

Stereotaxis, Inc.  
Form S-3  
August 06, 2009  
**Table of Contents**

As filed with the Securities and Exchange Commission on August 6, 2009

Registration No. 333-

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, DC 20549**

**FORM S-3**  
**REGISTRATION STATEMENT**  
**UNDER**  
**THE SECURITIES ACT OF 1933**

**STEREOTAXIS, INC.**

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

**94-3120386**  
*(I.R.S. Employer Identification No.)*

**4320 Forest Park Avenue, Suite 100**

**St. Louis, Missouri 63108**

Edgar Filing: Stereotaxis, Inc. - Form S-3

(314) 678-6100

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

**Michael P. Kaminski**

**President and Chief Executive Officer**

**4320 Forest Park Avenue, Suite 100**

**St. Louis, Missouri 63108**

**(314) 678-6100**

*(Name, address, including zip code, and*

*telephone number, including area code, of agent for service)*

*Copies of all correspondence to:*

**James L. Nouss, Jr., Esq.**

**Robert J. Endicott, Esq.**

**Bryan Cave LLP**

**One Metropolitan Square**

**211 North Broadway, Suite 3600**

**St. Louis, Missouri 63102-2750**

**(314) 259-2000**

**(314) 259-2020 (fax)**

**Approximate date of commencement of proposed sale to public:** From time to time after this registration statement becomes effective.

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

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

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

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

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

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

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.

Edgar Filing: Stereotaxis, Inc. - Form S-3

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller

Smaller reporting company

reporting company)

**CALCULATION OF REGISTRATION FEE**

	Amount to be	Offering Price	Aggregate	Amount Of
Title of Each Class Of Securities To Be Registered	Registered(1)(2)	Per Unit(3)	Offering Price(3)	Registration Fee
Common Stock, par value \$0.001 per share	2,154,526	\$4.63	\$9,975,456	\$557

- (1) This registration statement shall also cover any additional shares of common stock which become issuable by reason of any stock dividend, stock split, recapitalization or other similar transactions effected without the receipt of consideration which results in an increase in the number of outstanding shares of our common stock.
- (2) Includes shares issuable upon the exercise of Stereotaxis Inc. warrants.
- (3) Estimated for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act. The calculation of the fee is based on the average of the high and low sales prices of our common stock on the Nasdaq Global Market on August 3, 2009.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

---

**Table of Contents**

**THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. THE SECURITIES MAY NOT BE SOLD UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IT IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.**

**Subject to Completion, dated August 6, 2009**

**PROSPECTUS**

**Common Stock, \$0.001 par value**

**Up to 2,154,526 Shares**

This is an offering of up to 2,154,526 common shares, par value \$0.001 per share, of Stereotaxis, Inc. ( "Stereotaxis" ), all of which are common shares issuable upon the exercise of warrants having an average weighted exercise price of \$4.17 per share. All of these shares are being offered by the selling stockholders named in this prospectus. We do not know if any or all of the warrants will be exercised or if any or all of the shares will be resold. We will not receive any proceeds from the sale of the shares, but, assuming exercise of all warrants to which the shares relate, we will receive up to \$9,000,005 in proceeds from the exercise of the warrants prior to those sales, which proceeds would be used for general corporate purposes. Please see "Selling Stockholders" and "Plan of Distribution" for information about the selling stockholders and the manner of offering of the common stock.

Our common stock is listed on the Nasdaq Global Market under the symbol "STXS". On August 5, 2009, the last reported sale price for our common stock on the Nasdaq Global Market was \$4.96 per share.

**Investing in our common shares involves risks. See "Risk Factors" beginning on page 2 of this prospectus.**

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

The date of this prospectus is \_\_\_\_\_, 2009.

---

**Table of Contents****TABLE OF CONTENTS**

	<b>Page</b>
<u>PROSPECTUS SUMMARY</u>	1
<u>THE OFFERING</u>	1
<u>RISK FACTORS</u>	2
<u>FORWARD-LOOKING STATEMENTS</u>	22
<u>USE OF PROCEEDS</u>	23
<u>PRICE RANGE OF COMMON STOCK</u>	23
<u>SELLING STOCKHOLDERS</u>	24
<u>PLAN OF DISTRIBUTION</u>	26
<u>DESCRIPTION OF CAPITAL STOCK</u>	28
<u>LEGAL MATTERS</u>	29
<u>EXPERTS</u>	29
<u>WHERE YOU CAN FIND ADDITIONAL INFORMATION</u>	29
<u>INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE</u>	29

We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus. This prospectus does not constitute an offer to sell or the solicitation of any offer to buy common stock, nor does this prospectus constitute an offer to sell or the solicitation of any offer to buy common stock in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus is accurate on any date subsequent to the date of this prospectus or that any information we have incorporated by reference in this prospectus is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus is delivered or common stock sold on a later date.

**Table of Contents**

**PROSPECTUS SUMMARY**

**The Company**

Stereotaxis designs, manufactures and markets an advanced cardiology instrument control system for use in a hospital's interventional medical suite, or interventional lab, that we believe revolutionizes the treatment of arrhythmias and coronary artery disease by enabling important new therapeutic solutions and enhancing the efficiency and efficacy of existing catheter-based, or interventional, procedures. Our Niobe® system allows physicians to more effectively navigate proprietary catheters, guidewires and other delivery devices, both our own and those we are co-developing with strategic partners, through the blood vessels and chambers of the heart to treatment sites in order to effect treatment. This is achieved using computer-controlled, externally applied magnetic fields that precisely and directly govern the motion of the internal, or working, tip of the catheter, guidewire or other interventional device. We believe that our Niobe system represents a revolutionary technology in the interventional lab, bringing precise remote digital instrument control and programmability to the interventional lab, and has the potential to become the standard of care for a broad range of complex cardiology procedures. Our Odyssey Total Information Solution allows physicians to utilize a consolidated user interface and single mouse and keyboard control for multiple systems within the interventional lab.

We were incorporated in Delaware in June 1990 as Stereotaxis, Inc. Our principal executive offices are located at 4320 Forest Park Avenue, Suite 100, St. Louis, Missouri 63108, and our telephone number is (314) 678-6100. Our website address is [www.stereotaxis.com](http://www.stereotaxis.com). Information contained on our website is not incorporated by reference into and does not form any part of this prospectus. As used in this prospectus, references to Company, we, our, us and Stereotaxis refer to Stereotaxis, Inc. unless the context requires otherwise.

**THE OFFERING**

This prospectus relates to the sale or other disposition of 2,154,526 shares of our common stock, comprising shares issuable upon exercise of warrants held by the selling stockholders named in this prospectus or their transferees and having an average weighted exercise price of \$4.17 per share. The selling stockholders and the transactions in which the warrants were issued are all identified and described on in the section entitled Selling Stockholders below. We are registering the selling stockholders' resale of these securities. We will not receive any proceeds from the sale of the shares of common stock by the selling stockholders, but will receive proceeds related to the exercise of warrants for cash held by the selling stockholders to the extent not previously exercised. The registration of these common shares does not necessarily mean that any of them will be offered or sold by the selling stockholders. The securities may be sold directly or through brokers, dealers or agents in private or market transactions. In connection with any sales, the selling stockholders and any brokers, dealers or agents participating in such sales may be deemed to be underwriters within the meaning of the Securities Act. See Plan of Distribution.

---

**Table of Contents**

**RISK FACTORS**

*Investing in our securities involves a high degree of risk. Prior to making a decision about investing in our securities, you should carefully consider the risks described below and all other information contained or incorporated by reference in this prospectus. The risks and uncertainties described below and in other filings incorporated by reference in this prospectus are not the only ones facing the Company. Additional risks and uncertainties not currently known to us or that we currently consider immaterial may also adversely affect us. If any of the following risks actually occurs, our business, results of operations and financial condition will likely suffer. As a result, the trading price of our common stock and/or the value of any other securities we may issue may decline, and you might lose part or all of your investment.*

The following uncertainties and factors, among others, could affect future performance and cause actual results to differ materially from those expressed or implied by forward looking statements.

**Hospital decision-makers may not purchase our Niobe or Odyssey system or may think that such systems are too expensive.**

The market for our products and related technology is not well established. To achieve continued sales, hospitals must purchase our products, and in particular, our Niobe Magnetic Navigation System. The Niobe Magnetic Navigation System, which is the core of our Niobe system, is a novel device, and hospitals and physicians are traditionally slow to adopt new products and treatment practices. In addition, hospitals may delay their purchase or installation decision for the Niobe system based on the disposable interventional devices that have received regulatory clearance or approval. Moreover, the Niobe system is an expensive piece of capital equipment, representing a significant portion of the cost of a new or replacement interventional lab. Although priced significantly below a Niobe system, the Odyssey system is still an expensive piece of equipment. If hospitals do not widely adopt our systems, or if they decide that they are too expensive, we may never become profitable. Any failure to sell as many systems as our business plan requires could also have a seriously detrimental impact on our results of operations, financial condition, and cash flow.

**General economic conditions could materially adversely impact us.**

Our operating performance is dependent upon economic conditions in the United States and in other countries in which we operate. The recent economic downturn in the United States and in other countries in which we sell our products may cause customers to delay purchasing or installation decisions or cancel existing orders. The Niobe and Odyssey systems are typically purchased as part of a larger overall capital project and an economic downturn and financial turmoil affecting the banking system and financial markets might make it more difficult for our customers, including distributors, to obtain adequate financing to support the project or to obtain requisite approvals. Any delay in purchasing decisions or cancellation of purchasing commitments may result in a decrease in our revenues. The credit crisis could further affect our business if key suppliers are unable to obtain financing to manufacture our products or become insolvent and we are unable to manufacture product to meet customer demand. If conditions become more severe or continue longer than we anticipate, we may experience a material negative decrease on the demand for our products which may, in turn, have a material adverse effect on our revenue, profitability, financial condition, ability to raise additional capital and the market price of our stock.

**Physicians may not use our products if they do not believe they are safe, efficient and effective.**

We believe that physicians will not use our products unless they determine that the Niobe system provides a safe, effective and preferable alternative to interventional methods in general use today. Currently, there is only limited clinical data on the Niobe system with which to assess safety and efficacy. If longer-term patient studies or clinical experience indicate that treatment with our system or products is less effective, less efficient or less safe than our current data suggest, our sales would be harmed, and we could be subject to significant liability. Further, unsatisfactory patient outcomes

## **Table of Contents**

or patient injury could cause negative publicity for our products, particularly in the early phases of product introduction. In addition, physicians may be slow to adopt our products if they perceive liability risks arising from the use of these new products. It is also possible that as our products become more widely used, latent defects could be identified, creating negative publicity and liability problems for us and adversely affecting demand for our products. If physicians do not use our products, we likely will not become profitable or generate sufficient cash to survive as a going concern.

### **Our collaborations with Siemens, Philips, Biosense Webster or other parties may fail, or we may not be able to enter into additional partnerships or collaborations in the future.**

We are collaborating with Siemens, Philips, Biosense Webster and other parties to integrate our instrument control technology with their respective imaging products or disposable interventional devices and to co-develop additional disposable interventional devices for use with our Niobe system. A significant portion of our revenue from system sales will be derived from these integrated products. Siemens provides post-installation maintenance and support services to our customers for our integrated systems.

Our product commercialization plans could be disrupted, leading to lower than expected revenue and a material and adverse impact on our results of operations and cash flow, if:

any of our collaboration partners delays or fails in the integration of its technology with our Niobe system as planned;

any of our collaboration partners fails to develop or commercialize the integrated products in a timely manner;

any of our collaboration partners do not co-market and co-promote our integrated products diligently or do not provide maintenance and support services as we expect; or

we become involved in disputes with one or more of our collaboration partners regarding our collaborations.

Siemens, Philips and Biosense Webster, as well as some of our other collaborators, are large, global organizations with diverse product lines and interests that may diverge from our interests in commercializing our products. Accordingly, our collaborators may not devote adequate resources to our products, or may experience financial difficulties, change their business strategy or undergo a business combination that may affect their willingness or ability to fulfill their obligations to us.

The failure of one or more of our collaborations could have a material adverse effect on our financial condition, results of operations and cash flow. In addition, if we are unable to enter into additional partnerships in the future, or if these partnerships fail, our ability to develop and commercialize products could be impacted negatively and our revenue could be adversely affected.

## **Table of Contents**

### **We have limited experience selling, marketing, and distributing products, which could impair our ability to increase revenue.**

We currently market our products in the U.S., Europe and the rest of the world through a direct sales force of sales specialists, distributors and sales agents, supported by account managers and clinical specialists who provide training, clinical support, and other services to our customers. If we are unable to effectively utilize our existing sales force or increase our existing sales force in the foreseeable future, we may be unable to generate the revenue we have projected in our business plan. Factors that may inhibit our sales and marketing efforts include:

our inability to recruit and retain adequate numbers of qualified sales and marketing personnel;

the inability of sales personnel to obtain access to or persuade adequate numbers of hospitals and physicians to purchase and use our products;

unforeseen costs associated with maintaining and expanding an independent sales and marketing organization; and

unforeseen costs associated with maintaining and expanding an independent sales and marketing organization.

In addition, if we fail to effectively use distributors or contract sales agents for distribution of our products where appropriate, our revenue and profitability would be adversely affected.

### **Our marketing strategy is dependent on collaboration with physician thought leaders.**

Our research and development efforts and our marketing strategy depend heavily on obtaining support and collaboration from highly regarded physicians at leading commercial and research hospitals, particularly in the U.S. and Europe. If we are unable to gain and/or maintain such support and collaboration or if the reputation or standing of these physicians is impaired or otherwise adversely affected, our ability to market our products and, as a result, our financial condition, results of operations and cash flow could be materially and adversely affected.

### **We may not be able to rapidly train physicians in numbers sufficient to generate adequate demand for our products.**

In order for physicians to learn to use the Niobe system, they must attend one or more training sessions in order to familiarize themselves with a sophisticated user interface. Market acceptance could be delayed by lack of physician willingness to attend training sessions or by the time required to complete this training. An inability to train a sufficient number of physicians to generate adequate demand for our products could have a material adverse impact on our financial condition and cash flow.

### **Customers may choose to purchase competing products and not ours.**

Our products must compete with established manual interventional methods. These methods are widely accepted in the medical community, have a long history of use and do not require the purchase of an additional expensive piece of capital equipment. In addition, many of the medical conditions that can be treated using our products can also be treated with existing pharmaceuticals or other medical devices and procedures. Many of these alternative treatments are widely accepted in the medical community and have a long history of use.

---

**Table of Contents**

We also face competition from companies that are developing drugs or other medical devices or procedures to treat the conditions for which our products are intended. The medical device and pharmaceutical industries make significant investments in research and development, and innovation is rapid and continuous. We are aware of one public company that has commercialized a catheter delivery system which has been cleared by the FDA for mapping procedures only, and we are aware of one private company at a much earlier stage of development. If these or other new products or technologies emerge that provide the same or superior benefits as our products at equal or lesser cost, it could render our products obsolete or unmarketable. We cannot be certain that physicians will use our products to replace or supplement established treatments or that our products will be competitive with current or future products and technologies.

Many of our other competitors also have longer operating histories, significantly greater financial, technical, marketing and other resources, greater name recognition and a larger base of customers than we do. In addition, as the markets for medical devices develop, additional competitors could enter the market. We cannot assure you that we will be able to compete successfully against existing or new competitors. Our revenue would be reduced or eliminated if our competitors develop and market products that are more effective and less expensive than our products.

**If we are unable to fulfill our current purchase orders and other commitments on a timely basis or at all, we may not be able to achieve future sales growth.**

Our backlog, which consists of purchase orders and other commitments, is considered by some investors to be a significant indicator of future performance. Consequently, negative changes to this backlog or its failure to grow commensurate with expectations could negatively impact our future operating results or our share price. Our backlog includes those outstanding purchase orders and other commitments that management believes will result in recognition of revenue upon delivery or installation of our systems. We cannot assure you that we will recognize revenue in any particular period or at all because some of our purchase orders and other commitments are subject to contingencies that are outside our control. In addition, these orders and commitments may be revised, modified or cancelled, either by their express terms, as a result of negotiations or by project changes or delays. System installation is by its nature subject to the interventional lab construction or renovation process which comprises multiple stages, all of which are outside of our control. Although the actual installation of our Niobe system requires only a few weeks, and can be accomplished by either our staff or by subcontractors, successful installation of our system can be subjected to delays related to the overall construction or renovation process. If we experience any failures or delays in completing the installation of these systems, our reputation would suffer and we may not be able to sell additional systems. We have experienced situations in which our purchase orders and other commitments did not result in recognizing revenue from placement of a system with a customer. In addition to construction delays, there are risks that an institution will attempt to cancel a purchase order as a result of subsequent project review by the institution or the departure from the institution of physicians or physician groups who have expressed an interest in the Niobe or Odyssey system.

---

**Table of Contents**

These, or similar events, have occurred in the past and are likely to occur in the future, causing delays in revenue recognition or even removal of orders and other commitments from our backlog. Such events would have a negative effect on our revenue and results of operations.

**We will likely experience long and variable sales and installation cycles, which could result in substantial fluctuations in our quarterly results of operations.**

We anticipate that our Niobe system will continue to have a lengthy sales cycle because it consists of a relatively expensive piece of capital equipment, the purchase of which requires the approval of senior management at hospitals, inclusion in the hospitals' interventional lab budget process for capital expenditures, and, in some instances, a certificate of need from the state or other regulatory approval. In addition, historically the majority of our Niobe systems have been delivered less than one year after the receipt of a purchase order from a hospital, with the timing being dependant on the construction cycle for the new or replacement interventional suite in which the equipment will be installed. In some cases, this time frame has been extended further because the interventional suite construction is part of a larger construction project at the customer site (typically the construction of a new building), which may occur with our existing and future purchase orders. We cannot assure you that the time from purchase order to delivery for systems to be delivered in the future will be consistent with our historical experience. Moreover, the global economic slowdown may cause our customers to further delay construction or significant capital purchases, which could further lengthen our sales cycle. This may contribute to substantial fluctuations in our quarterly operating results. As a result, in future quarters our operating results could fall below the expectations of securities analysts or investors, in which event our stock price would likely decrease.

**If the magnetic fields generated by our system are not compatible with, or interfere with, other widely used equipment in the interventional labs, sales of our products would be negatively affected.**

Our Niobe system generates magnetic fields that directly govern the motion of the internal, or working, tip of disposable interventional devices. If other equipment in the interventional labs or elsewhere in a hospital is incompatible with the magnetic fields generated by our system, or if our system interferes with such equipment, we may be required to install additional shielding, which may be expensive and which may not solve the problem. If magnetic interference becomes a significant issue at targeted institutions, it would increase our installation costs at those institutions and could limit the number of hospitals that would be willing to purchase and install our systems, either of which would adversely affect our financial condition, results of operations and cash flow.

**The use of our products could result in product liability claims that could be expensive, divert management's attention, and harm our reputation and business.**

Our business exposes us to significant risks of product liability claims. The medical device industry has historically been litigious, and we could face product liability claims if the use of our products were to cause injury or death. The coverage limits of our product liability insurance policies may not be adequate to cover future claims, and we may be unable to maintain product liability insurance in the future at satisfactory rates or adequate amounts. A product liability claim, regardless of its merit or eventual outcome, could divert management's attention, result in significant legal defense costs, significant harm to our reputation and a decline in revenue.

**Table of Contents**

**Our costs could substantially increase if we receive a significant number of warranty claims.**

We generally warrant each of our products against defects in materials and workmanship for a period of 12 months following the installation of our system. If product returns or warranty claims increase, we could incur unanticipated additional expenditures for parts and service. In addition, our reputation and goodwill in the interventional lab market could be damaged. Unforeseen warranty exposure in excess of our established reserves for liabilities associated with product warranties could materially and adversely affect our financial condition, results of operations and cash flow.

**We may not generate cash from operations necessary to commercialize our existing products and invest in new products.**

We may require additional funds to meet our operational, working capital and capital expenditure needs in the future. We cannot be certain that we will be able to obtain additional financing on favorable terms or at all. If we need additional capital and cannot raise it on acceptable terms, we may not be able to, among other things:

enhance our existing products or develop new ones;

expand our operations;

hire, train and retain employees; or

respond to competitive pressures or capital requirements.

Our failure to do any of these things could result in lower revenue and adversely affect our financial condition and results of operations, and we may have to curtail or cease operations.

While we believe our existing cash, cash equivalents and investments, amounts outstanding under the Biosense Webster agreement related to prepaid royalties and research and development expenditures and funds available from our current borrowing sources will be sufficient to fund our operating expenses and capital equipment requirements through the next 12 months, we cannot assure you that we will not otherwise require additional financing before that time. If adequate funds are not available to us, we could be required to delay development or commercialization of new products, to license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize ourselves or to reduce the sales, marketing, customer support or other resources devoted to our products, any of which could have a material adverse effect on our business, financial condition and results of operations.

**We have incurred substantial losses in the past and may not be profitable in the future.**

We have incurred substantial net losses since inception, and we expect to incur substantial net losses into 2009 as we continue the commercialization of our products. We may not be successful in completing the development or commercialization of our technology. Moreover, the extent of our future losses and the timing of profitability are highly uncertain, and we may never achieve profitable operations. If we require more time than we expect to generate significant revenue and achieve profitability, we may not be able to continue our operations. Our failure to achieve profitability

## **Table of Contents**

could negatively impact the market price of our common stock. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Furthermore, even if we achieve significant revenue, we may choose to pursue a strategy of increasing market penetration and presence or expand or accelerate new product development or clinical research activities at the expense of profitability.

### **We may not be able to comply with debt covenants and may have to repay outstanding indebtedness**

We have financed our operations through equity transactions and bank and other borrowings. Our current bank loan agreement contains financial and other covenants which, if violated, could require the repayment of existing indebtedness and lead to the lack of availability of borrowings under that agreement. There can be no assurance that we will be able to maintain compliance with these covenants or that we could replace this source of liquidity if these covenants were to be violated and our loans were forced to be repaid.

### **Our reliance on contract manufacturers and on suppliers, and in some cases, a single supplier, could harm our ability to meet demand for our products in a timely manner or within budget.**

We depend on contract manufacturers to produce and assemble certain of the components of our systems and other products such as our guidewires and electrophysiology catheter advancement devices. We also depend on various third party suppliers for the magnets we use in our Niobe Magnetic Navigation Systems. In addition, some of the components necessary for the assembly of our products are currently provided to us by a single supplier, including the magnets for our Niobe Magnetic Navigation System, and we generally do not maintain large volumes of inventory. Our reliance on these third parties involves a number of risks, including, among other things, the risk that:

we may not be able to control the quality and cost of our system or respond to unanticipated changes and increases in customer orders;

we may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of our systems; and

we may not be able to find new or alternative components for our use or reconfigure our system and manufacturing processes in a timely manner if the components necessary for our system become unavailable.

If any of these risks materialize, it could significantly increase our costs and impair product delivery.

Lead times for materials and components ordered by us and our contract manufacturers vary and depend on factors such as the specific supplier, contract terms and demand for a component at a given time. We and our contract manufacturers acquire materials, complete standard subassemblies and assemble fully configured systems based on sales forecasts. If orders do not match forecasts, our contract manufacturers and we may have excess or inadequate inventory of materials and components.

## **Table of Contents**

In addition, if these manufacturers or suppliers stop providing us with the components or services necessary for the operation of our business, we may not be able to identify alternate sources in a timely fashion. Any transition to alternate manufacturers or suppliers would likely result in operational problems and increased expenses and could delay the shipment of, or limit our ability to provide, our products. We cannot assure you that we would be able to enter into agreements with new manufacturers or suppliers on commercially reasonable terms or at all.

Additionally, obtaining components from a new supplier may require a new or supplemental filing with applicable regulatory authorities and clearance or approval of the filing before we could resume product sales. Any disruptions in product flow may harm our ability to generate revenue, lead to customer dissatisfaction, damage our reputation and result in additional costs or cancellation of orders by our customers.

We also rely on our collaboration partner, Biosense Webster, and other parties to manufacture a number of disposable interventional devices for use with our Niobe system. If these parties cannot manufacture sufficient quantities of disposable interventional devices to meet customer demand, or if their manufacturing processes are disrupted, our revenue and profitability would be adversely affected.

### **Risks associated with international manufacturing and trade could negatively impact the availability and cost of our products because materials used to manufacture our magnets, one of our key system components, are sourced from overseas.**

We purchase the permanent magnets for our Niobe Magnetic Navigation System from a manufacturer that uses material produced in Japan, and we anticipate that certain of the production work for these magnets will be performed for this manufacturer in China. In addition, our subcontractor purchases magnets for our disposable interventional devices directly from a manufacturer in Japan. Any event causing a disruption of imports, including the imposition of import restrictions, could adversely affect our business. The flow of components from our vendors could also be adversely affected by financial or political instability in any of the countries in which the goods we purchase are manufactured, if the instability affects the production or export of product components from those countries. Trade restrictions in the form of tariffs or quotas, or both, could also affect the importation of those product components and could increase the cost and reduce the supply of products available to us. In addition, decreases in the value of the U.S. dollar against foreign currencies could increase the cost of products we purchase from overseas vendors.

### **We have limited experience in manufacturing and assembling our products and may encounter problems at our manufacturing facilities or those of our subcontractors or otherwise experience manufacturing delays that could result in lost revenue.**

We do not have extensive experience in manufacturing, assembling or testing our products on a commercial scale as we subcontract the manufacture, assembly and testing of subassemblies of our Niobe Magnetic Navigation System and all of our disposable devices. We may be unable to meet the expected future demand for our Niobe or Odyssey system. In addition, the products we design may not satisfy all of the performance requirements and we may need to improve or modify the design or ask our subcontractors to modify their production process in order to do so. We or our subcontractors may experience quality problems, substantial costs and unexpected delays related to

## **Table of Contents**

efforts to upgrade and expand manufacturing, assembly and testing capabilities. If we incur delays due to quality problems or other unexpected events, we will be unable to produce a sufficient supply of product necessary to meet our future growth expectations.

### **We may be unable to protect our technology from use by third parties.**

Our commercial success will depend in part on obtaining patent and other intellectual property right protection for the technologies contained in our products and on successfully defending these rights against third party challenges. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. We cannot assure you that we will obtain the patent protection we seek, that any protection we do obtain will be found valid and enforceable if challenged or that it will confer any significant commercial advantage. U.S. patents and patent applications may also be subject to interference proceedings and U.S. patents may be subject to re-examination proceedings in the U.S. Patent and Trademark Office, and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office, which proceedings could result in either loss of the patent or denial of the patent application or loss, or reduction in the scope of one or more of the claims of, the patent or patent application. In addition, such interference, re-examination, and opposition proceedings may be costly. Thus, any patents that we own or license from others may not provide any protection against competitors. Our pending patent applications, those we may file in the future, or those we may license from third parties may not result in patents being issued and certain foreign patent applications for medical related devices and methods may be found unpatentable. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology.

Some of our technology was developed in conjunction with third parties, and thus there is a risk that a third party may claim rights in our intellectual property. Outside the U.S., we rely on third-party payment services for the payment of foreign patent annuities and other fees. Non-payment or delay in payment of such fees, whether intentional or unintentional, may result in loss of patents or patent rights important to our business. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to work the invention in that country, or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. We also cannot assure you that we will be able to develop additional patentable technologies. If we fail to obtain adequate patent protection for our technology, or if any protection we obtain becomes limited or invalidated, others may be able to make and sell competing products, impairing our competitive position.

Our trade secrets, nondisclosure agreements and other contractual provisions to protect unpatented technology provide only limited and possibly inadequate protection of our rights. As a result, third parties may be able to use our unpatented technology, and our ability to compete in the market would be reduced. In addition, employees, consultants and others who participate in developing our products or in commercial relationships with us may breach their agreements with us regarding our intellectual property, and we may not have adequate remedies for the breach.

## **Table of Contents**

Our competitors may independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing any of our patent or other intellectual property rights, or may design around our proprietary technologies. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent, as do the laws of the U.S., particularly in the field of medical products and procedures.

### **Third parties may assert that we are infringing their intellectual property rights.**

Successfully commercializing our products will depend in part on not infringing patents held by third parties. It is possible that one or more of our products, including those that we have developed in conjunction with third parties, infringes existing patents. We may also be liable for patent infringement by third parties whose products we use or combine with our own and for which we have no right to indemnification. In addition, because patent applications are maintained under conditions of confidentiality and can take many years to issue, there may be applications now pending of which we are unaware and which may later result in issued patents that our products infringe. Determining whether a product infringes a patent involves complex legal and factual issues and may not become clear until finally determined by a court in litigation. Our competitors may assert that our products infringe patents held by them. Moreover, as the number of competitors in our market grows the possibility of a patent infringement claim against us increases. If we were not successful in obtaining a license or redesigning our products, we could be subject to litigation. If we lose in this kind of litigation, a court could require us to pay substantial damages or prohibit us from using technologies essential to our products covered by third-party patents. An inability to use technologies essential to our products would have a material adverse effect on our financial condition, results of operations and cash flow and could undermine our ability to continue operating as a going concern.

### **Expensive intellectual property litigation is frequent in the medical device industry.**

Infringement actions, validity challenges and other intellectual property claims and proceedings, whether with or without merit, can be expensive and time-consuming and would divert management's attention from our business. We have incurred, and expect to continue to incur, substantial costs in obtaining patents and may have to incur substantial costs defending our proprietary rights. Incurring such costs could have a material adverse effect on our financial condition, results of operations and cash flow.

### **We may not be able to obtain all the licenses from third parties necessary for the development of new products.**

As we develop additional disposable interventional devices for use with our system, we may find it advisable or necessary to seek licenses or otherwise make payments in exchange for rights from third parties who hold patents covering technology used in specific interventional procedures. If we cannot obtain the desired licenses or rights, we could be forced to try to design around those patents at additional cost or abandon the product altogether, which could adversely affect revenue and results of operations. If we have to abandon a product, our ability to develop and grow our business in new directions and markets would be adversely affected.

## **Table of Contents**

### **Our products and related technologies can be applied in different industries, and we may fail to focus on the most profitable areas.**

The Niobe system is designed to have the potential for expanded applications beyond electrophysiology and interventional cardiology, including congestive heart failure, structural heart repair, interventional neurosurgery, interventional neuroradiology, peripheral vascular, pulmonology, urology, gynecology and gastrointestinal medicine. We continue to develop the Odyssey system and the related Cinema and Connect features, for interventional labs that have a Niobe system installed as well as those standard interventional labs that do not have a Niobe system installed. However, we have limited financial and managerial resources and therefore may be required to focus on products in selected industries and sites and to forego efforts with regard to other products and industries. Our decisions may not produce viable commercial products and may divert our resources from more profitable market opportunities. Moreover, we may devote resources to developing products in these additional areas but may be unable to justify the value proposition or otherwise develop a commercial market for products we develop in these areas, if any. In that case, the return on investment in these additional areas may be limited, which could negatively affect our results of operations.

### **We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of their former employers.**

Many of our employees were previously employed at hospitals, universities or other medical device companies, including our competitors or potential competitors. We could in the future be subject to claims that these employees or we have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Incurring such costs could have a material adverse effect on our financial condition, results of operations and cash flow.

### **If we or our strategic partners fail to obtain or maintain necessary FDA clearances or approvals for our medical device products, or if such clearances or approvals are delayed, we will be unable to continue to commercially distribute and market our products.**

Our products are medical devices that are subject to extensive regulation in the U.S. and in foreign countries where we do business. Unless an exemption applies, each medical device that we wish to market in the U.S. must first receive either a 510(k) clearance or a pre-market approval, or PMA, from the U.S. Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act. The FDA's 510(k) clearance process usually takes from four to 12 months, but it can take longer. The process of obtaining PMA approval is much more costly, lengthy, and uncertain, generally taking from one to three years or even longer. Although we have 510(k) clearance for our current Stereotaxis system, including a limited number of disposable interventional devices, and are able to market our system commercially in the U.S., our business model relies significantly on revenue from disposable interventional devices, some of which may not achieve FDA clearance or approval. We cannot assure you that any of our devices will not be required to undergo the lengthier and more burdensome PMA process. We cannot commercially market any disposable interventional devices in the U.S. until the necessary clearances or approvals from the FDA have been received. In

## **Table of Contents**

addition, we are working with third parties to co-develop disposable products. In some cases, these companies are responsible for obtaining appropriate regulatory clearance or approval to market these disposable devices. If these clearances or approvals are not received or are substantially delayed or if we are not able to offer a sufficient array of approved disposable interventional devices, we may not be able to successfully market our system to as many institutions as we currently expect, which could have a material adverse impact on our financial condition, results of operations and cash flow.

Furthermore, obtaining 510(k) clearances, PMAs or PMA supplement approvals, from the FDA could result in unexpected and significant costs for us and consume management's time and other resources. The FDA could ask us to supplement our submissions, collect non-clinical data, conduct clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain a 510(k) clearance or PMA or PMA supplement approval, the clearance or approval could be revoked or other restrictions imposed if post-market data demonstrates safety issues or lack of effectiveness. We cannot predict with certainty how, or when, the FDA will act on our marketing applications. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be adversely affected. Also, a failure to obtain approvals may limit our ability to grow domestically and internationally.

### **If our strategic partners or we fail to obtain regulatory approvals in other countries for products under development, we will not be able to commercialize these products in those countries.**

In order to market our products outside of the U.S., we and our strategic partners must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects described above regarding FDA approval in the U.S. In addition, we are relying on our strategic partners in some instances to assist us in this regulatory approval process in countries outside the U.S. and Europe, for example, in Japan.

### **We may fail to comply with continuing regulatory requirements of the FDA and other authorities and become subject to substantial penalties.**

Even after product clearance or approval, we must comply with continuing regulation by the FDA and other authorities, including the FDA's Quality System Regulation, or QSR, requirements, labeling and promotional requirements and medical device adverse event and other reporting requirements. Any failure to comply with continuing regulation by the FDA or other authorities could result in enforcement action that may include suspension or withdrawal of regulatory approvals, recalling products, ceasing product manufacture and/or marketing, seizure and detention of products, paying significant fines and penalties, criminal prosecution and similar actions that could limit product sales, delay product shipment and harm our profitability. Congress could amend the Federal Food, Drug, and Cosmetic Act, and the FDA could modify its regulations promulgated under this law in a way to make ongoing regulatory compliance more burdensome and difficult.

## **Table of Contents**

Additionally, any modification to an FDA 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance. Modifications to a PMA approved device or its labeling may require either a new PMA or PMA supplement approval, which could be a costly and lengthy process. In the future, we may modify our products after they have received clearance or approval, and we may determine that new clearance or approval is unnecessary. We cannot assure you that the FDA would agree with any of our decisions not to seek new clearance or approval. If the FDA requires us to seek clearance or approval for any modification, we could be subject to enforcement sanctions and we also may be required to cease marketing or recall the modified product until we obtain FDA clearance or approval which could also limit product sales, delay product shipment and harm our profitability.

In many foreign countries in which we market our products, we are subject to regulations affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. Many of these regulations are similar to those of the FDA. In addition, in many countries the national health or social security organizations require our products to be qualified before procedures performed using our products become eligible for reimbursement. Failure to receive, or delays in the receipt of, relevant foreign qualifications could have a material adverse effect on our business, financial condition and results of operations. Due to the movement toward harmonization of standards in the European Union, we expect a changing regulatory environment in Europe characterized by a shift from a country-by-country regulatory system to a European Union-wide single regulatory system. We cannot predict the timing of this harmonization and its effect on us. Adapting our business to changing regulatory systems could have a material adverse effect on our business, financial condition, and results of operations. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension, or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

In addition, we are subject to the U.S. Foreign Corrupt Practices Act, antitrust and anti-competition laws, and similar laws in foreign countries, any violation of which could create a substantial liability for us and also cause a loss of reputation in the market. From time to time, we may face audits or investigations by one or more government agencies, compliance with which could be costly and time-consuming, and could divert our management and key personnel from our business operations. An adverse outcome under any such investigation or audit could subject us to fines or other penalties, which could adversely affect our business and financial results.

### **Our suppliers, subcontractors, or we may fail to comply with the FDA quality system regulation.**

Our manufacturing processes must comply with the FDA's quality system regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging and shipping of our products. The FDA enforces the QSR through inspections. We cannot assure you that we or our suppliers or subcontractors would pass such an inspection. If we or our suppliers or subcontractors fail to remain in compliance with the FDA or ISO 9001 standards, we or they may be required to cease all or part of our operations for some period of time

## **Table of Contents**

until we or they can demonstrate that appropriate steps have been taken to comply with such standards or face other enforcement action, such as a public warning letter. We cannot be certain that our facilities or those of our suppliers or subcontractors will comply with the FDA or ISO 9001 standards in future audits by regulatory authorities. Failure to pass such an inspection could force a shut down of manufacturing operations, a recall of our products or the imposition of other enforcement sanctions, which would significantly harm our revenue and profitability. Further, we cannot assure you that our key component suppliers are or will continue to be in compliance with applicable regulatory requirements and will not encounter any manufacturing difficulties. Any failure to comply with the FDA's QSR by us or our suppliers could significantly harm our available inventory and product sales.

### **Software or other defects may be discovered in our products.**

Our products incorporate many components, including sophisticated computer software. Complex software frequently contains errors, especially when first introduced. Because our products are designed to be used to perform complex interventional procedures, we expect that physicians and hospitals will have an increased sensitivity to the potential for software defects. We cannot assure you that our software or other components will not experience errors or performance problems in the future. If we experience software errors or performance problems, we would likely also experience:

loss of revenue;

delay in market acceptance of our products;

damage to our reputation;

additional regulatory filings;

product recalls;

increased service or warranty costs; and/or

product liability claims relating to the software defects.

**If we fail to comply with health care regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.**

While we do not control referrals of health care services or bill directly to Medicare, Medicaid or other third-party payors, many health care laws and regulations apply to our business. We could be subject to health care fraud and patient privacy regulation by the federal government, the states in which we conduct our business, and internationally. The regulations that may affect our ability to operate include:

the federal healthcare program Anti-Kickback Law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid programs;

**Table of Contents**

federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any health care benefit program or making false statements relating to health care matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;

federal self-referral laws, such as STARK, which prohibits a physician from making a referral to a provider of certain health services with which the physician or the physician's family member has a financial interest; and

regulations pertaining to receipt of CE mark for our products marketed outside of the United States and submission to periodic regulatory audits in order to maintain these regulatory approvals.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, loss of reimbursement for our products under federal or state government health programs such as Medicare and Medicaid and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment, or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expense and divert our management's attention from the operation of our business. Moreover, to achieve compliance with applicable federal and state privacy, security, and electronic transaction laws, we may be required to modify our operations with respect to the handling of patient information. Implementing these modifications may prove costly. At this time, we are not able to determine the full consequences to us, including the total cost of compliance, of these various federal and state laws.

## **Table of Contents**

### **The application of state certificate of need regulations and compliance by our customers with federal and state licensing or other international requirements could substantially limit our ability to sell our products and grow our business.**

Some states require health care providers to obtain a certificate of need or similar regulatory approval prior to the acquisition of high-cost capital items such as our Niobe system. In many cases, a limited number of these certificates are available. As a result of this limited availability, hospitals and other health care providers may be unable to obtain a certificate of need for the purchase of our Niobe system. Further, our sales and installation cycle for the Niobe system is typically longer in certificate of need states due to the time it takes our customers to obtain the required approvals. In addition, our customers must meet various federal and state regulatory and/or accreditation requirements in order to receive payments from government-sponsored health care programs such as Medicare and Medicaid, receive full reimbursement from third party payors, and maintain their customers. Our international customers may be required to meet similar or other requirements. Any lapse by our customers in maintaining appropriate licensure, certification or accreditation, or the failure of our customers to satisfy the other necessary requirements under government-sponsored health care programs or other requirements could cause our sales to decline.

### **Hospitals or physicians may be unable to obtain reimbursement from third-party payors for procedures using the Niobe system, or reimbursement for procedures may be insufficient to recoup the costs of purchasing our products.**

We expect that U.S. hospitals will continue to bill various third-party payors, such as Medicare, Medicaid and other government programs and private insurance plans, for procedures performed with our products, including the costs of the disposable interventional devices used in these procedures. If in the future our disposable interventional devices do not fall within U.S. reimbursement categories and our procedures are not reimbursed, or if the reimbursement is insufficient to cover the costs of purchasing our system and related disposable interventional devices, the adoption of our systems and products would be significantly slowed or halted, and we may be unable to generate sufficient sales to support our business. Our success in international markets also depends upon the eligibility of our products for reimbursement through government-sponsored health care payment systems and third-party payors. In both the U.S. and foreign markets, health care cost-containment efforts are prevalent and are expected to continue. These efforts could reduce levels of reimbursement available for procedures involving our products and, therefore, reduce overall demand for our products as well. A failure to generate sufficient sales could have a material adverse impact on our financial condition, results of operations and cash flow.

### **We may lose our key personnel or fail to attract and retain additional personnel.**

We are highly dependent on the principal members of our management, scientific and sales staff. To pursue our plans and accommodate planned growth, we may choose to hire additional personnel. Attracting and retaining qualified personnel will be critical to our success, and competition for qualified personnel is intense. We may not be able to attract and retain personnel on acceptable terms given the competition for qualified personnel among technology and healthcare companies and universities. The loss of personnel or our inability to attract and retain other qualified personnel could harm our business and our ability to compete. In addition, the loss of members of our scientific staff may significantly delay or prevent product development and other business objectives. A loss of key sales personnel could result in a reduction of revenue.

## **Table of Contents**

### **Our growth will place a significant strain on our resources, and if we fail to manage our growth, our ability to develop, market, and sell our products will be harmed.**

Our business plan contemplates a period of substantial growth and business activity. This growth and activity will likely result in new and increased responsibilities for management personnel and place significant strain upon our operating and financial systems and resources. To accommodate our growth and compete effectively, we will be required to improve our information systems, create additional procedures and controls and expand, train, motivate and manage our work force. We cannot be certain that our personnel, systems, procedures, and controls will be adequate to support our future operations. Any failure to effectively manage our growth could impede our ability to successfully develop market and sell our products.

### **We face currency and other risks associated with international operations.**

We intend to continue to devote significant efforts to marketing our systems and products outside of the U.S. This strategy will expose us to numerous risks associated with international operations, which could adversely affect our results of operations and financial condition, including the following:

currency fluctuations that could impact the demand for our products or result in currency exchange losses;

export restrictions, tariff and trade regulations and foreign tax laws;

customs duties, export quotas or other trade restrictions;

economic and political instability; and

shipping delays.

In addition, contracts may be difficult to enforce and receivables difficult to collect through a foreign country's legal system.

### **Risks Related To Our Common Stock**

#### **Our principal stockholders continue to own a large percentage of our voting stock, and they have the ability to substantially influence matters requiring stockholder approval.**

Our executive officers, directors and individuals or entities affiliated with them beneficially own or control a substantial percentage of the outstanding shares of our common stock. Accordingly, these executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. These stockholders may also delay or prevent a change of control, even if such a change of control would benefit our other stockholders. This significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

## **Table of Contents**

### **We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.**

We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings to fund the development and growth of our business. In addition, the terms of our loan agreement prohibit us from declaring dividends without the prior consent of our lender. As a result, capital appreciation, if any, of our common stock will be an investor's sole source of gain for the foreseeable future.

### **Our certificate of incorporation and bylaws, Delaware law and one of our alliance agreements contain provisions that could discourage a takeover.**

Our certificate of incorporation and bylaws and Delaware law contain provisions that might enable our management to resist a takeover. These provisions may:

discourage, delay or prevent a change in the control of the Company or a change in our management;

adversely affect the voting power of holders of common stock; and

limit the price that investors might be willing to pay in the future for shares of our common stock.

In addition, our alliance with Biosense Webster contains provisions that may similarly discourage a takeover and negatively affect our share price as described above.

### **Sales of a substantial number of shares of our common stock in the public market, or the perception that they may occur, may depress the market price of our common stock.**

Sales of substantial amounts of our common stock in the public market, or the perception that substantial sales may be made, could cause the market price of our common stock to decline. These sales might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate.

### **Evolving regulation of corporate governance and public disclosure may result in additional expenses and continuing uncertainty.**

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ Global Market rules have in the past created uncertainty for public companies. We continue to evaluate and monitor developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional compliance costs we may incur or the timing of such costs. These new or changed laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by courts and regulatory and governing bodies. This could result in uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Maintaining appropriate standards of corporate governance and public disclosure may result in increased general and administrative expense and a diversion of management time and attention from revenue-generating activities to compliance activities. In addition, if we fail to comply with new or changed laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business and reputation may be harmed.

**Table of Contents**

**Our future operating results may be below securities analysts or investors' expectations, which could cause our stock price to decline.**

The revenue and income potential of our products and our business model are unproven, and we may be unable to generate significant revenue or grow at the rate expected by securities analysts or investors. In addition, our costs may be higher than we, securities analysts, or investors expect. If we fail to generate sufficient revenue or our costs are higher than we expect, our results of operations will suffer, which in turn could cause our stock price to decline. Our results of operations will depend upon numerous factors, including:

demand for our products;

the performance of third-party contract manufacturers and component suppliers;

our ability to develop sales and marketing capabilities;

the success of our collaborations with Siemens, Philips and Biosense Webster and others;

our ability to develop, introduce and market new or enhanced versions of our products on a timely basis;

our ability to obtain regulatory clearances or approvals for our new products; and

our ability to obtain and protect proprietary rights.

Our operating results in any particular period may not be a reliable indication of our future performance. In some future quarters, our operating results may be below the expectations of securities analysts or investors. If this occurs, the price of our common stock will likely decline.

**We expect that the price of our common stock could fluctuate substantially, possibly resulting in class action securities litigation.**

Our common stock is traded on the NASDAQ Global Market and trading volume may be limited or sporadic. The market price of our common stock has experienced, and may continue to experience, substantial volatility. During 2008, our common stock traded between \$2.25 and \$12.57 per share, on trading volume ranging from approximately 23,000 to 2.9 million shares per day. The market price of our common stock will be affected by a number of factors, including:

actual or anticipated variations in our results of operations or those of our competitors;

the receipt or denial of regulatory approvals;

announcements of new products, technological innovations or product advancements by us or our competitors;

**Table of Contents**

developments with respect to patents and other intellectual property rights;

changes in earnings estimates or recommendations by securities analysts or our failure to achieve analyst earnings estimates; and

developments in our industry.

These factors, as well as general economic, political and market conditions, may materially adversely affect the market price of our common stock. As with the stock of many other public companies, the market price of our common stock has been particularly volatile during the recent period of upheaval in the capital markets and world economy. This excessive volatility may continue for an extended period of time following the filing date of this report. Furthermore, the stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Volatility in the price of our common stock on the NASDAQ Global Market may depress the trading price of our common stock, which could, among other things, allow a potential acquirer of the Company to purchase a significant amount of our common stock at low prices. Additionally, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Class action securities litigation, if instituted against us, could result in substantial costs and a diversion of our management resources, which could significantly harm our business.

**Future issuances of our securities could dilute current stockholders' ownership.**

A number of shares of our common stock are subject to stock options, stock appreciation rights and warrants. We may also decide to raise additional funds through public or private debt or equity financing to fund our operations. We cannot predict the effect, if any, that future sales of debt, our common stock, other equity securities or securities convertible into our common stock or other equity securities or the availability of any of the foregoing for future sale, will have on the market price of our common stock or notes. Sales of substantial amounts of our common stock (including shares issued upon the exercise of stock options, stock appreciation rights or the conversion of any convertible securities outstanding now or in the future), or the perception that such sales could occur, may adversely affect prevailing market prices for our common stock.

**Table of Contents**

**FORWARD-LOOKING STATEMENTS**

The prospectus contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1985. These statements relate to, among other things:

our business strategy;

our value proposition;

the timing and prospects for regulatory approval of our additional disposable interventional devices;

our estimates regarding our capital requirements;

the ability of physicians to perform certain medical procedures with our products safely, effectively and efficiently;

the adoption of our products by hospitals and physicians;

the market opportunity for our products, including expected demand for our products;

our plans for hiring additional personnel; and

any of our other plans, objectives, expectations and intentions contained in or incorporated by reference with this prospectus that are not historical facts.

These statements relate to future events or future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as *may*, *will*, *should*, *could*, *expects*, *plans*, *intends*, *anticipates*, *believes*, *estimates*, *potential* or *continue* or the negative of such terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. These statements are only predictions.

Factors that may cause our actual results to differ materially from our forward-looking statements include, among others, changes in general economic and business conditions and the risks and other factors set forth under *Risk Factors* beginning on page 2 of this prospectus.

Our actual results may be materially different from what we expect. We undertake no duty to update these forward-looking statements after the date of this prospectus, even though our situation may change in the future. The forward-looking statements included or incorporated by reference in this prospectus are only made as of the date of this prospectus or as of the date of such statement contained in the respective documents incorporated by reference herein, respectively, and we disclaim any obligation to publicly update any forward-looking statement to reflect subsequent events or circumstances. We qualify all of our forward-looking statements by these cautionary statements and the *Risk Factors* that appear elsewhere in this prospectus.



**Table of Contents****USE OF PROCEEDS**

We will not receive any proceeds from the selling stockholders' sales of our common stock. We could receive up to a maximum of approximately \$9,000,005 million in proceeds from the cash exercise of all the warrants by the selling stockholders, which proceeds would be used for general corporate purposes. As of the date hereof, none of the warrants have been exercised.

**PRICE RANGE OF COMMON STOCK**

Our common stock has been traded on the Nasdaq Global Market under the symbol STXS since August 12, 2004. The following table sets forth the high and low sale prices of our common stock for the periods indicated and are as reported by Nasdaq.

<b>Quarter</b>	<b>High</b>	<b>Low</b>
<b>Year Ended December 31, 2007</b>		
First Quarter	12.76	9.49
Second Quarter	13.55	9.95
Third Quarter	15.77	11.99
Fourth Quarter	16.88	11.90
<b>Year Ended December 31, 2008</b>		
First Quarter	\$ 12.57	\$ 3.37
Second Quarter	8.01	4.58
Third Quarter	7.99	4.63
Fourth Quarter	6.64	2.25
<b>Year Ending December 31, 2009</b>		
First Quarter	\$ 4.65	\$ 2.30
Second Quarter	\$ 4.88	\$ 2.98
Third Quarter (through August 5, 2009)	\$ 5.00	\$ 3.19

As of July 31, 2009, there were approximately 42,747,838 shares of common stock outstanding that were held of record by approximately 269 stockholders, although we believe that there is a significantly larger number of beneficial owners of our common stock.

**Table of Contents**

**SELLING STOCKHOLDERS**

This prospectus relates to the sale or other disposition of 2,154,526 shares of our common stock currently underlying warrants held by the selling stockholders or their transferees. The issuance of the shares upon exercise of warrants is not covered by this prospectus; only the resale of the shares underlying warrants are covered. The average weighted exercise price of the warrants is \$4.17 per share.

Effective February 7, 2008, we entered into a Note and Warrant Purchase Agreement with Alafi Capital Company and certain affiliates of Sanderling Venture Partners relating to (i) the commitment to lend to us up to an aggregate principal amount of \$20 million to be evidenced by promissory notes and (ii) the issuance of five-year warrants to purchase up to 572,246 shares of our common stock at an exercise price of \$6.99 per share.

Effective November 4, 2008, we executed a term sheet with Alafi Capital Company and certain affiliates of Sanderling Venture Partners under which they committed to extend their February 2008 agreement to loan us an aggregate of \$20 million on an unsecured basis though the earlier of March 31, 2010 or the date of a qualified financing. In February 2009, we exercised our option to extend the term of the Note and Warrant Purchase Agreement described above. In conjunction with this extension, we issued to Alafi Capital Company and certain affiliates of Sanderling Venture Partners five-year warrants to purchase an aggregate of 1,582,280 shares of our common stock at an exercise price of \$3.16 per share.

We have filed with the Commission, under the Securities Act, a registration statement on Form S-3, of which this prospectus forms a part, with respect to the resale of the shares issuable upon exercise of the warrants from time to time on the Nasdaq Global Market, in privately-negotiated transactions, or otherwise. We intend to prepare and file such amendments and supplements to the registration statement as may be necessary to keep the registration statement effective until all shares covered by the registration statement have been sold or may be resold in a 90-day period under Rule 144 of the Securities Act without volume limitation.

The following table sets forth the name of each selling stockholder, the number of shares of our common stock known by us to be beneficially owned by each selling stockholder as of July 31, 2009, the number of shares of our common stock that may be offered for resale for the account of each selling stockholder pursuant to this prospectus and the number of shares of our common stock to be held by each selling stockholder after the sale of all of the shares covered by this prospectus by that selling stockholder. Percentage ownership is based on approximately 42,747,838 shares of common stock outstanding as of July 31, 2009.

**Table of Contents**

The selling stockholders may sell all, some or none of the common stock being offered. This information is based upon our review of public filings, our stockholder, optionholder and warrant holder registers and information furnished by the selling stockholders.

Selling Stockholder	Shares Beneficially Owned Prior to the Offering (1)	Shares Offered by This Prospectus	Shares Beneficially Owned Subsequent to the Offering (1)(2)	
			Shares	Percent
Alafi Capital Company LLC (3)	3,891,373	1,077,263	4,968,636	11.62%
Sanderling Venture Partners VI Co-Investment, L.P. (4)	1,581,607	1,033,433	2,615,040	6.12%
Sanderling Beteiligungs GmbH & Co KG (4)	30,609	20,000	50,609	0.12%
Sanderling VI Limited Partnership (4)	36,470	23,830	60,300	0.14%
<b>Total</b>	<b>5,540,059</b>	<b>2,154,526</b>	<b>7,694,585</b>	<b>18.00%</b>

- (1) Beneficial ownership is determined in accordance with the rules of the Commission and generally includes voting or investment power with respect to securities.
- (2) Assumes for each stockholder the exercise in full of the warrant held by such stockholder and the sale of all shares offered hereby.
- (3) Mr. Christopher Alafi, one of our directors, and Moshe Alafi are the managing partners of Alafi Capital and have full voting and investment power with respect to the shares owned by Alafi Capital.
- (4) Mr. Fred A. Middleton, one of our directors, is affiliated with the Sanderling entities as detailed below.

Middleton-McNeil Associates IV, LLC is the general partner of Sanderling IV Biomedical Co-Investment Fund, L.P. and has voting and dispositive authority over the shares owned by Sanderling IV Biomedical Co-Investment Fund, L.P. Middleton-McNeil Associates IV, LLC is managed by its members, Fred A. Middleton and Robert G. McNeil.

Middleton-McNeil Associates IV, L.P. is the general partner of Sanderling Venture Partners IV Co-Investment Fund, L.P. and has voting and dispositive power over the shares owned by Sanderling Venture Partners IV Co-Investment Fund, L.P. Middleton-McNeil Associates IV, L.P. is managed by its general partners, Fred A. Middleton and Robert G. McNeil.

Middleton, McNeil & Mills Associates V, LLC is the Investment General Partner of Sanderling V Limited Partnership and Sanderling V Beteiligungs GmbH & Co. KG and the General Partner of Sanderling V Biomedical Co-Investment Fund, L.P. and Sanderling Venture Partners V Co-Investment Fund, L.P. and has voting and dispositive authority over the shares owned by such entities. Middleton, McNeil & Mills Associates V, LLC is managed by its managing directors, Fred A. Middleton, Robert G. McNeil, Timothy C. Mills, and Timothy J. Wollaeger.

**Table of Contents**

**PLAN OF DISTRIBUTION**

The selling stockholders, or, subject to applicable law, their pledgees, donees, distributees, transferees or other successors in interest, may sell shares from time to time in public transactions, on or off the Nasdaq Global Market, or in private transactions, at prevailing market prices or at privately negotiated prices, including but not limited to, one or any combination of the following types of transactions:

ordinary brokers transactions;

transactions involving cross or block trades or otherwise on the Nasdaq Global Market;

purchases by brokers, dealers or underwriters as principal and resale by these purchasers for their own accounts pursuant to this prospectus;

at the market, to or through market makers, or into an existing market for our common stock;

in other ways not involving market makers or established trading markets, including direct sales to purchasers or sales effected through agents;

through transactions in options, swaps or other derivatives (whether exchange-listed or otherwise);

in privately negotiated transactions; or

to cover short sales.

In effecting sales, brokers or dealers engaged by the selling stockholders may arrange for other brokers or dealers to participate in the resales. The selling stockholders may enter into hedging transactions with broker-dealers, and in connection with those transactions, broker-dealers may engage in short sales of the shares. The selling stockholders also may sell shares short and deliver the shares to close out such short positions. The selling stockholders also may enter into option or other transactions with broker-dealers that require the delivery to the broker-dealer of the shares, which the broker-dealer may resell pursuant to this prospectus. The selling stockholders also may pledge the shares to a broker or dealer. Upon a default, the broker or dealer may effect sales of the pledged shares pursuant to this prospectus.

Brokers, dealers or agents may receive compensation in the form of commissions, discounts or concessions from the selling stockholders in amounts to be negotiated in connection with the sale. The selling stockholders and any participating brokers or dealers may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commission, discount or concession these underwriters receive may be deemed to be underwriting compensation.

To the extent required, the following information will be set forth in a supplement to this prospectus:

information as to whether underwriters who the selling stockholders may select, or any other broker-dealer, is acting as principal or agent for the selling stockholders;

## Edgar Filing: Stereotaxis, Inc. - Form S-3

the compensation to be received by underwriters that the selling stockholders may select or by any broker-dealer acting as principal or agent for the selling stockholders; and

**Table of Contents**

the compensation to be paid to other broker-dealers, in the event the compensation of such other broker-dealers is in excess of usual and customary commissions.

Any dealer or broker participating in any distribution of the shares may be required to deliver a copy of this prospectus, including a prospectus supplement, if any, to any person who purchases any of the shares from or through this dealer or broker.

The selling stockholders will receive the aggregate proceeds from the sale of the common stock offered by them. The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any proceeds from the sale of common stock in this offering. We may receive proceeds from holders who exercise their warrants and pay the applicable cash exercise price in connection with those exercises.

We have advised the selling stockholders that they are required to comply with the anti-manipulation rules of Regulation M promulgated under the Securities Exchange Act during such time as they may be engaged in a distribution of the shares. With some exceptions, Regulation M precludes the selling stockholders, any affiliated purchasers and any broker-dealer or other person who participates in such distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security that is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the common stock.

---

**Table of Contents**

**DESCRIPTION OF CAPITAL STOCK**

As of the date of this prospectus, we are authorized to issue up to 110 million shares of capital stock, par value \$.001 per share, divided into two classes designated, respectively, common stock and preferred stock. Of such shares authorized, 100 million shares are designated as common stock, and 10 million shares are designated as preferred stock.

The following is a summary of the material terms of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws. Since the terms of our certificate of incorporation and bylaws, and Delaware law, are more detailed than the general information provided below, you should only rely on the actual provisions of those documents and Delaware law. If you would like to read those documents, they are on file with the SEC, as described under the heading *Where You Can Find Additional Information* below.

As of July 31, 2009, there were approximately 42,747,838 shares of common stock outstanding that were held of record by approximately 269 stockholders, although we believe that there is a significantly larger number of beneficial owners of our common stock. The holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the shares voting are able to elect all of the directors. Subject to preferences that may be granted to any then outstanding preferred stock, holders of common stock are entitled to receive ratably only those dividends as may be declared by the board of directors out of funds legally available therefor, as well as any distributions to the stockholders. In the event of our liquidation, dissolution or winding up, holders of common stock are entitled to share ratably in all of our assets remaining after we pay our liabilities and distribute the liquidation preference of any then outstanding preferred stock. Holders of common stock have no preemptive or other subscription or conversion rights. There are no redemption or sinking fund provisions applicable to the common stock.

**Anti-Takeover Provisions of Delaware Law and Charter Provisions**

*Interested Stockholder Transactions.* We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the number of shares outstanding those shares owned by persons who are directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines *business combination* to include the following:

any merger or consolidation involving the corporation and the interested stockholder;

any sale, transfer, pledge or other disposition involving the interested stockholder of assets with a value of 10% or more of either the total assets or all outstanding stock of the corporation;

subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or

the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation or any entity or person affiliated with or controlling or controlled by such entity or person.

In addition, some provisions of our amended and restated certificate of incorporation and amended and restated bylaws may be deemed to have an anti-takeover effect and may delay or prevent a tender offer or takeover attempt that a stockholder might consider in its best interest, including those attempts that might result in a premium over the market price for the shares held by stockholders.

*Cumulative Voting.* Our amended and restated certificate of incorporation expressly denies stockholders the right to cumulative voting in the election of directors.

*Classified Board of Directors.* Our board of directors is divided into three classes of directors serving staggered three-year terms. As a result, approximately one-third of the board of directors will be elected each year, which has the effect of requiring at least two annual stockholder meetings, instead of one, to replace a majority of the members of the board. These provisions, when coupled with the provision of our amended and restated certificate of incorporation authorizing only the board of directors to fill vacant directorships or increase the size of the board of directors, may deter a stockholder from removing incumbent directors and simultaneously gaining control of the board of directors by filling the vacancies created by such removal with its own nominees. The certificate of incorporation also provides that directors may be removed by stockholders only for cause. Since the board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management.

*Stockholder Action; Special Meeting of Stockholders.* Our amended and restated certificate of incorporation and bylaws do not permit stockholders to act by written consent. They provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer or a majority of our directors. Further, our amended and restated certificate of incorporation provides that the stockholders may amend bylaws adopted by the board of directors or specified provisions of the certificate of incorporation by the affirmative vote of at least 66 2/3% of our capital stock.

*Advance Notice Requirements for Stockholder Proposals and Directors Nominations.* Our amended and restated bylaws provide that stockholders seeking to bring business before an annual meeting of stockholders, or to nominate candidates for election as directors at an annual meeting of stockholders, must provide timely notice in writing. To be timely, a stockholder's notice must be delivered to or mailed and received at our principal executive offices not more than 120 days or less than 90 days prior to the anniversary date of the immediately preceding annual meeting of stockholders. However, in the event that the annual meeting is called for a date that is not within 30 days before or after such anniversary date, notice by the stockholder in order to be timely must be received not later than the close of business on the 10th day following the date on which notice of the date of the annual meeting was mailed to stockholders or made public, whichever first occurs. Our amended and restated bylaws also specify requirements as to the form and content of a stockholder's notice. These provisions may preclude stockholders from bringing matters before an annual meeting of stockholders or from nominating directors at an annual meeting of stockholders.

*Authorized But Unissued Shares.* Our authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of Stereotaxis by means of a proxy contest, tender offer, merger or otherwise.

*Amendments; Supermajority Vote Requirements.* The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless either a corporation's certificate of incorporation or bylaws require a greater percentage. Our amended and restated certificate of incorporation will impose supermajority vote requirements of 66 2/3% of the voting power of our capital stock in connection with the amendment of certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws, including those provisions relating to the classified board of directors, action by written consent and the ability of stockholders to call special meetings.

**Nasdaq Global Market Listing**

Our common stock is listed on the Nasdaq Global Market under the symbol STXS .

**Transfer Agent And Registrar**

The transfer agent and registrar for our common stock is BNY Mellon Shareowner Services LLC. Its address is 480 Washington Blvd., 27th Fl. Jersey City, NJ 07310, and its telephone number is (201) 680-4000.

---

**Table of Contents**

**LEGAL MATTERS**

The validity of the securities offered hereby has been passed upon for us by Bryan Cave LLP, St. Louis, Missouri. James L. Nouss, Jr., a partner of our legal counsel Bryan Cave LLP, beneficially owns 11,727 shares of our common stock, and is also our corporate secretary.

**EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements and schedule included in our Annual Report on Form 10-K (except as updated to reflect new information regarding our liquidity filed on a Current Report on Form 8-K on August 6, 2009) and our Current Report on Form 8-K filed on August 6, 2009 for the year ended December 31, 2008, and the effectiveness of our internal control over financial reporting as of December 31, 2008, as set forth in their reports, which are incorporated by reference in the registration statement. Our financial statements and schedule and the effectiveness of our internal control over financial reporting as of December 31, 2008 are incorporated herein by reference in reliance on Ernst & Young LLP's reports, given on their authority as experts in accounting and auditing.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>. The SEC's website contains reports, proxy and information statements and other information regarding issuers, such as us, that file electronically with the SEC. You may also read and copy any document we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the SEC. Please call the SEC at 1 800 SEC 0330 for further information on the operation of its Public Reference Room.

We have filed with the SEC a registration statement under the Securities Act of 1933 that registers the distribution of these securities. The registration statement, including the attached exhibits and schedules, contains additional relevant information about us and the securities. This prospectus does not contain all of the information set forth in the registration statement. You can get a copy of the registration statement, at prescribed rates, from the SEC at the address listed above. The registration statement and the documents referred to below under "Incorporation of Certain Documents by Reference" are also available on our Internet website, <http://www.stereotaxis.com>, under "Investors All SEC Filings." We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

**INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

The SEC allows us to incorporate by reference information into this prospectus, which means we can disclose important information to you by referring you to other documents that the company filed separately with the SEC. You should consider the incorporated information as if we reproduced it in this prospectus, except for any information directly superseded by information subsequently filed with the SEC and incorporated in this prospectus.

We incorporate by reference into this prospectus the following documents (SEC File No. 000-50884), which contain important information about us and our business and financial results:

our Annual Report on Form 10-K for the fiscal year ended December 31, 2008;

our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2009;

**Table of Contents**

our Current Reports on Form 8-K filed January 8, 2009, February 24, 2009, February 26, 2009 (regarding Item 3.02), February 27, 2009, March 16, 2009, April 10, 2009 and August 6, 2009 (regarding Item 5.02);

our Current Report on Form 8-K filed on August 6, 2009, which updated certain information in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008; and

the description of our common stock contained in our Registration Statement on Form 8-A filed August 2, 2004.

We incorporate by reference any additional documents that we may file with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 (other than the portions of those made pursuant to Item 2.02 or Item 7.01 of Form 8-K or other information furnished to the SEC) between August 30, 2006, the date we filed the registration statement to which this prospectus relates, and the termination of the offering of the securities. These documents may include periodic reports, like Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as Proxy Statements. Any material that we subsequently file with the SEC will automatically update and replace the information previously filed with the SEC.

For purposes of the registration statement of which this prospectus is a part, any statement contained in a document incorporated or deemed to be incorporated herein by reference shall be deemed to be modified or superseded to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated herein by reference modifies or supersedes such statement in such document. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of the registration statement of which this prospectus is a part.

You may get copies of any of the document incorporated by reference (excluding exhibits, unless the exhibits are specifically incorporated) at no charge to you by writing or calling the investor relations department at Stereotaxis, Inc. 4320 Forest Park Avenue, Suite 100, St. Louis, Missouri 63108, telephone (314) 678-6100.

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuances and Distribution.**

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, payable by Stereotaxis in connection with the issuance and distribution of the securities being registered. All amounts are estimates except the SEC registration fee.

Securities and Exchange Commission filing fee	\$ 557.00
Legal fees and expenses	10,000.00
Accounting fees and expenses	17,500.00
Printing expenses	2,500.00
<b>Total expenses</b>	<b>\$ 30,557.00</b>

**Item 15. Indemnification of Directors and Officers.**

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by the Delaware General Corporation Law as the same exists or may hereafter be amended, our directors shall not be liable to the Company or our stockholders for monetary damages for breach of fiduciary duty as a director. In addition, our certificate of incorporation provides that we may, to the fullest extent permitted by law, indemnify any person made or threatened to be made a party to an action, suit or proceeding, whether criminal, civil, administrative or investigative, by reason of the fact that such person or his or her testator or intestate is or was a director, officer or employee of the Company, or any predecessor of the Company, or serves or served at any other enterprise as a director, officer or employee at the request of the Company.

Our amended and restated bylaws provide that the Company shall indemnify our directors and officers to the fullest extent not prohibited by the Delaware General Corporation Law or any other law. We are not required to indemnify any director or officer in connection with a proceeding brought by such director or officer unless (i) such indemnification is expressly required by law; (ii) the proceeding was authorized by our board of directors; or (iii) such indemnification is provided by the Company, in its sole discretion, pursuant to the powers vested in the Company under the Delaware General Corporation Law or any other applicable law. In addition, our bylaws provide that the Company may indemnify its employees and other agents as set forth in the Delaware General Corporation Law or any other applicable law.

We have also entered into separate indemnification agreements with our directors that require us, among other things, to indemnify each of them against certain liabilities that may arise by reason of their status or service with the Company or on behalf of the Company, other than liabilities arising from willful misconduct of a culpable nature. The Company is not required to indemnify under the agreement for (i) actions initiated by the director without the authorization of consent of the board of directors; (ii) actions initiated to enforce the indemnification agreement unless the director is successful; (iii) actions resulting from violations of Section 16 of the Exchange Act in which a final judgment has been rendered against the director; and (iv) actions to enforce any non-compete or non-disclosure provisions of any agreement.

The indemnification provided for above provides for reimbursement of all losses of the indemnified party including, expenses, judgment, fines and amounts paid in settlement. The right to indemnification set forth above includes the right for us to pay the expenses (including attorneys fees) incurred in defending any such proceeding in advance of its final disposition in certain circumstances.

**Table of Contents**

The Delaware General Corporation Law provides that indemnification is permissible only when the director, officer, employee, or agent acted in good faith and in a manner reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the conduct was unlawful. The Delaware General Corporation Law also precludes indemnification in respect of any claim, issue, or matter as to which an officer, director, employee, or agent shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery of the State of Delaware or the court in which such action or suit was brought shall determine that, despite such adjudication of liability, but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court deems proper.

We have agreed to indemnify the underwriters and their controlling persons, and the underwriters have agreed to indemnify us and our controlling persons, against certain liabilities, including liabilities under the Securities Act. Reference is made to the Underwriting Agreement filed as part of the exhibits hereto.

See Item 17 for information regarding our undertaking to submit to adjudication the issue of indemnification for violation of the securities laws.

The Registrant maintains insurance policies that provide coverage to its directors and officers against certain liabilities.

**Item 16. Exhibits and Financial Statement Schedules.**

**Exhibit**

**Number Document Description**

- 4.1 Form of Specimen Stock Certificate, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 4.1.
- 4.2 Restated Articles of Incorporation of Stereotaxis, incorporated by reference to Exhibit 3.1 of the registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
- 4.3 Restated Bylaws of Stereotaxis, incorporated by reference to Exhibit 3.2 of the registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
- 4.4 Note and Warrant Purchase Agreement, effective February 7, 2008, between Stereotaxis and the investors named therein, incorporated by reference to Exhibit 10.31 of the registrant's Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2007.
- 4.5 First Amendment to Note and Warrant Purchase Agreement, effective December 29, 2008, between Stereotaxis and the investors named therein, incorporated by reference to Exhibit 10.32b of the registrant's Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2008.
- 5.1 Opinion of Bryan Cave LLP
- 23.1 Consent of Ernst & Young LLP
- 23.2 Consent of Bryan Cave LLP (included in Exhibit 5.1)
- 24.1 Power of Attorney (included on signature page)

**Item 17. Undertakings.**

- (a) The undersigned registrant hereby undertakes:

---

**Table of Contents**

- (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 Securities Exchange 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;
  - (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) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed 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) 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
  - (ii) 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

---

**Table of Contents**

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.

- (5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
  - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
  - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
  - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (b) The undersigned registrant hereby undertakes 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 that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (c) If the securities registered are to be offered at competitive bidding, the undersigned registrants hereby undertake: (1) to use their respective best efforts to distribute prior to the opening of bids, to prospective bidders, underwriters, and dealers, a reasonable number of copies of a prospectus which at that time meets the requirements of Section 10(a) of the Act, and relating to the securities offered at competitive bidding, as contained in the registration statement, together with any supplements thereto, and (2) to file an amendment to the registration statement reflecting the results of bidding, the terms of the reoffering and related matters to the extent required by the applicable form, not later than the first use, authorized by the issuer after the opening of bids, of a prospectus relating to the securities offered at competitive bidding, unless no further public offering of such securities by the issuer and no reoffering of such securities by the purchasers is proposed to be made.
- (d) 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

**Table of Contents**

Commission such indemnification is against public policy as expressed in said Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of 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 Act and will be governed by the final adjudication of such issue.

(e) The undersigned registrant hereby undertakes:

- (1) That for purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) That for the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus 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.

**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 for 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 St. Louis, State of Missouri, on August 6, 2009.

STEREOTAXIS, INC.

By: /s/ Michael P. Kaminski  
Michael P. Kaminski  
President and Chief Executive Officer

**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Fred A. Middleton, Michael P. Kaminski and James M. Stolze, and each of them (with full power of each to act alone), severally, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him to execute in his name, place and stead (individually and in any capacity stated below) any and all amendments to this registration statement (including post-effective amendments), and any additional registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, for the offerings contemplated by this registration statement, and all documents and instruments necessary or advisable in connection therewith, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission (or any other governmental regulatory authority), each of said attorneys-in-fact and agents to have power to act with or without the others and to have full power and authority to do and to perform in the name and on behalf of each of the undersigned every act whatsoever necessary or advisable to be done in the premises as fully and to all intents and purposes as any of the undersigned might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents and/or any of them, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities indicated and on the dates indicated.

<b>Signature</b>	<b>Title(s)</b>	<b>Date</b>
/s/ Fred A. Middleton	Chairman of the Board	July 31, 2009
<b>Fred A. Middleton</b>		
/s/ Michael P. Kaminski	President, Chief Executive Officer and Director (Principal Executive Officer)	July 31, 2009
<b>Michael P. Kaminski</b>		
/s/ James M. Stolze	Vice President and Chief Financial Officer (Principal Accounting Officer and Principal Financial Officer)	July 31, 2009
<b>James M. Stolze</b>		
/s/ Christopher Alafi	Director	July 31, 2009
<b>Christopher Alafi</b>		
/s/ David W. Benfer	Director	July 31, 2009
<b>David W. Benfer</b>		
/s/ Bevil J. Hogg	Director	July 31, 2009

Edgar Filing: Stereotaxis, Inc. - Form S-3

<b>Bevil J. Hogg</b>		
/s/ William M. Kelley	Director	July 31, 2009
<b>William M. Kelley</b>		
/s/ Abhijeet J. Lele	Director	July 31, 2009
<b>Abhijeet J. Lele</b>		
/s/ Robert J. Messey	Director	July 31, 2009
<b>Robert J. Messey</b>		
/s/ William C. Mills III	Director	July 31, 2009
<b>William C. Mills III</b>		
/s/ Eric N. Prystowsky	Director	July 31, 2009
<b>Eric N. Prystowsky</b>		

**Table of Contents**

**EXHIBIT INDEX**

**Exhibit**

**Number Document Description**

- 4.1 Form of Specimen Stock Certificate, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at exhibit 4.1.
- 4.2 Restated Articles of Incorporation of Stereotaxis, incorporated by reference to Exhibit 3.1 of the registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
- 4.3 Restated Bylaws of Stereotaxis, incorporated by reference to Exhibit 3.2 of the registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
- 4.4 Note and Warrant Purchase Agreement, effective February 7, 2008, between Stereotaxis and the investors named therein, incorporated by reference to Exhibit 10.31 of the registrant's Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2007.
- 4.5 First Amendment to Note and Warrant Purchase Agreement, effective December 29, 2008, between Stereotaxis and the investors named therein, incorporated by reference to Exhibit 10.32b of the registrant's Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2008.
- 5.1 Opinion of Bryan Cave LLP
- 23.1 Consent of Ernst & Young LLP
- 23.2 Consent of Bryan Cave LLP (included in Exhibit 5.1)
- 24.1 Power of Attorney (included on signature page)