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.