

Stereotaxis, Inc.  
Form S-3/A  
December 15, 2005  
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As filed with the Securities and Exchange Commission on December 15, 2005

Registration No. 333-129629

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

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**Pre-effective Amendment**  
**No. 1**  
**to**  
**FORM S-3**  
**REGISTRATION STATEMENT**  
*UNDER*  
*THE SECURITIES ACT OF 1933*

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**STEREOTAXIS, INC.**

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

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

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St. Louis, Missouri 63108

(314) 615-6940

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**St. Louis, Missouri 63108**

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

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

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**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. x

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. "

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

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

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

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**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 December 15, 2005**

**PROSPECTUS**

**\$75,000,000**

**Common Stock**

**Preferred Stock**

**Warrants**

**Units**

We may offer and sell from time to time up to \$75,000,000 of common stock, preferred stock, warrants, or units consisting of any two or more of such securities.

We will provide specific terms of these securities in supplements to this prospectus for each offering of securities. This prospectus may not be used to sell securities unless accompanied by a prospectus supplement.

Our common stock is listed on the Nasdaq National Market under the symbol STXS. Each prospectus supplement offering any securities other than our common stock will state whether those securities are listed or will be listed on any exchange, quotation system or market.

We may offer securities through underwriting syndicates managed or co-managed by one or more underwriters, or directly to purchasers. The prospectus supplement for each offering of securities will describe in detail the plan of distribution for that offering. For general information about the distribution of securities, see [Plan of Distribution](#) in this prospectus.

Investing in these securities involves significant 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 \_\_\_\_\_, 2005.

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**ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, which we refer to as the SEC, utilizing a shelf registration process. Under this shelf process, we may, from time to time, sell any combination of the securities described in this prospectus in one or more offerings up to a total amount of \$75,000,000.

This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. We will file each prospectus supplement with the SEC. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described under the heading Where You Can Find Additional Information below.

You should rely on the information contained in this prospectus and any prospectus supplement, including the information incorporated by reference. We have not authorized anyone to provide you with different information. The information contained in this prospectus is complete and accurate only as of the date on the front cover, but the information may have changed since that date.

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**THE COMPANY**

Stereotaxis, Inc. designs, manufactures and markets an advanced cardiology instrument control system for use in a hospital's interventional surgical suite to enhance the treatment of coronary artery disease, congestive heart failure, and arrhythmias. Our NIOBE cardiology magnet system, which is the core of our Stereotaxis System, is designed to enable physicians to complete more complex interventional procedures by providing image guided delivery of catheters and guidewires through the blood vessels and chambers of the heart to treatment sites. This is achieved using computer-controlled, externally applied magnetic fields that govern the motion of the working tip of the catheter or guidewire, which we believe will result in improved navigation, shorter procedure times and reduced x-ray exposure. The core components of our Stereotaxis System have received regulatory clearance in the U.S. and Europe and we intend to continue to seek clearance or approvals for new products or in other countries in which we intend to operate.

We were incorporated in Delaware in June 1990 as Stereotaxis, Inc. Our principal executive offices are located at 4041 Forest Park Avenue, St. Louis, Missouri 63108, and our telephone number is (314) 615-6940. 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 "we", "our", "us" and "Stereotaxis" refer to Stereotaxis, Inc. unless the context requires otherwise.

NIOBE®, CARDIODRIVE®, CRONUS®, HELIOS®, TELSTAR®, ILIAD®, and TANGENT® are some of our registered trademarks. NAVIGANT™ DIGITAL SOLUTIONS FOR INTERVENTIONAL MEDICINE, SYNOPSIS, ODYSSEY, ARGOSY, MAI, REDEFINING INTERVENTIONAL MEDICINE are some of our other trademarks. This prospectus also refers to trademarks and trade names of other organizations.

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**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 our 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.*

**Risks Related to Our Business**

**Hospital decision-makers may not purchase our Stereotaxis System or may think that it is 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 cardiology magnet system. The NIOBE, which is the core of our Stereotaxis System, is a novel device, and hospitals and physicians are traditionally slow to adopt new products and treatment practices. Moreover, the Stereotaxis System is an expensive piece of capital equipment, representing a significant portion of the cost of a new or replacement cath lab. If hospitals do not widely adopt our Stereotaxis System, or if they decide that it is too expensive, we may never become profitable. Any failure to sell as many Stereotaxis Systems as our business plan requires could also have a seriously detrimental impact on our results of operations, financial condition and cash flow.

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

We believe that physicians will not use our products unless they determine that the Stereotaxis System provides a safe, effective and preferable alternative to methods in general use today. Currently, there is only limited clinical data on the Stereotaxis 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 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 and J&J or others may fail, or we may not be able to enter into additional partnerships or collaborations in the future.**

We are collaborating with Siemens, Philips and J&J 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 Stereotaxis System. For the immediate future, a significant portion of our revenues from system sales will be derived from these integrated products. In addition, each of Siemens and Philips has agreed to provide post-installation maintenance and support services to our customers for our integrated systems.





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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 Stereotaxis System as planned;

any of our collaboration partners does not co-market and co-promote our integrated products diligently or does 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 J&J, 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. In particular, we have had only limited experience with respect to the integration of our system with Philips' imaging products.

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 revenues could be adversely affected.

**Investors may have difficulty evaluating our business and operating results because we are still in the early stages of commercializing our products.**

We have been engaged in research and product development since our inception in 1990. Our initial focus was on the development of neurosurgical applications for our technology, and during the first several years following our inception, we devoted our resources primarily to developing prototypes and performing research and development activities in this area. Starting around 1998, we shifted our primary focus over the next two years to developing applications for our technology to treat cardiovascular disease and, in 2003, began limited commercial shipments of products we developed for treatment in this area. To date, our investments in our products have produced relatively little revenue, and our operating expenses are high relative to that revenue. Our lack of a significant operating history also impairs an investor's ability to make a comparative evaluation of us, our products and our prospects.

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

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 that provide training, clinical support, and other services to our customers. If we are unable to increase our sales force or effectively utilize our existing sales force in the foreseeable future, we may be unable to generate the revenues we have projected in our business plan. Factors that may inhibit our sales and marketing efforts include:

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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

increased government scrutiny with respect to marketing activities in the health care industry.

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

### **We may lose or fail to attract 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 such support and collaboration, our ability to market the Stereotaxis System 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 Stereotaxis 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.

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. For example, we are aware that two private companies are developing non-magnetic assisted navigation devices that could compete directly with the Stereotaxis System. However, to the best of our knowledge, these products have not been commercialized. 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.

Most 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 revenues would be reduced or eliminated if our competitors develop and market products that are more effective and less expensive than our products.



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**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.**

We currently have outstanding purchase orders and other commitments for our systems. There can be no assurance 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 canceled, either by their express terms, as a result of negotiations or by project changes or delays. The installation of our system is inherently controlled by the cath lab construction or renovation process which comprises multiple stages, all of which are outside of our control. Although the actual installation of our system requires only a few weeks, and can be accomplished either by 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. Substantial delays in the installation process also increase the risk that a customer would attempt to cancel a purchase order. This would have a negative effect on our revenues and results of operations.

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

We anticipate that our 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' cath lab budget process for capital expenditures, and, in some instances, a certificate of need from the state or other regulatory approval. In addition, our system has typically been installed six to eight months after the receipt of a purchase order from a hospital due to 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 and this may happen with existing or future purchase orders. These factors have contributed, and may continue to contribute to substantial fluctuations in our quarterly operating results, particularly in the near term and during any other periods in which our sales volume is relatively low. 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 cath lab, sales of our products would be negatively affected.**

Our system generates magnetic fields that directly govern the motion of the internal, or working, tip of disposable interventional devices. If other equipment in the cath lab 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. Although we have modified our shielding approach, if magnetic interference is a problem at additional 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

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management's attention, result in significant legal defense costs, significant harm to our reputation and a decline in revenues.

### **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 from the acceptance of our product by a customer. 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 cath lab market could be damaged. While we have established reserves for liability associated with product warranties, unforeseen warranty exposure in excess of those reserves 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.**

In order to meet our working capital and capital expenditure needs in the future, we will need to obtain financing in addition to cash generated from operations. 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 unanticipated capital requirements.

Our failure to do any of these things could result in lower revenues and adversely affect our financial condition and results of operations, and we may have to curtail or cease 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 in the balance of 2005 and 2006 as we seek additional regulatory approvals, launch new products and generally continue to scale up our sales, marketing and manufacturing operations to continue the commercialization of our products. At September 30, 2005 we had cumulative operating losses of approximately \$145 million. Because we may not be successful in completing the development or commercialization of our technology, our return on these investments may be limited. 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 revenues and achieve profitability, we may not be able to continue our operations. Our failure to achieve profitability 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 revenues, we



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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.

**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 most of the components of our systems and other products, such as our guidewires and electrophysiology catheters. We also depend on various third party suppliers for the magnets we use in our NIOBE cardiology magnet systems. In addition, some of the

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components necessary for the assembly of our products are currently provided to us by a single supplier, including the magnets for our NIOBE cardiology magnet 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.

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 revenues, 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, J&J, and other parties to manufacture a number of disposable interventional devices for use with our Stereotaxis System. If these parties cannot manufacture sufficient quantities of disposable interventional devices to meet customer demand, or if their manufacturing processes are disrupted, our revenues and profitability would be adversely affected.

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

We purchase the permanent magnets for our NIOBE cardiology magnet system from a manufacturer that uses material produced in Japan, and certain of the production work for these magnets is performed for this manufacturer in China. In addition, we purchase our magnets for our disposable interventional devices directly from a manufacturer in Japan, and a number of other components for our system in foreign jurisdictions, including components sourced locally in connection with installations. 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.

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### **We have limited experience in manufacturing and assembling our products and may encounter problems at our manufacturing facilities 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. In addition, for our NIOBE cardiology magnet systems, we subcontract the manufacturing of major components and complete the final assembly and testing of those components in-house. As a result, we may be unable to meet the expected future demand for our Stereotaxis 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 production process in order to do so. We may also experience quality problems, substantial costs and unexpected delays in our efforts to upgrade and expand our 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 systems necessary to meet our future growth expectations. In addition, we design, test, and manufacture a portion of the disposable devices that are used with our NIOBE magnetic navigation system. In order to do so, we will need to retain qualified employees for our assembly and testing operations. In addition, we are dependent on the facilities we lease in St. Louis, Missouri and Maple Grove, Minnesota in order to manufacture and assemble certain products. We could encounter problems at either of these facilities, which could delay or prevent us from assembling or testing our products or otherwise conducting operations. We intend to move our St. Louis operations to new facilities in the St. Louis area at the end of 2005. Moving to a new facility could disrupt our systems assembly or testing activities, research and development activities and financial activities and might divert the attention of our management and other key personnel from our business operations.

### **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 reexamination 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, reexamination 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. 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.

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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.

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. 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. For example, we recently made a substantial payment to the University of Virginia Patent Foundation to eliminate any requirement for us to pay royalties on Stereotaxis products that address clinical applications in the cardiovascular, peripheral vascular and certain other clinical fields. 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 revenues 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.



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

The Stereotaxis System is designed to have the potential for expanded applications beyond interventional cardiology and electrophysiology, including congestive heart failure, structural heart repair, interventional neurosurgery, interventional neuroradiology, peripheral vascular, pulmonology, urology, gynecology and gastrointestinal medicine. However, we have limited financial and managerial resources and therefore may be required to focus on products in selected industries 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 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. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain potential products, which could severely harm our business. 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 510(k) clearance or 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 revenues from additional disposable interventional devices for which there is no current FDA clearance or approval. We cannot commercially market our unapproved disposable interventional devices in the U.S. until the necessary clearance or approvals from the FDA have been received. Until such time, we can only supply these devices to research institutions for permitted investigational use. In addition, we are working with third parties with whom we are co-developing 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, pre-market approvals, or PMAs, or premarket approval supplements, or PMA supplements, from the FDA could result in unexpected and significant costs for us and



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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. Obtaining regulatory approvals in foreign markets entails similar risks and uncertainties and can involve additional product testing and additional administrative review periods. 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 we or our strategic partners 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 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.

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. Device 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 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 addition, Congress could amend the Federal Food, Drug and Cosmetic Act, and the FDA could modify its regulations promulgated under this law in a way so as to make ongoing regulatory compliance more burdensome and difficult.

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

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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.

### **Our suppliers 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 would pass such an inspection. Failure to pass such an inspection could force a shut down of our manufacturing operations, a recall of our products or the imposition of other sanctions, which would significantly harm our revenues 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, due to their breadth, apply to our business. We could

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be subject to health care fraud and patient privacy regulation by both the federal government and the states in which we conduct our business. 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, offering or paying 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;

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; and

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

the federal Foreign Corrupt Practices Act, which makes it unlawful to bribe foreign government officials to obtain or retain business.

Regulations of the FDA, prohibiting, among other practices, false or misleading regulatory submissions and promotional activities.

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 expenses 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.

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### **The application of state certificate of need regulations and compliance 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 Stereotaxis 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 Stereotaxis System. Further, our sales and installation cycle for the Stereotaxis 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 Stereotaxis 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 could 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 and scientific staff, in particular Bevil J. Hogg, our President and Chief Executive Officer, and Michael P. Kaminski, our Chief Operating Officer. In order 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 any of these persons or our inability to attract and retain other qualified personnel could harm our business and our ability to compete. In addition, Douglas M. Bruce, our Senior Vice President, Research & Development, coordinates our scientific staff and the research and development projects they undertake; the loss of Mr. Bruce or other members of our scientific staff may significantly delay or prevent product development and other business objectives.

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**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 sales.**

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 an Investment in Our Securities**

**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.**

As of September 30, 2005, 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

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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.

**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 return 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

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appreciation, if any, of our common stock will be the sole source of gain to investors in our common stock 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 our 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, under our alliance with J&J, either party may terminate the alliance under certain circumstances involving a change of control of Stereotaxis. Any termination must be effected within 90 days of the change of control, but would be effective one year after the change of control. If we terminate under this provision, we must pay a termination fee to J&J equal to 5% of the total equity value of Stereotaxis in the change of control transaction, up to a maximum of \$10 million. We also agreed to notify J&J if we reasonably consider that we are engaged in substantive discussions in respect of the sale of the company or substantially all of our assets. These provisions 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 National Market rules are creating uncertainty for public companies. We are presently evaluating and monitoring 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 continuing 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 expenses and a diversion of management time and attention from revenue-generating activities to



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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.

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**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 revenues 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 revenues 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 J&J 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.**

We have only been publicly traded since August 12, 2004. A limited number of our shares trade actively in the market. 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;

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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.

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. Following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation

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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.

**Any securities we offer under this registration statement may not develop an active public market, which could depress the resale price of the securities.**

Any securities that we may offer, other than our common stock, will be new issues of securities for which there is currently no trading market. We cannot predict whether an active trading market for the securities will develop or be sustained. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. If an active trading market were to develop, the securities could trade at prices that may be lower than the initial offering price of the securities. We cannot guarantee the liquidity of the trading markets for any securities.

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**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;

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;

our estimates regarding our capital requirements; and

any of our other plans, objectives, expectations and intentions contained in this annual report 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. We qualify all of our forward-looking statements by these cautionary statements and the *Risk Factors* that appear elsewhere in this prospectus.



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**USE OF PROCEEDS**

Unless otherwise indicated in the applicable prospectus supplement, we anticipate that the net proceeds, if any, from the sale of the securities that we may offer under this prospectus and any accompanying prospectus supplement will be used for:

working capital;

continued sales, marketing and clinical support initiatives relating to the commercialization of our products;

continued research and development, including the enhancement of our existing system through ongoing product and software development, the design of new proprietary disposable interventional devices for use with our system and the development of next generation versions of our system; and

for general corporate purposes, which may include the purchase of equipment and the expansion or relocation of facilities.

We have not yet determined the amount or timing of the expenditures for each of the categories listed above and these expenditures may vary significantly depending on a variety of factors, including the timing of additional regulatory approvals and new product introductions. As a result, we will retain broad discretion in the allocation and use of the net proceeds of this offering.

From time to time, we have discussed potential strategic acquisitions and investments with third parties. Currently, we have no agreements or commitments to enter into any such transactions.

**Table of Contents****RATIO OF EARNINGS AVAILABLE TO COVER FIXED CHARGES**

The ratio of earnings to fixed charges and the ratio of earnings to combined fixed charges and preferred stock dividends for each of the periods indicated is as follows:

|  | Nine months   |                                |      |      |      |      |
|--|---------------|--------------------------------|------|------|------|------|
|  | ended         |                                |      |      |      |      |
|  | September 30, | Fiscal year ended December 31, |      |      |      |      |
|  | 2005          | 2004                           | 2003 | 2002 | 2001 | 2000 |
| Ratio of earnings available to cover fixed charges(1)                            |               |                                |      |      |      |      |
| Ratio of earnings available to combined fixed charges and preferred dividends(1) |               |                                |      |      |      |      |

- (1) Due to our losses in years ended December 31, 2000, 2001, 2002, 2003 and 2004 and the nine months ended September 30, 2005, the ratio coverage was less than 1:1. Additional earnings of \$9.5 million, \$17.0 million, \$21.5 million, \$24.0 million, \$27.3 million and \$30.6 million would have been required in each of those periods, respectively, to achieve a coverage of 1:1.

In calculating the ratio of earnings available to cover fixed charges and the ratio of earnings available to cover combined fixed charges and preferred dividends, earnings consists of net income (loss) before provisions for income taxes plus fixed charges. Fixed charges consist of: interest expense and a portion of rentals estimated to represent interest.

For the periods set forth in the table above, we had preferred stock outstanding only during 2000, 2001, 2002, 2003 and until August 17, 2004. All outstanding shares of preferred stock were converted into shares of common stock in connection with our initial public offering in August 2004. We have no preferred stock outstanding as of the date of this prospectus.



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**DESCRIPTION OF CAPITAL STOCK**

As of the date of this prospectus, we are authorized to issue up to 110,000,000 shares of capital stock, par value \$.001 per share, divided into two classes designated, respectively, common stock and preferred stock. Of such shares authorized, 100,000,000 shares are designated as common stock, and 10,000,000 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. It also summarizes some relevant provisions of the Delaware General Corporation Law, which we sometimes refer to as Delaware law. 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* on page 29.

**Common Stock**

As of September 30, 2005, there were 27,684,704 shares of common stock outstanding that were held of record by approximately 156 stockholders. 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.

**Preferred Stock**

Our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of Stereotaxis. We have no present plan to issue any shares of preferred 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 holder;

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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 of 10% or more of the assets of the corporation involving the interested stockholder;

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 loss, 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

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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 does 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 provide 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 provides 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 or between January 11, 2006 and February 10, 2006 in the case of the 2006 annual meeting. 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 making nominations for 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 National Market Listing**

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

## **Transfer Agent And Registrar**

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The transfer agent and registrar for our common stock is The Bank of New York. Its address is 101 Barclay Street, Floor 11E, New York, NY 10286, and its telephone number is (212) 815-3644.

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**DESCRIPTION OF WARRANTS**

We may issue warrants, including warrants to purchase preferred stock, common stock or other securities or any combination of the foregoing. Warrants may be issued independently or as part of a unit with any other securities and may be attached to or separate from the underlying securities. The warrants will be issued under warrant agreements to be entered into between us and a bank or trust company, as warrant agent, as detailed in the prospectus supplement relating to warrants being offered.

A prospectus supplement relating to any warrants being offered will include specific terms relating to the offering, including a description of any other securities sold together with the warrants. There items will include:

the title of the warrants;

the aggregate number of the warrants;

the price or prices at which the warrants will be issued;

the currencies in which the price or prices of the warrants may be payable;

the designation, amount, and terms of the common stock, preferred stock or other securities or rights, including rights to receive payment in cash or securities based on the value, rate or price of one or more specified commodities, currencies or indices, purchasable upon exercise of the warrants and procedures by which those numbers may be adjusted;

the designation and terms of the other offered securities, if any, with which the warrants are issued and the number of the warrants issued with each security;

if applicable, the date on and after which the warrants and the offered securities purchasable upon exercise of the warrants will be separately transferable;

the price or prices at which the offered securities purchasable upon exercise of the warrants may be purchased;

the date on which the right to exercise the warrants shall commence and the date on which the right shall expire;

the minimum or maximum amount of the warrants that may be exercised at any one time;

any terms relating to the modification of the warrants;

information with respect to book-entry procedures, if any;

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a discussion of any material federal income tax considerations; and

any other material terms of the warrants, including terms, procedures, and limitations relating to the transferability, exchange, exercise or redemption of the warrants.

Warrants issued for securities other than common stock or preferred stock will not be exercisable until at least one year from the date of sale of the warrant.



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The applicable prospectus supplement will describe the specific terms of any warrant units.

As of September 30, 2005, there were warrants outstanding to purchase 1,063,019 shares of common stock at a weighted average exercise price of \$8.58.

The descriptions of the warrant agreements in this prospectus and in any prospectus supplement are summaries of the applicable provisions of the applicable agreements. These descriptions do not restate those agreements in their entirety and do not contain all of the information that you may find useful. We urge you to read the applicable agreements because they, and not the summaries, define your rights as holders of the warrants or any warrant units. For more information, please review the form of the relevant agreements, which will be filed with the SEC promptly after the offering of the warrants or warrant units and will be available as described in the heading **Where You Can Find Additional Information** on page 29.

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**DESCRIPTION OF UNITS**

We may issue units comprised of one or more of the other securities described in this prospectus in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The units may be issued under units agreements to be entered into between us and a bank or trust company, as unit agent, as detailed in the prospectus supplement relating to units being offered. The prospectus supplement will describe:

the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances the securities comprising the units may be held or transferred separately;

a description of the terms of any unit agreement governing the units;

a description of the provisions for the payment, settlement, transfer or exchange of the units;

a discussion of material federal income tax considerations, if applicable; and

whether the units will be issued in fully registered or global form.

The descriptions of the units in this prospectus and in any prospectus supplement are summaries of the material provisions of the applicable agreements. These descriptions do not restate those agreements in their entirety and may not contain all the information that you may find useful. We urge you to read the applicable agreements because they, and not the summaries, define your rights as holders of the units. For more information, please review the form of the relevant agreements, which will be filed with the SEC promptly after the offering of units and will be available as described under the heading **Where You Can Find Additional Information** on page 29.

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**PLAN OF DISTRIBUTION**

We may sell any of the securities being offered pursuant to this prospectus:

directly to purchasers;

to or through underwriters;

through dealers or agents; or

through a combination of methods.

We may distribute the securities from time to time in one or more transactions at a fixed price or prices, which may be changed, at market prices prevailing at the time of sale, at prices related to the prevailing market prices or at negotiated prices. We may also determine the price or other terms of the securities offered under this prospectus by use of an electronic auction.

The prospectus supplement with respect to the securities being offered will set forth the terms of the offering, including the names of the underwriters, dealers or agents, if any, the purchase price of the securities, the net proceeds to us, any underwriting discounts and other items constituting underwriters' compensation, any discounts or concessions allowed or reallocated or paid to dealers and any securities exchanges on which the securities may be listed. Also, if applicable, we will describe in the prospectus supplement how any auction will determine the price or any other terms, how potential investors may participate in the auction and the nature of the underwriters' obligations with respect to the auction.

If underwriters are used in an offering, we will execute an underwriting agreement with the underwriters and will specify the name of each underwriter and the terms of the transaction (including any underwriting discounts and other terms constituting compensation of the underwriters and any dealers) in a prospectus supplement. If an underwriting syndicate is used, the managing underwriter(s) will be specified on the cover of the prospectus supplement. If underwriters are used in the sale, the offered securities will be acquired by the underwriters for their own accounts and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Any public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time. Unless otherwise set forth in the prospectus supplement, the obligations of the underwriters to purchase the offered securities will be subject to conditions precedent, and the underwriters will be obligated to purchase all of the offered securities if any are purchased.

If dealers are used in an offering, we will sell the securities to the dealers as principals. The dealers then may resell the securities to the public at varying prices which they determine at the time of resale. The names of the dealers and the terms of the transaction will be specified in a prospectus supplement.

The securities may be sold directly by us or through agents we designate. If agents are used in an offering, the names of the agents and the terms of the agency will be specified in a prospectus supplement. Unless otherwise indicated in a prospectus supplement, the agents will act on a best-efforts basis for the period of their appointment.

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Dealers and agents named in a prospectus supplement may be deemed to be underwriters (within the meaning of the Securities Act of 1933) of the securities described therein. In addition, we may sell the securities directly to institutional investors or others who may be deemed to be underwriters within the meaning of the Securities Act of 1933 with respect to any resales thereof.

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Underwriters, dealers and agents may be entitled to indemnification by us against specific civil liabilities, including liabilities under the Securities Act of 1933 or to contribution with respect to payments which the underwriters or agents may be required to make in respect thereof, under underwriting or other agreements. The terms of any indemnification provisions will be set forth in a prospectus supplement. Certain underwriters, dealers or agents and their associates may engage in transactions with, and perform services for us in the ordinary course of business.

Each series of securities is expected to be a new issue of securities with no established trading market, other than the common stock which is listed on the Nasdaq National Market. Any common stock sold pursuant to a prospectus supplement will be eligible for listing and trading on the Nasdaq National Market, subject to official notice of issuance. Any underwriters to whom securities are sold by us for public offering and sale may make a market in the securities, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. The securities, other than the common stock, may or may not be listed on a national securities exchange or eligible for quotation and trading on Nasdaq.

## **LEGAL MATTERS**

The validity of the securities offered hereby has been passed upon for us by Bryan Cave LLP, Washington, D.C. James L. Nouss, Jr., a partner of our legal counsel Bryan Cave LLP, owns 11,927 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 for the year ended December 31, 2004, as set forth in their report, which is incorporated by reference in the registration statement. Our financial statements and schedule are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

## **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 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.

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**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, 2004;

our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2005, June 30, 2005 and September 30, 2005;

our Current Reports on Form 8-K filed February 16, 2005, March 16, 2005, July 14, 2005, October 13, 2005 and November 10, 2005; 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 November 10, 2005, 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. 4041 Forest Park Avenue, St. Louis, Missouri 63108, telephone (314) 615-6940.

**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 | \$ 8,827.50  |
| Legal fees and expenses                       | 35,000.00    |
| Accounting fees and expenses                  | 15,000.00    |
| Printing expenses                             | 5,000.00     |
| Miscellaneous                                 | 1,172.50     |
|   | <hr/>        |
| Total expenses                                | \$ 65,000.00 |
|   | <hr/>        |

**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.



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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

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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.

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.**

| <u>Exhibit Number</u> | <u>Document Description</u>   |
|-----------------------|---|
| 1.1                   | Form of Underwriting Agreement (Equity)*  |
| 1.2                   | Form of Underwriting Agreement (Preferred Stock)*   |
| 1.3                   | Form of Underwriting Agreement (Warrants)*  |
| 1.4                   | Form of Underwriting Agreement (Units)*.  |
| 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                   | Fourth Amended and Restated Investor Rights Agreement, dated December 17, 2002 by and among Registrant and certain stockholders, 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 4.2.  |
| 4.3                   | Joinder Agreement to Series D-2 Preferred Stock Purchase Agreement, Fourth Amended and Restated Investor Rights Agreement and Amendment to Second Amended and Restated Stockholders' Agreement dated January 21, 2003 by and among Registrant and certain stockholders, 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 4.3. |

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| <b><u>Exhibit Number</u></b> | <b><u>Document Description</u></b>  |
|------------------------------|---|
| 4.4                          | Joinder and Amendment to Second Amended and Restated Stockholders Agreement and Fourth Amended and Restated Investor Rights Agreement, dated May 27, 2003 by and among Registrant and certain stockholders 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 4.4.              |
| 4.5                          | Second Joinder and Amendment to Second Amended and Restated Stockholders Agreement and Fourth Amended and Restated Investor Rights Agreement, dated December 22, 2003 by and among Registrant and certain stockholders, 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 4.5. |
| 4.6                          | Third Joinder and Amendment to Second Amended and Restated Stockholders Agreement and Fourth Amended and Restated Investor Rights Agreement, dated January 28, 2004 by and among Registrant and certain stockholders, 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 4.6.   |
| 4.7                          | Form of Warrant Agreement issued to Series D-1 investors, 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 4.7.   |
| 4.8                          | Warrant Agreement issued to Silicon Valley Bank dated January 31, 2002, 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 4.8.   |
| 4.9                          | Form of Warrant Agreement issued to Series D-2 investors, 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 4.9.   |
| 4.10                         | Form of Warrant Agreement issued to Series E-2 investors, 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 4.10.  |
| 4.11                         | Warrant Agreement issued to Silicon Valley Bank dated March 19, 2002, 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 4.11.  |
| 4.12                         | Warrant Agreement issued to Silicon Valley Bank dated September 30, 2002, 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 4.12.  |

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| <u>Exhibit Number</u> | <u>Document Description</u>                         |
|-----------------------|---|
| 5.1                   | Opinion of Bryan Cave LLP                           |
| 12.1                  | Computation of Ratio of Earnings to Fixed Charges   |
| 23.1                  | Consent of Ernst & Young LLP                        |
| 23.2                  | Consent of Bryan Cave LLP (included in Exhibit 5.1) |
| 24.1                  | Power of Attorney                                   |

Previously filed.

\* Indicates document to be filed by amendment or as an exhibit to a report on Form 8-K, Form 10-Q or Form 10-K pursuant to Item 601 of Regulation S-K and incorporated herein by reference.

**Item 17. Undertakings.**

(a) The undersigned registrant hereby undertakes:

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

- (i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;
- (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the 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) of this section 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.

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- (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 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.

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- (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) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in 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.
- (d) 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.
- (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.

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**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 pre-effective Amendment No. 1 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of St. Louis, State of Missouri, on December 15, 2005.

STEREOTAXIS, INC.

By:                    /s/ BEVIL J. HOGG  
**Bevil J. Hogg**  
**President and Chief Executive Officer**

Pursuant to the requirements of the Securities Act of 1933, this pre-effective Amendment No. 1 to the Registration Statement has been signed by the following persons in the capacities indicated on December 15, 2005.

| <u>Signature</u>         | <u>Title(s)</u>   | <u>Date</u>       |
|--------------------------|---|-------------------|
| *                        | Chairman of the Board   | December 15, 2005 |
| <hr/>                    |   |                   |
| <b>Fred A. Middleton</b> |   |                   |
| /s/ BEVIL J. HOGG        | President, Chief Executive Officer and Director                   | December 15, 2005 |
| <hr/>                    |   |                   |
| <b>Bevil J. Hogg</b>     | (Principal Executive Officer)                                     |                   |
| /s/ JAMES M. STOLZE      | Vice President and Chief Financial Officer                        | December 15, 2005 |
| <hr/>                    |   |                   |
| <b>James M. Stolze</b>   | (Principal Accounting Officer and Principal<br>Financial Officer) |                   |
| *                        | Director  | December 15, 2005 |
| <hr/>                    |   |                   |
| <b>Abhi Acharya</b>      |   |                   |
| *                        | Director  | December 15, 2005 |
| <hr/>                    |   |                   |
| <b>Christopher Alafi</b> |   |                   |

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| <u>Signature</u>                                   | <u>Title(s)</u> | <u>Date</u>       |
|--|-----------------|-------------------|
| *  | Director        | December 15, 2005 |
| <b>David W. Benfer</b>                             |                 |                   |
| *  | Director        | December 15, 2005 |
| <b>Ralph G. Dacey, Jr.</b>                         |                 |                   |
| *  | Director        | December 15, 2005 |
| <b>Gregory R. Johnson</b>                          |                 |                   |
| *  | Director        | December 15, 2005 |
| <b>William M. Kelley</b>                           |                 |                   |
| *  | Director        | December 15, 2005 |
| <b>Abhijeet J. Lele</b>                            |                 |                   |
| *  | Director        | December 15, 2005 |
| <b>Robert J. Messey</b>                            |                 |                   |
| *  | Director        | December 15, 2005 |
| <b>William C. Mills III</b><br>/s/ JAMES M. STOLZE |                 |                   |
| <b>James M. Stolze</b>                             |                 |                   |
| <b>Attorney-in-fact</b>                            |                 |                   |

\*By:



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| <b><u>Exhibit Number</u></b> | <b><u>Document Description</u></b>   |
|------------------------------|--|
| 1.1                          | Form of Underwriting Agreement (Equity)*   |
| 1.2                          | Form of Underwriting Agreement (Preferred Stock)*  |
| 1.3                          | Form of Underwriting Agreement (Warrants)*   |
| 1.4                          | Form of Underwriting Agreement (Units).*   |
| 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                          | Fourth Amended and Restated Investor Rights Agreement, dated December 17, 2002 by and among Registrant and certain stockholders, 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 4.2.   |
| 4.3                          | Joinder Agreement to Series D-2 Preferred Stock Purchase Agreement, Fourth Amended and Restated Investor Rights Agreement and Amendment to Second Amended and Restated Stockholders Agreement dated January 21, 2003 by and among Registrant and certain stockholders, 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 4.3. |
| 4.4                          | Joinder and Amendment to Second Amended and Restated Stockholders Agreement and Fourth Amended and Restated Investor Rights Agreement, dated May 27, 2003 by and among Registrant and certain stockholders 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 4.4.   |
| 4.5                          | Second Joinder and Amendment to Second Amended and Restated Stockholders Agreement and Fourth Amended and Restated Investor Rights Agreement, dated December 22, 2003 by and among Registrant and certain stockholders, 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 4.5.  |
| 4.6                          | Third Joinder and Amendment to Second Amended and Restated Stockholders Agreement and Fourth Amended and Restated Investor Rights Agreement, dated January 28, 2004 by and among Registrant and certain stockholders, 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 4.6.  |
| 4.7                          | Form of Warrant Agreement issued to Series D-1 investors, 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 4.7.  |

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| <b><u>Exhibit Number</u></b> | <b><u>Document Description</u></b>   |
|------------------------------|--|
| 4.8                          | Warrant Agreement issued to Silicon Valley Bank dated January 31, 2002, 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 4.8.    |
| 4.9                          | Form of Warrant Agreement issued to Series D-2 investors, 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 4.9.                  |
| 4.10                         | Form of Warrant Agreement issued to Series E-2 investors, 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 4.10.                 |
| 4.11                         | Warrant Agreement issued to Silicon Valley Bank dated March 19, 2002, 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 4.11.     |
| 4.12                         | Warrant Agreement issued to Silicon Valley Bank dated September 30, 2002, 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 4.12. |
| 5.1                          | Opinion of Bryan Cave LLP  |
| 12.1                         | Computation of Ratio of Earnings to Fixed Charges  |
| 23.1                         | Consent of Ernst & Young LLP   |
| 23.2                         | Consent of Bryan Cave LLP (included in Exhibit 5.1)  |
| 24.1                         | Power of Attorney  |

Previously filed.

\* Indicates document to be filed by amendment or as an exhibit to a report on Form 8-K, Form 10-Q or Form 10-K pursuant to Item 601 of Regulation S-K and incorporated herein by reference.