

# Edgar Filing: Stereotaxis, Inc. - Form 424B5

Stereotaxis, Inc.  
Form 424B5  
December 30, 2008  
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Filed pursuant to Rule 424(b)(5)  
Registration Nos. 333-137007, 333-129629 and 333-156466

PROSPECTUS SUPPLEMENT

(To the prospectus dated September 7, 2006)

**2,389,877 Shares of Common Stock**

**Series A Warrants to Purchase up to 1,792,408 Shares of Common Stock**

**Series B Warrants to Purchase up to 2,148,739 Shares of Common Stock**

**Series C Warrants to Purchase up to 341,412 Shares of Common Stock**

**Series D Warrants to Purchase up to 341,412 Shares of Common Stock**

We are selling 2,389,877 shares of our common stock, series A warrants to purchase up to 1,792,408 shares of our common stock, series B warrants to purchase up to 2,148,739 shares of our common stock, series C warrants to purchase up to 341,412 shares of our common stock and series D warrants to purchase up to 341,412 shares of our common stock (collectively, the warrants) to select investors. The common stock and warrants will be sold in units at a negotiated price of \$4.18 per unit. The shares of common stock and warrants are immediately separable and will be issued separately.

Our common stock is listed on the NASDAQ Global Market under the symbol STXS. The last reported sale price of our common stock on the NASDAQ Global Market on December 26, 2008 was \$4.64 per share.

**Investing in our common stock and warrants involves risks and uncertainties. See Risk Factors beginning on page S-6 of this prospectus supplement. You should read this prospectus supplement, the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus carefully before you make your investment decision.**

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS SUPPLEMENT OR THE ACCOMPANYING PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

We have retained Deutsche Bank Securities Inc. to act as our placement agent in connection with the common stock and warrants offered by this prospectus supplement and the accompanying prospectus. We have agreed to pay the placement agent the aggregate placement agent fees set forth in the table below. The placement agent is not purchasing or selling any of these securities nor is it required to sell any specific number or dollar amount of securities, but has agreed to use its best efforts to sell the securities offered by this prospectus supplement and the accompanying prospectus.

	Per unit	Total
Public offering price	\$ 4.18	\$ 10,000,000
Placement agent fees	\$ 0.3135	\$ 750,000
Proceeds to Stereotaxis, Inc. (before expenses)	\$ 3.8665	\$ 9,250,000

Delivery of the units is expected to be made on or about December 31, 2008, subject to the satisfaction of certain conditions.

## Deutsche Bank Securities

The date of this prospectus supplement is December 29, 2008.

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Unless otherwise mentioned or unless the context requires otherwise, all references in this prospectus supplement and the accompanying prospectus to the company, Stereotaxis, we, us, our, or similar references mean Stereotaxis, Inc.

In connection with this offering, we registered an additional \$10,970,100 of our securities pursuant to Rule 462(b) of the Securities Act on a registration statement on Form S-3.

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering of our common stock and warrants to purchase shares of common stock (the warrants) and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into the accompanying prospectus. The second part, the accompanying prospectus, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in the accompanying prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in the accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. You must not rely upon any information or representation not contained or incorporated

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by reference in this prospectus supplement or the accompanying prospectus. This prospectus supplement and the accompanying prospectus do not constitute an offer to sell or the solicitation of an offer to buy common stock or warrants, nor do this prospectus supplement and the accompanying prospectus constitute an offer to sell or the solicitation of an offer to buy common stock or warrants in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus supplement and the accompanying prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus supplement and any accompanying prospectus is delivered or either common stock or warrants is sold on a later date.

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**PROSPECTUS SUPPLEMENT SUMMARY**

This summary highlights selected information from this prospectus supplement and the accompanying prospectus. It does not contain all of the information that may be important to you. We encourage you to carefully read this entire prospectus supplement, the accompanying prospectus and the documents that are incorporated herein, especially the Risk Factors and the financial statements included elsewhere herein and incorporated by reference hereto from our Annual Report on Form 10-K, as amended by Form 10-K/A for the year ended December 31, 2007 and our Quarterly Reports on Form 10-Q filed during 2008, before making an investment decision.

**THE COMPANY**

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

We believe that our NIOBE System is the only technology to be commercialized that allows remote, computerized control of catheters, guidewires and other delivery devices directly at their working tip. We also believe that our technology represents an important advance in the ongoing trend toward digital instrumentation in the interventional lab and provides substantial, clinically important improvements and cost efficiencies over manual interventional methods, which require years of physician training and often result in long and unpredictable procedure times with suboptimal therapeutic outcomes.

We began commercial shipments in 2003, following U.S. and European regulatory approval of the core components of the NIOBE System. The NIOBE System is designed primarily for use by interventional electrophysiologists in the treatment of abnormal heart rhythms known as arrhythmias and by interventional cardiologists in the treatment of coronary artery disease. To date the preponderance of the Stereotaxis installations worldwide are intended for use in electrophysiology.

Our NIOBE System consists of the following proprietary components:

our NIOBE magnetic navigation system, which utilizes permanent magnets to navigate catheters, guidewires and other delivery devices through complex paths in the blood vessels and chambers of the heart to carry out treatment;

our NAVIGANT® advanced user interface, or physician control center, which physicians use to visualize and track procedures and to provide instrument control commands that govern the motion of the working tip of the catheter, guidewire or other delivery device; and

our CARDIODRIVE® automated catheter advancement system, which is used to remotely advance and retract the catheter in the patient's heart.

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The NIOBE System is designed to be used with our suite of interventional catheters, guidewires and other delivery devices, which we refer to as disposable interventional devices as further discussed below.

In addition to the NIOBE System and its components, Stereotaxis also has developed the ODYSSEY information management system, which consolidates the multiple sources of diagnostic and imaging information found in the interventional lab into a large-screen user interface with single mouse control, which can be connected via a private network line to other interventional labs or to a remote clinical call center. The ODYSSEY information management system may be acquired in conjunction with a NIOBE System or on a stand-alone basis for installation in interventional labs and other locations where clinicians often desire the benefits of Odyssey's consolidated large screen single mouse control, and potential real-time access to networked call center support that we believe can improve clinical workflows and related efficiencies.

The NIOBE System is designed to be installed in both new and replacement interventional labs worldwide. Current and potential purchasers of our NIOBE System include leading research and academic hospitals as well as community and regional medical centers around the world.

We currently have regulatory clearance to market our NIOBE magnetic navigation system, our NAVIGANT advanced user interface, our CARDIODRIVE automated catheter advancement system, our ODYSSEY information management system and various disposable interventional devices in the U.S., Canada, Europe, and various other countries and we anticipate applying through Siemens and Biosense Webster to begin clinical trials in Japan in 2008.

We have alliances with each of Siemens AG Medical Solutions, Philips Medical Systems and Biosense Webster, a subsidiary of Johnson & Johnson. Through these alliances, we integrate our NIOBE System with Siemens' and Philips' market leading digital imaging and Biosense Webster's 3D catheter location sensing technology, and develop compatible disposable interventional devices, in order to continue to introduce new solutions to the interventional lab. The Siemens and Philips alliances provide for coordination of our sales and marketing efforts with those of our partners to facilitate co-placement of integrated systems. In addition, Siemens provides worldwide service for our integrated systems and we are in discussions with Philips to provide the same.

The core elements of our NIOBE System are protected by an extensive patent portfolio, as well as substantial know-how and trade secrets.

## **Recent Developments**

As previously announced, on November 4, 2008, we, Sanderling Venture Partners and Alafi Capital (collectively, the Lenders) executed a term sheet under which the Lenders committed to extend their February 2008 agreement to loan us an aggregate of \$20 million on an unsecured basis through the earlier of March 31, 2010 or the date we receive at least \$20 million of third party, non-bank financing (a Qualified Financing). The Lenders are affiliates of Fred A. Middleton and Christopher Alafi, respectively, each of whom is a member of our Board of Directors. This facility may also be used by us to guarantee our loan commitments with Silicon Valley Bank, our primary bank lender, through the same extended term.

In connection with and conditioned upon the closing of this offering and the concurrent offering described below, the Lenders and we agreed that, effective at closing of the concurrent offering, the loan obligation would decrease from an aggregate of \$20 million to \$10 million. If exercised, the loan extension would only be for an aggregate of \$10 million. The Lenders would receive additional warrant coverage equal to 50% of the \$10 million extension amount upon our exercise of the extension of the facility. Such warrants would have a term of five years from the date of issuance and would be issued at the time we exercise the extension, with an exercise price equal to the average of the five-day closing sale price ending on the date prior to the exercise of the extension and issuance of the warrants, provided that the exercise price will not be lower than the closing bid price immediately preceding the time we exercise the extension right. The Qualified Financing definition was amended to exclude the proceeds from this offering.

## **Description of Concurrent Offering**

Concurrently with this offering of common stock and warrants, we are offering 2,024,260 shares of our common stock and warrants to purchase up to 4,859,504 shares of our common stock by means of a separate prospectus supplement and accompanying prospectus in an offering registered under the Securities Act, to certain of our existing shareholders as described therein. We expect that delivery of our common stock and warrants to our existing shareholders will be made on or about the closing date of the initial sale of the shares of common stock and warrants offered hereby.



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**THE OFFERING**

Common stock offered by us	2,389,877 shares
Common stock to be outstanding after this offering and the concurrent offering	41,802,297 shares
Warrants offered by us	Series A warrants to purchase up to 1,792,408 shares of common stock, series B warrants to purchase up to 2,148,739 shares of common stock, series C warrants to purchase up to 341,412 shares of common stock, and series D warrants to purchase up to 341,412 shares of common stock (collectively, the warrants ).
Purchaser	We are selling all of the common stock and warrants offered hereby to select investors.
Use of Proceeds	We intend to use the proceeds of this offering for working capital; sales, marketing and clinical support initiatives; research and development; and general corporate purposes. See Use of Proceeds on page S-22 of this prospectus supplement.
NASDAQ Global Market Symbol	STXS
Series A Warrants	<p>                     Holders of series A warrants are entitled to purchase up to 1,792,408 shares of our common stock. The warrant exercise price is \$5.11. The series A warrants are exercisable on or after the date immediately following the six month anniversary of their issuance (the Initial Exercisability Date ) and have a five year term from the Initial Exercisability Date. The warrants will have a provision for full ratchet adjustment of the warrant exercise price for the first two years following the closing, and a provision for weighted average adjustment thereafter. Upon three successive quarters of positive free cash flow (defined as cash flow from operations less non-acquisition related capital expenditures), the full ratchet anti-dilution protection will no longer apply and weighted average anti-dilution will apply thereafter. The warrant exercise price adjustment provisions will only reduce the exercise price, and will not result in any increase in the number of warrants or common shares underlying the warrants. The warrants will be exercisable for cash unless the registration statement covering the resale of the shares underlying the warrants is not effective.                 </p>
Series B Warrants	<p>                     Holders of series B warrants are entitled to purchase up to 2,148,739 shares of our common stock at a price of \$4.65 per share until six months after their date of issuance.                 </p>

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Series C Warrants	Holders of series C warrants are entitled to purchase up to a maximum eligibility number of shares of our common stock at a price of \$0.001 per share until the tenth trading day after the two month anniversary of the issuance date. The maximum eligibility number for the series C warrants means initially zero and on the second month anniversary of the issuance date will be increased to the number that is the difference between (I) \$5,000,000 divided by the arithmetic average of the volume weighted average price of our common stock during the 30 trading days immediately preceding the second month anniversary of the issuance date and (II) 1,194,939.
Series D Warrants	Holders of series D warrants are entitled to purchase up to a maximum eligibility number of shares of our common stock at a price of \$0.001 per share until the tenth trading day after the five month anniversary of the issuance date. The maximum eligibility number for the series D warrants means initially zero and on the fifth month anniversary of the issuance date will be increased to the number that is the difference between (I) \$5,000,000 divided by the arithmetic average of the volume weighted average price of our common stock during the 30 trading days immediately preceding the fifth month anniversary of the issuance date and (II) 1,194,939.
Effect of the Series C and D Warrants	The effect of the series C warrants will be to cause the purchase price on 50% of the common stock offered hereby to be reset to the lesser of the offering price in this offering or the simple average of the daily volume weighted average price of our common stock for the 30 trading days prior to the two month anniversary of closing. The effect of the series D warrants will be to cause the purchase price on the other 50% of the common stock purchased hereunder to reset to the lesser of the offering price in this transaction or the simple average of the daily volume weighted average price of our common stock for the 30 trading days prior to the five month anniversary of closing. In either case, the reset price will not be lower than \$3.25, which is a 30% discount to the simple average of the daily volume weighted average price of our common stock for the five trading days prior to date of the securities purchase agreement.

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**Right of Participation and Standstill**

The purchaser of our common stock may participate in any financings completed on a private placement basis by the Company for the first 18 months following closing. Such purchaser will have the right to purchase up to 50% of such subsequent financings on a pro rata basis with their original purchase of the common shares hereunder for the first four months following closing, and 35% thereafter.

Until February 16, 2009 the Company has agreed not to sell equity or equity equivalent securities, including securities convertible into or exchangeable or exercisable for common shares. From February 17, 2009 until the four month anniversary of the closing of the transaction, the Company will be permitted to raise a maximum of \$5 million in an equity financing, and after the four month anniversary there will be no restrictions.

The right of participation and standstill provisions described above do not include traditional bank financings and stock issued in connection with strategic partnerships and investments, qualified public offerings, employee or director equity incentive plans and other customary transactions.

**Dividend Policy**

We do not currently intend to pay cash dividends on our common stock.

**Risk Factors**

An investment in our common stock and warrants involves significant risks. Before making an investment in our common stock and warrants, you should carefully review the Risk Factors included and incorporated by reference into this prospectus supplement.

The number of shares of our common stock to be outstanding after this offering described above is based on 37,388,160 shares outstanding as of September 30, 2008 and also includes 2,024,260 shares of common stock to be issued to certain of our existing shareholders in the concurrent offering described above under The Company Description of Concurrent Offering. In addition, the information above assumes no exercise of:

- options or stock appreciation rights to purchase 4,555,133 shares of our common stock at a weighted average exercise price of \$7.58 per share as of September 30, 2008;
  - warrants to purchase 929,596 shares of our common stock at a weighted average exercise price of \$7.70 per share as of September 30, 2008;
  - warrants to purchase 4,623,971 shares of common stock included in this offering; and
  - warrants to purchase 4,859,504 shares of common stock issued to certain of our existing shareholders in the concurrent offering.
- To the extent that options or warrants are exercised, there will be further dilution to new investors.

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**RISK FACTORS**

You should carefully consider the following factors, the other information contained in this prospectus supplement and the accompanying prospectus and the information incorporated by reference in this prospectus supplement and the accompanying prospectus before deciding to purchase shares of our common stock or our warrants. Any of these risks could materially adversely affect our business, financial condition and results of operations, which could in turn materially adversely affect the price of our common stock and our warrants.

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

**General economic conditions may cause our customers to delay purchasing our products which may result in lower revenues for us.**

An economic downturn in the United States or in any other country in which we sell our products may cause customers to delay purchasing or installation decisions. The NIOBE System is typically purchased as part of a larger overall capital project and an economic downturn might make it more difficult for our customers to obtain adequate financing to support the project or to obtain requisite internal approvals. Any delay in purchasing decisions may result in a decrease in our revenues.

**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 NIOBE System provides a safe, effective and preferable alternative to interventional methods in general use today. Currently, there is only limited clinical data on the NIOBE System with which to assess safety and efficacy. If longer-term patient studies or clinical experience indicate that treatment with our system or products is less effective, less efficient or less safe than our current data suggest, our sales would be harmed, and we could be subject to significant liability. Further, unsatisfactory patient outcomes or patient injury could cause negative publicity for our products, particularly in the early phases of product introduction. In addition, physicians may be slow to adopt our products if they perceive liability risks arising from the use of these new products. It is also possible that as our products become more widely used, latent defects could be identified, creating negative publicity and liability problems for us and adversely affecting demand for our products. If physicians do not use our products, we likely will not become profitable or generate sufficient cash to survive as a going concern.

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

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

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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 NIOBE System as planned;

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

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

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

### **The recently announced halting of procedures performed with our partnered magnetic irrigated catheter may negatively affect our results of operations.**

On March 3, 2008, we announced that our catheter partner advised us that the external evaluation phase of the magnetic irrigated catheter launch had identified a relatively small number of catheters that exhibited signs of char or coagulum formation. Our partner advised us that these characteristics were inconsistent with the product specifications. Consequently, they temporarily halted procedures done with magnetic irrigated catheters and delayed full commercialization until this issue was resolved. After considerable remediation efforts, during week of July 7, 2008 our partner filed a PMA supplement with the U.S. Food and Drug Administration, immediately followed with a CE Mark filing with European regulators. While we are optimistic that, pending these regulatory approvals, we will be able to resume shipments of the irrigated catheter in Europe in the fourth quarter of 2008 and shortly thereafter in 2009 in the U.S., there can be no assurance as to the timing of such regulatory approvals or reintroduction, if at all, of the irrigated catheter into the market place. Any such delay in commercial re-launch would adversely affect our results of operations. Further, sales of our NIOBE System could be negatively affected as hospital decision-makers evaluate the status of this issue.

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

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

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

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

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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 revenue and profitability would be adversely affected.

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

Our research and development efforts and our marketing strategy depend heavily on obtaining support and collaboration from highly regarded physicians at leading commercial and research hospitals, particularly in the U.S. and Europe. If we are unable to gain and/or maintain such support and collaboration or if the reputation or standing of these physicians is impaired or otherwise adversely affected, our ability to market the NIOBE 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 NIOBE System, they must attend one or more training sessions in order to familiarize themselves with a sophisticated user interface. Market acceptance could be delayed by lack of physician willingness to attend training sessions or by the time required to complete this training. An inability to train a sufficient number of physicians to generate adequate demand for our products could have a material adverse impact on our financial condition and cash flow.

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

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

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

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

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

Our backlog, which consists of purchase orders and other commitments, is considered by some investors to be a significant indicator of future performance. Consequently, negative changes to this backlog or its failure to grow commensurate with expectations could negatively impact our future operating results or our share price. Our backlog includes those outstanding purchase orders and other commitments that management believes will result in recognition of revenue upon delivery or installation of our systems. We cannot assure you that we will recognize revenue in any particular period or at all because some of our purchase orders and other commitments are subject to contingencies that are outside our control. In addition, these orders and commitments may be revised, modified or cancelled, either by their express terms, as a result of negotiations or by project changes or delays. System installation is by its nature subject to the interventional lab construction or renovation process which comprises multiple stages, all of which are outside of our control. Although the actual installation of our system requires only a

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few weeks, and can be accomplished by either our staff or by subcontractors, successful installation of our system can be subjected to delays related to the overall construction or renovation process. If we experience any failures or delays in completing the installation of these systems, our reputation would suffer and we may not be able to sell additional systems. We have experienced situations in which our purchase orders and other commitments did not result in recognizing revenue from placement of a system with a customer. In addition to construction delays, there are risks that an institution will attempt to cancel a purchase order as a result of subsequent project review by the institution or the departure from the institution of physicians or physician groups who have expressed an interest in the Niobe System.

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

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

We anticipate that our system will continue to have a lengthy sales cycle because it consists of a relatively expensive piece of capital equipment, the purchase of which requires the approval of senior management at hospitals, inclusion in the hospitals' interventional lab budget process for capital expenditures, and, in some instances, a certificate of need from the state or other regulatory approval. In addition, the majority of our systems have historically been installed less than one year after the receipt of a purchase order from a hospital, with the timing being dependant on the construction cycle for the new or replacement interventional suite in which the equipment will be installed. In some cases, this time frame has been extended further because the interventional suite construction is part of a larger construction project at the customer site (typically the construction of a new building), which may occur with our existing and future purchase orders. This may contribute to substantial fluctuations in our quarterly operating results. As a result, in future quarters our operating results could fall below the expectations of securities analysts or investors, in which event our stock price would likely decrease.

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

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

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

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

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

We generally warrant each of our products against defects in materials and workmanship for a period of 12 months following the installation of our system. If product returns or warranty claims increase, we could incur unanticipated additional expenditures for parts and service. In addition, our reputation and goodwill in the interventional lab market could be damaged. 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.

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

We may require additional funds to meet our 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 revenue and adversely affect our financial condition and results of operations, and we may have to curtail or cease operations.

While we believe our existing cash, cash equivalents and investments, amounts outstanding under the Biosense Webster agreement and funds available and anticipated to be available from our current borrowing sources will be sufficient to fund our operating expenses and capital equipment requirements through the next 12 months, we cannot assure you that we will be able to renew our existing bank facility or will not otherwise require additional financing before that time. Although we anticipate that we will be able to extend our current credit facility before it reaches maturity date, we also cannot assure you that any such renewal or other additional financing will be available on a timely basis on terms acceptable to us or at all, or that any such other financing will not be further dilutive to our stockholders. If adequate funds are not available to us, we could be required to delay development or commercialization of new products, to license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize ourselves or to reduce the sales, marketing, customer support or other resources devoted to our products, any of which could have a material adverse effect on our business, financial condition and results of operations.

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

We have incurred substantial net losses since inception, and we expect to incur substantial net losses into 2008 as we seek additional regulatory approvals, launch new products and generally continue to scale up our sales and marketing operations to continue the commercialization of our products. We may not be successful in completing the development or commercialization of our technology. Moreover, the extent of our future losses and the timing of profitability are highly uncertain, and we may never achieve profitable operations. If we require more time than we expect to generate significant revenue and achieve profitability, we may not be able to continue our operations. Our failure to achieve profitability could negatively impact the market price of our common stock. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Furthermore, even if we achieve significant revenue, we may choose to pursue a strategy of increasing market penetration and presence or expand or accelerate new product development or clinical research activities at the expense of profitability.

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

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

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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

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

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

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

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

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

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

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

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

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

We do not have extensive experience in manufacturing, assembling or testing our products on a commercial scale as we subcontract the manufacture, assembly and testing of our NIOBE magnetic navigation system and our disposable devices. We may be unable to meet the expected future demand for our NIOBE System. In addition, the products we design may not satisfy all of the performance requirements and we may need to improve or modify the design or ask our subcontractors to modify their production process in order to do so. We or our subcontractors may experience quality problems, substantial costs and unexpected delays related to efforts to upgrade and expand manufacturing, assembly and testing capabilities. If we incur delays due to quality problems or other unexpected events, we will be unable to produce a sufficient supply of product necessary to meet our future growth expectations.

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

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

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

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

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

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

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

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### **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, in 2005 we 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 revenue and results of operations. If we have to abandon a product, our ability to develop and grow our business in new directions and markets would be adversely affected.

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

The NIOBE System is designed to have the potential for expanded applications beyond electrophysiology and interventional cardiology, including congestive heart failure, structural heart repair, interventional neurosurgery, interventional neuroradiology, peripheral vascular, pulmonology, urology, gynecology and gastrointestinal medicine. 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 hospitals, universities or other medical device companies, including our competitors or potential competitors. We could in the future be subject to claims that these employees or we have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Incurring such costs could have a material adverse effect on our financial condition, results of operations and cash flow.

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

Our products are medical devices that are subject to extensive regulation in the U.S. and in foreign countries where we do business. Unless an exemption applies, each medical device that we wish to market in the U.S. must first receive either a 510(k) clearance or a pre-market approval, or PMA, from the U.S. Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act. The FDA's 510(k) clearance process usually

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takes from four to 12 months, but it can take longer. The process of obtaining PMA approval is much more costly, lengthy, and uncertain, generally taking from one to three years or even longer. Although we have 510(k) clearance for our current Stereotaxis System, including a limited number of disposable interventional devices, and are able to market our system commercially in the U.S., our business model relies significantly on revenue from disposable interventional devices, some of which do not currently have FDA clearance or approval. We cannot assure you that any of our devices will not be required to undergo the lengthier and more burdensome PMA process. We cannot commercially market our unapproved disposable interventional devices in the U.S. until the necessary clearances or approvals from the FDA have been received. In addition, we are working with third parties to co-develop disposable products. In some cases, these companies are responsible for obtaining appropriate regulatory clearance or approval to market these disposable devices. If these clearances or approvals are not received or are substantially delayed or if we are not able to offer a sufficient array of approved disposable interventional devices, we may not be able to successfully market our system to as many institutions as we currently expect, which could have a material adverse impact on our financial condition, results of operations and cash flow.

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

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

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

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

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

Additionally, any modification to an FDA 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance. Modifications to a PMA approved device or its labeling may require either a new PMA or PMA supplement approval, which could be a costly and lengthy process. In the future, we may modify our products after they have received clearance or approval, and we may determine that new clearance or approval is unnecessary. We cannot

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assure you that the FDA would agree with any of our decisions not to seek new clearance or approval. If the FDA requires us to seek clearance or approval for any modification, we could be subject to enforcement sanctions and we also may be required to cease marketing or recall the modified product until we obtain FDA clearance or approval which could also limit product sales, delay product shipment and harm our profitability.

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

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

Our manufacturing processes must comply with the FDA's quality system regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging and shipping of our products. The FDA enforces the QSR through inspections. We cannot assure you that we or our suppliers or subcontractors would pass such an inspection. If we or our suppliers or subcontractors fail to remain in compliance with the FDA or ISO 9001 standards, we or they may be required to cease all or part of our operations for some period of time until we or they can demonstrate that appropriate steps have been taken to comply with such standards or face other enforcement action, such as a public warning letter. We cannot be certain that our facilities or those of our suppliers or subcontractors will comply with the FDA or ISO 9001 standards in future audits by regulatory authorities. Failure to pass such an inspection could force a shut down of manufacturing operations, a recall of our products or the imposition of other enforcement sanctions, which would significantly harm our revenue and profitability. Further, we cannot assure you that our key component suppliers are or will continue to be in compliance with applicable regulatory requirements and will not encounter any manufacturing difficulties. Any failure to comply with the FDA's QSR by us or our suppliers could significantly harm our available inventory and product sales.

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

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

loss of revenue;

delay in market acceptance of our products;

damage to our reputation;

additional regulatory filings;

product recalls;

increased service or warranty costs; and/or

product liability claims relating to the software defects.

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

While we do not control referrals of health care services or bill directly to Medicare, Medicaid or other third-party payors, many health care laws and regulations apply to our business. We could be subject to health care fraud and patient privacy regulation by 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 or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid programs;

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 with which the physician or the physician's family member has a financial interest.

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

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

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





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maintaining appropriate licensure, certification or accreditation, or the failure of our customers to satisfy the other necessary requirements under government-sponsored health care programs or other requirements could cause our sales to decline.

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

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

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

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

**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.

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

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

As of September 30, 2008, our executive officers, directors and individuals or entities affiliated with them beneficially own or control a substantial percentage of the outstanding shares of our common stock. Accordingly, these executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. These stockholders may also delay or prevent a change of control, even if such a change of control would benefit our other stockholders. This significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

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

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

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

discourage, delay or prevent a change in the control of 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, our alliance with Biosense Webster contains provisions that may similarly discourage a takeover and negatively affect our share price as described above.

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

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

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

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ Global Market rules are creating uncertainty for public companies. We continue to evaluate and monitor developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional compliance costs we may incur or the timing of such costs. These new or changed laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by courts and regulatory and governing bodies. This could result in 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 expense 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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**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 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 as compared to our operating expenses on a cumulative basis. Our lack of a significant operating history also impairs an investor's ability to make a comparative evaluation of our products, our prospects, and us.

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

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

demand for our products;

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

our ability to develop sales and marketing capabilities;

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

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

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

our ability to obtain and protect proprietary rights.

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

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

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;

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 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.

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

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

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**FORWARD-LOOKING STATEMENTS**

This prospectus supplement, the accompanying prospectus and other materials filed or to be filed by us with the SEC (as well as information included in oral statements or other written statements made or to be made by us or our representatives) contain or may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements can be identified by the fact that they do not relate strictly to historical or current facts and may include the words may, could, should, would, believe, expect, anticipate, estimate, intend, plan or other words or expressions having similar meaning. We have based these forward-looking statements on our current expectations about future events. The forward-looking statements include statements that reflect management's beliefs, plans, objectives, goals, expectations, anticipations and intentions with respect to our financial condition, results of operations, future performance and business, including statements relating to our business strategy and our current and future development plans. The forward-looking statements speak as of the date made and are not guarantees of future performance. Actual results or developments may differ materially from the expectations expressed or implied in the forward-looking statements.

From time to time, forward-looking statements are also included in our reports on Forms 10-K, 10-Q, 8-K and Schedule 14A, press releases and other materials released to the public. Although we believe that at the time made, the expectations reflected in all of these forward-looking statements are and will be reasonable, any or all of the forward-looking statements in this prospectus supplement, the accompanying prospectus, our reports on Forms 10-K, 10-K/A, 10-Q, 8-K and Schedule 14A and any other public statements that are made by us may prove to be incorrect. This may occur as a result of inaccurate assumptions or as a consequence of known or unknown risks and uncertainties. Many factors discussed in this prospectus supplement or the accompanying prospectus, some of which are beyond our control, will be important in determining our future performance. Consequently, actual results may differ materially from those that might be anticipated from forward-looking statements. In light of these and other uncertainties, you should not regard the inclusion of a forward-looking statement in this prospectus supplement, the accompanying prospectus or other public communications that we might make as a representation by us that our plans and objectives will be achieved, and you should not place undue reliance on such forward-looking statements.

You should carefully read the factors described under the Risk Factors section beginning on page S-6 of this prospectus supplement. All subsequent written and oral forward-looking statements attributable to us, or persons acting on our behalf, are expressly qualified in their entirety by the cautionary statements.

We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. However, your attention is directed to any further disclosures made on related subjects in our subsequent reports filed with the Commission on Forms 10-K, 10-Q, 8-K and Schedule 14A.



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**USE OF PROCEEDS**

We estimate that the net proceeds from this offering will be approximately \$9.0 million after deducting our estimated offering expenses.

We intend to use the net proceeds from this offering 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 of facilities.

We have not determined the amounts we plan to spend on any of the areas listed above or the timing of these expenditures. As a result, our management will have broad discretion to allocate the net proceeds from this offering. Pending application of the net proceeds as described above, we intend to temporarily invest the proceeds in short-term interest bearing instruments.

**DIVIDEND POLICY**

We have never declared or paid any dividends on our capital stock. We anticipate that we will retain any earnings to support operations and to finance the growth and development of our business. Additionally, under our credit facility, we are prohibited from declaring dividends without the prior consent of our lender. Therefore, we do not expect to pay cash dividends in the foreseeable future. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects and other factors that the board of directors may deem relevant.

**Table of Contents****DILUTION**

As of September 30, 2008, our net tangible book value was \$(6.6) million, or approximately \$(0.18) per share. Net tangible book value per share is the amount of our total tangible assets reduced by the amount of our total liabilities and divided by the total number of shares of common stock outstanding as of that date.

Net tangible book value dilution per share to new investors represents the difference between the weighted average amount per share paid by purchasers of units in this offering and the net tangible book value per share of our common stock immediately after completion of this offering and a concurrent offering to existing shareholders. After giving effect to the sale of 4,414,137 units in this offering and the concurrent offering and deducting our estimated offering expenses, our net tangible book value as of September 30, 2008 would have been \$0.30 per share. This amount represents an immediate increase in net tangible book value of \$0.48 per share to existing stockholders and an immediate dilution (on a weighted average basis) in net tangible book value of \$3.88 per share to purchasers of units in this offering, as illustrated in the following table:

Public offering price per unit	\$ 4.18
Net tangible book value per share as of September 30, 2008	\$ (.18)
Increase per share attributable to new investors after giving effect to this offering	\$ .22
Increase per share attributable to new investors after giving effect to the concurrent offering	\$ .26
<b>Pro forma net tangible book value per share after giving effect to this offering</b>	<b>\$ .30</b>
 Dilution in net tangible book value per share to new investors	 \$ 3.88

This table also includes 2,024,260 shares of common stock to be issued to certain of our existing shareholders in a concurrent offering. In addition, this table assumes no exercise of:

- options or stock appreciation rights to purchase 4,555,133 shares of our common stock at a weighted average exercise price of \$7.58 per share as of September 30, 2008;
- warrants to purchase 929,596 shares of our common stock at a weighted average exercise price of \$7.70 per share as of September 30, 2008;
- warrants to purchase 4,623,971 shares of common stock included in this offering; and
- warrants to purchase 4,859,504 shares of common stock issued to certain of our existing shareholders in a concurrent offering.

To the extent that options or warrants are exercised, there will be further dilution to new investors.

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**PLAN OF DISTRIBUTION**

We are offering the units through a placement agent. Subject to the terms and conditions contained in the placement agency agreement, dated December 29, 2008, Deutsche Bank Securities, Inc. has agreed to act as the placement agent for the sale of up to 2,389,877 shares of common stock, series A warrants to purchase up to 1,792,408 shares of common stock, series B warrants to purchase up to 2,148,739 shares of common stock, series C warrants to purchase up to 341,412 shares of common stock, and series D warrants to purchase up to 341,412 shares of common stock (collectively, the warrants). The placement agent is not purchasing or selling any common stock or warrants by this prospectus supplement or the accompanying prospectus, nor is it required to arrange for the purchase or sale of any specific number or dollar amount of common stock or warrants, but has agreed, subject to the terms and conditions of the placement agency agreement, to use its commercially reasonable efforts to arrange for the sale of all of the common stock and the warrants.

The placement agency agreement provides that the obligations of the placement agent and the investor are subject to certain conditions precedent, including the absence of any material adverse change in our business and the receipt of customary legal opinions, letters and certificates.

Confirmations and final prospectuses will be distributed to all investors who agree to purchase the common stock and warrants, informing investors of the closing date as to such securities. We currently anticipate that closing of the sale of the units offered hereby will take place on or about December 31, 2008. Investors will also be informed of the date and manner in which they must transmit the purchase price for the securities.

On the scheduled closing date, the following will occur:

we will receive funds in the amount of the aggregate purchase price for the securities we sell; and

Deutsche Bank Securities, Inc. will receive the placement agent's fee in accordance with the terms of the placement agency agreement.

In compliance with guidelines of the Financial Industry Regulatory Authority, Inc., or FINRA, the maximum consideration or discount to be received by any FINRA member or independent broker dealer may not exceed 8.0% of the aggregate amount of the securities offered pursuant to this prospectus supplement.

We will pay the placement agent an aggregate placement agent's fee equal to seven and one-half percent (7.5%) of the gross proceeds of the sale of the securities in the offering. We may also reimburse the placement agent for certain fees and expenses incurred by it in connection with this offering in an amount not to exceed \$75,000 in the aggregate, of which up to \$50,000 may be used to reimburse legal fees of counsel to the placement agent.

In addition, we have agreed to pay Deutsche Bank Securities, Inc. a warrant solicitation fee equal to seven percent (7.0%) of the gross proceeds received by us from the exercise of the series B warrants.

We have agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act of 1933, as amended, and liabilities arising from breaches of representations and warranties contained in the placement agency agreement. We have also agreed to contribute to payments the placement agent may be required to make in respect of such liabilities.

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Pursuant to the securities purchase agreement with the investors, until February 16, 2009 the Company has agreed not to sell equity or equity equivalent securities, including securities convertible into or exchangeable or exercisable for common shares. From February 17, 2009 until the four month anniversary of the closing of the transaction, the Company will be permitted to raise a maximum of \$5 million in an equity financing, and after the four month anniversary there will be no restrictions. The foregoing restrictions do not include traditional bank financings and stock issued in connection with strategic partnerships and investments, qualified public offerings, employee or director equity incentive plans and other customary transactions.

The placement agency agreement has been included as an exhibit to our Current Report on Form 8-K that we filed with the Commission in connection with this offering.

The shares of common stock sold in this offering and the shares of common stock issuable upon exercise of the warrants sold in this offering will be listed on the NASDAQ Global Market. 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) 815-4197.

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**DESCRIPTION OF SECURITIES**

**Common Stock**

The holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the shares voting are able to elect all of the directors. Subject to preferences that may be granted to any then outstanding preferred stock, holders of common stock are entitled to receive ratably only those dividends as may be declared by the board of directors out of funds legally available therefor, as well as any distributions to the stockholders. In the event of our liquidation, dissolution or winding up, holders of common stock are entitled to share ratably in all of our assets remaining after we pay our liabilities and distribute the liquidation preference of any then outstanding preferred stock. Holders of common stock have no preemptive or other subscription or conversion rights. There are no redemption or sinking fund provisions applicable to the common stock. Please refer to *Description of Capital Stock* at page 27 of the accompanying prospectus for additional information relating to the common stock offering hereby.

**Warrants**

The warrants offered in this offering will be issued pursuant to a subscription agreement between the purchasers and us. The following is a brief summary of the material terms of the warrants and is subject in all respects to the provisions contained in the warrants. The forms of warrants are being filed with a Current Report on Form 8-K and reference is made thereto for a complete description of the warrants.

*Transferability.* The warrants may be transferred at the option of the warrant holder upon surrender of the warrants with the appropriate instruments of transfer.

*Exchange Listing.* We do not plan on making an application to list the warrants on the NASDAQ Global Market, any national securities exchange or other nationally recognized trading system.

*Fundamental Transactions.* In the event of any fundamental transaction, as described in the warrants and generally including consolidation or merger with another entity in which we are not the survivor, the sale, transfer or other disposition of all or substantially all of our assets to another entity, certain sales of more than 50% of our outstanding shares of common stock or any reorganization, recapitalization or reclassification of our common stock, we will ensure that the successor entity in such fundamental transaction assumes in writing all of our obligations under the warrants and related transaction documents, including agreements to deliver a security to the warrant holders that is substantially similar in form and substance to the warrants, including an adjusted exercise price equal to the value of the shares of common stock reflected by the terms of such fundamental transaction and exercisable for a corresponding number of shares of capital stock equivalent to the shares of common stock acquirable upon the exercise of the warrants. We must also ensure that after a fundamental transaction, the holders of the warrants will thereafter have the right to receive upon exercise of the warrants such shares of stock, securities or assets as would have been issuable or payable with respect to or in exchange for a number of shares of our common stock equal to the number of shares of our common stock issuable upon exercise of the warrants immediately prior to the fundamental transaction, had the fundamental transaction not taken place, and appropriate provision will be made so that the provisions of the warrants (including, for example, provisions relating to the adjustment of the exercise price) will thereafter be applicable, as nearly equivalent as may be practicable in relation to any share of stock, securities or assets deliverable

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upon the exercise of the warrants after the fundamental transaction. The holder of the warrants shall also be entitled, upon request, within 90 days following a change of control of the company, to have the company purchase such warrant in cash using a Black-Scholes value of any unexercised warrants.

*Rights as a Stockholder.* Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their warrants.

*Specific Terms of the Series A Warrants*

*Price.* The exercise price per share of common stock purchasable upon exercise of the series A warrants is \$5.11 per share of common stock being purchased. The exercise price is subject to appropriate adjustment in the event of stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders. In addition, the series A warrants have a provision for full ratchet adjustment of the warrant exercise price for the first two years following the closing, and a provision for weighted average adjustment thereafter. Upon three successive quarters of positive free cash flow (defined as cash flow from operations less non-acquisition related capital expenditures), the full ratchet anti-dilution protection will no longer apply and weighted average anti-dilution will apply thereafter. The warrant exercise price adjustment provisions will only reduce the exercise price, and will not result in any increase in the number of warrants or common shares underlying the warrants. The warrants will be exercisable for cash unless the registration statement covering the resale of the shares underlying the warrants is not effective. The warrants will receive Black-Scholes treatment in the event of a change of control.

*Exercisability; Number of Shares.* The series A warrants are exercisable on or after the date immediately following the six month anniversary of their issuance (the Initial Exercisability Date) and have a five year term from the Initial Exercisability Date. The series A warrants will be exercisable for 1,792,408 of shares of common stock.

*Specific Terms of the Series B Warrants*

Holders of series B warrants are entitled to purchase up to 2,148,739 shares of our common stock at a price of \$4.65 per share until six months after their date of issuance. The exercise price is subject to appropriate adjustment in the event of stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

*Specific Terms of the Series C Warrants*

*Price.* The exercise price per share of common stock purchasable upon exercise of the series C warrants is \$0.001 per share of common stock being purchased. The exercise price is subject to appropriate adjustment in the event of stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

*Exercisability; Number of Shares.* The series C warrants are exercisable for maximum eligibility number of shares of our common stock at a price of \$0.001 per share until the tenth trading day after the two month anniversary of the issuance date. The maximum eligibility number for the series C warrants means initially zero and on the second month anniversary of the issuance date will be increased to the number that is the difference between (I) \$5,000,000 divided by the arithmetic average of the volume weighted average price of our common stock during the 30 trading days immediately preceding the second month anniversary of the issuance date and (II) 1,194,939. If such simple average is between \$4.18 and \$3.25, a portion of the series C warrants will be exercisable; if each such simple average is below \$3.25, all of the series C warrants will be exercisable.

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### *Specific Terms of the Series D Warrants*

*Price.* The exercise price per share of common stock purchasable upon exercise of the series D warrants is \$0.001 per share of common stock being purchased. The exercise price is subject to appropriate adjustment in the event of stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

*Exercisability; Number of Shares.* The series D warrants are exercisable for maximum eligibility number of shares of our common stock at a price of \$0.001 per share until the tenth trading day after the five month anniversary of the issuance date. The maximum eligibility number for the series D warrants means initially zero and on the fifth month anniversary of the issuance date will be increased to the number that is the difference between (I) \$5,000,000 divided by the arithmetic average of the volume weighted average price of our common stock during the 30 trading days immediately preceding the fifth month anniversary of the issuance date and (II) 1,194,939. If such simple average is between \$4.18 and \$3.25, a portion of the series D warrants will be exercisable; if each such simple average is below \$3.25, all of the series D warrants will be exercisable.

*Effect of the Series C and D Warrants.* The effect of the series C warrants will be to cause the purchase price on 50% of the common stock offered hereby to be reset to the lesser of the offering price in this offering or the simple average of the daily volume weighted average price of our common stock for the 30 trading days prior to the two month anniversary of closing. The effect of the series D warrants will be to cause the purchase price on the other 50% of the common stock purchased hereunder to reset to the lesser of the offering price in this transaction or the simple average of the daily volume weighted average price of our common stock for the 30 trading days prior to the five month anniversary of closing. In either case, the reset price will not be lower than \$3.25, which is a 30% discount to the simple average of the daily volume weighted average price of our common stock for the five trading days prior to date of the securities purchase agreement.

## **LEGAL MATTERS**

The validity of the securities offered hereby has been passed upon for us by Bryan Cave LLP, St. Louis, Missouri. James L. Nouss, Jr., a partner of our legal counsel Bryan Cave LLP, beneficially owns 11,727 shares of our common stock, and is also our corporate secretary. Goodwin Procter LLP, New York, New York, has acted as counsel to the placement agent in connection with certain legal matters related to this offering.

## **EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements included in our Form 10-K/A for the year ended December 31, 2007 and has audited our financial statement schedule and effectiveness of internal control over financial reporting included in our Annual Report on Form 10-K, for the year ended December 31, 2007, as set forth in their reports (which contain a paragraph describing that since the completion of the audit of the financial statements and initial issuance of their report thereon dated March 13, 2008, the Company, as discussed in Note 19 to the financial statements, has experienced net losses and negative operating cash flows adversely affecting the Company's current results of operations and liquidity), which are 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.

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**WHERE YOU CAN FIND MORE 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, as amended, 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.

**INCORPORATION 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. 0-50884), 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, 2007, as amended by our Annual Report on Form 10-K/A for the year ended December 31, 2007;

our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2008, June 30, 2008 and September 30, 2008;

our Current Reports on Form 8-K filed on January 2, 2008, February 7, 2008, February 11, 2008, February 12, 2008, March 6, 2008, March 11, 2008, June 3, 2008, July 24, 2008, August 8, 2008, August 25, 2008, November 10, 2008, November 14, 2008, December 15, 2008; December 19, 2008 and December 29, 2008; and

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

We incorporate by reference any additional documents that we may file with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 (other than the portions of those made pursuant to Item 2.02 or Item 7.01 of Form 8-K or other information furnished to the SEC) after the date of this prospectus supplement until the termination of this offering of the securities. These documents may include periodic reports, like Annual Reports on Form 10-K, Quarterly Reports on



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

You may get copies of any of the document incorporated by reference (excluding exhibits, unless the exhibits are specifically incorporated) at no charge to you by writing or calling the investor relations department at Stereotaxis, Inc. 4320 Forest Park Avenue, Suite 100, St. Louis, Missouri 63108, telephone (314) 678-6100. You may also obtain copies of these filings, at no cost, by accessing our website at [www.stereotaxis.com](http://www.stereotaxis.com).

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**PROSPECTUS**

**\$75,000,000**

**Debt Securities**

**Common Stock**

**Preferred Stock**

**Warrants**

**Units**

We may offer and sell from time to time up to \$75,000,000 of debt securities, 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 Global 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 September 7, 2006.**

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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., Europe and Canada, 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 4320 Forest Park Avenue, Suite 100, St. Louis, Missouri 63108, and our telephone number is (314) 678-6100. Our website address is [www.stereotaxis.com](http://www.stereotaxis.com). Information contained on our website is not incorporated by reference into and does not form any part of this prospectus. As used in this prospectus, references to 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 cardiology magnet system, 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. In addition, hospitals may delay their purchase or installation decision based on the disposable interventional devices that have received regulatory clearance or approval. 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 interventional 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, Biosense Webster or other parties may fail, or we may not be able to enter into additional partnerships or collaborations in the future.**

We are collaborating with Siemens, Philips, Biosense Webster and other parties to integrate our instrument control technology with their respective imaging products or disposable interventional devices and to co-develop additional disposable interventional devices for use with our Stereotaxis System. For the immediate future, a significant portion of our revenues from system sales will be derived from these integrated products. In addition, Siemens has agreed to provide post-installation maintenance and support services to our customers for our integrated systems and we are in discussions with Philips to provide the same.

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;

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

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.

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.

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

Our research and development efforts and our marketing strategy depend heavily on obtaining support and collaboration from highly regarded physicians at leading commercial and research hospitals, particularly in the



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U.S. and Europe. If we are unable to gain and/or maintain such support and collaboration or if the reputation or standing of these physicians is impaired or otherwise adversely affected, our ability to market 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.

### **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 by either our staff or by subcontractors, successful installation of our system can be subjected to delays related to the overall construction or renovation process. If we experience any failures or delays in completing the installation of these systems, our



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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 and installation 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 historically been installed six to eight months after the receipt of a purchase order from a hospital depending on the construction cycle for the new or replacement interventional suite in which the equipment will be installed. In some cases, this time frame has been extended further to as much as 12 to 24 months because the interventional suite construction is part of a larger construction project at the customer site (typically the construction of a new building), which may occur with our existing and future purchase orders. Recently, these factors, in particular within the context of FDA approval delays for some of our disposable devices, have resulted in a conversion cycle of nine months or longer between the date of a given purchase order and recognition of that purchase order into revenue. This in turn has 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 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

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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.**

Although we recently completed a public offering of our common stock in early 2006, we may 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 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. We had net losses of approximately \$43.6 million in 2005, \$27.3 million in 2004 and \$24.0 million in 2003, and at December 31, 2005 we had an accumulated deficit of approximately \$158 million. A small portion of our accumulated deficit is attributable to investments in development of products for neurosurgical applications, which was our primary focus in the first several years after our inception in 1990. Because we may not be successful in completing the development or commercialization of our technology, your 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 increased reliance on contract manufacturers and on suppliers, and in some cases, a single supplier, could harm our ability to meet demand for our products in a timely manner or within budget.**

We depend on contract manufacturers to produce and assemble 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 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;



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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, Biosense Webster, 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 materials used to manufacture our magnets, one of our key system components, are sourced from Japan and China.**

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.

### **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 and assembly 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

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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. We could encounter problems at either of these facilities, which could delay or prevent us from assembling or testing our products or maintaining our pilot manufacturing capabilities or otherwise conducting operations. We moved our St. Louis operations to new facilities in the St. Louis area in early 2006.

**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.

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.

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### **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 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.

### **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.

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### **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 for our medical device products, or if such clearances 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 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

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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 and China.

**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 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



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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 apply to our business. We could 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 or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid programs;

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;

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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

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

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.

**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 would be significantly slowed or halted, and we may be unable to generate sufficient sales to support our business. Our success in international markets also depends upon the eligibility of our products for reimbursement through government-sponsored health care payment systems and third-party payors. In both the U.S. and foreign markets health care cost-containment efforts are prevalent and are expected to continue. These efforts could reduce levels of reimbursement available for procedures involving our products and, therefore, reduce overall demand for our products as well. A failure to generate sufficient sales could have a material adverse impact on our financial condition, results of operations and cash flow.

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### **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 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, the loss of members of our scientific staff may significantly delay or prevent product development and other business objectives.

### **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 TO 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 July 31, 2006, our executive officers, directors and individuals or entities affiliated with them beneficially own or control a substantial percentage of the outstanding shares of our common stock. Accordingly, these executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. These stockholders may also delay or prevent a change of control, even if such a change of control would benefit our other stockholders. This significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.



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**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 appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

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

discourage, delay or prevent a change in the control of 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 Biosense Webster, 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 Biosense Webster equal to 5% of the total equity value of Stereotaxis in the change of control transaction, up to a maximum of \$10.0 million. We also agreed to notify Biosense Webster 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 Global Market rules are creating uncertainty for public companies. We continue to evaluate and monitor developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional compliance costs we may incur or the timing of such costs. These new or changed laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by courts and regulatory and governing bodies. This could result in 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 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 Biosense Webster and others;

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

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

our ability to obtain and protect proprietary rights.

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

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

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;

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

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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 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;

our estimates regarding our capital requirements;

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

the adoption of our products by hospitals and physicians;

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

our plans for hiring additional personnel; and

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

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

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

Our actual results may be materially different from what we expect. We undertake no duty to update these forward-looking statements after the date of this prospectus, even though our situation may change in the future. 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.

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**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:

	<b>Six months ended June 30, 2006</b>	<b>Fiscal year ended December 31,</b>				
		<b>2005</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>
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, 2001, 2002, 2003, 2004 and 2005 and the six months ended June 30, 2006, the ratio coverage was less than 1:1. Additional earnings of \$17.0 million, \$21.5 million, \$24.0 million, \$27.3 million, \$43.6 million and \$28.2 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 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 DEBT SECURITIES**

The following description sets forth some general terms and provisions of the debt securities we may offer, but is not complete. The particular terms of the debt securities offered and the extent, if any, to which the general provisions may not apply to the debt securities so offered will be described in the prospectus supplement relating to the debt securities. For a more detailed description of the terms of the debt securities, please refer to the indenture relating to the issuance of the particular debt securities.

Any senior debt securities will be issued under a senior indenture to be entered into between us and the trustee named in the senior indenture. Any subordinated debt securities will be issued under a subordinated indenture to be entered into between us and the trustee named in the subordinated indenture. As used in this registration statement, the term "indentures" refers to both the senior indenture and the subordinated indenture. The indenture(s) will be qualified under the Trust Indenture Act of 1939. As used in this registration statement, the term "debt trustee" refers to either the senior trustee or the subordinated trustee, as applicable.

The following summaries of the material provisions of the senior debt securities, the subordinated debt securities and the indentures are subject to, and qualified in their entirety by reference to, all the provisions of the indenture applicable to a particular series of debt securities, including the definitions therein of some terms. Except as otherwise indicated, the terms of any senior indenture and subordinated indenture, will be identical.

**General**

If applicable, each prospectus supplement will describe the following terms relating to a series of debt securities:

the title of the debt securities;

whether the debt securities are senior debt securities or subordinated debt securities and the terms of subordination;

any limit on the amount of debt securities that may be issued;

whether any of the debt securities will be issuable, in whole or in part, in temporary or permanent global form or in the form of book-entry securities;

the maturity dates of the debt securities;

the annual interest rates (which may be fixed or variable) or the method for determining the rates and the dates interest will begin to accrue on the debt securities, the dates interest will be payable, and the regular record dates for interest payment dates or the method for determining the dates;

the places where payments with respect to the debt securities shall be payable;

our right, if any, to defer payment of interest on the debt securities and extend the maximum length of any deferral period;

the date, if any, after which, and the prices at which, the series of debt securities may, pursuant to any optional redemption provisions, be redeemed at our option, and other related terms and provisions;

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the dates, if any, on which, and the prices at which we are obligated, pursuant to any sinking fund provisions or otherwise, to redeem, or at the holder's option to purchase, the series of debt securities and other related terms and provisions;

the denominations in which the series of debt securities will be issued, if other than denominations of \$1,000 and any integral multiple thereof;

any mandatory or optional sinking fund or similar provisions with respect to the debt securities;

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any index used to determine the amount of payments of the principal of, and premium, if any, and interest on, the debt securities and the manner in which the amounts shall be determined;

the terms pursuant to which the debt securities are subject to defeasance;

the terms and conditions, if any, pursuant to which the debt securities are secured; and

any other terms of the debt securities not inconsistent with the applicable indenture.

The debt securities may be issued as original issue discount securities. An original issue discount security is a debt security, including any zero-coupon debt security, which:

is issued at a price lower than the amount payable upon its stated maturity; and

provides that upon redemption or acceleration of the maturity, an amount less than the amount payable upon the stated maturity, shall become due and payable.

United States federal income tax considerations applicable to debt securities sold at an original issue discount will be described in the applicable prospectus supplement.

Under the indentures, we will have the ability, in addition to the ability to issue debt securities with terms different from those of debt securities previously issued, without the consent of the holders, to reopen a previous issue of a series of debt securities and issue additional debt securities of that series, unless the reopening was restricted when the series was created, in an aggregate principal amount determined by us.

**Conversion or Exchange Rights**

The terms, if any, on which a series of debt securities may be convertible into or exchangeable for common stock or other of our securities will be detailed in the prospectus supplement relating thereto. The terms will include provisions as to whether conversion or exchange is mandatory, at the option of the holder, or at our option, and may include provisions pursuant to which the number of shares of our common stock or other of our securities to be received by the holders of the series of debt securities would be subject to adjustment.

**Consolidation, Merger or Sale of Assets**

We may not consolidate with or merge into any other person, in a transaction in which we are not the surviving corporation, or convey, transfer or lease our properties and assets substantially as an entirety to, any person, unless:

the successor entity, if any, is a corporation, limited liability company, partnership, trust or other entity existing under the laws of the United States, or any State or the District of Columbia;

the successor entity assumes our obligations on the debt securities and under the indentures;

immediately prior to and after giving effect to the transaction, no default or event of default shall have occurred and be continuing; and

certain other conditions are met.

**Events of Default Under the Indentures**

The following will be events of default under the indentures with respect to any series of debt securities issued:

failure to pay interest on the debt securities when due, which failure continues for a specified period set forth in the applicable prospectus supplement and the time for payment has not been deferred;

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failure to pay the principal or premium of the debt securities, if any, when due;

failure to deposit any sinking fund payment, when due, which failure continues for 60 days;

failure to observe or perform any other covenant contained in the debt securities or the indentures other than a covenant specifically relating to another series of debt securities, which failure continues for a specified period set forth in the applicable prospectus supplement after we receive notice from the debt trustee or holders of a specified percentage, set forth in the applicable prospectus supplement, of the aggregate principal amount of the outstanding debt securities of that series; or

particular events of our bankruptcy, insolvency or reorganization.

The supplemental indenture or the form of note for a particular series of debt securities may include additional events of default or changes to the events of default described above. For any additional or different events of default applicable to a particular series of debt securities, see the prospectus supplement relating to the series.

If an event of default with respect to debt securities of any series occurs and is continuing, the debt trustee or the holders of a specified percentage of the aggregate principal amount of the outstanding debt securities of that series, by notice in writing to us (and to the debt trustee if notice is given by the holders), may declare the unpaid principal of, premium, if any, and accrued interest, if any, due and payable immediately.

The holders of a specified percentage of the aggregate principal amount of the outstanding debt securities of an affected series may waive any default or event of default with respect to the series and its consequences, except defaults or events of default regarding:

payment of principal, premium, if any, or interest on the debt securities; or

those covenants described under the subsection **Modification of Indenture; Waiver** that cannot be modified or amended without the consent of each holder of any outstanding debt securities affected.

Any waiver shall cure the default or event of default.

Subject to the terms of the indentures (as supplemented), if an event of default under an indenture shall occur and be continuing, the debt trustee will be under no obligation to exercise any of its rights or powers under the indenture at the request or direction of any of the holders of the applicable series of debt securities, unless the holders have offered the debt trustee reasonable indemnity. The holders of a specified percentage of the aggregate principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the debt trustee, or exercising any trust or power conferred on the debt trustee, with respect to the debt securities of that series, provided that:

it is not in conflict with any law or the applicable indenture;

the debt trustee may take any other action deemed proper by it that is not inconsistent with the direction;

subject to its duties set forth under the applicable indenture, the debt trustee need not take any action that might involve it in personal liability; and



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in the case of the debt trustee under the senior indenture, subject to its duties set forth under such indenture, the debt trustee need not take any action that it determines, upon the advice of counsel, may not lawfully be taken or in good faith determines would be unduly prejudicial to the holders of the debt securities.

A holder of the debt securities of any series will only have the right to institute a proceeding under the indentures or to appoint a receiver or trustee, or to seek other remedies if:

the holder has given written notice to the debt trustee of a continuing event of default with respect to that series;

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the holders of a specified percentage of the aggregate principal amount of the outstanding debt securities of that series have made written request to the debt trustee, and the holders have offered reasonable indemnity to the debt trustee to institute proceedings; and

the debt trustee does not institute a proceeding, and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series other conflicting directions within a specified period set forth in the applicable prospectus supplement after the notice, request and offer.

These limitations will not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities.

We will periodically file statements with the debt trustee regarding our compliance with some of the covenants in the indentures.

### **Modification of Indenture; Waiver**

We and the debt trustee may change an indenture without the consent of any holders with respect to specific matters, including:

to fix any ambiguity, defect, or inconsistency in the indenture, provided that such action does not materially adversely affect the interests of any holder of debt securities of any series;

to provide for the assumption by a successor person or the acquirer of all or substantially all of our assets or obligations under such indenture;

to evidence and provide for successor trustees;

to add, change or eliminate any provision affecting only debt securities not yet issued; and

to comply with any requirement of the SEC in connection with qualification of an indenture under the Trust Indenture Act of 1939. In addition, under the indentures, the rights of holders of a series of debt securities may be changed by us and the debt trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series that is affected. However, the following changes may only be made with the consent of each holder of any outstanding debt securities affected:

extend the fixed maturity of the series of debt securities;

change any obligation of ours to pay additional amounts with respect to the debt securities;

reduce the principal amount of, the rate of interest on, or any premium payable upon the redemption of, any debt securities;

reduce the amount of principal of an original issue discount security or any other debt security payable upon acceleration of the maturity thereof;

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impair the right to enforce any payment on, or with respect to, any debt security;

adversely change the right to convert or exchange, including decreasing the conversion rate or increasing the conversion price of, the debt security (if applicable);

in the case of the subordinated indenture, modify the subordination provisions in a manner adverse to the holders of the subordinated debt securities;

if the debt securities are secured, change the terms and conditions pursuant to which the debt securities are secured in a manner adverse to the holders of the secured debt securities;

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reduce the percentage in principal amount of outstanding debt securities of any series, the consent of whose holders is required for modification or amendment of the applicable indenture or for waiver of compliance with certain provisions of the applicable indenture or for waiver of certain defaults; or

modify any of the above provisions.

### **Form, Exchange and Transfer**

The debt securities of each series will be issuable only in fully registered form without coupons and, unless otherwise specified in the applicable prospectus supplement, in denominations of \$1,000 and any integral multiple thereof. The indentures will provide that debt securities of a series may be issuable in temporary or permanent global form and may be issued as book-entry securities that will be deposited with, or on behalf of, The Depository Trust Company unless the prospectus supplement provides otherwise.

At the option of the holder, subject to the terms of the indentures and the limitations applicable to global securities described in the applicable prospectus supplement, debt securities of any series will be exchangeable for other debt securities of the same series, in any authorized denomination and of like tenor and aggregate principal amount.

Subject to the terms of the indentures and the limitations applicable to global securities detailed in the applicable prospectus supplement, debt securities may be presented for exchange or for registration of transfer (duly endorsed or with the form of transfer endorsed thereon duly executed if so required by us or the security registrar) at the office of the security registrar or at the office of any transfer agent designated by us for that purpose. Unless otherwise provided in the debt securities to be transferred or exchanged, no service charge will be made for any registration of transfer or exchange, but we may require payment of any taxes or other governmental charges. The security registrar and any transfer agent (in addition to the security registrar) initially designated by us for any debt securities will be named in the applicable prospectus supplement. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

If the debt securities of any series are to be redeemed, we will not be required to:

issue, register the transfer of, or exchange any debt securities of that series during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the day of the mailing; or

register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any debt securities being redeemed in part.

### **Information Concerning the Debt Trustee**

The debt trustee, other than during the occurrence and continuance of an event of default under an indenture, undertakes to perform only the duties specifically detailed in the indentures and, upon an event of default under an indenture, must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs. Subject to this provision, the debt trustee is under no obligation to exercise any of the powers given it by the indentures at the request of any holder of debt securities unless it is offered reasonable security and indemnity against the costs, expenses, and liabilities that it might incur. The debt trustee is not required to spend or risk its own money or otherwise become financially liable while performing its duties unless it reasonably believes that it will be repaid or receive adequate indemnity.

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### **Payment and Paying Agents**

Unless otherwise indicated in the applicable prospectus supplement, payment of the interest on any debt securities on any interest payment date will be made to the person in whose name the debt securities (or one or more predecessor securities) are registered at the close of business on the regular record date for the payment of interest.

Principal of and any premium and interest on the debt securities of a particular series will be payable at the office of the paying agents designated by us, except that unless otherwise indicated in the applicable prospectus supplement, interest payments may be made by check mailed to the holder. Unless otherwise indicated in the prospectus supplement, the corporate trust office of the debt trustee in the City of New York will be designated as our sole paying agent for payments with respect to debt securities of each series. Any other paying agents initially designated by us for the debt securities of a particular series will be named in the applicable prospectus supplement. We will be required to maintain a paying agent in each place of payment for the debt securities of a particular series.

All moneys paid by us to a paying agent or the debt trustee for the payment of the principal of, or any premium or interest on, any debt securities which remains unclaimed at the end of two years after the principal, premium, or interest has become due and payable will be repaid to us, and the holder of the security thereafter may look only to us for payment thereof.

### **Governing Law**

Unless otherwise indicated in the applicable prospectus supplement, the indentures and the debt securities will be governed by and construed in accordance with the laws of the State of New York except for conflicts of laws provisions and to the extent that the Trust Indenture Act of 1939 is applicable.

### **Subordination of Subordinated Debt Securities**

Any subordinated debt securities will be unsecured and will be subordinate and junior in priority of payment to some of our other indebtedness to the extent described in a prospectus supplement. The subordinated indenture will not limit the amount of subordinated debt securities which we may issue, nor will it limit us from issuing any other secured or unsecured debt.

### **Book Entry Debt Securities**

We will make payments on each series of book-entry debt securities to The Depository Trust Company or DTC or its nominee, as the sole registered owner and holder of the global security. Neither we nor the Trustee nor any of their agents will be responsible or liable for any aspect of DTC's records relating to or payments made on account of beneficial ownership interests in a global security or for maintaining, supervising or reviewing any of DTC's records relating to the beneficial ownership interests.

DTC has informed us that, when it receives any payment on a global security, it will immediately, on its book-entry registration and transfer system, credit the accounts of participants with payments in amounts proportionate to their beneficial interests in the global security as shown on DTC's records. Payments by participants to you, as an owner of a beneficial interest in the global security, will be governed by standing instructions and customary practices (as is now the case with securities held for customer accounts registered in street name) and will be the sole responsibility of the participants.

A global security representing a series will be exchanged for certificated debt securities of that series if (a) DTC notifies us that it is unwilling or unable to continue as Depository or if DTC ceases to be a clearing agency registered under the Securities Exchange Act of 1934 and we don't appoint a successor within 90 days or (b) we decide that the global security shall be exchangeable. If that occurs, we will issue debt securities of that

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series in certificated form in exchange for the global security. An owner of a beneficial interest in the global security then will be entitled to physical delivery of a certificate for debt securities of the series equal in principal amount to that beneficial interest and to have those debt securities registered in its name. We would issue the certificates for the debt securities in denominations of \$1,000 or any larger amount that is an integral multiple thereof, and we would issue them in registered form only, without coupons.

DTC has advised us that it is a limited-purpose trust company organized under the New York Bank Law, a banking organization within the meaning of the New York Banking Law, a member of the Federal Reserve System, a clearing corporation within the meaning of the New York Uniform Commercial Code, and a clearing agency registered under the Securities Exchange Act of 1934 Act. DTC was created to hold the securities of its participants and to facilitate the clearance and settlement of securities transactions among its participants through electronic book-entry changes in accounts of the participants, thereby eliminating the need for physical movement of securities certificates. DTC's participants include securities brokers and dealers, banks, trust companies, clearing corporations, and certain other organizations, some of whom (and/or their representatives) own DTC. Access to DTC's book-entry system is also available to others, such as banks, brokers, dealers and trust companies that clear through or maintain a custodial relationship with a participant, either directly or indirectly. The rules applicable to DTC and its participants are on file with the SEC. No fees or costs of DTC will be charged to you.

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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 30.

**Common Stock**

As of July 31, 2006, there were 34,159,285 shares of common stock outstanding that were held of record by approximately 150 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;

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

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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 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.



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*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

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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 27, 2007 and February 26, 2007 in the case of the 2007 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 Global Market Listing**

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

## **Transfer Agent And Registrar**

The transfer agent and registrar for our common stock is 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. These 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.

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

As of July 31, 2006, there were warrants outstanding to purchase 985,706 shares of common stock at a weighted average exercise price of \$7.98.

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 30.

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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 30.

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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.

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.

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.



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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 Global Market. Any common stock sold pursuant to a prospectus supplement will be eligible for listing and trading on the Nasdaq Global 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.



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**LEGAL MATTERS**

The validity of the securities offered hereby has been passed upon for us by Bryan Cave LLP, St. Louis, Missouri. James L. Nouss, Jr., a partner of our legal counsel Bryan Cave LLP, is one of three managers of a private investment fund that 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, 2005, and management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2005, as set forth in their reports, which are incorporated by reference in the registration statement. Our financial statements and schedule and management's assessment are incorporated by reference in reliance on Ernst & Young LLP's reports, given on their authority as experts in accounting and auditing.

**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, 2005;

our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2006 and June 30, 2006;

our Current Reports on Form 8-K filed January 23, 2006, January 27, 2006, February 1, 2006, February 28, 2006, March 9, 2006 and May 17, 2006; and

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

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

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

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

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**2,389,877 SHARES OF COMMON STOCK**

**SERIES A WARRANTS TO PURCHASE UP TO 1,792,408 SHARES OF COMMON STOCK**

**SERIES B WARRANTS TO PURCHASE UP TO 2,148,739 SHARES OF COMMON STOCK**

**SERIES C WARRANTS TO PURCHASE UP TO 341,412 SHARES OF COMMON STOCK**

**SERIES D WARRANTS TO PURCHASE UP TO 341,412 SHARES OF COMMON STOCK**

PROSPECTUS SUPPLEMENT

**Deutsche Bank Securities**

December 29, 2008