NUVASIVE INC
Form S-3ASR
June 30, 2009

Table of Contents

As filed with the Securities and Exchange Commission on June 30, 2009
Commission File No. 333- _____

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933
NUVASIVE, INC.
(Exact name of registrant as specified in its charter)

Delaware	**33-0768598**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

7475 Lusk Boulevard
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.
7475 Lusk Boulevard
San Diego, California 92121
(858) 909-1800
(Name, address, including zip code, and telephone number, including area code of agent for service)

Copy to:
Michael S. Kagnoff, Esq.
DLA Piper LLP (US)
4365 Executive Drive
Suite 1100
San Diego, California 92122
(858) 677-1400

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

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

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

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

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

for the same offering. o

If 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. þ

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. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company
þ	o	o	o

(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Share (2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee
Common Stock, par value $0.001 per share	293,331(1)	$42.37	$12,428,434.47	$693.51

(1) All such shares are currently owned by the selling stockholders.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act, based upon the average of the high and low sales prices of the registrant s common stock, as reported on the NASDAQ Global Select Market, on June 24, 2009.

Table of Contents

PROSPECTUS

293,331 Shares
Common Stock

The selling stockholder identified in this prospectus may sell up to 293,331 shares of our common stock. Those shares of common stock were originally issued by us in connection with a milestone closing held on June 30, 2009 pursuant to an Asset Purchase Agreement between Osiris Therapeutics, Inc. (Osiris) and us dated May 8, 2008, as amended, whereby we purchased Osteocel®, Osteocel® XO and certain related assets from Osiris. 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 Select Market under the symbol NUVA. On June 29, 2009, the last reported sale price of our common stock on the NASDAQ Global Select Market was $44.50.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 1 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 June 30, 2009.

TABLE OF CONTENTS

Table of Contents

ABOUT THIS PROSPECTUS

This prospectus relates to the resale of up to 293,331 shares of our common stock by the selling stockholder, Osiris Therapeutics, Inc. (Osiris). The shares of common stock were originally issued by us to Osiris on June 30, 2009 in connection with a milestone closing pursuant to an Asset Purchase Agreement between Osiris and us dated May 8, 2008, as amended, whereby we purchased Osteocel®, Osteocel® XO and certain related assets from Osiris. 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 7475 Lusk Boulevard, 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 re to NuVasive, Inc., a Delaware corporation.

RISK FACTORS

Risk factors which could cause actual results to differ from our expectations and which could negatively impact our financial condition and results of operations are discussed below. 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. Further, additional risks not currently known to us or that we currently believe are immaterial also may impair our business, operations, liquidity and stock price materially and adversely.

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 numerous niche companies with singular product focus, as well as 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 and achieve profitability.

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.

Table of Contents

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, as well as numerous regional nerve monitoring companies. 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. We also compete with numerous smaller companies with respect to our implant products, many of whom have a significant regional market presence. 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 a greater number of spine surgeons, hospitals, other healthcare providers and third-party payors;
- larger and more well established distribution networks with significant international presence;
- products supported by long-term clinical data;
- greater experience in obtaining and maintaining U.S. 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.

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

It is important to our business that we continue to build a more complete product offering to surgeons and hospitals, and enhance the products we currently offer. 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

Table of Contents

to successfully develop, obtain regulatory approval for or market new products or that any of our future products or enhancements will be accepted by the surgeons who use our products or the payors who financially support many of the procedures performed with our products.

The success of any new product offering or enhancement to an existing product will depend on several factors, including our ability to:

- properly identify and anticipate surgeon and patient needs;
- develop and introduce new products or product enhancements in a timely manner;
- develop products based on technology that we acquire, such as the technology acquired from Cervitech, Inc., Osiris Therapeutics, Inc., Pearsalls Limited and RSB Spine 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 may suffer.

If our acquisitions are unsuccessful, our business may be harmed.

As part of our business strategy, we have acquired companies, technologies and product lines to maintain our objectives of developing or acquiring innovative technologies. Acquisitions involve numerous risks, including the following:

- the possibility that we will pay more than the value we derive from the acquisition, which could result in future non-cash impairment charges;
- difficulties in integration of the operations, technologies, and products of the acquired companies, which may require significant attention of our management that otherwise would be available for the ongoing development of our business;
- the assumption of certain known and unknown liabilities of the acquired companies; and
- difficulties in retaining key relationships with employees, customers, partners and suppliers of the acquired companies.

Any of these factors could have a negative impact on our business, results of operations or financing position. Specifically, our recent Osteocel acquisition is the largest acquisition we have ever completed, with a potential total acquisition price of $85 million. If we failed to properly value that business, or fail to generate expected revenues or profits from operation of that business, our results of operations will suffer. Likewise, if the PCM technology we acquired through our purchase of Cervitech, Inc. is not approved for sale in the United States by the FDA, it could adversely affect our results of operations. Additionally, our investment in Progentix Orthobiology BV, a private company working to develop a novel synthetic biologic, includes options and obligations to buy Progentix Orthobiology BV over time as development milestones are achieved. If the Progentix products are not commercially

successful or unable to meet expected commercial success, but certain development milestones are achieved, we may be obligated to purchase Progentix Orthobiology BV at a price greater than the value of the company.

Further, past and potential acquisitions entail risks, uncertainties and potential disruptions to our business, especially where we have little experience as a company developing or marketing a particular product or technology (as is the case with the Osteocel biologic product). 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. Acquisitions may also further strain our existing financial and managerial controls, and divert management s attention away from our other business concerns.

Table of Contents

Our reliance on single source suppliers could limit our ability to meet demand for our products in a timely manner or within our budget.

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. If we are unable to obtain sufficient quantities of high quality components to meet customer demand on a timely basis, we could lose customers, our reputation may be harmed and our business could suffer.

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

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, Inc., pursuant to which we have agreed to purchase our entire supply of polyetheretherketone for our current product lines from Invibio, Inc. We also have an exclusive supply arrangement with Delphi Medical Systems, pursuant to which Delphi Medical Systems is our exclusive supplier of NeuroVision ® systems. In the event we experience delays, shortages, or stoppages of supply with either supplier, we would be forced to locate a suitable alternative supplier which could take significant time and result in significant expense. Any inability to meet our customers demands for these products could lead to decreased sales, harm our reputation and result in the loss of customers to our competitors, which could cause the market price of our common stock to decline.

Maxigen Biotech, Inc., or MBI, is our exclusive supplier of our 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. 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 we may not be able to secure an adequate source of supply of FormaGraft, which could adversely affect our operational results.

We have entered into an agreement with Allosource, Inc. to act as our exclusive supplier of Osteocel Plus. In that capacity, we will be highly dependent on Allosource, Inc. for supply of Osteocel Plus and any failure on their part to process and supply such product will negatively impact our ability to meet projected sales and distribution of the product. Osteocel Plus is processed from allograft, which is donated human tissue. Allograft is a supply-constrained material and there is ongoing risk that there will be insufficient supply to produce the necessary quantity of Osteocel Plus. Allograft also carries with it the possibility of disease transmission, which could result in negative patient outcomes and negative publicity for our company.

Further, Tissue Banks International, Inc. and AlloSource, Inc. 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, Inc. and AlloSource, Inc. 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 reduce our revenues.

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 and Chief Operating Officer, 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.

Table of Contents

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:

- generate higher revenues to cover a higher level of operating expenses, and our ability to do so may depend on factors that we do not control;
- attract and retain highly qualified management, scientific, manufacturing and sales and marketing personnel;
- assimilate new staff members and manage the complexities associated with a larger, faster growing and more geographically diverse organization;
- expand our clinical development resources to manage and execute increasingly global, larger and more complex clinical trials;
- expand our sales and marketing resources for international expansion and to launch an increasing number of new products from our product pipeline;
- accurately anticipate demand for the products we manufacture and maintain adequate manufacturing capacity for both commercial and clinical supply while maintaining quality standards; and
- upgrade our internal business processes and capabilities (e.g., information technology platform and systems, product distribution and tracking) to create the scalability that a growing business demands.

We completed the implementation of our new enterprise resource planning, or ERP, software system in 2008 to support our increasingly complex business and business processes. After the initial implementation, we determined that additional consulting time was important for a successful transition and therefore incurred incremental expenses related to the on-going support costs for the implementation. These investments minimize the potential for transitional risk of moving to the new ERP system and will assist in driving expected efficiencies in the future. We expect to continue to move to a more traditional and leverageable on-going support model, without significant incremental costs.

Further, our anticipated growth, both internationally and domestically, 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.

Additionally, as the number of products we offer grows, it will become more difficult for our sales force to focus on selling each product and, thereby, possibly limiting the sales potential of certain products.

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

Several investigational devices in our development pipeline, including our NeoDisc® cervical disc replacement device, PCM cervical total disc replacement, or TDR, and lateral 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, PCM 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.

Our NeoDisc and PCM devices are currently the subject of Investigational Device Exemption clinical studies. We have fully enrolled each clinical study and are in the follow-up period. Data is being collected from patients in each clinical study, and we will rely on that data to determine whether each device is safe and effective. There is no assurance that the NeoDisc or PCM device will be approved for sale in the United States by the FDA. The clinical studies may prove that either or both devices do not provide the intended benefit or that there are unintended negative side effects of either or both devices that make it unsafe or not effective. In addition, the NeoDisc device includes embroidery technology, which has not been thoroughly studied for use as permanent implants in the spine. Any failure or delay in obtaining regulatory approval for NeoDisc will hamper our ability to commercialize the device in the United States.

Table of Contents

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. Additionally, 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 may not agree with any of our decisions regarding whether new clearances or approvals are necessary.

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.

Pursuant to FDA regulations, we can only market our products for cleared or approved uses. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities.

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

The safety of our products is not yet supported by long-term clinical data and our products 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 and we may be subject to an enforcement action by the FDA.

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 April 2005 regarding our allograft implant

business and another FDA inspection in June 2007 regarding our medical device activities. In connection with these inspections as well as prior inspections, the FDA requested minor corrective actions, which we have taken to satisfy the corrective actions. There can be no assurance the FDA will not subject us to further enforcement action and the FDA may impose additional inspections at any time.

Additionally, we are the legal manufacturer of record for the products that are distributed and labeled by NuVasive, regardless of whether the products are manufactured by us or our suppliers. Thus, a failure by us or our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

fines, injunctions, and civil penalties;

recall or seizure of our products;

Table of Contents

operating restrictions, partial suspension or total shutdown of production;

refusing our request for 510(k) clearance or premarket approval of new products;

withdrawing 510(k) clearance or premarket approvals that are already granted; and

criminal prosecution.

Risks Related to Our Financial Results and Need for Financing

We have always incurred losses and have incurred significant total operating losses since our inception, and we cannot assure you that we will achieve profitability or that, if profitability is achieved, that we will be able to sustain profitability.

Since our inception in 1997, we have yet to generate ongoing sufficient sales of our products to achieve profits on an annual basis or to become profitable overall. Our net loss for the twelve months ended December 31, 2008 was approximately $27.5 million, as compared to approximately $11.3 million for the twelve months ended December 31, 2007. At December 31, 2008, we had an accumulated deficit of approximately $195.5 million, and cash, cash equivalents and short and long term investments totaling approximately $223.4 million. Even if we do achieve profitability as planned, we may not be able to sustain or increase profitability on an ongoing basis.

The recent financial crisis and general slowdown of the economy may adversely affect our liquidity and the liquidity of our customers.

At December 31, 2008, we had $132.3 million in cash and cash equivalents and $91.0 million in investments in marketable securities. We have historically invested these amounts in U.S. treasuries and government agencies, corporate debt, money market funds, commercial paper and municipal bonds meeting certain criteria. Certain of these investments are subject to general credit, liquidity and other market risks. The general condition of the financial markets and the economy has exacerbated those risks and may affect the value of our current investments and restrict our ability to access the capital markets. Due to the continued downward yield trends on our cash, cash equivalents and marketable securities, our net interest income has progressively been reduced and, in the fourth quarter of 2008, it resulted in a net interest expense position. As our effective yield from our cash, cash equivalents and marketable securities is lower than our coupon rate, we will likely continue to record interest expense, net, through 2009. If there are further declines in the yield of our investment portfolio and we are unable to find alternative sources of liquidity, our results of operations, liquidity and financial condition may be adversely affected.

The liquidity of our customers and suppliers may also be affected by the current financial crisis. If our suppliers experience credit or liquidity problems important sources of raw materials or manufactured goods may be affected. If our customers liquidity and creditworthiness is negatively impacted by the current financial crisis and the condition of the economy, our ability to collect on our outstanding invoices and our collection cycles may be adversely affected.

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 may 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 increase sales of our products to hospitals and surgeons;

our ability to expand 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 launches, 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 and meet our quality requirements;

the evolving product offerings of our competitors and the potential introduction of new and competing technologies;

Table of Contents

regulatory approvals and legislative and reimbursement policy 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.

We may not be able to sublease our former headquarters or receive rental income on any such sublease to cover our lease obligations.

We completed our relocation to the new facility, which serves as our current headquarters, in the third quarter of 2008. Subsequent to the relocation, we have attempted to sublease our former facility through August 2012, the date on which the related lease agreement expires. We have encountered and may continue to encounter significant difficulties or delays in subleasing our current headquarters and may not be able to sublease it for rents equal to or greater than those which we are obligated to pay. To date, we have incurred an additional $4.8 million in operating expenses for 2008. Continued difficulty in subleasing our former headquarters will cause us to incur further increases in operating expenses, which could cause us to exceed our planned expense levels and adversely affect our financial results. Furthermore, inability to sublease such facility may adversely affect our liquidity and capital resources.

Upon the achievement of certain milestones related to our acquisitions, we may be required to make payments which may affect our liquidity and our financial results.

In connection with our recent acquisitions, we may be obligated to make payments in the future upon the achievement of certain milestones. The likelihood of those milestones being achieved and the timing of such payments are uncertain and are subject to change over time. If we are required to make those payments, particularly at a time when we are experiencing financial difficulty, our liquidity, financial results and financial condition may be adversely affected.

Risks Related to Our Intellectual Property and Potential Litigation

We are currently involved in a patent litigation action involving Medtronic and, if we do not prevail in this action, we could be liable for past damages and might be prevented from making, using, selling, offering to sell, importing or exporting certain of our products.

On August 18, 2008, Medtronic Sofamor Danek USA, Inc. and its related entities (Medtronic) filed suit against NuVasive in the United States District Court for the Southern District of California, alleging that certain of our products infringe, or contribute to the infringement of, U.S. patents owned by Medtronic. Medtronic is a large, publicly-traded corporation with significantly greater financial resources than us.

Intellectual property litigation is expensive, complex and lengthy and its outcome is difficult to predict. We may also be subject to negative publicity due to the litigation. Pending or future patent litigation 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, and may significantly divert the attention of our technical and management personnel. In the event that our right to market any of our products is successfully challenged, and if we fail to obtain a required license or are unable to design around a patent, our business, financial condition or results of operations could be materially adversely affected. 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 and any licenses may require substantial royalties or other payments by us. 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. Furthermore, if we are found to

infringe patent claims of a third party, we may, among other things, be required to pay damages, including up to treble damages and attorney s fees and costs, which may be substantial.

An unfavorable outcome for us in this patent litigation could significantly harm our business if such outcome makes us unable to commercialize some of our current or potential products or cease some of our business operations. In addition, costs of defense and any damages resulting from the litigation may materially adversely affect our business and financial results. The litigation may also harm our relationships with existing customers and subject us to negative publicity, each of which could harm our business and financial results.

Table of Contents

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, shareowners, 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 addition, there are numerous proposed changes to the patent laws and rules of the U.S. Patent and Trademark Office which, if enacted, may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, proposed changes to the patent rules of the U.S. Patent and Trademark Office were scheduled to take effect on November 1, 2007 which would have significantly limited the right to pursue continuation applications. On October 31, 2007, a temporary injunction was granted in a lawsuit against the U.S. Patent and Trademark Office which served to stay the application of the proposed rules. The U.S. Court of Appeals for the Federal Circuit heard argument on the appeal of the case in early December 2008, and is expected to rule in the coming months. If the injunction is lifted, the proposed rules may take effect and may adversely impact our ability to prevent others from designing around our existing patents. Moreover, Congress is considering several significant changes to the U.S. patent laws, including (among other things) changing from a first to invent to a first inventor to file system, limiting the for a where a patentee may file a patent suit, requiring the apportionment of patent damages, and creating a post-grant opposition process to challenge patents after they have issued.

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 II 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. It is not unusual for parties to exchange letters surrounding allegations of intellectual property infringement and licensing arrangements. 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, including treble damages in some cases. 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 technologies similar to ours. Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to adequately 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 of our strategic partners or licensees may force us or such 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 our 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 and any licenses may require substantial royalties or other payments by us. Even if our 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 and our reputation would be harmed.

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 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.

Our relationship with surgeons, hospitals and the marketers of our products are subject to scrutiny under various state and federal anti-kickback, self-referral, false claims and similar laws, often referred to collectively as healthcare fraud and abuse laws. Healthcare fraud and abuse laws are complex, and even minor, inadvertent violations can potentially give rise to claims that the relevant law has been violated. Any violations of these laws could result in a material adverse effect on the market price of our common stock, as well as our business, financial condition and results of operations. We cannot assure you that any of the healthcare fraud and abuse laws will not change or be interpreted in the future in a manner which restricts or adversely affects our business activities or relationships with surgeons, hospitals and marketers of our products.

Federal anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation or receipt of any form of remuneration by an individual or entity in return for, or to induce:

- the referral of an individual for a service or product for which payment may be made by Medicare, Medicaid or other government-sponsored healthcare program; or
- purchasing, leasing, ordering or arranging for any service or product for which payment may be made by a government-sponsored healthcare program.

Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of such prohibitions. In 2007, several medical device manufacturers entered into deferred prosecution agreements with the federal government and paid over $300 million, in aggregate, to the government over allegations that the companies had paid kickbacks to surgeons to reward and incentivize use of their surgical implant products. Additionally, the majority of states in which we market our products have similar anti-kickback, anti-fee splitting and self-referral laws, imposing substantial penalties for violations.

In addition to the anti-kickback law, federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Examples of enforcement under this law include the prosecution of several pharmaceutical and device companies for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company s marketing of the product for unapproved, and thus non-reimbursable, uses. Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although surgeons are permitted to use medical devices for indications other than those cleared or approved by the FDA based on their medical judgment, we are prohibited from promoting products for such off-label uses. We market

our products and provide promotional materials and training programs to surgeons regarding the use of our products. Although we believe our marketing, promotional materials and training programs for surgeons do not constitute promotion of unapproved uses of our products, if it is determined that our marketing, promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure and criminal penalty. To enforce compliance with federal laws, the U.S. Department of Justice, or DOJ, has increased its scrutiny of the interactions between healthcare companies and healthcare providers, which has led to an unprecedented level of investigations and settlements in the healthcare industry. Dealing with DOJ investigations can be time- and resource-consuming. Additionally, if a healthcare company settles an investigation with the DOJ, or other law enforcement agencies, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Further, the commercial compliance environment is continually evolving in the healthcare industry with certain states mandating implementation of commercial compliance programs and disclosure requirements while similar legislation has been proposed on the federal level.

Table of Contents

We must comply with a variety of other laws, such as the Healthcare Insurance Portability and Accountability Act of 1996, which protects the privacy of individually identifiable healthcare information, and the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections.

The scope and enforcement of these laws is uncertain and subject to rapid change, especially in light of the lack of applicable precedent and regulations. There can be no assurance that federal or state regulatory authorities will not challenge or investigate our current or future activities under these laws. Any such challenge or investigation could have a material adverse effect on our business, financial condition and results of operations. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

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 products.

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 products does not comply with applicable FDA regulations or other relevant statutes and regulations. Allegations like these could cause regulators or other authorities to take investigative or other action against us, or could cause negative publicity for us or our industry generally. These actions or any negative publicity could cause us to incur substantial costs, divert the attention of our management from our business, harm our reputation and cause the market price of our shares to decline.

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

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

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

- general market conditions and other factors (such as the effect the recent financial crisis is having on stock markets as a whole), including factors unrelated to our operating performance or the operating performance of our competitors;
- 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 businesses, products, assets or technology;
- litigation, including intellectual property litigation;

announcements of actions by the FDA or other regulatory agencies; and

changes in earnings estimates or recommendations by securities analysts.

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

Table of Contents

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

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

- authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, with rights senior to those of the common stock;
- provide for a classified board of directors, with each director serving a staggered three-year term;
- 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 and 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.

We do not intend to pay cash dividends.

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. 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.

Table of Contents

SELLING STOCKHOLDER

All of the shares of common stock registered for sale pursuant to this prospectus are owned by the selling stockholder, Osiris Therapeutics, Inc. (Osiris). All of the shares offered hereby were acquired by the selling stockholder in a milestone closing held on June 30, 2009 pursuant to an Asset Purchase Agreement between Osiris and us dated May 8, 2008, as amended, whereby we purchased Osteocel®, Osteocel® XO and certain related assets from Osiris.

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 37,301,877 shares of our common stock outstanding as of June 24, 2009. 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 have, to our knowledge, sole voting and investment power with respect to the shares beneficially owned by it.

	Beneficial Ownership Before Offering			Beneficial Ownership After Offering	
Selling Stockholder	Number of Shares Owned	Percent	Number of Shares Being Registered	Shares	Percent
Osiris Therapeutics, Inc.	293,331	*	293,331		*

* Less than 1%.

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

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

Table of Contents

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 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.

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, 2008, and the effectiveness of internal control over financial reporting as of December 31, 2008, 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 are incorporated by reference in reliance on Ernst & Young LLP s report, given on their authority as experts in accounting and auditing.

LEGAL MATTERS

The validity of the issuance of the shares of common stock offered hereby and certain other legal matters in connection therewith have been passed upon for us by DLA Piper LLP (US), 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.

Table of Contents

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, 2008, as filed on March 2, 2009;

(2) Quarterly Report on Form 10-Q for the quarter ended March 31, 2009, as filed on May 8, 2009;

(3) Current Reports on Form 8-K, as filed on January 8, 2009, January 15, 2009, March 30, 2009, April 22, 2009 (with respect to Cervitech, Inc.), May 8, 2009 and June 30, 2009; and

(4) The description of our Common Stock contained in the Registration Statement on Form 8-A (No. 000-50744) filed with the Commission on May 5, 2004, pursuant to Section 12 of the Exchange Act of 1934 (the Exchange Act), 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.
7475 Lusk Boulevard
San Diego, California 92121
Attn: Chief Financial Officer
(858) 909-1800

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.

Table of Contents

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

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

		Amount to be paid
SEC registration fee	$	693.51
Legal fees and disbursements	$	20,000
Accounting fees and disbursements	$	15,500
Miscellaneous	$	5,000
Total expenses	$	41,193.51

Item 15. Indemnification of Directors and Officers

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

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

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

We have entered into indemnification agreements with each of our directors and executive officers to give such directors and officers additional contractual assurances regarding the scope of the indemnification set forth in our certificate of incorporation and to provide additional procedural protections. We also intend to enter into indemnification agreements with any new directors and executive officers in the future. At present, there is no pending litigation or proceeding involving any of our directors, officers, employees, or agents where indemnification by us will be required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

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

We have obtained liability insurance for our officers and directors.

Table of Contents

Item 16. Exhibits

(a) Exhibits

Exhibit Number	Description
2.1(1)	Asset Purchase Agreement, dated as of June 3, 2005, by and between NuVasive, Inc. and RSB Spine LLC
2.2(2)	Agreement, dated as of January 3, 2007, by and between NuVasive, Inc. and RSB Spine LLC
2.3(3)	Asset Purchase Agreement, dated as of August 4, 2005, by and among NuVasive, Inc., Pearsalls Limited and American Medical Instruments Holdings, Inc.
2.4(4)	Amendment No. 1 to Asset Purchase Agreement, dated as of September 26, 2006, by and among NuVasive, Inc., Pearsalls Limited and American Medical Instruments Holdings, Inc.
2.5(5)	Asset Purchase Agreement, dated as of January 23, 2007, by and among NuVasive, Inc. and Radius Medical, LLC, Biologic, LLC, Antone Family Partners, Russel Cook and Duraid Antone
2.7(6)	Asset Purchase Agreement, dated May 8, 2008, by and between the Company and Osiris Therapeutics, Inc.
2.8(7)	Amendment to Asset Purchase Agreement, dated September 30, 2008, by and between the Company and Osiris Therapeutics, Inc.
2.9(8)	Amendment No. 2 to Asset Purchase Agreement, dated March 25, 2009, by and between the Company and Osiris Therapeutics, Inc.
2.10(9)	Share Purchase Agreement, by and among NuVasive, Inc. and the stockholders of Cervitech, Inc., as listed therein, dated April 22, 2009
4.1(10)	Second Amended and Restated Investors Rights Agreement, dated July 11, 2002, by and among NuVasive, Inc. and the other parties named therein
4.2(10)	Amendment No. 1 to Second Amended and Restated Investors Rights Agreement, dated June 19, 2003, by and among NuVasive, Inc. and the other parties named therein
4.3(10)	Amendment No. 2 to Second Amended and Restated Investors Rights Agreement, dated February 5, 2004, by and among NuVasive, Inc. and the other parties named therein
4.4(3)	Registration Rights Agreement, dated as of August 4, 2005, between NuVasive, Inc. and Pearsalls Limited
4.5(4)	Registration Rights Agreement Termination Agreement, dated as of September 26, 2006, between NuVasive, Inc. and Pearsalls Limited
4.6(11)	Indenture, dated March 7, 2008, between the NuVasive, Inc. and U.S. Bank National Association, as Trustee

4.7(11)	Form of 2.25% Convertible Senior Note due 2013
4.8(11)	Registration Rights Agreement, dated March 7, 2007, among NuVasive, Inc. and Goldman, Sachs & Co., and J.P. Morgan Securities Inc., related to the 2.25% Convertible Senior Notes due 2013
4.9(12)	Specimen Common Stock Certificate
5.1*	Opinion of DLA Piper LLP (US)
23.1*	Consent of Independent Registered Public Accounting Firm
23.2	Consent of DLA Piper LLP (US) (included in exhibit 5.1)
24.1	Power of Attorney (included in signature page)

* Filed herewith

The Commission has granted confidential treatment to us with respect to certain omitted portions of this exhibit (indicated by asterisks). We have filed separately with the Commission an unredacted copy of the exhibit.

(1) Incorporated by reference to our Current Report on Form 8-K filed with the Securities and Exchange Commission (the Commission) on June 9, 2005.

Table of Contents

(2) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 9, 2007.

(3) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on August 10, 2005.

(4) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on September 29, 2006.

(5) Incorporated by reference to our Current Report on Form 8-K filed with the Commission on January 25, 2006.

(6) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on August 8, 2008.

(7) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on November 7, 2008.

(8) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 8, 2009.

(9) Incorporated by reference to our Registration Statement on Form S-3 (File No. 333-159098) filed with the Commission on May 8, 2009.

(10) Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-113344) filed with the Commission on March 5, 2004.

(11) Incorporated by reference to our Quarterly Report on Form 10-Q filed with the Commission on May 9, 2008.

(12) Incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 16, 2006.

Table of Contents

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the registration statement is on Form S-3 or Form F-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) If the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. *Provided, however* , that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement

or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

Table of Contents

(ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(b) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by a registrant of expenses incurred or paid by a director, officer or controlling person of such registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements of filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, State of California on June 30, 2009.

NUVASIVE, INC.

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

POWER OF ATTORNEY

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

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities indicated on June 30, 2009.

Signature	Title
/s/ Alexis V. Lukianov	**Alexis V. Lukianov** Chairman and Chief Executive Officer (principal executive officer)
/s/ Kevin C. O Boyle	**Kevin C. O Boyle** Executive Vice President and Chief Financial Officer (principal financial and accounting officer)
/s/ Jack R. Blair	**Jack R. Blair** Director
/s/ Peter C. Farrell. Ph.D., AM	**Peter C. Farrell. Ph.D., AM** Director
	Lesley H. Howe Director
/s/ Robert J. Hunt	**Robert J. Hunt** Director

/s/ Hansen A. Yuan, M.D.	**Hansen A. Yuan, M.D.** Director
/s/ Eileen M. More	**Eileen M. More** Director

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