents where indemnification by us will be required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

The indemnification provisions in our restated certificate of incorporation, restated bylaws and the indemnification agreements entered into between us and each of our directors and executive officers may be sufficiently broad to permit indemnification of our directors and executive officers for liabilities arising under the Securities Act.

We have obtained liability insurance for our officers and directors.

Item 16. Exhibits

(a) Exhibits

Exhibit No.	Description
2.1(1)	Asset Purchase Agreement, dated as of June 3, 2005, by and between NuVasive, Inc. and RSB Spine LLC
2.2(2)	Asset Purchase Agreement, dated as of August 4, 2005, by and among NuVasive, Inc., Pearsalls Limited, and American Medical Instruments Holdings, Inc.
2.3(3)	Intellectual Property Purchase Agreement, dated as of August 12, 2005, by and between NuVasive, Inc. and RiverBend Design LLC
4.1(4)	Second Amended and Restated Investors Rights Agreement, dated July 11, 2002, by and among us and the other parties named therein
4.2(4)	Amendment No. 1 to Second Amended and Restated Investors Rights Agreement, dated June 19, 2003, by and among us and the other parties named therein
4.3(4)	Amendment No. 2 to Second Amended and Restated Investors Rights Agreement, dated February 5, 2004, by and among us and the other parties named therein
4.4(4)	Specimen Common Stock Certificate
4.5(2)	Registration Rights Agreement, dated August 4, 2005, by and between NuVasive, Inc. and Pearsalls Limited
5.1*	Opinion of Heller Ehrman LLP
23.1*	Consent of Independent Registered Public Accounting Firm
23.2*	Consent of Heller Ehrman LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included in signature page)

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* Filed herewith

(1) This exhibit was previously filed as an exhibit to our Current Report on Form 8-K filed with the Securities and Exchange Commission on June 9, 2005, and is incorporated herein by reference.

(2) This exhibit was previously filed as an exhibit to our Current Report on Form 8-K filed with the Securities and Exchange Commission on August 10, 2005, and is incorporated herein by reference.

(3) This exhibit was previously filed as an exhibit to our Current Report on Form 8-K filed with the Securities and Exchange Commission on August 17, 2005, and is incorporated herein by reference.

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

Item 17. Undertakings

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof;

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant s annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934, as amended) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements of filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, State of California on August 17, 2005.

NUVASIVE, INC.

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Alexis V. Lukianov and Kevin C. O Boyle, and each of them individually, as his or her true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, with full powers to each of them, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and any registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, in connection with the registration under the Securities Act of 1933 as amended, of securities of the registrant, and to file or cause to be filed the same, with exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent, and each of them individually, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the foregoing, as fully to all intents and purposes as he or she might or could do in person, lawfully do or cause to be done by virtue thereof, and hereby ratifying and confirming all that said attorneys, and each of them, or their substitute or substitutes, shall do or cause to be done by virtue of this Power of Attorney. This Power of Attorney may be executed in counterparts.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities indicated on August 17, 2005.

Signature	Title
/s/ Alexis V. Lukianov	**Alexis V. Lukianov** Chairman and Chief Executive Officer (principal executive officer)
/s/ Kevin C. O Boyle	**Kevin C. O Boyle** Executive Vice President and Chief Financial Officer (principal financial and accounting officer)
/s/ Jack R. Blair	**Jack R. Blair** Director
/s/ James C. Blair	**James C. Blair**

Director

	Peter C. Farrell Director
/s/ Robert J. Hunt	**Robert J. Hunt** Director
	Arda M. Minocherhomjee Director
/s/ Lesley H. Howe	**Lesley H. Howe** Director

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