NUVASIVE INC
Form 424B1
February 13, 2007

Table of Contents

Filed pursuant to Rule 424(b)(1)
Registration No. 333-140432

PROSPECTUS

451,677 Shares
Common Stock

The selling stockholder identified in this prospectus may sell up to 451,677 shares of our common stock. Those shares of common stock were originally issued by us in connection with our acquisition of assets from Radius Medical, LLC. The selling stockholder may offer and sell its 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 stockholder 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 stockholder, 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 stockholder.

Our common stock is quoted on the NASDAQ Global Market under the symbol NUVA. On February 12, 2007, the last reported sale price of our common stock on the NASDAQ Global Market was $24.30.

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 February 13, 2007.

Table of Contents

TABLE OF CONTENTS

Table of Contents

ABOUT THIS PROSPECTUS

This prospectus relates to the resale of up to 451,677 shares of our common stock by the selling stockholder. The shares were issued to the selling stockholder in January 2007 in connection with our acquisition of assets from Radius Medical, LLC. We will not receive any proceeds from the potential sale of the shares offered by the selling stockholder.

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 (the Securities Act), 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 stockholder. 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 ou refer to NuVasive, Inc., a Delaware corporation.

RISK FACTORS

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

Risks Related to Our Business and Industry

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

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

Table of Contents

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

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

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

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

- significantly greater name recognition;
- established relations with spine surgeons, hospitals, other healthcare providers and third-party payors;
- large and established distribution networks with significant international presence;
- products supported by long-term clinical data;
- greater experience in obtaining and maintaining United States Food and Drug Administration, or FDA, and other regulatory approvals or clearances for products and product enhancements;
- more expansive portfolios of intellectual property rights; and
- greater financial and other resources for product research and development, sales and marketing and litigation.

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

Table of Contents

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

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

lack of experience with our products;

lack of evidence supporting additional patient benefits;

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

limited availability of reimbursement within healthcare payment systems;

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

the time that must be dedicated for training.

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

Our failure to continue building an effective and exclusive distribution network for our products could significantly impair our ability to increase sales of our products.

We utilize a hybrid model of independent sales agencies and directly-employed sales professionals for product sales. The majority of the sales professionals selling our products are paid on a commission basis. We have recently completed a significant effort to convert our sales force to exclusivity, meaning their spine sales efforts are focused exclusively on our products. This transition process has been lengthy and expensive. In order to realize benefits from this large investment of time, money and resources, our sales force must continue to grow and expand sales of our products, which all of our sales projections and budgeting processes have assumed. Since this sales force is extremely new, there is risk that unanticipated problems will be encountered with generating sales and introducing customers to our products. Any failure to generate expected sales would adversely affect our operational results.

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

It is important to our business that we continue to build a more complete product offering to surgeons and hospitals. 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. We also cannot provide assurance that we will be able to successfully integrate acquired products, such as our Formagraft product recently acquired from Radius Medical, LLC, into our product lines. Specifically, we have little experience selling biologic products as a company, and we may have unanticipated difficulty.

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;

Table of Contents

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

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

avoid infringing upon the intellectual property rights of third parties;

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

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

provide adequate training to potential users of our products;

receive adequate reimbursement; and

develop an effective and dedicated marketing and distribution network.

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

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

We recently acquired products and/or assets from each of Radius Medical, LLC, Pearsalls Limited, RSB Spine LLC, and RiverBend Design LLC, and may in the future acquire technology, products or businesses related to our current or future business. We have limited experience in acquisition activities and may have to devote substantial time and resources in order to complete any future acquisitions. Further, these past and potential acquisitions entail risks, uncertainties and potential disruptions to our business. For example, we may not be able to successfully integrate an acquired company s operations, technologies, products and services, information systems and personnel into our business. Further, products we acquire, such as the biologic product we acquired from Radius Medical, LLC or 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 or approval. An acquisition may further strain our existing financial and managerial controls, and divert management s attention away from our other business concerns. In connection with in-process research and development activities, we would likely experience an increase in development expenses and capital expenditures. There may also be unanticipated costs and liabilities associated with an acquisition that could adversely affect our operating results.

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

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

Table of Contents

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

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

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

Maxigen Biotech, Inc., or MBI, is our exclusive supplier of our recently-acquired Formagraft product. We are party to a supply agreement with MBI, pursuant to which we have agreed to purchase our entire supply of Formagraft from MBI. As this is a new relationship, we have no prior experience dealing with MBI and there can be no assurance that this supply arrangement will function as successfully as we hope. Specifically, we will require that MBI significantly expand its manufacturing capacity to meet our forecasted needs, and no assurance can be given that MBI will be able to meet our requirements. If we experience difficulties in dealing with MBI, our ability to integrate our Formagraft product into our product line will be substantially harmed, which could adversely affect our operational results.

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.

Table of Contents

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

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

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

The rapid growth of our business has placed a significant strain on our managerial, operational and financial resources and systems. To execute our anticipated growth successfully, we must attract and retain qualified personnel and manage and train them effectively. We will be dependent on our personnel and third parties to effectively market our products to an increasing number of surgeons. We will also depend on our personnel to develop next generation technologies.

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

If clinical trials of our current or future product candidates do not produce results necessary to support regulatory approval in the United States or elsewhere, we will be unable to commercialize these products.

Several investigational devices in our development pipeline, including our NeoDisc cervical disc replacement device, Cerpass cervical total disc replacement (TDR) and lateral lumbar TDR, will require premarket approval, or PMA, from the FDA. A PMA application must be submitted if the device cannot be cleared through the less rigorous 510(k) process. A PMA application must be supported by extensive data including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA s satisfaction the safety and effectiveness of the device for its intended use.

As a result, to receive regulatory approval for NeoDisc, Cerpass or other devices requiring PMA approval, we must conduct, at our own expense, adequate and well controlled clinical trials to demonstrate efficacy and safety in humans. Clinical testing is expensive, takes many years and has an uncertain outcome. Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. Our failure to adequately demonstrate the efficacy and safety of any of our devices would prevent receipt of regulatory approval and, ultimately, the commercialization of that device.

We depend on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control.

As a company, we have limited experience in conducting clinical trials, demonstrated by the fact that all of our commercialized products to date have been cleared via 510(k). We recently received conditional approval of an Investigational Device Exemption (IDE) from the FDA to begin clinical trial enrollment of our NeoDisc cervical disc replacement device. In connection with this and other planned studies, we will rely on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trial and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials or fail to ensure compliance by patients with clinical protocols or fail to comply with regulatory requirements, we will be unable to complete these trials, which could prevent us from

Table of Contents

obtaining regulatory approvals for our products. Our agreements with clinical investigators and clinical sites for clinical testing place substantial responsibilities on these parties and, if these parties fail to perform as expected, our trials could be delayed or terminated. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, or the clinical data may be rejected by the FDA, and we may be unable to obtain regulatory approval for, or successfully commercialize, our devices.

Delays in the commencement or completion of clinical testing could significantly affect our product development costs. Delays in the clinical trial process may require us to engage additional clinical sites and extend our agreements with the third parties who monitor the clinical trials and collect and analyze data. Additionally, delays in the completion of, or the potential termination of, our clinical trials, will cause the commercial prospects for our investigational devices to be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a device.

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

Our medical devices are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device, particularly from the FDA, can be costly and time consuming, and there can be no assurance that such clearances or approvals will be granted on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved premarket approval application, or PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA s satisfaction the safety and efficacy of the device for its intended use.

Our failure to comply with such regulations could lead to the imposition of injunctions, suspensions or loss of regulatory approvals, product recalls, termination of distribution, or product seizures. In the most egregious cases, criminal sanctions or closure of our manufacturing facilities are possible.

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

Further, pursuant to FDA regulations, we can only market our products for cleared or approved uses. Certain of our products may be used by physicians for indications other than those cleared or approved by the FDA, but we cannot promote the products for such off-label uses. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities.

Table of Contents

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

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

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

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

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

Table of Contents

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, 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 difficult to predict. At September 30, 2006, we had an accumulated deficit of approximately $154 million, and cash, cash equivalents and short term investments totaling approximately $121 million, compared to approximately $144 million as of June 30, 2006. Our net loss for the three months ended September 30, 2006 was approximately $19 million. Even if we do achieve profitability as planned, we may not be able to sustain or increase profitability on an ongoing basis. In addition, our independent distributors are entitled to certain payments in the event their services are terminated in connection with (or shortly following) a change of control of our company. These payments are the responsibility of our successor, but may represent an additional significant expense or reduce the price paid in connection with any such event.

Our quarterly financial results are likely to fluctuate significantly because our sales prospects are uncertain.

Our quarterly operating results are difficult to predict and may fluctuate significantly from period to period, particularly because our sales prospects are uncertain. These fluctuations will also affect our annual operating results and may cause those results to fluctuate unexpectedly from year to year. The level of our revenues and results of operations at any given time will be based primarily on the following factors:

- our ability to drive increased sales of our products to hospitals and surgeons;
- our ability to establish and maintain an effective and dedicated sales force;
- pricing pressure applicable to our products, including adverse third-party reimbursement outcomes;
- results of clinical research and trials on our existing products and products in development and our ability to obtain FDA approval or clearance;
- the mix of our products sold (i.e., profit margins differ between our products);
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- the ability of our suppliers to timely provide us with an adequate supply of materials and components;
- the evolving product offerings of our competitors and the potential introduction of new and competing technologies;
- regulatory approvals and legislative changes affecting the products we may offer or those of our competitors; and
- interruption in the manufacturing or distribution of our products.

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

Table of Contents

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 costly, difficult and time consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive 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.

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

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Patent litigation can involve complex factual and legal questions and its outcome is uncertain. Any claim relating to infringement of patents that is successfully asserted against us may require us to pay substantial damages. Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Our success will also depend in part on our not infringing patents issued to others, including our competitors and potential competitors. If our products are found to infringe the patents of others, our development, manufacture and sale of such potential products could be severely restricted or prohibited. In addition, our competitors may independently develop similar technologies. Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to protect our intellectual property rights.

As the number of entrants into our market increases, the possibility of a patent infringement claim against us grows. While we make an effort to ensure that our products do not infringe other parties patents and proprietary rights, our products and methods may be covered by patents held by our competitors. In addition, our competitors may assert that future products we may market infringe their patents.

A patent infringement suit brought against us or any strategic partners or licensees may force us or any strategic partners or licensees to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party s intellectual property, unless that party grants us or any strategic partners or licensees rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if any strategic partners, licensees or we were able to obtain rights to the third party s intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable

to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

Table of Contents

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

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

Currently, we maintain product liability insurance in the amount of $10 million. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, if our product liability insurance proves to be inadequate to pay a damage award, we may have to pay the excess out of our cash reserves, if such reserves are not sufficient, which may harm our financial condition. If longer-term patient results and experience indicate that our products or any component cause tissue damage, motor impairment or other adverse effects, we could be subject to significant liability. Finally, even a meritless or unsuccessful product liability claim could harm our reputation in the industry, lead to significant legal fees and could result in the diversion of management s attention from managing our business.

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

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

The regulations governing the interactions between medical device companies and health care providers continue to evolve. Compliance with these regulations is costly, especially as accepted methods of compliance are developed. We expect to continue to incur costs related to compliance with these new measures, such as the requirement to comply with the new California Prescription Drug Marketing Act.

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

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

Table of Contents

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 volatile and may fluctuate substantially due to many factors, including:

- volume and timing of orders for our products;
- the introduction of new products or product enhancements by us or our competitors;
- disputes or other developments with respect to intellectual property rights or other potential legal actions;
- our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis;
- 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, clearances or applications;
- changes in the availability of third-party reimbursement in the United States or other countries;
- the acquisition or divestiture of products, assets or technology;
- 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.

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

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS No. 123R, which focuses primarily on accounting for transactions in which an entity obtains employee services through share-based payment transactions. SFAS 123R requires us to measure the cost of employee services received in exchange for the award of equity instruments based on the fair value of the award at the date of grant. The cost will be recognized over the period during which an employee is required to provide services in exchange for the award. We adopted SFAS 123R in the first quarter of 2006, as required. As a result, our reported earnings have been reduced, which may affect our stock price.

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

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

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

Table of Contents

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;

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

require advance written notice of stockholder proposals and director nominations.

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

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. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including, but not limited to, statements regarding our future financial position, business strategy and plans and objectives of management for future operations. When used in this prospectus, the words believe, may, could, will, estimate, continue, anticipate expect and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to certain risks and uncertainties that could cause our actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this prospectus, and in particular, the risks discussed under the heading Risk Factors and those discussed in other documents we file with the Securities and Exchange Commission. Except as required by law, we do not intend to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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

USE OF PROCEEDS

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

SELLING STOCKHOLDER

All of the shares of common stock registered for sale pursuant to this prospectus are owned by the selling stockholder. All of the shares offered hereby were acquired by the selling stockholder in connection with our acquisition of assets of Radius Medical, LLC pursuant to an Asset Purchase Agreement, dated as of January 23, 2007, among us, Radius Medical, LLC and certain members and managers of Radius Medical, LLC. The selling stockholder does not have a material relationship with us.

Table of Contents

The following table sets forth the name of the selling stockholder, the number of shares of common stock beneficially owned by the selling stockholder immediately prior to the date of this prospectus, and the total number of shares that may be offered pursuant to this prospectus. The table also provides information regarding the beneficial ownership of our common stock by the selling stockholder 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 34,406,170 shares of our common stock outstanding as of January 31, 2007. The selling stockholder may offer the shares for sale from time to time in whole or in part. Except where otherwise noted, the 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				
	Number of Shares		Number of Shares Being	Beneficial Ownership After Offering	
Selling Stockholder	**Owned**	**Percent**	**Registered**	**Shares**	**Percent**
Radius Medical, LLC(1)	451,677	1.3%	451,677		*

* Less than 1%.

(1) Power to vote or dispose of the shares is held jointly by Russell Cook and Duraid Antone as managers of Radius Medical, LLC. The address of Radius Medical, LLC is 3700 Campus Drive, Newport Beach, CA 92660.

The selling stockholder provided us with information with respect to its share ownership. Because the selling stockholder may sell all, part or none of its shares, we are unable to estimate the number of shares that will be held by the selling stockholder 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 stockholder will sell all of its shares. See Plan of Distribution.

PLAN OF DISTRIBUTION

The selling stockholder and any of its pledgees, assignees and successors-in-interest may, from time to time, sell any or all of the 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 stockholder 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 stockholder 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.

Table of Contents

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

Broker-dealers engaged by the selling stockholder may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholder (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholder does 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 stockholder 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 stockholder 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 stockholder 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 stockholder 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 stockholder has informed us that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the common stock.

Because the selling stockholder may be deemed to be an underwriter within the meaning of the Securities Act, it 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 stockholder has advised us that it has 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 stockholder.

The 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 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 (the Exchange Act), 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 stockholder will be subject to applicable provisions of the Exchange Act 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 stockholder or any other person. We will make copies of this prospectus available to the selling stockholder and have informed the selling stockholder 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 stockholder.

Table of Contents

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, 2005 and management s assessment of the effectiveness of internal control over financial reporting as of December 31, 2005, as set forth in their reports, which are incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and schedule and management s assessment are incorporated by reference in reliance on Ernst & Young LLP s reports, 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, 100 F Street, N.E., 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, 2005, as filed on March 15, 2006;

(2) Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as filed May 10, 2006;

(3) Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, as filed August 8, 2006;

(4) Quarterly Report on Form 10-Q for the quarter ended September 30, 2006, as filed November 8, 2006;

(5) Current Reports on Form 8-K, as filed on January 9, 2006, February 7, 2006, March 13, 2006, May 30, 2006, September 29, 2006, November 16, 2006, January 9, 2007, January 22, 2007 and January 25, 2007; and

Table of Contents

(6) the description of our common stock contained in our registration statement on Form S-1, filed March 5, 2004, under the caption Description of Capital Stock Common Stock , together with Amendments Nos. 1, 2, 3 and 4 on Form S-1/A filed with the Securities and Exchange Commission on April 8, 2004, April 26, 2004, May 5, 2004 and May 11, 2004, respectively, and in any report filed for the purpose of amending such description.

All documents subsequently filed by us with the Securities and Exchange Commission pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act 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.