

Stereotaxis, Inc.
Form S-3
November 10, 2005
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As filed with the Securities and Exchange Commission on November 10, 2005

Registration No. 333-_____

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

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

STEREOTAXIS, INC.

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

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

4041 Forest Park Avenue

St. Louis, Missouri 63108

(314) 615-6940

Copies of all correspondence to:

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President and Chief Executive Officer
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St. Louis, Missouri 63108
(314) 615-6940

*(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. "

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. "

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered(1)(2)(3)	Proposed maximum offering price per unit(4)	Proposed maximum aggregate offering price	Amount of registration fee
Common Stock (5)				
Preferred Stock(5)				
Warrants(6)				
Units(7)	\$75,000,000	100%	\$75,000,000	\$8,827.50

- (1) The total amount registered under this registration statement is \$75,000,000.
- (2) Includes an indeterminate number of shares of common stock and preferred stock of Stereotaxis, Inc. (Stereotaxis), an indeterminate number or amount of warrants of Stereotaxis.
- (3) Represents the aggregate initial offering price of all securities sold.
- (4) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933 and exclusive of accrued interest and dividends, if any.
- (5) Also includes such indeterminate number of shares of common stock as may be issued upon conversion of or exchange for any preferred stock that provide for conversion into or exchange for other securities. No separate consideration will be received for the common stock issuable upon conversion of or in exchange for preferred stock. Also includes of such indeterminate number of shares of common stock, or preferred stock or other securities of Stereotaxis to be issuable by Stereotaxis upon settlement of warrants.
- (6) The warrants may be combined with common stock or preferred stock registered under this registration statement and sold as units.
- (7) Each Unit consists of any combination of two or more of the securities registered hereby.

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 November 10, 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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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 More 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. 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.

You 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. 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 may 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.

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

enhance our existing products or develop new ones;

expand our operations;

hire, train and retain employees; or

respond to competitive pressures or 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 June 30, 2005 we had cumulative operating losses of approximately \$133.3 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

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. 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.