NUVASIVE INC Form S-3/A January 31, 2006 Table of Contents

As filed with the Securities and Exchange Commission on January 31, 2006

Commission File No. 333 -130354

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 2

to

FORM S-3

REGISTRATION STATEMENT UNDER

THE SECURITIES ACT OF 1933

NUVASIVE, INC.

(Exact name of Registrant as specified in its charter)

Delaware (State or other jurisdiction of

3841 (Primary Standard Industrial 33-0768598 (I.R.S. Employer

incorporation or organization)

Classification Code Number)

Identification Number)

4545 Towne Centre Court

San Diego, California 92121

(858) 909-1800

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

Alexis V. Lukianov

Chairman and Chief Executive Officer

NuVasive, Inc.

4545 Towne Centre Court

San Diego, California 92121

(858) 909-1800

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

Copies to:

Michael S. Kagnoff, Esq. Jason M. Hannon, Esq. Alejandro E. Camacho, Esq. **Heller Ehrman LLP** Clifford Chance US LLP **Vice President of Legal Affairs** 31 West 52nd Street 4350 La Jolla Village Drive NuVasive, Inc. Seventh Floor **4545 Towne Centre Court** New York, NY 10019 San Diego, CA 92122 San Diego, CA 92121 (212) 878-8000 (858) 450-8400 (858) 909-1800

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

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

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

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

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

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

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

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

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

SUBJECT TO COMPLETION, DATED JANUARY 31, 2006

PROSPECTUS

6,500,000 Shares

Common Stock

We are offering 5,704,120 shares of our common stock and the selling stockholders named in this prospectus, which are affiliates of William Blair & Company, an underwriter in this offering, are offering 795,880 shares of our common stock. We will not receive any proceeds from the sale of any shares of our common stock by the selling stockholders.

Our common stock is quoted on the Nasdaq National Market under the symbol NUVA. The last reported sale price of our common stock on the Nasdaq National Market on January 26, 2006 was \$18.23 per share.

Investing in our common stock involves a high degree of risk. See <u>Risk Factors</u> beginning on page 7.

	Per Share	Total
Public offering price	\$	\$
Underwriting discount and commissions	\$	\$
Proceeds, before expenses, to NuVasive	\$	\$
Proceeds, before expenses, to the selling stockholders	\$	\$

We have granted the underwriters a 30-day option to purchase up to 975,000 additional shares of our common stock from us at the public offering price, less underwriting discounts and commissions.

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

The underwriters expect to deliver the shares of common stock to investors on or about

, 2006.

BANC OF AMERICA SECURITIES LLC

LEHMAN BROTHERS

THOMAS WEISEL PARTNERS LLC

WILLIAM BLAIR & COMPANY

STANFORD GROUP COMPANY

, 2006

TABLE OF CONTENTS

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

About This Prospectus

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

PROSPECTUS SUMMARY

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

NuVasive, Inc.

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

Our MAS platform combines three categories of our product offerings:

NeuroVision® a proprietary software-driven nerve avoidance system;

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

specialized implants, like our Sphe Rx^{\circledast} pedicle screw system, CoRoent $^{\circledast}$ suite of implants and new ExtenSure dynamic stabilization and fusion system.

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

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

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

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

Developments Since Our Initial Public Offering

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

1

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2

Our Strategy

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

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

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

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

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

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

Corporate Information

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

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

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

3

The Offering

Common stock offered by NuVasive 5,704,120 shares

Common stock offered by the selling

stockholders

795,880 shares

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

Use of proceeds We expect to use a majority of the net proceeds from this offering to expand our sales and

marketing activities, fund research and development relating to potential new products, acquire or invest in complementary businesses, products or technologies, pay up to \$31.5 million of additional acquisition costs related to recently acquired assets and technology, and finance continued development costs related to recently acquired assets and technology. We also expect to use the net proceeds of this offering to finance regulatory approval activities and clinical

trials, expand our operating facilities and for general corporate purposes.

We will not receive any of the proceeds from the selling stockholders sale of 795,880 shares in

this offering. The selling stockholders are affiliates of William Blair & Company, an

underwriter in this offering.

Nasdaq National Market symbol NUVA

Risk Factors Investing in our common stock involves certain risks. You should carefully consider the risk

factors discussed under the heading Risk Factors beginning on page 7 of this prospectus and other information contained or incorporated by reference in this prospectus before deciding to

invest in our common stock.

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

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

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

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

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

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

4

Summary Consolidated Financial Data

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

	Years	Years Ended December 31,		Nine Months Ended September 30,	
	2002	2003	2004	2004	2005
				(unaudited)	
Consolidated Statement of Operations Datas		(in thousand	s, except per sh	are amounts)	
Consolidated Statement of Operations Data: Revenues:					
MAS	\$ 5,269	\$ 12,069	\$ 28,135	\$ 19,017	\$ 34,144
Classic Fusion	6,991	10,586	10,268	7,564	9,090
Total revenues	12,260	22,655	38,403	26,581	43,234
Cost of goods sold	5,303	6,791	10,228	7,309	9,107
Gross profit	6,957	15,864	28,175	19,272	34,127
Operating expenses:					
Research and development	6,107	6,310	8,348	4,855	7,511
Sales and marketing	10,024	12,609	19,740	13,906	26,382
General and administrative	5,568	6,185	8,584	6,874	11,972
Stock-based compensation	113	743	6,143	5,244	2,455
In-process research and development					12,897
	21.012	25015	12.01.5		
Total operating expenses	21,812	25,847	42,815	30,879	61,217
Interest income (expense), net	(200)	(280)	477	170	949
Other expense, net	(55)	136	(47)	(12)	
Net loss	\$ (15,110)	\$ (10,127)	\$ (14,210)	\$ (11,449)	\$ (26,141)
Historical net loss per share(1): Basic and diluted	\$ (13.20)	\$ (6.30)	\$ (0.91)	\$ (0.89)	\$ (1.08)
Dasic and diluted	\$ (13.20)	\$ (0.30)	\$ (0.91)	\$ (0.89)	\$ (1.08)
Weighted average shares basic and diluted	1,145	1,607	15,605	12,859	24,263
Pro forma net loss per share(1):					
Basic and diluted	\$ (1.23)	\$ (0.71)	\$ (0.70)	\$ (0.60)	
Weighted average shares basic and diluted	12,290	14,332	20,264	19,082	

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

5

As of	Septem	ber 30.	2005

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