Stereotaxis, Inc.
Form 10-K
March 15, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(MARK ONE)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2009

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NUMBER 000-50884

STEREOTAXIS, INC.

(Exact name of Registrant as Specified in its Charter)

DELAWARE	**94-3120386**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

4320 Forest Park Avenue, Suite 100

St. Louis, MO 63108

(Address of Principal Executive Offices including Zip Code)

(314) 678-6100

(Registrant s Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act: Common Stock, $.001 Par Value

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K, or any amendment to this Form 10-K. ¨

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

Large accelerated filer ¨	Accelerated filer x	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No x

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant on the last business day of the registrant s most recently completed second fiscal quarter (based on the closing sales prices on the NASDAQ Global Market on June 30, 2009) was approximately $120 million.

The number of outstanding shares of the registrant s common stock on February 28, 2010 was 50,306,376.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Registrant s 2010 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

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PART I

ITEM 1. BUSINESS
FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K, including the sections entitled Business and Management s Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements. These statements relate to, among other things:

- our business strategy;
- our value proposition;
- the timing and prospects for regulatory approval of our additional disposable interventional devices;
- the success of our partnerships and strategic alliances;
- our estimates regarding our capital requirements;
- our ability to fund operations through cash flows from operations or by raising additional capital;
- 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 this annual report that are not historical facts.

These statements relate to future events or future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as may , will , should , could , expects , plans , intends , anticipates , believes , e 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 in Item 1A Risk Factors and elsewhere in this annual report on Form 10-K.

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 annual report, even though our situation may change in the future. We qualify all of our forward-looking statements by these cautionary statements.

OVERVIEW

We design, manufacture and market an advanced cardiology instrument control system for use in a hospital s interventional medical suite, or interventional lab , that we believe revolutionizes the treatment of arrhythmias and coronary artery disease by enabling important 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

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we are co-developing with strategic partners, through the blood vessels and chambers of the heart to treatment sites in order to effect treatment. This is achieved using computer-controlled, externally applied magnetic fields that precisely and directly govern the motion of the internal, or working, tip of the catheter, guidewire or other interventional device. We believe that our Niobe system represents a revolutionary technology in the interventional lab, bringing precise remote digital instrument control and programmability to the interventional lab, and has the potential to become the standard of care for a broad range of complex cardiology procedures. Additionally, our Odyssey Enterprise Solution allows physicians to utilize a consolidated user interface and single mouse and keyboard control for multiple systems within the interventional lab.

We believe that our Niobe system is the only commercialized technology 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 often result in long and unpredictable procedure times with suboptimal therapeutic outcomes. We believe that our technology represents an important advance supporting efficient and effective information management and physician collaboration.

Enhancements to the Odyssey Enterprise Solution allow physicians to remotely view, record, and collaborate with other Odyssey users either with or without a Niobe system. We believe that our Odyssey Enterprise Solution will enhance physician workflow and efficiency in the interventional lab.

We began commercial shipments of our Niobe system in 2003, following U.S. and European regulatory approval of its core components. Niobe system revenue represented 54%, 67%, and 78% of revenue for the years ended December 31, 2009, 2008, and 2007, respectively. As of December 31, 2009, we had recognized revenue on 143 Niobe systems, 37 Odyssey Vision systems and 6 Odyssey Enterprise Cinema systems and had approximately $37 million of backlog, consisting of outstanding purchase orders and other commitments for these systems, which we expect will be recognized to revenue within the next 18 months. We had backlog of approximately $45 million as of December 31, 2008 and 2007, using the same 18-month criteria. Of the December 31, 2009 backlog, we expect approximately 82% to be recognized as revenue over the course of 2010. There can be no assurance that we will recognize such 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. 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. In addition, the sales cycle for the Niobe system is lengthy and generally involves construction or renovation activities at customer sites. Consequently, revenues and/or orders resulting from sales of our Niobe system can vary significantly from one reporting period to the next.

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 significant majority 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 interventional 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 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.

In addition to the Niobe system and its components, Stereotaxis also has developed the Odyssey Enterprise Solution, which consolidates all lab information enabling doctors to focus on the patient for optimal procedure efficiency. The system also features a remote viewing and recording capability called Odyssey Enterprise Cinema, which is an innovative solution delivering synchronized content for optimized workflow, advanced care and improved productivity. This tool includes an archiving capability that allows clinicians to store and replay entire procedures or segments of procedures. This information can be accessed from locations throughout the hospital local area network and over the global Odyssey Network, providing physicians with a tool for clinical collaboration, remote consultation and training. The Odyssey Enterprise Solution is intended to be acquired in conjunction with a Niobe system or on a stand-alone basis for installation in interventional labs and other locations where clinicians desire improved clinical workflows and related efficiencies.

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 Enterprise Solution and various disposable interventional devices in the U.S., Canada, Europe, and various other countries. We continue to pursue regulatory approvals for additional products and in additional countries as appropriate.

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. Siemens accounted for 13% of total net revenue for the year ended December 31, 2009.

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

BACKGROUND

We have focused our clinical and commercial efforts on applications of the Niobe system in electrophysiology procedures for the treatment of arrhythmias and in complex interventional cardiology procedures for the treatment of coronary artery disease.

The rhythmic beating of the heart results from the transmission of electrical impulses. When these electrical impulses are mistimed or uncoordinated, the heart fails to function properly, resulting in complications that can range from fatigue to stroke or death. Several million people in the U.S. currently suffer from the resulting abnormal heart rhythms, which are known as arrhythmias.

Nearly half a million people die annually from coronary artery disease, a condition in which the formation of plaque in the coronary arteries obstructs the supply of blood to the heart, making this the leading cause of death in the U.S. Despite various attempts to reduce risk factors, each year approximately one million patients undergo interventional procedures in an attempt to open blocked vessels and another half a million patients undergo open heart surgery to bypass blocked coronary arteries.

Electrophysiology is a fast-growing clinical specialty focused on the treatment of cardiac arrhythmias which can occur in any chamber of the heart and typically treats patients with a combination of drug therapy and/or interventional catheter ablation of cardiac tissue to interrupt errant electrical signals.

Interventional cardiology and electrophysiology procedures have proven to be very effective at treating arrhythmias and coronary artery disease at sites accessible through the vasculature without the patient trauma, complications, recovery times and cost generally associated with open-heart surgery. With the advent of drug-eluting stents, the number of potential patients who could benefit from interventional cardiology procedures has grown. However, we believe major challenges associated with manual approaches to interventional cardiology and electrophysiology persist. In interventional cardiology, these challenges include difficulty in navigating the disposable interventional device through tortuous vasculature and crossing certain types of complex lesions to deliver balloons or stents to effect treatment. As a result, numerous patients who could be candidates for an interventional approach continue to be referred to bypass surgery. In electrophysiology, these challenges include precisely navigating the tip of the mapping and ablation catheter to the treatment site on the heart wall and maintaining tissue contact throughout the cardiac cycle to effect treatment, and, for atrial fibrillation, performing complex ablations within the left atrium of the heart. A major limitation is the manual dexterity required to perform complex ablations. As a result, large numbers of patients are referred to palliative drug therapy that can have harmful side effects.

We believe the Niobe system represents a revolutionary step in the trend toward highly effective, but less invasive, cardiac procedures. As the first technology to permit direct, computerized control of the working tip of a disposable interventional device, the Niobe system enables physicians to perform cardiac procedures interventionally that historically would have been very difficult or impossible to perform in this way and has the potential to significantly improve both the efficiency and efficacy of these treatments. We believe that the Odyssey Enterprise Solution will provide physicians the ability to enhance procedure workflow, more effectively manage their interventional procedures, collaborate with other physicians, and provide the capability to record and review segments or the entire procedure.

CURRENT CHALLENGES IN INTERVENTIONAL MEDICINE

Although great strides have been made in manual device technology and in related manual interventional techniques, significant challenges remain that reduce interventional productivity and limit both the number of complex procedures and the types of diseases that can be treated manually. These challenges primarily involve the inherent mechanical limitations of manual instrument control and the lack of integration of the information systems used by physicians in the interventional lab as well as a significant amount of training and experience required to ensure proficiency. As a result, many complex cases in electrophysiology are treated with palliative drug therapy and many complex procedures in interventional cardiology are still referred to highly invasive bypass surgery.

Limitations of Instrument Control

Manually controlled catheters, guidewires and other delivery devices, even in the hands of the most skilled specialist, have inherent instrument control limitations. In traditional interventional procedures, the device is manually manipulated by the physician who twists and pushes the external end of the instrument in an iterative process to thread the instrument through often tortuous blood vessels or into the chambers of the heart to the treatment site.

Lack of Integration of Information Systems

While sophisticated imaging, mapping and location-sensing systems have provided visualization for interventional procedures and allowed interventional physicians to treat more complex conditions, the substantial lack of integration of these information systems requires the physician to mentally integrate and process large quantities of information from different sources in real time during an interventional procedure. For example, a physician ablating heart tissue to eliminate an arrhythmia will often be required to mentally integrate information from a number of sources, including:

- real-time x-ray fluoroscopy images;

- a real-time location-sensing system providing the 3D location of the catheter tip;

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a pre-operative map of the electrical activity or anatomy of the patient s heart;

real-time recording of electrical activity of the heart; and

temperature feedback from an ablation catheter.

Each of these systems displays data differently, requiring physicians to continuously reorient themselves to the different formats and displays as they shift their focus from one data source to the next while at the same time manually controlling the interventional instrument. Also, each of these information systems requires a separate control panel, which further reduces the efficiency of the procedure.

THE STEREOTAXIS VALUE PROPOSITION

Our products address the current challenges in the interventional lab by providing precise computerized control of the working tip of the interventional instrument and by integrating this control with the visualization and information systems used during interventional cardiology and electrophysiology procedures, on a cost-justified basis. We believe that the Niobe system is the only commercialized technology that allows remote, computerized control of disposable interventional devices directly at their working tip.

We believe that our systems will:

Expand the market by enhancing the treatment of more complex existing cases and potentially enabling new treatments for major diseases. Treatment of a number of major diseases, including atrial fibrillation, cardiac chronic total occlusions, critical limb ischemia due to chronic total occlusions of peripheral arteries, and heart failure through the placement of bi-ventricular pacing devices, is highly problematic using conventional wire and/or catheter-based techniques. Additionally, many patients with multi-vessel disease and certain complex arrhythmias, such as atrial fibrillation, are often referred to other more invasive or less curative therapies because of the difficulty in precisely and safely controlling the working tip of disposable interventional devices used to treat these complex cases interventionally. Because the Niobe system provides precise, computerized control of the working tip of disposable interventional devices, we believe that it will potentially enable difficult total occlusions and atrial fibrillation to be treated interventionally on a much broader scale than today.

Improve outcomes by optimizing therapy. Difficulty in controlling the working tip of disposable interventional devices leads to sub-optimal results in many procedures. Precise instrument control is necessary for treating a number of cardiac conditions. To treat arrhythmias, precise placement of an ablation catheter against a beating inner heart wall is necessary. For coronary artery disease, precise and correct navigation and placement of expensive stents also have a significant impact on procedure costs and outcomes. We believe the Niobe system can enhance procedure results by improving navigation of disposable interventional devices to treatment sites, and by effecting more precise, safe, treatments once these sites are reached.

Improve clinical workflow and information management. The Odyssey Enterprise Solution will improve clinical workflow and information management efficiency by integrating and synchronizing the multiple sources of diagnostic and imaging information found in the interventional labs into a large-screen user interface with single mouse control via the Odyssey Vision system. Odyssey Enterprise Cinema systems can provide the customer with remote viewing and recording capabilities. By connecting the lab to other Odyssey sites both within and outside of the hospital via a secure private network, Odyssey Network Connect will provide the customer with on-demand support and the ability to participate in site-to-site collaboration and remote training.

Enhance hospital efficiency by reducing and standardizing procedure times, disposables utilization and staffing needs. Interventional procedure times currently range from several minutes to many hours as physicians often engage in repetitive, trial and error maneuvers due to difficulties with manually controlling the working tip of disposable interventional devices. By reducing both navigation time and

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the time needed to carry out therapy at the target site, we believe that the Niobe system can reduce complex procedure times compared to manual procedures. We believe the Niobe system can also reduce the variability in procedure times compared to manual methods. Greater standardization of procedure times allows for more efficient scheduling of interventional cases including staff requirements. We also believe that additional cost savings from the Niobe system result from decreased use of multiple catheters, guidewires and contrast media in procedures compared with manual methods further enhancing the rate of return to hospitals.

Enhance physician skill levels in order to improve the efficacy of complex cardiology procedures. Training required for physicians to safely and effectively carry out manual interventional procedures typically takes years, over and above the training required to become a specialist in cardiology. This has led to a shortage of physicians for more complex procedures. The Niobe system can allow procedures that previously required the highest levels of manual dexterity and skill to be performed effectively by a broader range of interventional physicians, with more standardized outcomes. In addition, interventional physicians can learn to use the Niobe system in a relatively short period of time. The Niobe system can also be programmed to carry out sequences of complex navigation automatically further enhancing ease of use.

Improve patient and physician safety. The Niobe system has been used in more than 26,000 procedures and the incidence of all reported major adverse cardiac events associated with the use of the system for all procedures is approximately 0.1%. This represents what we believe to be a clinically significant improvement in major complication rates over conventional procedures, which can range as high as 2-5% for complex ablations. Additionally, during conventional catheter-based procedures, each of the physicians who stand by the patient table to manually control the catheter, the nursing staff assisting with the procedure, and the patient are exposed to the potentially harmful x-ray radiation from the fluoroscopy field. This exposure can be minimized by reducing procedure times. Reducing procedure times is also beneficial to the patient because of the direct correlation between complication rates and procedure length. The Niobe system can further improve physician safety by enabling them to conduct procedures remotely from an adjacent control room, which reduces their exposure to harmful radiation, and the orthopedic burden of wearing lead.

OUR PRODUCTS

Niobe® System

Our proprietary Niobe system provides the physician with precise remote digital instrument control through user friendly point and click computer mouse control, in combination with sophisticated image integration and 3D reconstruction. It can be operated either from beside the patient table, as in traditional interventional procedures, or from a room adjacent to the patient and outside the x-ray fluoroscopy field. The Niobe Magnetic Navigation System navigates disposable interventional devices to the treatment site through complex paths in the blood vessels and chambers of the heart to deliver treatment using computer controlled, externally applied magnetic fields to directly govern the motion of the working tip of these devices, each of which has a magnetically sensitive tip that predictably responds to magnetic fields generated by our system. Because the working tip of the disposable interventional device is directly controlled by these external magnetic fields, the physician has the same degree of control regardless of the number or type of turns, or the distance traveled by the working tip to arrive at its position in the blood vessels or chambers of the heart. This results in highly precise digital control of the working tip of the disposable interventional device while still giving the physician the option to manually advance the device.

Through our alliances with Siemens, Philips and Biosense Webster, this precise digital instrument control has been integrated with the visualization and information systems used during electrophysiology procedures in order to provide the physician with a fully-integrated and automated information and instrument control system. We have integrated our Niobe system with Siemens and with Philips digital x-ray fluoroscopy systems. In addition, we have integrated the Niobe system with Biosense Webster s 3D catheter location sensing technology

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to provide accurate real-time information as to the 3D location of the working tip of the instrument, and with Biosense Webster s ablation tip technology. The combination of these technologies was fully launched in 2005.

The components of the Niobe system are identified and described below:

Niobe® Magnetic Navigation System. Our Niobe Magnetic Navigation System utilizes two permanent magnets mounted on articulating and pivoting arms that are enclosed within a stationary housing, with one magnet on either side of the patient table. These magnets generate magnetic navigation fields that are less than 10% of the strength of fields typically generated by MRI equipment and therefore require significantly less shielding, and cause significantly less interference, than MRI equipment. The Niobe system is indicated for use in cardiac, peripheral and neurovascular applications.

Navigant Advanced User Interface. The Navigant advanced user interface is an integrated information and control center that integrates the key information sources used by physicians to provide instrument control directions to precisely govern the motion of the working tip of disposable interventional devices.

The Navigant advanced user interface consists of:

- configurable display screens located both next to the patient table inside the interventional labs and in the adjacent control room, outside the x-ray field, that provide advanced visualization and information integration to the physician;
- sophisticated embedded device software and system control algorithms that are integrated with our disposable interventional devices to facilitate ease of use automation, and improved navigation of these devices;
- virtual catheter or mouse control which the physician uses to direct the motion of the working tip of the disposable interventional device, either from inside the interventional labs or from the adjacent control room; and
- a software package for specific clinical procedures.

Cardiodrive® Automated Catheter Advancement System. As the physician conducts the procedure from the adjacent control room, the Cardiodrive or QuikCAS automated catheter advancement system is used to remotely advance and retract the electrophysiology catheter in the patient s heart while the Niobe magnets precisely steer the working tip of the device.

Odyssey Enterprise Solution

The Odyssey Enterprise Solution offers a fully integrated, real-time information solution to manage, control, record and share procedures across networks or around the world. Odyssey enhances the physician workflow in both interventional and electrophysiology labs through a consolidated user interface of multiple systems on a single display to enable greater focus on the case and improve the efficiency of the lab. Odyssey includes one mouse and keyboard to command multiple systems in the lab from a single point of control. In addition, Odyssey acquires a real-time, remote view of the lab capturing synchronized procedure data for review of important events during cases. Odyssey also enables physicians to review recorded cases and create snapshots following procedures for enhanced clinical reporting, auditing and presentation. Odyssey enables physicians to establish a comprehensive master archive of procedures performed in the lab providing an excellent tool for training new staff on the standard practices. Odyssey further enables procedures to be observed remotely around the world with high speed internet access even wirelessly using a standard laptop or tablet PC.

Regulatory Approval

We have received regulatory marketing clearance, licensing and CE Mark approvals necessary for us to market the Niobe Magnetic Navigation System, the Navigant advanced user interface and the Cardiodrive automated catheter advancement system in the U.S., Canada, Europe and various other countries. We have

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received regulatory marketing clearance, licensing and CE Mark approvals necessary for us to market the Odyssey Vision in the U.S. and Europe and are in the process of obtaining necessary approvals for all of our products in various other countries. Our total U.S. revenue was $22,309,477, $29,052,328, and $25,930,305 for the years ended December 31, 2009, 2008, and 2007, respectively. Our total international revenue was $28,840,078, $11,312,845, and $13,368,504, for the years ended December 31, 2009, 2008, and 2007, respectively.

DISPOSABLES AND OTHER ACCESSORIES

Our Niobe system is designed to use a toolkit of proprietary disposable interventional devices. The toolkit currently consists of:

- our Cardiodrive or QuikCAS automated catheter advancement disposable used to provide precise remote advancement of proprietary electrophysiology catheters;

- our suite of Cronus®, Assert®, Titan® and Pegasus coronary guidewires suitable for use in interventional cardiology procedures for the introduction and placement of over-the-wire therapeutic devices, such as stents and angioplasty balloons; and

- the CARTO® RMT navigation and ablation system, CELSIUS® RMT, NAVISTAR® RMT, NAVISTAR® RMT DS, and NAVISTAR® RMT THERMOCOOL® Irrigated Tip Diagnostic/Ablation Steerable Tip Catheters co-developed with Biosense Webster, as described below.

We have received FDA clearance and the CE Mark necessary for us to market our suite of Cronus, Assert and Titan and Pegasus coronary and RF PowerAssert Peripheral guidewires and our Helios II electrophysiology ablation catheter in the U.S. and Europe. We continue to seek approvals to market our products as appropriate.

Biosense Webster has received FDA approval and CE Mark for the CARTO® RMT navigation system for use with the Niobe system, the 4mm CELSIUS RMT Diagnostic/Ablation Steerable Tip Catheter, the 4mm NAVISTAR RMT Diagnostic/Ablation Steerable Tip Catheter, the Navistar RMT DS Diagnostic/Ablation Steerable Tip Catheter and the 8mm NAVISTAR RMT THERMOCOOL Irrigated Tip Catheter. We will continue to co-develop catheters that can be navigated with our system, both with and without Biosense Webster s 3D catheter location sensing technology. In addition, we can utilize technology which allows our system to recognize specific disposable interventional devices in order to prevent unauthorized use of our system.

We believe that we can adapt most disposable interventional devices for use with our system by using our proprietary technology to add an inexpensive micro-magnet at their working tip. This micro-magnet is activated by an external magnetic field, which allows interventional devices with tip dimensions as small as 14 thousandths (0.014) of an inch to be oriented and positioned in a predictable and controllable fashion. We believe this approach to bringing digital control to disposable interventional devices using embedded magnets can simplify the overall design of these devices because mechanical controls are no longer required.

CLINICAL APPLICATIONS

We have focused our clinical and commercial efforts on applications of the Niobe system in electrophysiology procedures for the treatment of arrhythmias and in complex interventional cardiology procedures for the treatment of coronary artery disease. Our system potentially has broad applicability in other areas, such as interventional neurosurgery, interventional neuroradiology, peripheral vascular, pulmonology, urology, gynecology and gastrointestinal medicine, and our patent portfolio has been structured to permit expansion into these areas.

Electrophysiology

The rhythmic beating of the heart results from the transmission of electrical impulses. When these electrical impulses are mistimed or uncoordinated, the heart fails to function properly, resulting in symptoms that can range from fatigue to stroke or death. Several million people in the U.S. currently suffer from the resulting abnormal heart rhythms, which are known as arrhythmias. The most common arrhythmia in adults is atrial fibrillation. This chaotic electrical activity of the top chambers of the heart is estimated to be present in over two million people in the United States and over five million people worldwide. The incidence is expected to continue to rise as the population ages and life expectancy continues to increase. Atrial fibrillation is a major physical and economic burden. This arrhythmia is associated with stroke, heart failure, and adverse symptoms causing patients to be very motivated to seek treatment. The combination of symptoms, prevalence and co-morbidities make atrial fibrillation a major economic factor in healthcare. We believe payers are very interested in therapies that may reduce the financial impact of this disease.

Drug therapies for arrhythmias often fail to adequately control the arrhythmia and may have significant side effects. Consequently, physicians have increasingly sought more permanent, non-pharmacological, solutions for arrhythmias. The most common interventional treatment for arrhythmias, and in particular tachyarrhythmias, where the patient s heart rate is too high or irregular, is an ablation procedure in which the diseased tissue giving rise to the arrhythmia is isolated or destroyed. Prior to performing an electrophysiology ablation, a physician typically performs a diagnostic procedure in which the electrical signal patterns of the heart wall are mapped to identify the heart tissue generating the aberrant electrical signals. Following the mapping procedure, the physician may then use an ablation catheter to eliminate the aberrant signal or signal path, restoring the heart to its normal rhythm. In cases where an ablation is anticipated, physicians will choose an ablation catheter and perform both the mapping and ablation with the same catheter. In February 2009 the FDA approved the Biosense Webster NAVISTAR THERMOCOOL irrigated catheter to be labeled for the treatment of atrial fibrillation. This is the first device approved by the FDA to be labeled for the interventional treatment of this arrhythmia. We believe this important milestone will accelerate acceptance of ablations for the treatment of atrial fibrillation.

We believe the Niobe system is particularly well-suited for those electrophysiology procedures which are time consuming or which can only be performed by highly experienced physicians. These procedures include:

General Mapping and Ablations. For the more routine mapping and ablation procedures, our system offers the unique benefit of precise catheter movement and consistent heart wall contact. Additionally, the system can control the procedure and direct catheter movement from the control room, saving the physician time and helping to avoid unnecessary exposure to high doses of radiation.

Atrial Fibrillation. The most commonly diagnosed abnormal heart rhythm, atrial fibrillation, is a particular type of arrhythmia characterized by rapid, disorganized contractions of the heart s upper chambers, the atria, which lead to ineffective heart pumping and blood flow and can be a major risk factor for stroke. The number of potential patients for manual catheter-based procedures for atrial fibrillation has been limited because the procedures are extremely complex and are performed by only the most highly skilled electrophysiologists. They also typically have much longer procedure times than general ablation cases and the success rates have been lower and more variable. We believe that our system can allow these procedures to be performed by a broader range of electrophysiologists and, by automating some of the more complex catheter maneuvers, can standardize and reduce procedure times and significantly improve outcomes.

Ventricular Tachycardia. Ventricular tachycardia is a malignant, potentially lethal arrhythmia that is extremely difficult and time consuming to treat by catheter ablation because of the mechanical force of a conventional catheter against the heart wall. The magnetic catheter has been characterized as the ideal tool for this application. These arrhythmias can often be modified or interrupted by the pressure of a conventional catheter making it very difficult to identify the appropriate location for the ablation, whereas magnetic catheters produce fewer extra beats and provide for easier and more efficient mapping of the diseased tissue. Successful ablation of ventricular tachycardia can extend the useful life of an implantable defibrillator, reduce shocks to the patient, reduce the need for antiarrhythmic drugs or, in some cases, obviate the need for an expensive implantable device and its associated follow-up.

Cardiac Resynchronization Therapy (CRT). Heart failure is a potentially fatal condition in which the heart muscle is damaged to the point that it is unable to provide adequate blood flow to the body. CRT,

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or bi-ventricular pacing, has shown promise in the treatment of heart failure in which the ventricles of the heart do not contract in a coordinated manner. The procedure used to carry out this therapy involves the placement of a pacemaker lead into the coronary venous system of the heart. Interventional treatment of this patient population is growing rapidly but the placement of the venous pacing lead with manual interventional technologies is highly challenging and time consuming. The unpredictability of procedure times also makes efficient interventional lab scheduling very difficult in these cases. There is growing evidence that lead placement can contribute to clinical outcomes, and we believe our system enhances the physician s ability to achieve optimal lead placements.

We believe that our system can address the current challenges in electrophysiology by permitting the physician to remotely navigate disposable interventional devices from a control room outside the x-ray field. Additionally, we believe that our system allows for more predictable and efficient navigation of these devices to the treatment site, including the left atrium for atrial fibrillation procedures, and enables appropriate contact force to be maintained to efficiently apply energy on the wall of the beating heart. We also believe that our system will significantly lower the skill barriers required for physicians to perform complex electrophysiology procedures and, additionally, improve interventional lab efficiency and reduce disposable interventional device utilization.

Interventional Cardiology

Nearly half a million people die annually from coronary artery disease, a condition in which the formation of plaque in the coronary arteries obstructs the supply of blood to the heart, making this the leading cause of death in the U.S. Despite various attempts to reduce risk factors, each year over one million patients undergo interventional procedures in an attempt to open blocked vessels and another half a million patients undergo open heart surgery to bypass blocked coronary arteries.

Blockages within a coronary artery, often called lesions, are categorized by degree of obstruction as partial occlusions, non-chronic total occlusions and chronic total occlusions. Lesions are also categorized by the degree of difficulty with which they can be opened as simple or complex. Complex lesions, such as chronic total occlusions, longer lesions, and lesions located within smaller diameter vessels, are often very difficult or time consuming to open with manual interventional techniques.

We estimate that approximately 10-15% of these interventional cardiology procedures currently being performed are complex and therefore require longer procedure times and may have sub-optimal outcomes. We believe that our system can substantially benefit this subset of complex interventional cardiology procedures, including procedures involving:

Occlusions. Because our system provides precise computerized control of the working tip of a guidewire, it can enable physicians to more easily locate small openings in, and to advance a guidewire across, these lesions. Since approximately one-fifth of patients referred to bypass surgery have chronic total occlusions, we believe a significant number of patients could be treated interventionally instead of surgically if more of these lesions could be opened for stenting.

Tortuous Anatomy. Because our system allows the working tip of disposable interventional devices to be precisely oriented regardless of the number of turns that have occurred, our technology allows physicians to more effectively navigate these devices through complex vasculature and deliver balloons and stents to treatment sites for therapy.

Peripheral Arterial Disease (PAD)

PAD is a form of atherosclerosis or blockage of an artery which restricts blood flow to the extremities, typically the lower legs. It is the third most prevalent disease in the U.S. and the number of people affected is expected to grow to over 22 million in 2020. Individuals suffering from PAD often experience chronic total occlusions.

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Chronic total occlusions are classified as blockages that completely obstruct the flow of blood through an artery for an extended period of time, usually 30 days or more. Chronic total occlusions, which are often a factor in peripheral vascular disease, pose a serious health risk and require a safe, effective method of treatment. We believe the Niobe system can help overcome the significant challenges faced by clinicians in manually delivering guidewires and other devices across chronic total occlusions, by providing precise magnetic tip control in combination with 3-D image reconstruction of these complex vascular lesions. We do not anticipate any significant revenue from these applications in the near term.

Interventional Neuroradiology, Neurosurgery and Other Interventional Applications

Physicians used a predecessor to our Niobe system to conduct a number of procedures for the treatment of brain aneurysms, a condition in which a portion of a blood vessel wall balloons and which can result in debilitating or fatal bleeding and strokes. The Niobe system also has a range of potential applications in minimally invasive neurosurgery, including biopsies and the treatment of tumors, treatment of vascular malformations and, when deliverables are commercialized by third parties, delivery of pharmacological compounds and deep brain stimulators. We do not anticipate any significant revenue from these programs in the near term.

COLLABORATIONS

We have entered into collaborations with technology leaders in the global interventional market, including Siemens, Philips, and Biosense Webster that we believe will aid us in commercializing our Niobe system. We believe our two imaging partners, Siemens and Philips, have a significant percentage of the installed base of imaging systems worldwide.

We believe that these collaboration arrangements are favorable to Stereotaxis because they:

- provide for the integration of our system with market leading digital imaging and 3D catheter location sensing technology, as well as disposable interventional devices;
- allow us to leverage the sales, distribution, service and maintenance expertise of our strategic partners; and
- enable operational flexibility by not requiring us to provide any of our strategic partners with a right of first refusal in the event that another party wants to acquire us or with board representation where a strategic partner has made a debt or equity investment in us.

Imaging Partners

Siemens Alliance. We have successfully integrated our Niobe system with Siemens digital fluoroscopy system to provide advanced interventional lab visualization and instrument control through user-friendly computerized interfaces. We also coordinate our sales efforts with Siemens to co-place integrated systems at leading hospital sites in the U.S., Europe and in Asia. Under this alliance and under a separate services agreement, Siemens provides site planning, project management, equipment maintenance and support services for our products directly to our customers. To date, the majority of our systems placed for clinical use have been integrated with Siemens digital fluoroscopy systems. We have also entered into a separate development agreement for the Japanese market under which Siemens will coordinate regulatory approval and distribute, install and service our Niobe systems, whether integrated with the x-ray system of Siemens, or other third parties, in Japan. We have also entered into a software distribution agreement with Siemens under which we have the right to sublicense Siemens 3D pre-operative image navigation software as part of our Navigant advanced user interface.

Philips Alliance. We have successfully integrated our Niobe system with Philips digital x-ray fluoroscopy system. We also coordinate our sales and marketing efforts with Philips in order to co-place our integrated systems in addition to collaborating on the development of new solutions and sharing engineering and development costs.

Disposables Devices Partner

Biosense Webster Alliance. We entered into an alliance in May 2002 pursuant to which we agreed to integrate Biosense Webster s advanced 3D catheter location sensing technology, which we believe has the leading market position in this important field of visualization for electrophysiology procedures, with our instrument control system, and to jointly develop associated location sensing electrophysiology mapping and ablation catheters that are navigable with the Niobe system. We believe that these integrated products will provide physicians with the elements required for effective complex electrophysiology procedures: highly accurate information as to the exact location of the catheter in the body and highly precise control over the working tip of the catheter. We also agreed to coordinate our sales force efforts with Biosense Webster in order to place Biosense Carto® RMT systems and our Niobe systems that, together with the co-developed catheters, comprise the full integration of our instrument control and 3D location sensing technologies in the interventional lab. We expanded this alliance in November 2003 to include the parallel integration of our instrument control technology with Biosense Webster s full line of non-location sensing mapping and ablation catheters that are relevant to our targeted applications in electrophysiology.

The co-developed catheters are manufactured and distributed by Biosense Webster, and both of the parties agreed to contribute to the resources required for their development. We are entitled to royalty payments from Biosense Webster, payable quarterly based on a profit formula for sales of the co-developed catheters, and our royalty increases under certain circumstances. Under this alliance, we agreed to certain restrictions on our ability to co-develop and distribute catheters competitive with those we are developing with Biosense Webster and granted Biosense Webster certain notice and discussion rights for product development activities we undertake relating to localization and magnetically enabling interventional disposable devices in cardiology fields outside of electrophysiology and mapping.

Either party may terminate this alliance in certain specified change of control situations, although the termination would not be effective until one year after the change of control and then would be subject to a wind-down period during which Biosense Webster would continue to supply co-developed catheters to us or to our customers for three years (or, for non-location sensing mapping and ablation catheters, until our first sale of a competitive product after a change of control, if earlier than three years). If we terminate the agreement 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 million. We also agreed to notify Biosense Webster if we reasonably believe that we are engaged in substantive discussions with respect to the sale of the Company or substantially all of our assets.

In May 2007 we amended our agreement with Biosense Webster to extend the development and distribution alliance related to the magnetically enabled irrigated tip catheters until December 31, 2011 and also to explore opportunities for expanding their integrated technology for the delivery of cells and other biological agents for the treatment of heart failure.

In July 2008, we reached an agreement with Biosense Webster under which Biosense Webster advanced us $10 million and allowed us to defer up to $8 million of payments due to Biosense Webster for research and development related to jointly developed products. Repayment of these advances will be recouped by Biosense Webster from royalties otherwise owing to us on the sale of magnetically enabled co-developed catheters and/or through periodic minimum payments. If not fully recouped, any remaining advances will be due to Biosense on December 31, 2011.

Our agreement with Biosense Webster relating to exclusive integration with their 3D localization system expired in May 2009 and certain aspects of our agreement relating to exclusive development and sale of magnetically enabled non-irrigated catheters, including Biosense Webster s distribution rights, were extended to May 2010. We are in discussion with Biosense Webster to determine the ongoing relationship between Biosense Webster and us as it relates to future co-development, integration, and distribution of the 3D localization system and non-irrigated magnetically enabled mapping and ablation catheters.

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RESEARCH AND DEVELOPMENT

We have assembled an experienced group of engineers and physicists with recognized expertise in magnetics, software, control algorithms, systems integration and disposable interventional device modeling and design.

Our research and development efforts are focused in the following areas:

- continuing to enhance our existing Niobe and Odyssey systems through ongoing product and software development; and
- designing new proprietary disposable interventional devices for use with our system.

Our research and development team collaborates with our strategic partners, Siemens, Philips, and Biosense Webster, to integrate our Niobe system s open architecture platform with key imaging, location sensing and information systems in the interventional lab. We have also collaborated with a number of highly regarded interventional physicians in key clinical areas and have entered into agreements with a number of universities and research institutions, which serve to increase our access to world class physicians and scientists and to expand our name recognition in the medical community.

CUSTOMER SERVICE AND SUPPORT

Stereotaxis provides worldwide maintenance and support services to our customers for our integrated products with the assistance of certain strategically-based partners. By utilizing these relationships, we provide direct, on-site technical support activities, including call center, customer support engineers and service parts logistics and delivery. In certain situations, we use these third parties as a single point of contact for the customer, which allows us to focus on providing installation, training, and back-up technical support.

Our back-up technical support includes a combination of on-line, telephone and on-site technical assistance services 24 hours a day, seven days a week. We have also hired service and support engineers with networking and medical equipment expertise, and have outsourced a portion of our installation and support services. We offer several different levels of support to our customers, including basic hardware and software maintenance, extended product maintenance, and rapid response capability for both parts and service.

We have established a call center in our St. Louis facilities, which provides real-time clinical and technical support to our Odyssey customers worldwide via our Odyssey private network.

MANUFACTURING

Niobe and Odyssey systems

Our manufacturing strategy for our Niobe and Odyssey systems is to sub-contract the manufacture of major subassemblies of our system to maximize manufacturing flexibility and lower fixed costs while maintaining quality control by completing final system assembly and inspection in-house.

Disposable Interventional Devices

Our manufacturing strategy for disposable interventional devices is to outsource their manufacture through subcontracting and through our alliance with Biosense Webster and to expand partnerships for other interventional devices. We currently maintain pilot level manufacturing capability along with strong relationships with component level suppliers. We have approximately 5,000 square feet available for disposables manufacturing, assembly, testing and inspection with approximately 1,300 square feet of clean rooms in Maple Grove, Minnesota. We have entered into manufacturing agreements to provide high volume capability for devices other than catheters.

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Software

The software components of the Niobe and Odyssey systems, including control and application software, are developed both internally and with integrated modules we purchase or license. We perform final testing of software products in-house prior to their commercial release.

General

Our manufacturing facilities operate under processes that meet the FDA s requirements under the Quality System Regulation, or QSR. In 2003 and 2006, the FDA audited our Maple Grove, Minnesota facility for regulatory compliance, and no deficiencies were noted. In 2007 and 2008, the FDA conducted pre-approval audits related to the Helios II ablation catheter pre-market approval, with only three minor observations noted. A European notified body has regularly audited each facility annually since 2001 and found the facilities to be in compliance with European requirements. The initial certification was issued in January 2002 for compliance with ISO 9001. The most recent issuance of formal certification is for ISO 13485:2003.

SALES AND MARKETING

We market our products in the U.S and internationally through a direct sales force of senior sales specialists, distributors and sales agents, supported by account managers and clinical specialists who provide training, clinical support, and other services to our customers. In addition, our strategic alliances form an important part of our sales and marketing strategy. We leverage the sales forces of our imaging partners to co-market integrated systems on a worldwide basis. This approach allows us to maximize our leads and knowledge of the market opportunities while using our resources to sell directly to the customer. Under the terms of our agreement, Biosense Webster exclusively distributes our electrophysiology mapping and ablation catheters, co-developed pursuant to our alliance with them.

Our sales and marketing efforts include three important elements: (1) selling Niobe systems directly and through co-marketing agreements with our imaging partners, Siemens and Philips and through distributors; (2) leveraging our installed base of systems to drive recurring sales of disposable interventional devices, software and service; and (3) increasing the market penetration of Odyssey in standard labs.

REIMBURSEMENT

We believe that substantially all of the procedures, whether commercial or in clinical trials, conducted in the U.S. with the Niobe system have been reimbursed to date. We expect that third-party payors will reimburse, under existing billing codes, our line of guidewires, as well as our line of ablation catheters and those on which we are collaborating with Biosense Webster. We expect healthcare facilities in the U.S. to bill various third-party payors, such as Medicare, Medicaid, other government programs and private insurers, for services performed with our products. We believe that procedures performed using our products, or targeted for use by products that do not yet have regulatory clearance or approval, are generally already reimbursable under government programs and most private plans. Accordingly, we believe providers in the U.S. will generally not be required to obtain new billing authorizations or codes in order to be compensated for performing medically necessary procedures using our products on insured patients. We cannot assure you that reimbursement policies of third-party payors will not change in the future with respect to some or all of the procedures using the Niobe system. See Item 1A Risk Factors for a discussion of various risks associated with reimbursement from third-party payors.

INTELLECTUAL PROPERTY

Our strategy is to patent the technology, inventions and improvements that we consider important to the development of our business. As a result, we have an extensive patent portfolio that we believe protects the fundamental scope of our technology, including our magnet technology, navigational methods, procedures,

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systems, disposables interventional devices and our 3D integration technology. As of December 31, 2009, we had 83 issued U.S. patents, 2 co-owned U.S. patents and 7 licensed U.S. patents. In addition, we had 115 pending U.S. patent applications, 7 co-owned U.S. patent applications, 5 licensed U.S. patent applications. As of December 31, 2009 we had 9 issued foreign patents and one licensed-in foreign patent, 3 pending Patent Cooperation Treaty applications and 24 owned and one co-owned Foreign Patent Applications. We also have a number of invention disclosures under consideration and several applications that are being prepared for filing.

The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. One or more of the above patent applications may be denied. In addition, our issued patents may be challenged, based on prior art circumvented or otherwise not provide protection for the products we develop. Furthermore, we may not be able to obtain patent licenses from third parties required for the development of new products for use with our system. We also note that U.S. patents and patent applications may 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. In the event that we seek to enforce any of our owned or exclusively licensed patents against an infringing party, it is likely that the party defending the claim will seek to invalidate the patents we assert, which, if successful could result in the entire loss of our patent or the relevant portion of our patent and not just with respect to that particular infringer. Any litigation to enforce or defend our patents rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations.

It would be technically difficult and costly to reverse engineer our Niobe system, which contains numerous complex algorithms that control our disposable devices inside the magnetic fields generated by the Niobe system. We further believe that our patent portfolio is broad enough in scope to enable us to obtain legal relief if any entity not licensed by us attempted to market disposable devices that can be navigated by the Niobe system. We can also utilize security keys, such as embedded smart chips or associated software that could allow our system to recognize specific disposable interventional devices in order to prevent unauthorized use of our system.

We have also developed substantial know-how in magnet design, magnet physics and magnetic instrument control that was developed in connection with the development of the Niobe system, which we maintain as trade secrets. This know-how centers around our proprietary magnet design, which is a critical aspect of our ability to design, manufacture and install a cost-effective Magnetic Navigation System that is small enough to be installed in a standard interventional lab. It would also be technically difficult and costly to reverse engineer our Odyssey Enterprise System, which contains numerous complex algorithms and proprietary software and hardware configurations, and requires substantial knowledge to design and assemble, which we maintain as trade secrets. These proprietary software and hardware, some of which is owned by Stereotaxis, and some of which is licensed to Stereotaxis exclusively in its field of use, is a material aspect of the ability to design, manufacture and install a cost-effective and efficient information integration, storage, and delivery platform.

We seek to protect our proprietary information by requiring our employees, consultants, contractors, outside partners and other advisers to execute nondisclosure and assignment of invention agreements upon commencement of their employment or engagement, through which we seek to protect our intellectual property. These agreements to protect our unpatented technology provide only limited and possibly inadequate protection of our rights. Third parties may therefore be able to use our unpatented technology, reducing our ability to compete. In addition, employees, consultants and other parties to these agreements may breach them and adequate remedies may not be available to us for their breaches. Many of our employees were previously employed at universities or other medical device companies, including 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 divert the attention of management and key personnel from our business operations. We also generally seek confidentiality agreements from third parties that receive our confidential data or materials.

Our intellectual property involves certain risks and uncertainties. Please refer to Item 1A Risk Factors in this annual report for a description of these risks and uncertainties.

COMPETITION

The markets for medical devices are intensely competitive and are characterized by rapid technological advances, frequent new product introductions, evolving industry standards and price erosion.

We consider the primary competition to our Niobe system to be existing manual catheter-based interventional techniques and surgical procedures. To our knowledge, we are the only company that has commercialized remote, digital and direct control of the working tip of catheters and guidewires for interventional use. Our success depends in part on convincing hospitals and physicians to convert existing interventional procedures to computer-assisted procedures.

We also face competition from companies that are developing new approaches and products for use in interventional procedures, including robotic approaches that are directly competitive with our technology. Some of these companies may have an established presence in the field of interventional cardiology, including the major imaging, capital equipment and disposables companies that are currently selling products in the interventional lab. 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. We also face competition from companies who currently market or are developing drugs, gene or cellular therapies to treat the conditions for which our products are intended.

We face direct competition to certain products in our Odyssey Enterprise Solution, such as the Odyssey Vision. These competitor products primarily compete with individual components of our Odyssey Enterprise Solution. We expect to continue to face competitive pressure in this market in the future, based on the rapid pace of advancements with this technology.

We believe that the primary competitive factors in the market we address are capability, safety, efficacy, ease of use, price, quality, reliability and effective sales, support, training and service. The length of time required for products to be developed and to receive regulatory and reimbursement approval is also an important competitive factor. See Item 1A Risk Factors for a discussion of other competitive risks facing our business.

GOVERNMENT REGULATION

The healthcare industry, and thus our business, is subject to extensive federal, state, local and foreign regulation. Some of the pertinent laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. In addition, these laws and their interpretations are subject to change.

Both federal and state governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. As indicated by work plans and reports issued by these agencies, the federal government will continue to scrutinize, among other things, the billing practices of healthcare providers and the marketing of healthcare products. The federal government also has increased funding in recent years to fight healthcare fraud, and various agencies, such as the U.S. Department of Justice, the Office of Inspector General of the Department of Health and Human Services, or OIG, and state Medicaid fraud control units, are coordinating their enforcement efforts.

We believe that we have structured our business operations and relationships with our customers to comply with all applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert otherwise. We discuss below the statutes and regulations that are most relevant to our business and most frequently cited in enforcement actions.

U.S. Food and Drug Administration Regulation

The Food and Drug Administration (FDA) strictly regulates the medical devices we produce under the authority of the Federal Food, Drug and Cosmetic Act, or FFDCA, the regulations promulgated under the FFDCA, and other federal and state statutes and regulations. The FFDCA governs, among other things, the pre-clinical and clinical testing, design, manufacture, safety, efficacy, labeling, storage, record keeping, post market reporting and advertising and promotion of medical devices.

Our medical devices are categorized under the statutory framework described in the FFDCA. This framework is a risk-based system which classifies medical devices into three classes from lowest risk (Class I) to highest risk (Class III). In general, Class I and II devices are either exempt from the need for FDA clearance or cleared for marketing through a premarket notification, or 510(k), process. Our devices that are considered to be general tools, such as our Niobe Magnetic Navigation System and our suite of guidewires, or that provide diagnostic information, such as our Tangent electrophysiology mapping catheters, are subject to 510(k) requirements. These devices are cleared for use as general tools which have utility in a variety of interventional procedures. Our therapeutic devices, such as our Helios II ablation catheters, are subject to the premarket approval, or PMA, process.

If clinical data are needed to support a marketing application for our devices, generally, an investigational device exemption, or IDE, is assembled and submitted to the FDA. The FDA reviews and must approve the IDE before the study can begin. In addition, the study must be approved by an Institutional Review Board covering each clinical site. When all approvals are obtained, we initiate a clinical study to evaluate the device. Following completion of the study, we collect, analyze and present the data in an appropriate submission to the FDA, either a 510(k) or PMA.

Under the 510(k) process, the FDA determines whether or not the device is substantially equivalent to a predicate device. In making this determination, the FDA compares both the new device and the predicate device. If the two devices are comparable in intended use, safety, and effectiveness, the device may be cleared for marketing.

Under the PMA process, the FDA examines detailed data relating to the safety and effectiveness of the device. This information includes design, development, manufacture, labeling, advertising, pre-clinical testing, and clinical study data. Prior to approving the PMA, the FDA generally will conduct an inspection of the facilities producing the device and one or more clinical sites where the study was conducted. The facility inspection evaluates the Company s readiness to commercially produce and distribute the device. The inspection includes an evaluation of compliance under the Quality System Regulation (QSR). Under certain circumstances, the FDA may convene an advisory panel meeting to seek review of the data presented in the PMA. If the FDA s evaluation is favorable, the PMA is approved, and we can market the device in the U.S. The FDA may approve the PMA with conditions, such as post-market surveillance requirements.

We evaluate changes made following 510(k) clearance or PMA approval for significance and if appropriate, make a subsequent submission to the FDA. In the case of a significant change being made to a 510(k) device, we submit a new 510(k). For a PMA device, we will either need approval through a PMA supplement or will need to notify the FDA.

For our 510(k) devices, we design the submission to cover multiple models or variations in order to minimize the number of submissions. For our PMA devices, we often rely upon the PMA approvals of our

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strategic partners to utilize the PMA supplement regulatory path rather than pursue an original PMA. Because of the differences in the amount of data and numbers of patients in clinical trials, a PMA supplement process is often much shorter than the amount of time and data required for approval of an original PMA.

Currently our Niobe Magnetic Navigation System, Navigant advanced user interface, Cardiodrive automated catheter advancement system, Odyssey Vision, Tangent electrophysiology mapping catheter, Helios II electrophysiology ablation catheter, the Cronus and Assert families of coronary guidewires, the Titan and Pegasus families of guidewires and our RF guidewire have been cleared by the FDA to be used in interventional procedures. In addition, Biosense Webster received FDA approval for the Celsius® RMT, the Navistar® RMT, the Navistar® RMT DS, and the Navistar® RMT Thermocool® Irrigated Tip diagnostic/ablation steerable tip catheters as described above.

Foreign Regulation

In order for us to market our products in other countries, we must obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. These regulations, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. Failure to obtain regulatory approval in any foreign country in which we plan to market our products may harm our ability to generate revenue and harm our business.

The primary regulatory environment in Europe is that of the European Union, which consists of 27 countries encompassing most of the major countries in Europe. The European Union requires that manufacturers of medical products obtain the right to affix the CE Mark to their products before selling them in member countries of the European Union. The CE Mark is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain the right to affix the CE Mark to products, a manufacturer must obtain certification that its processes meet certain European quality standards. Compliance with the Medical Device Directive, as certified by a recognized European Notified Body, permits the manufacturer to affix the CE Mark on its products and commercially distribute those products throughout the European Union.

We have received the right to affix the CE Mark to each of our products that has received 510(k) clearance or PMA approval in the U.S. We have not applied for the right to affix the CE Mark to our Tangent mapping catheter as it is not currently marketed. If we modify existing products or develop new products in the future, including new devices, we will need to apply for permission to affix the CE Mark to such products. We will be subject to regulatory audits, currently conducted biannually, in order to maintain any CE Mark permissions we have already obtained. We cannot be certain that we will be able to obtain permission to affix the CE Mark for new or modified products or that we will continue to meet the quality and safety standards required to maintain the permissions we have already received. If we are unable to maintain permission to affix the CE Mark to our products, we will no longer be able to sell our products in member countries of the European Union. In addition, Biosense Webster has obtained the right to affix the CE Mark to the Celsius® RMT, the Navistar® RMT, the Navistar® RMT DS, and the Navistar® RMT ThermoCool® Irrigated Tip diagnostic/ablation steerable tip catheters.

We are actively pursuing approvals for our system and for various disposable devices in various other countries in which we conduct business or intend to conduct business. Where appropriate, we work through our strategic partners to obtain the requisite approvals. We will evaluate regulatory approval on additional products and in other foreign countries on an opportunistic basis.

Anti-Kickback Statute

The federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made

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under a federal healthcare program such as the Medicare and Medicaid programs. The definition of remuneration has been broadly interpreted to include anything of value, including for example gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash and waivers of payments. Several courts have interpreted the statute s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. In addition, some kickback allegations have been claimed to violate the Federal False Claims Act, discussed in more detail below.

The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the OIG to issue a series of regulations, known as the safe harbors which it did, beginning in July 1991. These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG.

Many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

Government officials have focused their enforcement efforts on marketing of healthcare services and products, among other activities, and recently have brought cases against sales personnel who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business. As part of our compliance program, we have established a formal Clinical Compliance Committee and appointed a Clinical Compliance Officer to help ensure compliance with the Anti-Kickback Statute and similar state laws and we train our employees on our healthcare compliance policies. However, we cannot rule out the possibility that the government or other third parties could interpret these laws differently and assert otherwise.

HIPAA

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created two federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

In addition to creating the two new federal healthcare crimes, HIPAA also establishes uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses. Two standards have been promulgated under HIPAA: the Standards for Privacy of Individually Identifiable Health Information, which restrict the use and disclosure of certain individually identifiable health information, and the Standards for Electronic Transactions, which establish standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures. In addition, the Security Standards required covered entities to implement certain security measures to safeguard certain electronic health information by April 2005. Although we believe we are not a covered entity and therefore do not need to comply with these standards, our customers generally are covered entities and frequently ask us to comply with certain aspects of these standards. While the government intended this legislation to reduce administrative expenses and burdens for the healthcare industry, our compliance with certain provisions of these standards may entail significant and costly changes for us. If we fail to comply with these standards, it is possible that we could be subject to criminal penalties.

In addition to federal regulations issued under HIPAA, some states and foreign countries have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. In those cases, it may be necessary to modify our operations and procedures to comply with the more stringent state laws, which may entail significant and costly changes for us. We believe that we are in compliance with such state laws and regulations. However, if we fail to comply with applicable state laws and regulations, we could be subject to additional sanctions.

Federal False Claims Act

Another trend affecting the healthcare industry is the increased use of the federal False Claims Act and, in particular, actions under the False Claims Act s whistleblower or qui tam provisions. Those provisions allow a private individual to bring actions on behalf of the government alleging that the defendant has defrauded the federal government. The government must decide whether to intervene in the lawsuit and to become the primary prosecutor. If it declines to do so, the individual may choose to pursue the case alone, although the government must be kept apprised of the progress of the lawsuit. Whether or not the federal government intervenes in the case, it will receive the majority of any recovery. If the individual s litigation is successful, the individual is entitled to no less than 15%, but no more than 30%, of whatever amount the government recovers. In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. In addition, various states have enacted laws modeled after the federal False Claims Act.

When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties from $5,500 to $11,000 for each separate false claim. There are many potential bases for liability under the federal False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. Although simple negligence should not give rise to liability, submitting a claim with reckless disregard or deliberate ignorance of its truth or falsity could result in substantial civil liability. The False Claims Act has been used to assert liability on the basis of inadequate care, improper referrals, and improper use of Medicare numbers when detailing the provider of services, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. We are unable to predict whether we could be subject to actions under the False Claims Act, or the impact of such actions. However, the costs of defending claims under the False Claims Act, as well as sanctions imposed under the Act, could significantly affect our financial performance.

Certificate of Need Laws

In approximately two-thirds of the states, a certificate of need or similar regulatory approval is required prior to the acquisition of high-cost capital items or various types of advanced medical equipment, such as our Niobe system. At present, many of the states in which we sell Niobe systems have laws that require institutions located in those states to obtain a certificate of need in connection with the purchase of our system, and some of our purchase orders are conditioned upon our customer s receipt of necessary certificate of need approval. Certificate of need laws were enacted to contain rising health care costs, prevent the unnecessary duplication of health resources, and increase patient access for health services. In practice, certificate of need laws have prevented hospitals and other providers who have been unable to obtain a certificate of need from acquiring new equipment or offering new services. A further increase in the number of states regulating our business through certificate of need or similar programs could adversely affect us. Moreover, some states may have additional requirements. For example, we understand that California s certificate of need law also incorporates seismic safety requirements which must be met before a hospital can acquire our Niobe system.

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Employees

As of December 31, 2009, we had 186 employees, 42 of whom were engaged directly in research and development, 79 in sales and marketing activities, 24 in manufacturing and service, 12 in regulatory, clinical affairs and quality activities, 6 in training activities and 23 in general administrative and accounting activities. None of our employees is covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

Availability of Information

We make certain filings with the SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments and exhibits to those reports, available free of charge in the Investor Relations section of our website, *http://www.stereotaxis.com*, as soon as reasonably practicable after they are filed with the SEC. The filings are also available through the SEC at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 or by calling 1-800-SEC-0330. Further, these filings are available on the Internet at http://www.sec.gov. Information contained on our website is not part of this report and such information is not incorporated by reference into this report.

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ITEM 1A. RISK FACTORS

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

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

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

General economic conditions could materially adversely impact us.

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

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

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

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additional disposable interventional devices for use with our Niobe system. A significant portion of our revenue from system sales will be derived from these integrated products. Siemens provides post-installation maintenance and support services to our customers for our integrated systems.

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

- any of our collaboration partners delays or fails in the integration of its technology with our Niobe system as planned;
- any of our collaboration partners fails to develop or commercialize the integrated products in a timely manner;
- any of our collaboration partners do not co-market and co-promote our integrated products diligently or do not provide maintenance and support services as we expect; or
- we become involved in disputes with one or more of our collaboration partners regarding our collaborations.

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

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

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

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

- our inability to recruit and retain adequate numbers of qualified sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of hospitals and physicians to purchase and use our products; and
- unforeseen costs associated with maintaining and expanding an independent sales and marketing organization.

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

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

Our research and development efforts and our marketing strategy depend heavily on obtaining support and collaboration from highly regarded physicians at leading commercial and research hospitals, particularly in the U.S. and Europe. If we are unable to gain and/or maintain such support and collaboration or if the reputation or

standing of these physicians is impaired or otherwise adversely affected, our ability to market our products and, as a result, our financial condition, results of operations and cash flow could be materially and adversely affected.

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

In order for physicians to learn to use the Niobe system, they must attend structured 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, by the time required to complete this training, or by state or institutional restrictions on the ability of the Company to provide 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 we are aware of one private company at a much earlier stage of development. If these or other new products or technologies emerge that provide the same or superior benefits as our products at equal or lesser cost, it could render our products obsolete or unmarketable. We cannot be certain that physicians will use our products to replace or supplement established treatments or that our products will be competitive with current or future products and technologies.

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

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

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

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

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

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

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

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

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

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

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

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

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

We may not generate cash from operations or be able to raise the necessary capital to commercialize our existing products and invest in new products.

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

- enhance our existing products or develop new ones;
- expand our operations;
- hire, train and retain employees; or
- respond to competitive pressures or capital requirements.

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

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

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

We have incurred substantial net losses since inception, and we expect to incur substantial net losses into 2010 as we continue the commercialization of our products. We may not be successful in completing the development or commercialization of our technology. Moreover, the extent of our future losses and the timing of profitability are highly uncertain, and we may never achieve profitable operations. If we require more time than we expect to generate significant revenue and achieve profitability, we may not be able to continue our operations. Our failure to achieve profitability could negatively impact the market price of our common stock. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Furthermore, even if we achieve significant revenue, we may choose to pursue a strategy of increasing market penetration and presence or expand or accelerate new product development or clinical research activities at the expense of profitability.

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

We have financed our operations through equity transactions and bank and other borrowings. Our current bank loan agreement contains financial and other covenants which, if violated, could require the repayment of existing indebtedness and lead to the lack of availability of borrowings under that agreement. There can be no

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assurance that we will be able to maintain compliance with these covenants or that we could replace this source of liquidity if these covenants were to be violated and our loans were forced to be repaid.

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

We depend on contract manufacturers to produce and assemble certain of the components of our systems and other products such as our guidewires and electrophysiology catheter advancement devices. We also depend on various third party suppliers for the magnets we use in our Niobe Magnetic Navigation Systems and certain components of our Odyssey Enterprise Solution. 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 certain components of our Odyssey Enterprise Solution, and we generally do not maintain large volumes of inventory. Our reliance on these third parties involves a number of risks, including, among other things, the risk that:

- we may not be able to control the quality and cost of our system or respond to unanticipated changes and increases in customer orders;
- we may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of our systems; and
- we may not be able to find new or alternative components for our use or reconfigure our system and manufacturing processes in a timely manner if the components necessary for our system become unavailable.

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

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

In addition, if these manufacturers or suppliers stop providing us with the components or services necessary for the operation of our business, we may not be able to identify alternate sources in a timely fashion. Any transition to alternate manufacturers or suppliers would likely result in operational problems and increased expenses and could delay the shipment of, or limit our ability to provide, our products. We cannot assure you that we would be able to enter into agreements with new manufacturers or suppliers on commercially reasonable terms or at all. Additionally, obtaining components from a new supplier may require a new or supplemental filing with applicable regulatory authorities and clearance or approval of the filing before we could resume product sales. Any disruptions in product flow may harm our ability to generate revenue, lead to customer dissatisfaction, damage our reputation and result in additional costs or cancellation of orders by our customers.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The rate of technological innovation of the Odyssey Enterprise Solution might not keep pace with the rest of the market.

The rate of innovation for the market in which Odyssey competes is fast-paced and requires significant resources and innovation. The technology surrounding these products is still in its growth stages and if a larger competitor with significant capital entered the market, it could be difficult for us to maintain our advantages associated with being an early developer of this technology. In addition, connectivity with other devices in the electrophysiology lab is a key driver of value for the Odyssey system. If the Company is not able to continue to commit sufficient resources to ensure that its products are compatible with other products within the electrophysiology lab, this could have a negative impact on Odyssey revenue.

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

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

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

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

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PMA process. We cannot commercially market any disposable interventional devices in the U.S. until the necessary clearances or approvals from the FDA have been received. In 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 addition, if we are unable to obtain on-label approval for key applications, we may face product market adoption barriers that we cannot overcome. 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

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

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

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

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

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

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- damage to our reputation;
- additional regulatory filings;
- product recalls;
- increased service or warranty costs; and/or
- product liability claims relating to the software defects.

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

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

- the federal healthcare program Anti-Kickback Law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any health care benefit program or making false statements relating to health care matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- federal self-referral laws, such as STARK, which prohibits a physician from making a referral to a provider of certain health services with which the physician or the physician s family member has a financial interest;
- regulations pertaining to receipt of CE mark for our products marketed outside of the United States and submission to periodic regulatory audits in order to maintain these regulatory approvals; and

the Health Information Technology for Economic and Clinical Health Act (HITECH), which imposes breach notification requirements for vendors of personal health records and their third party service providers.

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

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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.

Healthcare policy changes, including legislation pending in Congress to reform the U.S. healthcare system, may have a material adverse effect on us.

In response to perceived increases in health care costs in recent years, there have been and continue to be proposals by the Obama administration, members of Congress, state governments, regulators and third-party payors to control these costs and, more generally, to reform the U.S. healthcare system. Legislative proposals currently pending in Congress would impose significant new taxes on medical device makers such as us. The adoption of some or all of these proposals could have a material adverse effect on our financial position and results of operations.

On November 7, 2009, the U.S. House of Representatives passed the Affordable Health Care for America Act, and on December 24, 2009, the U.S. Senate enacted similar, but not identical, healthcare reform legislation, and various proposals are being considered to bring such legislation into law, including budget reconciliation. We cannot predict whether legislation will be enacted, the final form any legislation might take or the effects of such legislation. The current versions of both the House and Senate proposals would impose significant new taxes on medical device makers. The total cost to the medical device industry could exceed $20 billion over ten years. These taxes, if implemented, would result in a significant increase in the tax burden on our industry, which could have a material, negative impact on our results of operations and our cash flows. Proposed legislation would also impose new payroll taxes, excise taxes, income taxes and other taxes; provide for taxes/fees based upon domestic sales of devices; implement changes to Medicare and Medicaid; establish a government health insurance option; and allow the government to mandate minimum levels of coverage and make comparative effectiveness recommendations. In summary, if legislation is enacted and depending on the form it takes, it could change the way healthcare is developed and delivered, and may materially impact numerous aspects of our business.

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

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

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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 operations.

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

- currency fluctuations that could impact the demand for our products or result in currency exchange losses;
- export restrictions, tariff and trade regulations and foreign tax laws;
- customs duties, export quotas or other trade restrictions;
- economic and political instability; and
- shipping delays.

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

Risks Related To Our Common Stock

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

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

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 have in the past created uncertainty for public companies. We continue to evaluate and monitor developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional compliance costs we may incur or

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the timing of such costs. These new or changed laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by courts and regulatory and governing bodies. This could result in uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Maintaining appropriate standards of corporate governance and public disclosure may result in increased general and administrative expense and a diversion of management time and attention from revenue-generating activities to compliance activities. In addition, if we fail to comply with new or changed laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business and reputation may be harmed.

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

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

- demand for our products;
- the performance of third-party contract manufacturers and component suppliers;
- our ability to develop sales and marketing capabilities;
- the success of our collaborations with Siemens, Philips and Biosense Webster and others;
- our ability to develop, introduce and market new or enhanced versions of our products on a timely basis;
- our ability to obtain regulatory clearances or approvals for our new products; and
- our ability to obtain and protect proprietary rights.

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

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

Our common stock is traded on the NASDAQ Global Market and trading volume may be limited or sporadic. The market price of our common stock has experienced, and may continue to experience, substantial volatility. During 2009, our common stock traded between $2.30 and $5.19 per share, on trading volume ranging from approximately 76,000 to 1.7 million shares per day. The market price of our common stock will be affected by a number of factors, including:

- actual or anticipated variations in our results of operations or those of our competitors;
- the receipt or denial of regulatory approvals;

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

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;

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- developments in our industry; and

- participants in the market for our common stock may take short positions with respect to our common stock.

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

Future issuances of our securities could dilute current stockholders ownership.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

We have not received any written comments regarding our periodic or current reports from the staff of the SEC that were issued 180 days or more preceding the end of our 2009 fiscal year and that remain unresolved.

ITEM 2. PROPERTIES

Our primary company facilities are located in St. Louis, Missouri where we lease approximately 65,000 square feet of office and 12,000 square feet of demonstration and assembly space. This space is leased under an agreement through 2018. We also lease approximately 10,000 square feet in Maple Grove, Minnesota. The Minnesota facility is leased through May 31, 2010.

In addition, we have leased office space in Amsterdam, The Netherlands; and in Beijing, China. These locations are leased through May 31, 2010 and September 30, 2010, respectively.

ITEM 3. LEGAL PROCEEDINGS

We are involved from time to time in various lawsuits and claims arising in the normal course of business. Although the outcomes of these lawsuits and claims are uncertain, we do not believe any of them will have a material adverse effect on our business, financial condition or results of operations.

ITEM 4. [RESERVED]

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ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

PRICE RANGE OF COMMON STOCK

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

	High	Low
Year Ended December 31, 2009		
First Quarter	$ 4.65	$ 2.30
Second Quarter	4.88	2.98
Third Quarter	5.19	3.19
Fourth Quarter	4.67	3.49
Year Ended December 31, 2008		
First Quarter	$ 12.57	$ 3.37
Second Quarter	8.01	4.58
Third Quarter	7.99	4.63
Fourth Quarter	6.64	2.25

As of February 28, 2010, there were approximately 275 stockholders of record of our common stock, although we believe that there is a significantly larger number of beneficial owners of our common stock.

DIVIDEND POLICY

We have never declared or paid any cash dividends. We currently expect to retain earnings for use in the operation and expansion of our business, and therefore do not anticipate paying any cash dividends for the next several years. In addition, the terms of our loan agreement prohibit us from declaring dividends without the prior consent of our lender.

The information required by this item regarding equity compensation is incorporated by reference to the information set forth in Item 12 of this Annual Report on Form 10-K.

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STOCK PRICE PERFORMANCE GRAPH

The following graph shows the total stockholder return from December 31, 2004 through December 31, 2009 for a $100 investment in Stereotaxis, Inc., the NASDAQ Composite (U.S.) Index and the NASDAQ Medical Device Index. All values assume reinvestment of the full amount of all dividends although dividends have never been declared on Stereotaxis common stock. The stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.

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ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data has been derived from, and should be read in conjunction with our financial statements and the accompanying notes and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this report. The selected data in this section is not intended to replace the financial statements. Historical results are not indicative of the results to be expected in the future.

	Year Ended December 31,				
	2009	2008	2007	2006	2005
Consolidated Statements of Operations Data:					
Revenue	$ 51,149,555	$ 40,365,173	$ 39,298,809	$ 27,191,706	$ 15,026,390
Cost of revenue	17,021,633	14,177,790	15,346,220	12,892,749	7,720,706
Gross margin	34,127,922	26,187,383	23,952,589	14,298,957	7,305,684
Operating costs and expenses:					
Research and development	14,260,854	17,422,828	25,471,809	21,794,177	17,829,282
Sales and marketing	28,694,540	28,660,663	29,021,117	22,533,882	16,106,621
General and administrative	15,010,490	21,121,164	18,701,726	16,642,359	14,449,326
Royalty settlement					2,923,111
Total operating expenses	57,965,884	67,204,655	73,194,652	60,970,418	51,308,340
Operating loss	(23,837,962)	(41,017,272)	(49,242,063)	(46,671,461)	(44,002,656)
Interest and other income (expense), net	(3,656,495)	(2,868,702)	1,120,549	951,691	444,821
Net loss	$ (27,494,457)	$ (43,885,974)	$ (48,121,514)	$ (45,719,770)	$ (43,557,835)
Basic and diluted net loss per common share	$ (0.63)	$ (1.20)	$ (1.34)	$ (1.39)	$ (1.60)
Shares used in computing basic and diluted net loss per common share	43,344,324	36,585,086	35,793,973	32,979,403	27,301,822
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 30,546,550	$ 30,355,657	$ 23,656,378	$ 36,983,781	$ 10,735,587
Working capital	22,878,277	23,331,906	21,925,716	40,383,798	15,896,719
Total assets	56,120,516	59,440,365	60,475,794	69,290,660	36,658,189
Long-term debt, less current maturities	20,346,655	25,271,547	6,000,000	305,556	1,972,222
Accumulated deficit	(323,452,784)	(295,958,327)	(252,072,353)	(203,950,839)	(158,231,069)
Total stockholders equity	7,641,343	4,770,681	24,194,407	44,788,992	18,125,842

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ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our financial statements and notes thereto included in this report on Form 10-K. Operating results are not necessarily indicative of results that may occur in future periods.

This report includes various forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results could differ materially from those anticipated in these forward looking statements as a result of various factors, including those set forth in Item 1A. Risk Factors. Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include, but are not limited to, discussions regarding our operating strategy, sales and marketing strategy, regulatory strategy, industry, economic conditions, financial condition, liquidity and capital resources and results of operations. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words believes, expects, anticipates, intends, estimates, projects, can, could, may, will, would, or similar expressions. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You should not unduly rely on these forward-looking statements, which speak only as of the date on which they were made. They give our expectations regarding the future but are not guarantees. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Overview

Stereotaxis designs, manufactures and markets an advanced cardiology instrument control system for use in a hospital s interventional surgical suite to enhance the treatment of arrhythmias and coronary artery disease. The Niobe 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 externally applied magnetic fields that govern the motion of the working tip of the catheter or guidewire, resulting in improved navigation, efficient procedures and reduced x-ray exposure. The core components of the Niobe system have received regulatory clearance in the U.S., Canada, Europe, and various other countries.

We believe that our Niobe system represents a revolutionary technology in the interventional surgical suite, or interventional lab , and has the potential to become the standard of care for a broad range of complex cardiology procedures. We also believe that our system is the only technology to be commercialized that allows remote, computerized control of catheters and guidewires 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 and sub-optimal therapeutic outcomes.

In addition to the Niobe system and its components, Stereotaxis also has developed the Odyssey Enterprise Solution which consolidates all lab information enabling doctors to focus on the patient for optimal procedure efficiency. The system also features a remote viewing and recording capability called Odyssey Enterprise Cinema, which is an innovative solution delivering synchronized content for optimized workflow, advanced care and improved productivity. This tool includes an archiving capability that allows clinicians to store and replay entire procedures or segments of procedures. This information can be accessed from locations throughout the hospital local area network and over the global Odyssey Network providing physicians with a tool for clinical collaboration, remote consultation and training. The Odyssey Enterprise Solution 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 that we believe can improve clinical workflows and related efficiencies.

In the mid 1990 s, we began focusing on developing applications for our technology to treat cardiovascular diseases because of the significant market opportunities for these applications. During 2003, following receipt of marketing clearance from the FDA for our current system, we emerged from the development stage and began to generate revenue from the placement of investigational systems and the commercial launch of our cardiology system in the U.S. and Europe.

In August 2006, the Company filed a universal shelf registration statement for the issuance and sale from time to time to the public of up to $75 million in securities, including debt, preferred stock, common stock and warrants. The shelf registration was declared effective by the SEC in September 2006. In March 2007, we completed an offering of 1,919,000 shares of our common stock at $10.50 per share, receiving approximately $20.1 million in net proceeds.

In December 2008 we completed two concurrent registered direct offerings of our common stock. In one of the offerings, affiliates of two members of our board of directors (the Lenders) purchased a total of 2,024,260 shares of our common stock at $4.94 per share including warrants to purchase 4,859,504 shares of our common stock at $4.64 per share exercisable through June 2014. In the other offering, we sold 2,389,877 shares of our common stock at $4.18 per share including Series A warrants to purchase an additional 1,792,408 shares of our common stock at $5.11 per share exercisable through June 2014, Series B warrants to purchase an additional 2,148,739 shares of our common stock at $4.65 per share with an expiration date in June 2009, and Series C and D warrants to purchase up to an aggregate of 682,824 shares of our common stock which were exercisable under certain defined conditions at an exercise price of $0.001 per share through May 2009. The investors in this transaction became entitled to exercise and did exercise, all of their Series C warrants to purchase 341,412 shares of common stock in March 2009 and 279,170 of their Series D warrants in May 2009; the balance of the Series D warrants, for 62,242 shares, went unexercised. The Series A warrants to purchase 1,792,408 shares had an anti-dilution protection that was triggered in February 2009, reducing the exercise price to $3.16 per share. The Series B warrants expired unexercised. In conjunction with these transactions, we received approximately $18.8 million in net proceeds after deducting offering expenses.

In August 2009 we filed a universal shelf registration statement for the issuance and sale from time to time to the public of up to $75 million in securities, including debt, preferred stock, common stock, and warrants. The registration statement was declared effective by the SEC in September 2009.

In October 2009 we completed a public offering of our common stock in which we issued 7,475,000 shares at $4.00 per share and realized approximately $27.8 million in proceeds, net of fees and expenses.

We generate revenue from both the initial capital sales of the Niobe and Odyssey systems as well as recurring revenue from the sale of our proprietary disposable devices, from ongoing license and service contracts, and from royalties paid to the Company on the sale by Biosense Webster of co-partnered catheters. We market our products to a broad base of hospitals in the United States and internationally as detailed in Note 14 to the financial statements. Due to an increase in our installed base and to the introduction and regulatory approval of a broader range of catheters and guidewires for use with the Niobe system, recurring revenue has increased from 23% of total revenues in 2007 to 30% in 2008 and 36% in 2009.

Since our inception, we have generated significant losses. As of December 31, 2009, we had incurred cumulative net losses of approximately $323 million. We expect to incur additional losses into 2010 as we continue the development and commercialization of our products, conduct our research and development activities and advance new products into clinical development from our existing research programs and fund additional sales and marketing initiatives.

We have alliances with each of Siemens AG Medical Solutions, Philips Medical Systems and Biosense Webster, Inc., through which we integrate our Niobe system with market leading digital imaging and 3D catheter location sensing technology, as well as disposable interventional devices, in order to continue to develop new solutions in the interventional lab. Each of these alliances provides for coordination of our sales and marketing activities with those of our partners. In addition, Siemens is our product distributor in certain countries and has agreed to provide worldwide service for our integrated systems.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and related disclosures. We review our estimates and judgments on an on-going basis. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates. We believe the following accounting policies are critical to the judgments and estimates we use in preparing our financial statements.

Revenue Recognition

The Company adopted Accounting Standards Update 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU 2009-13) in the fourth quarter of 2009, effective as of January 1, 2009. Prior to the adoption of this guidance, the Company followed previously issued guidance for general accounting principles for revenue arrangements with multiple deliverables. Under this guidance, we were required to continually evaluate whether we had proper evidence to identify separate units of accounting for deliverables within certain contractual arrangements with customers. If we were unable to support the determination of vendor-specific objective evidence (VSOE) or third party evidence (TPE) of fair value on the undelivered element, we could not recognize revenue for the delivered elements.

ASU 2009-13 permits management to estimate the selling price of undelivered components of a bundled sale for which it is unable to establish VSOE or TPE. This requires management to record revenue for certain elements of a transaction even though it might not have delivered other elements of the transaction, for which it was unable to meet the requirements for establishing VSOE or TPE. The Company believes that the new guidance will significantly improve the reporting of these types of transactions to more closely reflect the underlying economic circumstances. This guidance also prohibits the use of the residual method for allocating revenue to the various elements of a transaction and requires that the revenue be allocated proportionally based on the relative estimated selling prices.

Under our revenue recognition policy before and after the adoption of ASU 2009-13, a portion of revenue for Niobe system sales is recognized upon delivery, provided that title has passed, there are no uncertainties regarding acceptance, persuasive evidence of an arrangement exists, the sales price is fixed and determinable, and collection of the related receivable is reasonably assured. When installation is the responsibility of the customer, revenue from system sales is recognized upon shipment since these arrangements do not include an installation element or right of return privileges. We may deliver systems to a non-hospital site at the customer s request. We evaluate whether delivery has occurred considering general accounting principles for revenue recognition with respect to bill and hold transactions. Revenue is recognized for Odyssey systems upon completion of installation. Amounts collected prior to satisfying the above revenue recognition criteria are reflected as deferred revenue. Revenue from services and license fees, whether sold individually or as a separate unit of accounting in a multi-element arrangement, is deferred and amortized over the service or license fee period, which is typically one year. Revenue from services is derived primarily from the sale of annual product maintenance plans. We recognize revenue from disposable device sales or accessories upon shipment and establish an appropriate reserve for returns. The return reserve, which is applicable only to disposable devices, is estimated based on historical experience which is periodically reviewed and updated as necessary. In the past, changes in estimate have had only a de minimus effect on revenue recognized in the period. We believe that the estimate is not likely to change significantly in the future.

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Stock-based Compensation

Stock compensation expense, which is a non-cash charge, results from stock option and stock appreciation rights grants made to employees, directors and consultants at the fair value of the option granted, and from grants of restricted shares to employees. The fair value of options and stock appreciation rights granted was determined using the Black-Scholes valuation method which gives consideration to the estimated value of the underlying stock at the date of grant, the exercise price of the option, the expected dividend yield and volatility of the underlying stock, the expected life of the option and the corresponding risk-free interest rate. The fair value of the grants of restricted shares, all of which were granted after we became a public company, was determined based on the closing price of our stock on the date of grant. Stock compensation expense for options, stock appreciation rights and for time-based restricted share grants is amortized on a straight-line basis over the vesting period of the underlying issue, generally over four years except for grants to directors which generally vest over one to two years. Stock compensation expense for performance-based restricted shares is amortized on a straight-line basis over the anticipated vesting period and is subject to adjustment based on the actual achievement of objectives. Compensation expenses related to option grants to non-employees are remeasured quarterly through the vesting date. Compensation expense is recognized only for those options expected to vest, net of estimated forfeitures. Estimates of the expected life of options has been based on the average of the vesting and expiration periods, the simplified method under general accounting principles for share-based payments. Estimates of volatility and forfeiture rates utilized in calculating stock-based compensation have been prepared based on historical data and future expectations. Actual experience to date has been consistent with these estimates.

The amount of compensation expense to be recorded in future periods may increase if we make additional grants of options, stock appreciation rights or restricted shares or if we determine that actual forfeiture rates are less than anticipated. The amount of expense to be recorded in future periods may decrease if we do not achieve the performance objectives by which certain restricted shares are contingent, if the requisite service periods are not completed or if the actual forfeiture rates are greater than anticipated.

Valuation of Inventory

We value our inventory at the lower of the actual cost of our inventory, as determined using the first-in, first-out (FIFO) method, or its current estimated market value. We periodically review our physical inventory for excess, obsolete, and potentially impaired items and reserve accordingly. Our reserve estimate for excess and obsolete is based on expected future use. Our reserve estimates have historically been consistent with our actual experience as evidenced by actual sale or disposal of the goods.

Deferred Income Taxes

Deferred assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. We have established a valuation allowance against the entire amount of our deferred tax assets because we are not able to conclude, due to our history of operating losses, that it is more likely than not that we will be able to realize any portion of the deferred tax assets.

In assessing whether and to what extent deferred tax assets are realizable, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. We consider projected future taxable income and tax planning strategies in making this assessment. Based upon the level of historical taxable losses, limitations imposed by Section 382 of the Internal Revenue Code and projections for future losses over periods which the deferred tax assets are deductible, we determined that a 100% valuation allowance of deferred tax assets was appropriate.

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Results of Operations

Comparison of the Years ended December 31, 2009 and 2008

Revenue. Revenue increased to $51.1 million for the year ended December 31, 2009 from $40.4 million for the year ended December 31, 2008, an increase of approximately 27%. Revenue from sales of systems increased to $32.7 million for the year ended December 31, 2009 from $28.4 million for the year ended December 31, 2008, an increase of approximately 15%. The number of units recognized to revenue was 25 Niobe systems, 23 Odyssey Vision systems, and 6 Odyssey Enterprise Cinema systems during the 2009 reporting period compared to 25 Niobe systems and 14 Odyssey Vision systems during the 2008 reporting period. The Niobe units recognized in the 2009 period carried a slightly higher average selling price, also contributing to the year over year increase in systems revenue. Revenue from sales of disposable interventional device royalties, service and accessories increased to $18.5 million for the year ended December 31, 2009 from $12.0 million for the year ended December 31, 2008, an increase of approximately 54%. This increase was attributable to price increases and a larger base of installed systems.

Cost of Revenue. Cost of revenue increased to $17.0 million for the year ended December 31, 2009 from $14.2 million for the year ended December 31, 2008, an increase of approximately 20%. Cost of revenue for systems sold increased to $13.2 million for the year ended December 31, 2009 from $12.0 million for the year ended December 31, 2008, an increase of approximately 10% primarily due to the costs associated with the additional 9 Odyssey Vision systems and 6 Odyssey Enterprise Cinema systems recognized in 2009. Cost of revenue for disposable interventional devices, service and accessories increased to $3.8 million for the year ended December 31, 2009 from $2.2 million for the year ended December 31, 2008, an increase of approximately 74%. This increase was due to the costs associated with the increased volume of disposable devices sold, higher software costs associated with new generation software upgrades and service costs associated with first generation Niobe systems. As a percentage of our revenue, total cost of revenue was approximately 33% in the year ended December 31, 2009 compared to 35% for the year ended December 31, 2008.

Research and Development Expense. Research and development expense decreased to $14.3 million for the year ended December 31, 2009 from $17.4 million for the year ended December 31, 2008, a decrease of approximately 18%. The decrease was due principally to a decrease in development costs related to new product introductions.

Sales and Marketing Expense. Sales and marketing expense remained unchanged at $28.7 million for the year ended December 31, 2009, consistent with the year ended December 31, 2008. Decreases in selected marketing activities and personnel costs were offset by the increase related to stock-based compensation expense, as well as mobile showroom disposal and demo system impairment.

General and Administrative Expense. General and administrative expense decreased to $15.0 million for the year ended December 31, 2009 from $21.1 million for the year ended December 31, 2008, a decrease of approximately 29%. The decrease relates to certain one-time expenses incurred in 2008, including expenses associated with the retirement of our CEO of $1.7 million, regulatory activity to further the Company s product registration in Japan, and an impairment charge of $0.5 million for a long-term investment.

Other Income. Other income represents the decrease in market value of certain warrants classified as a derivative and recorded as a current liability under general accounting principles for determining whether an instrument (or embedded feature) is indexed to an entity s own stock.

Interest Income. Interest income decreased approximately 77% to $45,000 for the year ended December 31, 2009 from $195,000 for the year ended December 31, 2008. Interest income decreased due principally to lower average invested balances during 2009.

Interest Expense. Interest expense increased to $4.6 million for the year ended December 31, 2009 from $3.1 million for the year ended December 31, 2008. Interest expense increased primarily due to the write off of

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warrants issued during 2009 related to the guarantees under the line of credit received from stockholders who are affiliates of two members of our board of directors (Lenders), which expired upon our October 2009 equity offering.

Comparison of the Years ended December 31, 2008 and 2007

Revenue. Revenue increased to $40.4 million for the year ended December 31, 2008 from $39.3 million for the year ended December 31, 2007, an increase of approximately 3%. Revenue from sales of systems decreased to $28.4 million for the year ended December 31, 2008 from $30.1 million for the year ended December 31, 2007, a decrease of approximately 6%. The number of units recognized to revenue decreased from 27 Niobe systems during the 2007 reporting period to 25 Niobe systems and 14 Odyssey Vision systems during the 2008 reporting period. The Niobe units recognized in the 2007 period carried a somewhat higher average selling price, also contributing to the year over year decrease in systems revenue. Revenue from sales of disposable interventional devices, service and accessories increased to $12.0 million for the year ended December 31, 2008 from $9.2 million for the year ended December 31, 2007, an increase of approximately 31%. This increase was attributable to the increased base of installed systems.

Cost of Revenue. Cost of revenue decreased to $14.2 million for the year ended December 31, 2008 from $15.3 million for the year ended December 31, 2007, a decrease of approximately 8%. Cost of revenue for systems sold increased to $12.0 million for the year ended December 31, 2008 from $11.0 million for the year ended December 31, 2007, an increase of approximately 9% primarily due to the costs associated with the 14 Odyssey Vision systems recognized in 2008 as well as increased installation costs incurred in 2008 compared to 2007. Cost of revenue for disposable interventional devices, service and accessories decreased to $2.2 million for the year ended December 31, 2008 from $2.5 million for the year ended December 31, 2007 a decrease of approximately 13%. This decrease was due principally to a reduction in labor costs allocated to service revenues. As a percentage of our revenue, total cost of revenue was approximately 35% in the year ended December 31, 2008 compared to 39% for the year ended December 31, 2007. The adjustment to the carrying value of the Niobe system in the year ended December 31, 2007 was 5% of total revenue.

Research and Development Expense. Research and development expense decreased to $17.4 million for the year ended December 31, 2008 from $25.5 million for the year ended December 31, 2007, a decrease of approximately 32%. The decrease was due principally to a decrease in development costs related to new product introductions.

Sales and Marketing Expense. Sales and marketing expense remained almost unchanged at $28.7 million for the year ended December 31, 2008 compared to $29.0 million for the year ended December 31, 2007. Decreases in selected marketing activities and non-cash compensation were offset by increased compensation and related expenses associated with expanded sales operations.

General and Administrative Expense. General and administrative expense increased to $21.1 million for the year ended December 31, 2008 from $18.7 million for the year ended December 31, 2007, an increase of approximately 13%. The increase relates to certain one-time expenses incurred in 2008, including expenses associated with the retirement of our CEO of $1.7 million, regulatory activity to further the Company s product registration in Japan, an impairment charge of $0.5 million for a long-term investment and a recorded foreign exchange loss during the 2008 reporting period compared with a foreign exchange gain during the 2007 reporting period.

Interest Income. Interest income decreased approximately 87% to $0.2 million for the year ended December 31, 2008 from $1.5 million for the year ended December 31, 2007. Interest income decreased due principally to lower average invested balances during 2008.

Interest Expense. Interest expense increased to $3.1 million for the year ended December 31, 2008 from $0.4 million for the year ended December 31, 2007. Interest expense increased primarily due to the amortization of warrants issued during 2008 related to the guarantees under the line of credit received from the Lenders and higher average outstanding balances due to our bank loan balances during the 2008 reporting period as well as the amounts received or deferred in connection with the July 2008 Biosense Webster agreement.

Income Taxes

Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. Accordingly, net deferred tax assets have been fully offset by valuation allowances as of December 31, 2009, 2008 and 2007 to reflect these uncertainties. As of December 31, 2009, we had federal net operating loss carryforwards of approximately $290.8 million of which approximately $4.0 million will expire between 2010 and 2012 and approximately $286.8 million will expire between 2018 and 2029. As of December 31, 2009, we had state net operating loss carryforwards of approximately $6.4 million which will expire at various dates between 2010 and 2029 if not utilized. We may not be able to utilize all of these loss carryforwards prior to their expiration.

Liquidity and Capital Resources

Borrowing facilities

In February 2008 we entered into a Loan and Warrant Purchase Agreement with the Lenders, providing for a $20 million commitment of funds to be provided either as direct loans to us or as a guarantee of amounts borrowed by us under our working capital facility with our primary lending bank. In connection with this transaction, in March 2008 we amended our loan agreement with our primary lender to increase availability under the working capital line to $30 million subject to qualifying receivable and inventory balance limitations, including up to $10 million to be secured by guarantees from the Lenders, and to extend the maturity of the line to March 31, 2009.

In July 2008, we amended our existing agreements with Biosense Webster. Pursuant to the amendment, Biosense Webster agreed to advance us $10.0 million against royalty amounts that were owed to us from Biosense Webster at the time the amendment was executed or that would be owed in the future. We also agreed that an aggregate of up to $8.0 million of certain agreed upon research and development expenses that were owed at the time the amendment was executed or may be owed in the future by us to Biosense Webster would be deferred and will be due, together with any unrecouped portion of the $10.0 million royalty advance, on the Final Payment Date, as defined in the amendment, but in no event later than December 31, 2011. See Note 7 for additional description of Final Payment Date. We have the right to prepay any amounts due pursuant to the amendment at any time without penalty. As of December 31, 2009, approximately $18.0 million had been advanced by Biosense Webster to us pursuant to the amendment. As of December 31, 2009, $5.9 million of royalty amounts earned had been used to reduce the advances and the remaining approximately $13.3 million of amounts owed to Biosense Webster has been classified as debt on our balance sheet including $3.0 million as short-term debt and $10.3 million as long-term debt. Commencing on May 15, 2010 we are required to make quarterly payments to Biosense Webster equal to the difference between certain aggregate royalty payments recouped by Biosense Webster from us in such quarter and $1 million, until the earlier of (1) the date all funds owed by us to Biosense Webster pursuant to the amendment are fully repaid or (2) the Final Payment Date. Interest on the outstanding and unrecouped amounts of the royalty advance and deferred research and development expenses will accrue at an interest rate of the prime rate plus 0.75%. Outstanding royalty advances and deferred research and development expenses and accrued interest thereon will be recouped by Biosense Webster from time to time by deductions from royalty amounts otherwise payable to us.

In November 2008, the Lenders committed to extend their February 2008 agreement to loan us an aggregate of $20 million on an unsecured basis. As amended, the commitment expired on the earlier of March 31, 2010 or the date we received at least $20 million of third party, non-bank financing. This facility could also be used by us to guarantee our loan commitments to our primary bank lender, through the same extended term. In February

2009 we issued the Lenders warrants to purchase an aggregate of 1,582,280 shares of common stock at an exercise price of $3.16 per share in exchange for the extension of the commitment. The Company recorded a fair value of $2,072,786 related to these warrants.

In March 2009, the Company and its primary lending bank entered into an agreement to amend the revolving line of credit to change the total availability under the line to $25 million, to extend the term of the agreement to March 31, 2010, to modify the tangible net worth requirements, and to provide for additional borrowing capacity as it relates to advances against accounts receivable from non-U.S. customers.

In October 2009, the Company received from the Lenders an extension of their commitment to provide $10 million in either direct loans to the Company or loan guarantees to the Company s primary bank lender through the earlier of March 31, 2011 or the date the Company receives $30 million of third party, non-bank financing, coincidental with the proposed maturity of the bank line of credit, as amended. The Company granted to the Lenders warrants to purchase 664,064 shares in exchange for their extension. The warrants are exercisable at $4.25 per share, beginning on March 1, 2010 and expiring on February 28, 2015. The fair value of these warrants of $1,232,503, calculated using the Black Scholes method, will be deferred and amortized to interest expense ratably. As the previous guarantee was no longer in effect, the Company expensed in 2009 the entire balance on the warrants issued to the Lenders in February 2009.

In December 2009, we amended our loan agreement with our primary lender to extend the maturity of the current working capital line of credit from March 31, 2010 to March 31, 2011 and to increase the total availability under the line from $25 million to $30 million, retaining the $10 million sublimit for borrowings supported by guarantees from the Lenders. Under the revised facility we are required to maintain a minimum tangible net worth as defined in the agreement. As of December 31, 2009, the Company is in compliance with all of the requirements of the loan agreement.

Common Stock

In August 2006, the Company filed a universal shelf registration statement for the issuance and sale from time to time to the public of up to $75 million in securities, including debt, preferred stock, common stock and warrants. The shelf registration was declared effective by the SEC in September 2006. In March 2007, the Company completed an offering of 1,919,000 shares of its common stock at $10.50 per share pursuant to the shelf registration. In conjunction with this transaction, the Company received approximately $20.1 million in net proceeds after deducting offering expenses.

In December 2008, we completed a registered direct offering in which we issued and sold 2,389,877 units (the Units) at the negotiated price of $4.18 per Unit, with each Unit consisting of (i) one share of the Company s common stock, (ii) one warrant to purchase 0.75 shares of common stock at an exercise price of $5.11 per share (the Series A Warrant), for an aggregate of up to 1,792,408 shares of common stock, (iii) one six-month warrant to purchase 0.90 shares of common stock at an exercise price of $4.65 per share (the Series B Warrant), for an aggregate of up to 2,148,739 shares of common stock, and (iv) two warrants to purchase 0.286 shares of common stock at an exercise price of $0.001 per share (the Series C and D Warrants), for an aggregate of up to 682,824 shares of common stock. Exercise of the Series C and Series D warrants were conditioned upon certain events. The Series B Warrants expired unexercised. The exercise price of the Series A warrants was adjusted to $3.16 in February 2009, and is subject to further adjustment, as described in Note 9 to the Financial Statements. The investors in this transaction became entitled to exercise and did exercise, the Series C and D warrants to purchase an aggregate of 620,582 shares of common stock in March and May 2009, respectively. In addition, concurrently with such offering, we completed a registered direct offering with the Lenders in which we issued and sold 2,024,260 shares of common stock and warrants to purchase up to 4,859,504 shares of common stock, for a purchase price of $4.94 per unit. The warrants are exercisable at $4.64 per share, are exercisable on or after the date immediately following the six month anniversary of their issuance and have a five year term from that initial exercisability date. In conjunction with the two offerings, we received

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proceeds of approximately $18.8 million net of offering expenses. Conditioned upon the closing of the registered direct offerings, we agreed that the loan obligations of the Lenders would decrease from an aggregate of $20 million to $10 million.

In August 2009 we filed a universal shelf registration statement for the issuance and sale from time to time to the public of up to $75 million in securities, including debt, preferred stock, common stock, and warrants. The registration statement was declared effective by the SEC in September 2009.

In October 2009, we completed an offering of 7,475,000 shares of our common stock at $4.00 per share, receiving approximately $27.8 million in net proceeds.

Liquidity refers to the liquid financial assets available to fund our business operations and pay for near-term obligations. These liquid financial assets consist of cash and cash equivalents.

The following table summarizes our cash flow by operating, investing and financing activities for each of years ended December 31, 2009, 2008 and 2007 (in thousands):

	2009	2008	2007
Cash Flow used in operating activities	$ (22,309)	$ (28,655)	$ (35,713)
Cash Flow provided by (used in) investing activities	(1,484)	4,986	10,596
Cash Flow provided by financing activities	23,984	37,002	26,929

Net cash used in operating activities. We used approximately $22.3 million, $28.7 million and $35.7 million of cash in operating activities during the years ended December 31, 2009, 2008 and 2007, respectively, primarily as a result of operating losses during these periods. We used approximately $1.6 million to fund operating assets and liabilities during the year ended December 31, 2009 compared to $6.2 million generated during the year ended December 31, 2008 primarily as a result of an increase in accounts receivable and fewer customer deposits in deferred revenue.

Net cash provided by (used in) investing activities. We used approximately $1.5 million to fund investing activities during the year ended December 31, 2009 for the purchase of property and equipment. We generated cash from investing activities of $5.0 million and $10.6 million during the years ended December 31, 2008 and 2007, respectively. The cash generated from 2008 and 2007 investing activities was due to the sale of investments partially offset by purchases of property and equipment of $1.7 million and $4.7 million in 2008 and 2007, respectively.

Net cash provided by financing activities. We realized approximately $24.0 million from financing activities during the year ended December 31, 2009 principally from the sale of our common stock in which we realized approximately $27.8 million in net proceeds. We realized approximately $37.0 million from financing activities during the year ended December 31, 2008 principally from the $10 million in borrowings under our line of credit, $10 million received under our agreement with Biosense Webster as described above, and the $19.7 million in net proceeds from the sale of our common stock. We realized approximately $26.9 million from financing activities during the year ended December 31, 2007 principally from the sale of our common stock in which we realized approximately $20.1 million in net proceeds and from a $5.0 million borrowing under our line of credit.

At December 31, 2009, we had working capital of approximately $22.9 million, compared to $23.3 million at December 31, 2008.

As of December 31, 2009, we had outstanding balances under various equipment loan agreements, consisting of an aggregate of approximately $0.3 million. In addition, we had $10 million outstanding under the revolving line of credit and had an unused line of approximately $20 million with current borrowing capacity of $15.9 million, including amounts already drawn. As such, we had the ability to borrow an additional $5.9 million under the revolving line of credit at December 31, 2009. As of December 31, 2009, we were in compliance with all covenants of the bank loan agreement.

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These credit facilities are secured by substantially all of our assets. The credit agreements include customary affirmative, negative and financial covenants. For example, we are restricted from incurring additional debt, disposing of or pledging our assets, entering into merger or acquisition agreements, making certain investments, allowing fundamental changes to our business, ownership, management or business locations, and from making certain payments in respect of stock or other ownership interests, such as dividends and stock repurchases. Under our loan arrangements, as in effect at December 31, 2009 and as modified in December 2009, we are required to maintain various levels of tangible net worth as defined in the loan agreement. We are also required under the credit agreements to maintain our primary operating account and the majority of our cash and investment balances in accounts with our primary lending bank. As of the amendment date and as of December 31, 2009, we were in compliance with all covenants of this agreement.

We expect to have negative cash flow from operations into 2010. Throughout 2010, we expect to continue the development and commercialization of our existing products and, to a lesser extent, our research and development programs and the advancement of new products into clinical development. We expect that our sales and marketing expenditures and our general and administrative expenses will increase in 2010 in order to support our product commercialization efforts. Until we can generate significant cash flow from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from the proceeds of our public offerings, private sales of our equity securities and working capital and equipment financing loans. In the future, we may finance future cash needs through the sale of other equity securities, strategic collaboration agreements and debt financings. We cannot accurately predict the timing and amount of our utilization of capital, which will depend on a number of factors outside of our control.

While we believe our existing cash, cash equivalents and borrowing facilities will be sufficient to fund our operating expenses and capital equipment requirements through the next 12 months, we cannot assure that we will not require additional financing before that time. We also cannot assure that such additional financing will be available on a timely basis on terms acceptable to us or at all, or that such financing will not be 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.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As a result, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

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Contractual Obligations

The following table summarizes all significant contractual payment obligations by payment due date:

	Payments by Period				
Contractual Obligations	Under 1 Year	1 3 Years	3 5 Years	Over 5 Years	Total
			(In thousands)		
Long-term debt (1)	$ 3,333	$ 20,347	$	$	$ 23,680
Operating leases	1,667	3,042	3,090	7,622	15,421
Capital leases	10	17	2		29
Total	$ 5,010	$ 23,406	$ 3,092	$ 7,622	$ 39,130

(1) We have not included interest payable on our term notes or our revolving credit agreement in these amounts because the interest on these obligations is calculated at a variable rate.

Commercial Commitments

We have entered into letters of credit to support certain commitments in the aggregate amount of $0.5 million. These letters of credit expire in March 2010, June 2010 and February 2011.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

Foreign Exchange Risk

We operate mainly in the U.S., Europe and Asia and we expect to continue to sell our products both within and outside of the U.S. Although the majority of our revenue and expenses are transacted in U.S. dollars, a portion of our operations are conducted in Euros and to a lesser extent, in other currencies. As such, we have foreign exchange exposure with respect to non-U.S. dollar revenues and expenses as well as cash balances, accounts receivable and accounts payable balances denominated in non-US dollar currencies. Our international operations are subject to risks typical of international operations, including, but not limited to, differing economic conditions, changes in political climate, differing tax structures, other regulations and restrictions, and foreign exchange rate volatility. Future fluctuations in the value of these currencies may affect the price competitiveness of our products. In addition, because we have a relatively long installation cycle for our systems, we will be subject to risk of currency fluctuations between the time we execute a purchase order and the time we deliver the system and collect payments under the order, which could adversely affect our operating margins. As of December 31, 2009 we have not hedged exposures in foreign currencies or entered into any other derivative instruments.

For the year ended December 31, 2009, sales denominated in foreign currencies were approximately 28% of total revenue. For the year ended December 31, 2009, our revenue would have decreased by approximately $1.5 million if the U.S. dollar exchange rate used would have strengthened by 10%. For the year ended December 31, 2009, expenses denominated in foreign currencies were approximately 14% of our total expenses. For the year ended December 31, 2009, our operating expenses would have decreased by approximately $0.8 million if the U.S. dollar exchange rate used would have strengthened by 10%. In addition, we have assets and liabilities denominated in foreign currencies. A 10% strengthening of the U.S. dollar exchange rate against all currencies with which we have exposure at December 31, 2009 would have resulted in a $0.3 million decrease in the carrying amounts of those net assets.

Interest Rate Risk

We have exposure to interest rate risk related to our investment portfolio. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing the risk of loss. Our interest income is sensitive to changes in the

general level of U.S. interest rates, particularly since the majority of our investments are in short-term debt instruments. We invest our excess cash primarily in U.S. government securities and marketable debt securities of financial institutions and corporations with strong credit ratings. These instruments generally have maturities of two years or less when acquired. We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions. Accordingly, we believe that while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments.

We have exposure to market risk related to any investments we might hold. Market liquidity issues might make it impossible for the Company to liquidate its holdings or require that the Company sell the securities at a substantial loss. As of December 31, 2009, the Company did not hold any investments.

We have exposure to interest rate risk related to our borrowings as the interest rates for certain of our outstanding loans are subject to increase should the interest rate increase above a defined percentage. However, because our outstanding debt is subject to minimum interest rates ranging from 5.75% to 7.0%, a hypothetical increase in interest rates of 100 basis points would have resulted in no increase in the interest we paid as of December 31, 2009.

Inflation Risk

We do not believe that inflation has had a material adverse impact on our business or operating results during the periods covered by this report.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial Statements

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All other schedules have been omitted because they are not applicable or the required information is shown in the Financial Statements or the Notes thereto.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Stereotaxis, Inc.

We have audited the accompanying balance sheets of Stereotaxis, Inc. (the Company) as of December 31, 2009 and 2008, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2009. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Stereotaxis, Inc. at December 31, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth herein.

As discussed in Note 2 to the financial statements, on January 1, 2009, the Company changed its method for accounting for revenue recognition for arrangements with multiple deliverables and its method for accounting for instruments indexed to an entity s own stock.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Stereotaxis, Inc. s internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 15, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

St. Louis, Missouri

March 15, 2010

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STEREOTAXIS, INC.

BALANCE SHEETS

	December 31, 2009	December 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	$ 30,546,550	$ 30,355,657
Accounts receivable, net of allowance of $322,463 and $328,307 in 2009 and 2008, respectively	11,152,648	9,739,008
Current portion of long-term receivables	66,800	197,351
Inventories	4,403,675	8,086,956
Prepaid expenses and other current assets	3,872,535	2,966,510
Total current assets	50,042,208	51,345,482
Property and equipment, net	4,790,310	6,420,600
Intangible assets, net	1,144,445	1,277,778
Long-term receivables	138,441	298,123
Other assets	5,112	98,382
Total assets	$ 56,120,516	$ 59,440,365
Liabilities and stockholders equity		
Current liabilities:		
Current maturities of long-term debt	$ 3,333,333	$ 3,901,491
Accounts payable	3,881,205	4,561,928
Accrued liabilities	8,615,287	9,873,818
Deferred contract revenue	7,191,492	9,676,339
Warrants	4,142,614	
Total current liabilities	27,163,931	28,013,576
Long-term debt, less current maturities	20,346,655	25,271,547
Long-term deferred contract revenue	948,574	1,225,656
Other liabilities	20,013	158,905
Stockholders equity:		
Preferred stock, par value $0.001; 10,000,000 shares authorized at 2009 and 2008, none outstanding at 2009 and 2008		
Common stock, par value $0.001; 100,000,000 shares authorized at 2009 and 2008, 50,208,171 and 42,049,792 shares issued at 2009 and 2008, respectively	50,208	42,050
Additional paid in capital	331,249,918	300,892,957
Treasury stock, 40,151 shares at 2009 and 2008	(205,999)	(205,999)
Accumulated deficit	(323,452,784)	(295,958,327)
Total stockholders equity	7,641,343	4,770,681
Total liabilities and stockholders equity	$ 56,120,516	$ 59,440,365

See accompanying notes.

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STEREOTAXIS, INC.

STATEMENTS OF OPERATIONS

	Year Ended December 31, 2009	2008	2007
Revenue:			
Systems	$ 32,661,573	$ 28,375,880	$ 30,118,627
Disposables, service and accessories	18,487,982	11,989,293	9,180,182
Total revenue	51,149,555	40,365,173	39,298,809
Cost of revenue:			
Systems	13,240,430	12,008,090	10,978,108
Disposables, service and accessories	3,781,203	2,169,700	2,497,459
Inventory impairment			1,870,653
Total cost of revenue	17,021,633	14,177,790	15,346,220
Gross margin	34,127,922	26,187,383	23,952,589
Operating expenses:			
Research and development	14,260,854	17,422,828	25,471,809
Sales and marketing	28,694,540	28,660,663	29,021,117
General and administrative	15,010,490	21,121,164	18,701,726
Total operating expenses	57,965,884	67,204,655	73,194,652
Operating loss	(23,837,962)	(41,017,272)	(49,242,063)
Other income	911,977		
Interest income	44,768	194,870	1,471,503
Interest expense	(4,613,240)	(3,063,572)	(350,954)
Net loss	$ (27,494,457)	$ (43,885,974)	$ (48,121,514)
Net loss per common share:			
Basic and diluted	$ (0.63)	$ (1.20)	$ (1.34)
Weighted average shares used in computing net loss per common share:			
Basic and diluted	43,344,324	36,585,086	35,793,973

See accompanying notes.

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STEREOTAXIS, INC.

STATEMENTS OF STOCKHOLDERS EQUITY

	Common Stock						
	Shares	Amount	Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
Balance at December 31, 2006	34,755,397	$ 34,755	$ 248,908,918	$ (205,999)	$ (203,950,839)	$ 2,157	$ 44,788,992
Issuance common stock	1,919,000	1,919	20,105,317				20,107,236
Share-based compensation			5,597,800				5,597,800
Issuance of stock under stock purchase plan	62,254	63	502,308				502,371
Exercise of stock warrants	93,050	93	373,381				373,474
Exercise of stock options and stock appreciation rights	210,745	211	946,030				946,241
Grant of restricted shares, net of forfeitures	92,083	92	(92)				
Components of comprehensive loss:							
Net Loss					(48,121,514)		(48,121,514)
Unrealized loss on short term investments						(193)	(193)
Comprehensive Loss							(48,121,707)
Balance at December 31, 2007	37,132,529	$ 37,133	$ 276,433,662	$ (205,999)	$ (252,072,353)	$ 1,964	$ 24,194,407
Issuance of common stock and warrants	4,414,137	4,414	20,563,270				20,567,684
Share-based compensation			2,994,202				2,994,202
Issuance of stock under stock purchase plan	85,525	86	574,954				575,040
Exercise of stock warrants	479		3,741				3,741
Exercise of stock options	48,193	48	323,497				323,545
Grant of restricted shares, net of forfeitures	368,929	369	(369)				
Components of comprehensive loss:							
Net Loss					(43,885,974)		(43,885,974)
Unrealized loss on short term investments						(1,964)	(1,964)
Comprehensive Loss							(43,887,938)
Balance at December 31, 2008	42,049,792	$ 42,050	$ 300,892,957	$ (205,999)	$ (295,958,327)	$	$ 4,770,681
Issuance of common stock and warrants	7,475,000	7,475	31,050,602				31,058,077
Share-based compensation	106,756	107	4,229,076				4,229,183
Reclass of warrants to liability (1)			(5,054,591)				(5,054,591)
Issuance of stock under stock purchase plan	32,142	33	123,473				123,506
Exercise of stock warrants	620,582	620					620
Exercise of stock options	5,138	5	8,319				8,324
Grant of restricted shares, net of forfeitures	(81,239)	(82)	82				
Components of comprehensive loss:							
Net Loss					(27,494,457)		(27,494,457)
Comprehensive Loss							(27,494,457)
Balance at December 31, 2009	50,208,171	$ 50,208	$ 331,249,918	$ (205,999)	$ (323,452,784)	$	$ 7,641,343

(1) See Note 9 for additional details.

See accompanying notes.

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STEREOTAXIS, INC.

STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2009	2008	2007
Cash flows from operating activities			
Net loss	$ (27,494,457)	$ (43,885,974)	$ (48,121,514)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation	2,050,507	2,252,384	1,752,471
Amortization (accretion)	133,333	115,231	(131,820)
Amortization of warrants	2,346,027	1,653,161	
Share-based compensation	4,229,183	2,994,202	5,597,800
Loss on asset disposal	557,152	2,387	9,797
Inventory impairment charge			1,870,653
Asset impairment	338,821	500,000	
Non-cash expense (royalty income), net	(1,983,414)	1,467,245	
Warrant adjustment	(911,977)		
Changes in operating assets and liabilities:			
Accounts receivable	(1,413,640)	3,454,376	1,523,358
Interest receivable on investments		316	164,455
Other receivables	290,233	(86,185)	(245,927)
Inventories	3,851,283	1,877,504	(3,549,288)
Prepaid expenses and other current assets	53,238	532,575	(840,429)
Other assets	93,270	245,939	(522,769)
Accounts payable	(680,723)	(221,498)	1,794,305
Accrued liabilities	(866,678)	(570,745)	1,888,187
Deferred revenue	(2,761,929)	1,184,464	2,833,804
Other	(138,892)	(169,885)	263,423
Net cash used in operating activities	(22,308,663)	(28,654,503)	(35,713,494)
Cash flows from investing activities			
Sale of equipment		2,200	100,640
Purchase of equipment	(1,484,192)	(1,665,808)	(4,744,376)
Proceeds from the maturity/sale of available-for-sale investments		6,650,000	29,050,000
Purchase of available-for-sale investments			(13,810,385)
Net cash provided by (used in) investing activities	(1,484,192)	4,986,392	10,595,879
Cash flows from financing activities			
Proceeds from long-term debt	3,000,000	24,000,000	7,000,000
Payments under long-term debt	(6,901,489)	(6,737,398)	(2,000,000)
Proceeds from issuance of stock and warrants, net of issuance costs	27,885,237	19,738,966	21,929,322
Net cash provided by financing activities	23,983,748	37,001,568	26,929,322
Net increase in cash and cash equivalents	190,893	13,333,457	1,811,707
Cash and cash equivalents at beginning of period	30,355,657	17,022,200	15,210,493
Cash and cash equivalents at end of period	$ 30,546,550	$ 30,355,657	$ 17,022,200
Supplemental disclosures of cash flow information:			
Interest paid	$ 864,279	$ 698,245	$ 166,868

See accompanying notes.

Notes to Financial Statements

1. Description of Business

Stereotaxis, Inc. (the Company) designs, manufactures, and markets an advanced cardiology instrument control system for the interventional treatment of arrhythmias and coronary artery disease. The Company also markets and sells various disposable interventional devices, including catheters, guidewires and other delivery devices, for use in conjunction with its system. The Company has received regulatory approval for the core components of its system in the U.S., Europe, Canada and various other countries.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

The Company considers all short-term investments purchased with original maturities of three months or less to be cash equivalents. The Company places its cash with high-credit-quality financial institutions and invests primarily in money market accounts. No cash was restricted at December 31, 2009 or 2008.

Investments

In accordance with general accounting principles for accounting for certain investments in debt and equity securities, the Company s investment securities are classified as available-for-sale and are carried at market value, which approximates cost. Realized gains or losses, calculated based on the specific identification method, were not material for the years ended December 31, 2009, 2008 and 2007. Interest and dividends on securities classified as available-for-sale are included in interest income.

Accounts Receivable and Allowance for Uncollectible Accounts

Accounts receivable primarily include amounts due from hospitals and distributors for acquisition of magnetic systems, associated disposable device sales and service contracts. Credit is granted on a limited basis, with balances due generally within 30 days of billing. The provision for bad debts is based upon management s assessment of historical and expected net collections considering business and economic conditions and other collection indicators.

Financial Instruments

Financial instruments consist of cash and cash equivalents, short-term investments, accounts receivable, accounts payable and debt. The carrying value of such amounts reported at the applicable balance sheet dates approximates fair value. See Note 7 for disclosure of the fair value of debt.

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents and warrants. General accounting principles for fair value measurement established a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy, as defined below, gives the highest priority to unadjusted quoted prices in active markets for identical assets and liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

The Company s financial assets consist of cash equivalents invested in money market funds in the amount of $27,239,083 and $27,359,488 at December 31, 2009 and 2008, respectively. These assets are classified as Level 1 as described above and total interest income recorded for these investments was approximately $38,000 and $123,000 during the years ended December 31, 2009 and 2008, respectively.

The Company s financial liabilities consist of warrants in the amount of $4,142,614 at December 31, 2009. These liabilities are classified as Level 3 as described above and are measured using the Black-Scholes valuation model. The mark-to-market adjustment recorded in other income for these warrants was $911,977 during the year

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ended December 31, 2009. There were no purchases, sales, issuances, or settlements of Level 3 investments during the year. These warrants were transferred in to Level 3 on January 1, 2009 based on the adoption of general accounting principles for determining whether an instrument (or embedded feature) is indexed to an entity s own stock. See Note 9 for additional details.

Inventory

The Company values its inventory at the lower of cost, as determined using the first-in, first-out (FIFO) method, or market. The Company periodically reviews its physical inventory for obsolete items and provides a reserve upon identification of potential obsolete items.

Property and Equipment

Property and equipment consist primarily of computer, office, and research and demonstration equipment held for lease and leasehold improvements and are stated at cost. Depreciation is calculated using the straight-line method over the estimated useful lives or life of the base lease term, ranging from three to ten years.

Long-Lived Assets

If facts and circumstances suggest that a long-lived asset may be impaired, the carrying value is reviewed. If this review indicates that the carrying value of the asset will not be recovered, as determined based on projected undiscounted cash flows related to the asset over its remaining life, the carrying value of the asset is reduced to its estimated fair value.

Intangible Assets

Intangible assets consist of purchased technology arising out of collaboration with a strategic partner valued at cost on the acquisition date and amortized over its estimated useful life of 15 years. Accumulated amortization at December 31, 2009 and 2008 is $855,555 and $722,222, respectively. Amortization expense in 2009, 2008 and 2007 is $133,333 during each year, as determined under the straight-line method. The estimated future amortization of intangible assets is $133,333 annually through July 2018.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and loss during the reporting period. Actual results could differ from those estimates.

Revenue and Costs of Revenue

The Company adopted Accounting Standards Update 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU 2009-13) in the fourth quarter of 2009, effective as of January 1, 2009. Prior to the adoption of this guidance, the Company followed previously issued guidance for general accounting principles for revenue arrangements with multiple deliverables. Under this guidance, we were required to continually evaluate whether we had proper evidence to identify separate units of accounting for deliverables within certain contractual arrangements with customers. If we were unable to support the determination of vendor-specific objective evidence (VSOE) or third party evidence (TPE) of fair value on the undelivered element, we could not recognize revenue for the delivered elements.

ASU 2009-13 permits management to estimate the selling price of undelivered components of a bundled sale for which it is unable to establish VSOE or TPE. This requires management to record revenue for certain elements of a transaction even though it might not have delivered other elements of the transaction, for which it was unable to meet the requirements for establishing VSOE or TPE. The Company believes that the new guidance will significantly improve the reporting of these types of transactions to more closely reflect the underlying economic circumstances. This guidance also prohibits the use of the residual method for allocating revenue to the various elements of a transaction and requires that the revenue be allocated proportionally based on the relative estimated selling prices.

Under our revenue recognition policy before and after the adoption of ASU 2009-13, a portion of revenue for Niobe system sales is recognized upon delivery, provided that title has passed, there are no uncertainties regarding acceptance, persuasive evidence of an arrangement exists, the sales price is fixed and determinable, and collection of the related receivable is reasonably assured. When installation is the responsibility of the customer, revenue from system sales is recognized upon shipment since these arrangements do not include an installation element or right of return privileges. We may deliver systems to a non-hospital site at the customer s request. We evaluate whether delivery has occurred considering general accounting principles for revenue recognition with respect to bill and hold transactions. Revenue is recognized for Odyssey systems upon completion of installation. Amounts collected prior to satisfying the above revenue recognition criteria are reflected as deferred revenue. Revenue from services and license fees, whether sold individually or as a separate unit of accounting in a multi-element arrangement, is deferred and amortized over the service or license fee period, which is typically one year. Revenue from services is derived primarily from the sale of annual product maintenance plans. We recognize revenue from disposable device sales or accessories upon shipment and establish an appropriate reserve for returns. The return reserve, which is applicable only to disposable devices, is estimated based on historical experience which is periodically reviewed and updated as necessary. In the past, changes in estimate have had only a de minimus effect on revenue recognized in the period. We believe that the estimate is not likely to change significantly in the future.

Costs of systems revenue include direct product costs, installation labor and other costs, estimated warranty costs, and initial training and product maintenance costs. These costs are recorded at the time of sale. Costs of disposable revenue include direct product costs and are recorded at the time of sale. Cost of revenue from services and license fees are recorded when incurred. During the 2007 year, the Company recorded approximately $1.9 million of charges for inventory impairment related to the first generation Niobe system.

Research and Development Costs

Internal research and development costs are expensed in the period incurred. Amounts receivable from strategic partners under research reimbursement agreements are recorded as a contra-research and development expense in the period reimbursable costs are incurred. Advance receipts or other unearned reimbursements are included in accrued liabilities on the accompanying balance sheet until earned.

Share-Based Compensation

The Company utilizes the Black-Scholes valuation model to determine the fair value of share-based payments at the date of grant with the following inputs: 1) expected dividend rate of 0%; 2) expected volatility of 50-65% based on the Company s historical volatility and a review of the volatilities of comparable companies; 3) risk-free interest rate based on the Treasury yield on the date of grant and; 4) expected term for grants made subsequent to the revision of general accounting principles for share-based payments on January 1, 2006, generally using the simplified method which results in an expected term ranging from 3.75 to 6.25 years. The resulting compensation expense is recognized over the requisite service period, generally one to four years. Compensation expense is recognized only for those awards expected to vest, with forfeitures estimated based on the Company s historical experience and future expectations.

Stock options or stock appreciation rights issued to certain non-employees are recorded at their fair value as determined in accordance with general accounting principles for revenue recognition and accounting for equity instruments that are issued to other than employees for acquiring, or in conjunction with selling, goods or services, and recognized over the service period. Deferred compensation for options granted to non-employees is remeasured on a quarterly basis through the vesting or forfeiture date.

Restricted shares granted to employees are valued at the fair market value at the date of grant. The Company amortizes the amount to expense over the service period on a straight-line basis for those shares with graded vesting. If the shares are subject to performance objectives, the resulting compensation expense is amortized over the anticipated vesting period and is subject to adjustment based on the actual achievement of objectives.

Shares purchased by employees under the 2004 Employee Stock Purchase Plan were considered to be compensatory and were accounted for in accordance with general accounting principles for share-based payments.

Net Loss per Share

Basic loss per common share is computed by dividing the net loss for the period by the weighted average number of common shares outstanding during the period. Diluted loss per share is computed by dividing the loss for the period by the weighted average number of common and common equivalent shares outstanding during the period. In addition, the application of the two-class method of computing earnings per share under general accounting principles for participating securities is not applicable because the Company s unearned restricted shares do not contractually participate in its losses.

The Company has excluded all outstanding options, stock appreciation rights, warrants, shares subject to repurchase and unearned restricted shares from the calculation of diluted loss per common share because all such securities are anti-dilutive for all periods presented. As of December 31, 2009, the Company had 4,675,450 shares of common stock issuable upon the exercise of outstanding options and stock appreciation rights at a weighted average exercise price of $6.63 per share and 9,623,711 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $4.26 per share.

Income Taxes

In accordance with general accounting principles for income taxes, a deferred income tax asset or liability is determined based on the difference between the financial statement and tax basis of assets and liabilities as measured by the enacted tax rates that will be in effect when these differences reverse. The Company provides a valuation allowance against net deferred income tax assets unless, based upon available evidence, it is more likely than not the deferred income tax assets will be realized.

Product Warranty Provisions

The Company s standard policy is to warrant all systems against defects in material or workmanship for one year following installation. The Company s estimate of costs to service the warranty obligations is based on historical experience and current product performance trends. A regular review of warranty obligations is performed to determine the adequacy of the reserve and adjustments are made to the estimated warranty liability (included in other accrued liabilities) as appropriate.

The warranty activity for the year ended December 31, 2009 is as follows:

	December 31, 2009
Warranty accrual at December 31, 2008	$ 534,122
Warranty expense incurred	453,138
Payments made	(439,777)
Warranty accrual at December 31, 2009	$ 547,483

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Patent Costs

Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain.

Concentrations of Risk

The majority of the Company s cash, cash equivalents and investments are deposited with one major financial institution in the U. S. Deposits in this institution exceed the amount of insurance provided on such deposits.

One customer, Siemens AG, Medical Solutions and its affiliated entities, as our distributor, accounted for $6,771,693, $3,022,007 and $5,611,496, or 13%, 7% and 14% of total net revenue for the years ended December 31, 2009, 2008 and 2007, respectively. No other single customer accounted for more than 10% of total revenue for the year ended December 31, 2009.

Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders equity except those resulting from investments by stockholders, and includes the Company s unrealized income (loss) on marketable securities. Comprehensive loss for the year ended December 31, 2009, 2008, and 2007 was $(27,494,457), $(43,887,938), and $(48,121,707), respectively. Accumulated other comprehensive income (loss) at December 31, 2009 and 2008 was not material.

Reclassifications

Costs of revenue in the prior years financial statements have been reclassified to disclose components related to systems and disposables, service and accessories to conform to current year presentation with no impact to reported net income.

Recently Adopted Accounting Pronouncements

Effective October 1, 2009, the Company adopted ASU 2009-13. ASU 2009-13 permits management to estimate the selling price of undelivered components of a bundled sale for which it is unable to establish vendor-specific objective evidence (VSOE) or third party evidence (TPE). This requires management to record revenue for certain elements of a transaction even though it might not have delivered other elements of the transaction, for which it was unable to meet the requirements for establishing VSOE or TPE. This guidance also prohibits the use of the residual method for allocating revenue to the various elements of a transaction and requires that the revenue be allocated proportionally based on the relative estimated selling prices. The Company adopted this standard in the fourth quarter of 2009, with retrospective application to January 1, 2009.

The Company s adoption of ASU 2009-13 did not have a material impact on any amounts previously reported for the first three quarters of 2009. The fourth quarter of 2009 was the first period during which we sold a Niobe system with an uninstalled Odyssey Enterprise Cinema system. Due to the fact that we had not established VSOE or TPE for uninstalled Odyssey Enterprise Cinema systems under the previous guidance, we would not have been able to recognize revenue for any portion of these transactions, which amounted to $2.0 million in revenue and $1.3 million in gross margin. Under the new guidance, we were able to use management s estimate of selling price to establish new elements, including the Odyssey Enterprise Cinema, and recognize revenue for the delivered elements that were included in bundled transactions with these undelivered elements. The Company believes that the new guidance significantly improves the reporting of these types of transactions to more closely reflect the underlying economic circumstances.

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Effective June 30, 2009, the Company adopted new guidance related to general accounting principles for subsequent events. This guidance modifies the names of the two types of subsequent events either as recognized subsequent events (previously referred to in practice as Type I subsequent events) or non-recognized subsequent events (previously referred to in practice as Type II subsequent events). In addition, this guidance modifies the definition of subsequent events to refer to events or transactions that occur after the balance sheet date, but before the financial statements are issued (for public entities). The adoption did not have any impact on the Company s results of operations, financial condition or cash flows.

In June 2008, the FASB issued new general accounting principles for determining whether instruments granted in share-based payment transactions are participating securities. This new guidance addresses whether instruments granted in share-based payment awards that entitle their holders to receive non-forfeitable dividends or dividend equivalents before vesting should be considered participating securities and need to be included in the earnings allocation in computing EPS under the two-class method . The two-class method of computing EPS is an earnings allocation formula that determines EPS for each class of common stock and participating security according to dividends declared (or accumulated) and participation rights in undistributed earnings. The new guidance was effective for fiscal years beginning after December 15, 2008 (January 1, 2009 for the Company) with all prior period EPS data being adjusted retrospectively. This guidance did not have a material impact on the Company s EPS calculation because the participating security holders do not contractually participate in losses.

In June 2008, the FASB ratified the consensus reached on general accounting principles for determining whether an instrument (or embedded feature) is indexed to an entity s own stock. This new guidance clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity s own stock, which would qualify as a scope exception under general accounting principles for accounting for derivative instruments and hedging activities. The new guidance was effective for financial statements issued for fiscal years beginning after December 15, 2008 and resulted in a reclass from equity to liabilities in the amount of $5.1 million on January 1, 2009. See Note 9 for additional details.

3. Inventory

Inventory consists of the following:

	December 31, 2009	December 31, 2008
Raw materials	$ 1,785,908	$ 1,551,794
Work in process	312,797	480,400
Finished goods	3,117,438	6,638,040
Reserve for obsolescence	(812,468)	(583,278)
Total inventory	$ 4,403,675	$ 8,086,956

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31, 2009	December 31, 2008
Prepaid expenses	$ 733,966	$ 1,239,805
Deferred cost of revenue	960,145	816,096
Other assets	2,178,424	910,609
Total prepaid expenses and other current assets	$ 3,872,535	$ 2,966,510

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Deferred cost of revenue represents the cost of systems for which title has transferred from the Company but for which revenue has not been recognized.

5. Property and Equipment

Property and equipment consist of the following:

	December 31, 2009	December 31, 2008
Equipment	$ 8,541,355	$ 10,504,504
Equipment held for lease	547,416	547,416
Leasehold improvements	2,317,753	1,918,653
	11,406,524	12,970,573
Less: Accumulated depreciation	(6,616,214)	(6,549,973)
Net property and equipment	$ 4,790,310	$ 6,420,600

6. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2009	December 31, 2008
Accrued salaries, bonus, and benefits	$ 5,160,246	$ 5,215,219
Accrued research and development	140,284	399,405
Accrued legal and other professional fees	539,651	622,862
Other	2,775,106	3,636,332
Total accrued liabilities	$ 8,615,287	$ 9,873,818

7. Long-Term Debt and Credit Facilities

Long-term debt consists of the following:

	December 31, 2009		December 31, 2008	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
Revolving credit agreement, due March 2011	$ 10,000,000	$ 10,261,547	$ 13,234,824	$ 13,570,334
June 2007 term note, due June 2010	333,334	334,243	1,000,000	1,006,173
Biosense Webster Advance	13,346,654	13,683,595	14,938,214	15,455,766
Total debt	23,679,988	24,279,385	29,173,038	30,032,273
Less current maturities	(3,333,333)	(3,359,455)	(3,901,491)	(3,986,400)
Total long term debt	$ 20,346,655	$ 20,919,930	$ 25,271,547	$ 26,045,873

Contractual principal maturities of debt at December 31, 2009 are as follows:

2010	3,333,333
2011	20,346,655
	$ 23,679,988

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Revolving line of credit

In February 2008, the Company entered into a Note and Warrant Purchase Agreement with stockholders who are affiliates of two members of its board of directors (Lenders) and considered to be related parties, pursuant to which the Lenders agreed to loan the Company up to an aggregate of $20 million. The Company could draw down these funds at its election. These funds were unsecured and subordinated to any bank debt, and if drawn, were due at a maturity date in February 2009. The Lenders also agreed to guarantee advances made to the Company pursuant to the credit agreement with the Company s primary lending bank. Warrants to purchase 572,246 shares of the Company s common stock at an exercise price of $6.99 were issued to the Lenders in exchange for the financing commitment. The warrants were exercisable immediately upon grant and expire five years from the date of grant. See Note 9 describing the December 2008 equity funding transaction. The Company recorded the fair value of the warrants in the amount of $1.7 million to be amortized to interest expense over the one year commitment period through February 2009. Interest expense related to these warrants was $0.1 million and $1.6 million for the years ended December 31, 2009 and 2008, respectively.

In March 2008, the Company and its primary lending bank amended the revolving line of credit by increasing the line to $30 million subject to a borrowing base of qualifying accounts receivable and inventory, with up to $10 million available under the line supported by the guarantees described above.

In November 2008, the Lenders committed to extend their February 2008 agreement to loan the Company an aggregate of $20 million on an unsecured basis. As amended, the commitment would expire on the earlier of March 31, 2010 or the date the Company received at least $20 million of third party, non-bank financing. This facility could also be used by the Company to guarantee its loan commitments to the Company s primary bank lender, through the same extended term. In February 2009, the Company exercised its option to extend the term of this agreement through March 2010. In conjunction with this agreement, the Company issued warrants to purchase 1,582,280 shares of common stock at $3.16 per share. During 2009, the Company expensed $2.1 million related to these warrants.

In December 2008, the Company completed a registered direct offering in which the Lenders purchased $10 million of the Company s common stock. In connection with and conditioned upon the closing of the registered direct offerings, the Company agreed that the loan obligation would decrease from an aggregate of $20 million to $10 million.

In March 2009, the Company and its primary lending bank entered into an agreement to amend the revolving line of credit to change the total availability under the line to $25 million, to extend the term of the agreement to March 31, 2010, to modify the tangible net worth requirements, and to provide for additional borrowing capacity as it relates to advances against accounts receivable from non-U.S. customers.

In October 2009, the Company received from the Lenders an extension of their commitment to provide $10 million in either direct loans to the Company or loan guarantees to the Company s primary bank lender through the earlier of March 31, 2011 or the date the Company receives $30 million of third party, non-bank financing, coincidental with the proposed maturity of the bank line of credit, as amended. The Company granted to the Lenders warrants to purchase 664,064 shares of common stock in exchange for their extension. The warrants are exercisable at $4.25 per share, beginning on March 1, 2010 and expiring on February 28, 2015. The fair value of these warrants of $1,232,503, calculated using the Black Scholes method, will be deferred and amortized to interest expense ratably. As the previous guarantee was no longer in effect, the Company expensed, in 2009, the entire balance on the warrants issued to the Lenders in February 2009.

In December 2009, the Company amended its agreement with its primary lender to extend the maturity of the current working capital line of credit from March 31, 2010 to March 31, 2011 and to increase the total availability under the line from $25 million to $30 million, retaining the $10 million sublimit for borrowings supported by guarantees from the Lenders. Under the revised facility the Company is required to maintain a minimum tangible net worth as defined in the agreement. Interest on the facility accrues at the rate of prime plus 0.5% subject to a floor of 6% for the amount under guarantee and prime plus 1.75% subject to a floor of 7% for the remaining amounts.

As of December 31, 2009, the Company had $10 million outstanding under the revolving line of credit and had an unused line of approximately $20 million with current borrowing capacity of $15.9 million, including amounts already drawn. As such, the Company had the ability to borrow an additional $5.9 million under the revolving line of credit at December 31, 2009. As of December 31, 2009, the Company was in compliance with all covenants of the bank loan agreement. As of December 31, 2009 the Company had no remaining availability on its Lender loan and guarantee.

Term note

In June 2007, the Company entered into a term note due in June 2010 with its primary lender for $2,000,000. The Company is required to make equal payments of principal and interest, at prime plus 1%, through June 2010.

The Revolving Credit Agreement and the Company s term notes (collectively, the Credit Agreements) are secured by substantially all of the Company s assets. The Company is also required under the Credit Agreements to maintain its primary operating account and the majority of its cash and investment balances in accounts with the primary lender.

Biosense Webster Advance

In July 2008, the Company and Biosense Webster entered into an amendment to their existing agreements relating to the development and sale of catheters. Pursuant to the amendment, Biosense Webster agreed to pay to the Company $10.0 million as an advance on royalty amounts that were owed at the time the amendment was executed or would be owed in the future by Biosense Webster to the Company pursuant to the royalty provisions of one of the existing agreements. The Company and Biosense Webster also agreed that an aggregate of up to $8.0 million of certain agreed upon research and development expenses that were owed at the time the amendment was executed or may be owed in the future by the Company to Biosense Webster pursuant to the existing agreement would be deferred and will be due, together with any unrecouped portion of the $10.0 million royalty advance, on the Final Payment Date (as defined below). Interest on the outstanding and unrecouped amounts of the royalty advance and deferred research and development expenses will accrue at an interest rate of the prime rate plus 0.75%. Outstanding royalty advances and deferred research and development expenses and accrued interest thereon will be recouped by Biosense Webster by deductions from royalty amounts otherwise owed to the Company from Biosense Webster pursuant to the existing agreement. The Company has the right to prepay any amounts due pursuant to the Amendment at any time without penalty. As of December 31, 2009, approximately $18.0 million had been advanced by Biosense Webster to the Company pursuant to the amendment. As of December 31, 2009, $5.9 million of royalty payments owed by Biosense had been used to reduce the advances and the remaining approximately $13.3 million of amounts owed to Biosense Webster has been classified as debt in the accompanying balance sheet including $3.0 million as short-term debt and $10.3 million as long-term debt. The Company recorded research and development expenses of $1.7 million, $3.4 million, and $4.6 million and disposables, service and accessories revenue of $3.3 million, $2.0 million, and $1.6 million for the years ended December 31, 2009, 2008, and 2007, respectively, related to this agreement.

All funds owed by the Company to Biosense Webster must be repaid on the sooner of December 31, 2011 or the date of an Accelerating Recoupment Event as defined below (the Final Payment Date). Commencing on May 15, 2010 the Company is required to make quarterly payments (the Supplemental Payments) to Biosense Webster equal to the difference between the aggregate royalty payments recouped by Biosense Webster from the Company (other than royalty amounts attributable to Biosense Webster s sales of irrigated catheters) in such quarter and $1 million, until the earlier of (1) the date all funds owed by the Company to Biosense Webster

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pursuant to the Amendment are fully repaid or (2) the Final Payment Date. An Accelerating Recoupment Event means any of the following: (i) the closing of any equity-based registered public financing transaction or in the event of convertible debt, the conversion of such debt into equity which raises at least $50 million for the Company; (ii) the failure of the Company to make any Supplemental Payment; or (iii) a change of control of the Company (as defined in the amendment).

8. Lease Obligations

The Company leases its facilities under operating leases. For the years ended December 31, 2009, 2008, and 2007 rent expense was $1,727,375, $1,559,584, and $1,195,617 respectively.

In January 2006, the Company moved its primary operations into new facilities. The facility is subject to a lease which expires in 2018. Under the terms of the lease, the Company has options to renew for up to three additional years. The lease contains an escalating rent provision which the Company has straight-lined over the term of the lease.

The future minimum lease payments under non-cancelable leases as of December 31, 2009 are as follows:

Year	Operating Lease
2010	$ 1,666,881
2011	1,518,175
2012	1,524,133
2013	1,524,133
2014	1,565,876
2015 and Beyond	7,622,107
Total minimum lease payments	$ 15,421,305

9. Stockholders Equity

Public Offerings of Common Stock

In August 2006, the Company filed a universal shelf registration statement for the issuance and sale from time to time to the public of up to $75 million in securities, including debt, preferred stock, common stock and warrants. The shelf registration was declared effective by the SEC in September 2006. In March 2007, the Company completed an offering of 1,919,000 shares of its common stock at $10.50 per share pursuant to the shelf registration. In conjunction with this transaction, the Company received approximately $20.1 million in net proceeds after deducting offering expenses.

In December 2008, the Company completed a registered direct offering in which it issued and sold 2,389,877 units (the Units) at the negotiated price of $4.18 per Unit, with each Unit consisting of (i) one share of the Company s common stock (Common Stock), (ii) one warrant to purchase 0.75 shares of Common Stock at an exercise price of $5.11 per share (the Series A Warrant), (iii) one six-month warrant to purchase 0.90 shares of Common Stock at an exercise price of $4.65 per share (the Series B Warrant), for an aggregate of up to 2,148,739 shares of Common Stock, and (iv) two warrants to purchase 0.286 shares of Common Stock at an exercise price of $0.001 per share (the Series C and D Warrants), for an aggregate of up to 682,824 shares of Common Stock. The ability of the Investors to exercise the Series C and D Warrants was conditioned upon the trading price of Common Stock during certain periods prior to May 30, 2009, as described further below. The Series B, C and D Warrants all expired prior to June 30, 2009 and represented the right to acquire in the aggregate up to 2,831,563 shares of Common Stock. The Series A Warrants, which were exercisable on or after the date immediately following the six month anniversary of their issuance (the Initial Exercisability Date) and had a five year term from the Initial Exercisability Date, represented the right to acquire an aggregate of up to

1,792,408 shares of Common Stock. The Series A Warrants have a provision for full ratchet adjustment of the exercise price for the first two years following the closing, and a provision for weighted average adjustment thereafter, provided that, in any event 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 exercise price adjustment provisions included in the Series A Warrant only reduce the exercise price, and will not result in any increase in the number of Series A Warrants or shares of Common Stock underlying the Series A Warrants. As discussed below, these provisions were triggered in February 2009. Under certain conditions, holders of Series C Warrants were entitled to purchase up to 341,412 shares of Common Stock until ten trading days after the two month anniversary of the issuance date of such warrants and holders of Series D Warrants were entitled to purchase up to 341,412 shares of Common Stock until ten trading days after the five month anniversary of the issuance date of such warrants. The ability of the holders to exercise the Series C Warrants was conditioned on the simple average of the daily volume weighted average price of the Common Stock for the 30 trading days prior to the two month anniversary of closing, and the ability of the holders to exercise the Series D Warrants was conditioned on the simple average of the daily volume weighted average price of the Company s Common Stock for the 30 trading days prior to the five month anniversary of closing. If either such simple average was between $4.18 and $3.25, a portion of the Series C and D Warrants would be exercisable; if each such simple average was below $3.25, all of the Series C and D Warrants would be exercisable. The investors in this transaction became entitled to exercise and did exercise Series C and D Warrants to purchase 341,412 and 279,170 shares of common stock in March 2009 and June 2009, respectively.

As described above, this offering contained a provision that required a reduction of the exercise price for Series A Warrants if certain equity events occurred. Such an event occurred in February 2009 and as a result, the exercise price for the Series A Warrants was reduced to $3.16 per share. Under the provisions of general accounting principles for hedging and new guidance for determining whether an instrument (or embedded feature) is indexed to an entity s own stock, such a reset provision no longer meets the exemptions for equity classification and as such, the Company accounts for these warrants as derivative instruments. The calculated fair value of the warrants is classified as a liability and is periodically remeasured with any changes in value recognized in Other income (expense) in the Statement of Operations. This new guidance became effective for the Company as of January 1, 2009. Accordingly, the fair value of the warrants of $5.1 million was reclassified from stockholder s equity into current liabilities at that date. The Company determined that no change in fair value had occurred between the date of closing and December 31, 2008 and as such, the Company did not record a cumulative effect for the change in accounting principal upon adoption of the new guidance. See Note 2 for fair value as of December 31, 2009.

In addition, concurrently with the offering discussed above, the Company completed a second registered direct offering for an aggregate of 2,024,260 shares of Common Stock and warrants to purchase up to 4,859,504 shares of Common Stock to the Lenders, for a purchase price of $4.94 per unit (representing the closing bid price of the Common Stock on the trading day preceding the execution of the agreement, plus an additional $0.125 per warrant share underlying the warrant). The warrants are exercisable at $4.64 per share, are exercisable on or after the date immediately following the six month anniversary of their issuance and have a five year term from that initial exercisability date. In conjunction with the two concurrent offerings, the Company received approximately $18.8 million net of offering expenses.

In August 2009 we filed a universal shelf registration statement for the issuance and sale from time to time to the public of up to $75 million in securities, including debt, preferred stock, common stock, and warrants. The registration statement was declared effective by the SEC in September 2009.

In October 2009, we completed an offering of 7,475,000 shares of our common stock at $4.00 per share, receiving approximately $27.8 million in net proceeds.

The holders of common stock are entitled one vote for each share held and to receive dividends whenever funds are legally available and when declared by the Board of Directors subject to the prior rights of holders of

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all classes of stock having priority rights as dividends and the conditions of the our Revolving Credit Agreement. No dividends have been declared or paid as of December 31, 2009.

The Company has reserved shares of common stock for the exercise of warrants, the issuance of options granted under the Company s stock option plan and its stock purchase plan as follows:

	December 31,	
	2009	2008
Warrants	9,623,711	10,413,071
Stock award plans	5,380,371	5,411,026
Employee Stock Purchase Plan	243,398	25,540
	15,247,480	15,849,637

Stock Award Plans

The Company has various stock plans that permit the Company to provide incentives to employees and directors of the Company in the form of equity compensation. In 1994, the Board of Directors adopted the 1994 Stock Option Plan. In 2002, the Board of Directors adopted a stock incentive plan (the 2002 Stock Incentive Plan) and a non-employee directors stock plan (2002 Director Plan). Each of these plans was subsequently approved by the Company s stockholders. At December 31, 2009 and 2008, the Board of Directors has reserved a total of 5,380,371 and 5,411,026, shares respectively, of the Company s common stock to provide for current and future grants under the 2002 Stock Incentive Plan and the 2002 Director Plan and for all current grants under the 1994 Stock Option Plan.

The 2002 Stock Incentive Plan allows for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted shares and restricted share units to employees, directors, and consultants. Options granted under the 2002 Stock Incentive Plan expire no later than ten years from the date of grant. The exercise price of each incentive stock option shall not be less than 100% of the fair value of the stock subject to the option on the date the option is granted. The vesting provisions of individual options may vary, but incentive stock options generally vest 25% on the first anniversary of each grant and 1/48 per month over the next three years. Stock appreciation rights are rights to acquire a calculated number of shares of the Company s common stock upon exercise of the rights. The number of shares to be issued is calculated as the difference between the exercise price of the right and the aggregate market value of the underlying shares on the exercise date divided by the market value as of the exercise date. Stock appreciation rights granted under the 2002 Stock Incentive Plan generally vest 25% on the first anniversary of such grant and 1/48 per month over the next three years and expire no later than five years from the date of grant. The Company generally issues new shares upon the exercise of stock options and stock appreciation rights.

Restricted share grants under the 2002 Stock Incentive Plan are either time-based or performance-based. Time-based restricted shares generally vest 25% on each anniversary of such grant. Performance-based restricted shares vest upon the achievement of performance objectives which are determined by the Company s Board of Directors.

The 2002 Director Plan allows for the grant of non-qualified stock options to the Company s non-employee directors. Options granted under the 2002 Director Plan expire no later than ten years from the date of grant. The exercise price of options under the 2002 Director Plan shall not be less than 100% of the fair value of the stock subject to the option on the date the option is granted. Initial grants of options to new directors generally vest over a two year period. Annual grants to directors generally vest upon the earlier of one year or the next stockholder meeting.

During the third quarter of 2009, the Company allowed certain option holders to participate in a one-time stock option exchange program. Participants in the program were allowed to cancel certain stock options in exchange for the grant of a lesser amount of stock options with lower exercise prices. The exchange ratios used resulted in a fair value of the replacement options to be granted that was approximately equal to the fair value of the options that were surrendered, and thus no incremental expense was recognized by the Company in conjunction with this option exchange. Of the 975,121 options eligible under the program, 407,832 options were cancelled by the Company in exchange for the granting of 149,976 replacement options. This exchange program was approved by our stockholders on June 10, 2009.

A summary of the options and stock appreciation rights activity for the year ended December 31, 2009 is as follows:

	Number of Options/SARS	Range of Exercise Price	Weighted Average Exercise Price per Share
Outstanding, December 31, 2008	4,480,683	$ 0.25-$14.84	$ 7.52
Granted	1,093,580	$ 3.38-$4.50	$ 4.02
Exercised	(5,138)	$ 1.62	$ 1.62
Forfeited	(893,675)	$ 0.25-$14.84	$ 7.96
Outstanding, December 31, 2009	4,675,450	$ 0.78-$14.84	$ 6.63

As of December 31, 2009 the weighted average remaining contractual life of the options and stock appreciation rights outstanding was 3.4 years. Of the 4,675,450 options and stock appreciation rights that were outstanding as of December 31, 2009, 3,054,663 were vested and exercisable with a weighted average exercise price of $7.43 per share and a weighted average remaining term of 2.8 years.

A summary of the options and stock appreciation rights outstanding by range of exercise price is as follows:

	Year Ended December 31, 2009				
Range of Exercise Prices	Options Outstanding	Weighted Average Remaining Life	Weighted Average Exercise Price	Number of Options Currently Exercisable	Weighted Average Exercise Price Per Share
$0.78 - $5.94	2,446,036	4.1 years	$ 4.61	1,183,930	$ 5.04
$6.77 - $9.90	1,332,573	2.7 years	7.49	1,106,461	7.60
$10.06 - $14.84	896,841	2.4 years	10.86	764,272	10.89
	4,675,450	3.4 years	$ 6.63	3,054,663	$ 7.43

The intrinsic value of options and stock appreciation rights is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company s common stock for the 306,121 options and stock appreciation rights that were in-the-money at December 31, 2009. The intrinsic value of the options and stock appreciation rights outstanding at December 31, 2009 was approximately $0.5 million based on a closing share price of $3.93 on December 31, 2009. The intrinsic value of fully vested options and stock appreciation rights outstanding at December 31, 2009 was approximately $0.3 million based on a closing price of $3.93 on December 31, 2009. During the year ended December 31, 2009, the aggregate intrinsic value of options and stock appreciation rights exercised under the Company s stock option plans was less than $0.1 million. The weighted average grant date fair value of options and stock appreciation rights granted during the year ended December 31, 2009 was $2.00 per share.

During the years ended December 31, 2009, 2008 and 2007, the Company realized less than $0.1 million, $0.3 million and $1.0 million, respectively, from the exercise of stock options and stock appreciation rights.

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A summary of the restricted share grant activity for the year ended December 31, 2009 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Outstanding, December 31, 2008	1,021,718	$ 6.84
Granted	41,800	$ 4.06
Vested	(81,541)	$ 8.29
Forfeited	(123,039)	$ 6.18
Outstanding, December 31, 2009	858,938	$ 5.62

A summary of the restricted stock outstanding as of December 31, 2009 is as follows:

	Number of Shares
Time based restricted shares	323,222
Performance based restricted shares	535,716
Outstanding, December 31, 2009	858,938

The intrinsic value of restricted shares outstanding at December 31, 2009 was approximately $3.4 million based on a closing share price of $3.93 as of December 31, 2009. During the year ended December 31, 2009, the aggregate intrinsic value of restricted shares vested was approximately $313,000 determined at the date of vesting.

During the years ended December 31, 2009 and December 31, 2008, the Company determined that it was not probable that the performance conditions related to certain of its outstanding restricted share awards would be achieved and accordingly, recorded approximately $(0.5) million and $(3.8) million, respectively, as a cumulative catch-up adjustment resulting in a reduction of share based compensation. During the year ended December 31, 2008, the Company also expensed approximately $1.1 million related to modifications of exercise provision of certain outstanding equity awards and to vesting and exercise provisions in conjunction with the retirement of its CEO.

As of December 31, 2009, the total compensation cost related to options, stock appreciation rights and non-vested stock granted to employees under the Company s stock award plans but not yet recognized was approximately $5.9 million, net of estimated forfeitures of approximately $0.8 million. This cost will be amortized over a period of up to four years on a straight-line basis over the underlying estimated service periods and will be adjusted for subsequent changes in estimated forfeitures.

2009 Employee Stock Purchase Plan

In 2009, the Company adopted its 2009 Employee Stock Purchase Plan and reserved 250,000 shares of common stock for issuance pursuant to the plan. The Company offered employees the opportunity to participate in the plan beginning July 1, 2009 with an initial purchase date of September 30, 2009. Eligible employees have the opportunity to participate in a new purchase period every 3 months. Under the terms of the plan, employees can purchase up to 15% of their compensation of the Company s common stock, subject to an annual maximum of $25,000, at 95% of the fair market value of the stock at the end of the purchase period, subject to certain plan limitations. As of December 31, 2009, a total of 6,602 shares had been purchased under this plan. As of December 31, 2009 there were 243,398 remaining shares available for issuance under the Employee Stock Purchase Plan.

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2004 Employee Stock Purchase Plan

Upon the effectiveness of the initial public offering in August 2004, the Company adopted its 2004 Employee Stock Purchase Plan and reserved 277,777 shares of common stock for issuance pursuant to the plan. The Company offered employees the opportunity to participate in the plan beginning January 1, 2005 with an initial purchase date of June 30, 2005. Eligible employees had the opportunity to participate in a new purchase period every 6 months. Under the terms of the plan, employees could purchase up to $12,500 of the Company s common stock at 85% of the fair market value of the stock at the beginning or the end of the purchase period, subject to certain plan limitations. As of December 31, 2009, 2008, and 2007, a total of 277,777, 252,237, and 166,712 shares, respectively, had been purchased under this plan.

Warrants

Prior to its public offering in 2004, the Company issued warrants to purchase 446,063 shares of common stock at $7.81 exercisable through December 2007 and warrants to purchase 298,936 shares of common stock at $10.55 per share exercisable through February 2009 in connection with a corresponding issuance of convertible preferred stock.

During 2005, the Company issued warrants to purchase 306,418 shares of common stock at $6.53 in conjunction with a commitment for unsecured borrowing capacity from the Lenders. Such warrants are exercisable through November 2010. In February 2008, the Company issued warrants to the Lenders to purchase 572,246 shares of common stock at $6.99 per share exercisable through February 2013 in conjunction with a $20 million loan commitment as described in Note 7. In February 2009, the Company exercised its option to extend the terms of its guarantee with the same stockholders and issued warrants to the Lenders to purchase 1,582,280 shares of common stock at $3.16 per share exercisable through February 2014 as described in Note 7.

In December 2008, the Company issued warrants associated with two direct offerings as discussed above in Public Offerings of Common Stock.

In October 2009, the Company issued warrants to purchase 664,064 shares of common stock in conjunction with an extension of the commitment for unsecured borrowing capacity from the Lenders as described in Note 7.

During 2009, 2008, and 2007, warrants for 620,582, 479 and 147,619 shares, respectively, were exercised. Certain of these shares were exercised under the cashless exercise provision of the warrant agreements for a net issuance of 620,582, 479, and 93,050 shares of common stock during 2009, 2008, and 2007, respectively.

10. Income Taxes

The provision for income taxes consists of the following:

	Year Ended December 31,		
	2009	2008	2007
Deferred:			
Federal	$ 9,850,636	$ 13,322,273	$ 11,396,216
State and local	1,299,941	781,188	(2,378,549)
	11,150,577	14,103,461	9,017,667
Valuation allowance	(11,150,577)	(14,103,461)	(9,017,667)
	$	$	$

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The provision for income taxes varies from the amount determined by applying the U.S. federal statutory rate to income before income taxes as a result of the following:

	Year Ended December 31,		
	2009	2008	2007
U.S. statutory income tax rate	34.0%	34.0%	34.0%
State and local taxes, net of federal tax benefit	4.4%	1.8%	(4.9)%
Permanent differences between book and tax and other	1.5%	(3.7)%	(10.4)%
Valuation allowance	(39.9)%	(32.1)%	(18.7)%
Effective income tax rate	0.0%	0.0%	0.0%

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. The Company considers projected future taxable income and tax planning strategies in making this assessment. Based upon the level of historical taxable losses, and projections for future periods over which the deferred tax assets are deductible, the Company determined that a 100% valuation allowance of deferred tax assets was appropriate. The valuation allowance for deferred tax assets includes amounts for which subsequently recognized tax benefits will be applied directly to contributed capital.

The components of the deferred tax asset are as follows:

	December 31,	
	2009	2008
Current accruals	$ 1,933,934	$ 2,428,663
Depreciation and amortization	2,120,283	2,099,867
Deferred compensation	3,946,580	2,021,670
Net operating loss carryovers	105,266,308	96,004,376
Deferred tax assets	113,267,105	102,554,576
Valuation allowance	(113,267,105)	(102,554,576)
Net deferred tax assets	$	$

As of December 31, 2009, the Company has federal net operating loss carryforwards of approximately $290.8 million. The net operating loss carryforwards will expire at various dates beginning in 2010, approximately $4.0 million will expire between 2010 and 2012 and approximately $286.8 million will expire between 2018 and 2029, if not utilized. As of December 31, 2009, the Company has state net operating loss carryforwards of approximately $6.4 million, which will expire at various dates between 2010 and 2029, if not utilized.

The Company files income tax returns in the U.S. federal jurisdiction and various state and local jurisdictions. As the Company has a federal Net Operating Loss carryforward from the year ended December 31, 1994 forward, all tax years from 1994 forward are subject to examination. As states have varying carryforward periods, and the Company has recently entered into additional states, the states are generally subject to examination for the previous 10 years or less.

The Company recognizes interest accrued, net of tax and penalties, related to unrecognized tax benefits as components of income tax provision as applicable. As of December 31, 2009, accrued interest and penalties were not material.

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11. Net Loss per Share

The following is a reconciliation of the numerator (net loss) and the denominator (number of shares) used in the basic and diluted earnings per share calculations:

	Year Ended December 31,		
	2009	2008	2007
Basic and diluted:			
Net loss	$ (27,494,457)	$ (43,885,974)	$ (48,121,514)
Weighted average common shares outstanding	43,344,324	36,585,086	35,793,973
Net loss per share	$ (0.63)	$ (1.20)	$ (1.34)

The following table sets forth the number of common shares that were excluded from the computation of diluted earnings per share because their inclusion would have been anti-dilutive as follows:

	December 31,		
	2009	2008	2007
Shares outstanding			
Restricted shares	858,938	1,021,718	675,078
Shares issuable upon exercise of:			
Options to purchase common stock	4,675,450	4,480,683	3,324,509
Warrants	9,623,711	10,413,071	357,350
	15,158,099	15,915,472	4,356,937

12. Employee Benefit Plan

Beginning in 2002, the Company offered employees the opportunity to participate in a 401(k) plan. The Company matches employee contributions dollar for dollar up to 3% of the employee s salary during the employee s period of participation. For the years ended December 31, 2009, 2008 and 2007, the Company expensed $540,168, $621,389 and $605,063, respectively, related to the plan.

13. Commitments and Contingencies

The Company at times becomes a party to claims in the ordinary course of business. Management believes that the ultimate resolution of pending or threatened proceedings will not have a material effect on the financial position, results of operations, or liquidity of the Company.

The Company has entered into letters of credit to support certain commitments in the aggregate amount of $0.5 million. These letters of credit expire in March 2010, June 2010 and February 2011.

14. Segment Information

The Company considers reporting segments in accordance with general accounting principles for disclosures about segments of an enterprise and related information. The Company s system and disposable devices are developed and marketed to a broad base of hospitals in the United States and internationally. The Company considers all such sales to be part of a single operating segment.

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Geographic revenue is as follows:

	Year Ended December 31,		
	2009	2008	2007
United States	$ 22,309,477	$ 29,052,328	$ 25,930,305
International	28,840,078	11,312,845	13,368,504
Total	$ 51,149,555	$ 40,365,173	$ 39,298,809

All of the Company s long-lived assets are located in the United States.

15. Quarterly Data (Unaudited)

The following tabulations reflect the unaudited quarterly results of operations for the years ended December 31, 2009 and 2008:

	Net Sales	Gross Profit	Net Loss	Basic and Diluted Loss Per Share
2009				
First quarter	$ 11,133,134	$ 7,672,452	$ (7,530,087)	$ (0.18)
Second quarter	12,644,337	7,978,452	(7,439,777)	(0.18)
Third quarter	13,290,693	9,005,112	(5,813,743)	(0.14)
Fourth quarter	14,081,391	9,471,906	(6,710,850)	(0.14)
2008				
First quarter	$ 7,028,451	$ 4,602,389	$ (13,531,166)	$ (0.37)
Second quarter	10,658,592	6,475,955	(12,789,661)	(0.35)
Third quarter	10,551,649	6,910,101	(10,073,125)	(0.28)
Fourth quarter	12,126,481	8,198,938	(7,492,022)	(0.20)

16. Subsequent Events

The Company noted that there were no subsequent events after the balance sheet date of December 31, 2009 through the filing of this report with the Securities and Exchange Commission.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Report on Internal Control Over Financial Reporting

As of December 31, 2009, the Company s management, with the participation of the Company s Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company s disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act)). Based on such evaluation, the Company s Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, the Company s disclosure controls and procedures were effective.

The Company s management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act. The

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Company s internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. The Company s management assessed the effectiveness of our internal control over financial reporting as of December 31, 2009. In making the assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework. Based on our assessment, our management has concluded that our internal control over financial reporting is effective as of December 31, 2009.

A control system, no matter how well conceived or operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

The Company s independent registered public accounting firm, Ernst & Young LLP, has issued an audit report on the effectiveness of our internal control over financial reporting, which can be found below.

Based on the evaluation of internal control over financial reporting, the Chief Executive Officer and Chief Financial Officer have concluded that there have been no changes in the Company s internal controls over financial reporting during the period that is covered by this report that has materially affected or is reasonably likely to materially affect, the Company s internal control over financial reporting.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders

Stereotaxis, Inc.

We have audited Stereotaxis, Inc. s internal control over financial reporting as of December 31, 2009, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Stereotaxis, Inc. s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Stereotaxis, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Stereotaxis, Inc. as of December 31, 2009 and 2008, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2009, of Stereotaxis, Inc., and our report dated March 15, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

St. Louis, Missouri

March 15, 2010

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ITEM 9B. OTHER INFORMATION

None.

PART III

Certain information required by Part III is omitted from this Report on Form 10-K since we intend to file our definitive Proxy Statement for our next Annual Meeting of Stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended (the Proxy Statement), no later than April 30, 2010, and certain information to be included in the Proxy Statement is incorporated herein by reference.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Information required by this item concerning our executive officers and directors is incorporated by reference to the information set forth in the section entitled Directors and Executive Officers in our Proxy Statement. Information regarding Section 16 reporting compliance is incorporated by reference to the information set forth in the section entitled Section 16(a) Beneficial Ownership Reporting Compliance in our Proxy Statement.

Our Board of Directors adopted a Code of Business Conduct and Ethics for all of our directors, officers and employees effective August 1, 2004 as amended from time to time. Stockholders may request a free copy of our Code of Business Conduct and Ethics from our Chief Financial Officer as follows:

Stereotaxis, Inc.

Attention: Daniel J. Johnston

4320 Forest Park Avenue, Suite 100

St. Louis, MO 63108

314-678-6100

To the extent required by law or the rules of the NASDAQ Global Market, any amendments to, or waivers from, any provision of the Code of Business Conduct and Ethics will be promptly disclosed publicly. To the extent permitted by such requirements, we intend to make such public disclosure by posting the relevant material on our website (*www.stereotaxis.com*) in accordance with SEC rules.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item regarding executive compensation is incorporated by reference to the information set forth in the sections titled Executive Compensation in our Proxy Statement.

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ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth in the section titled Security Ownership of Certain Beneficial Owners and Management in our Proxy Statement.

The following table summarizes certain information regarding our securities that may be issued pursuant to our equity compensation plans as of December 31, 2009.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))(1) (c)
Equity compensation plans approved by security holders	4,675,450	$ 6.63	948,320
Equity compensation plans not approved by security holders			
Total	4,675,450		948,320

(1) Includes 243,398 shares reserved for issuance under the 2009 Employee Stock Purchase Plan. Number of shares of common stock is subject to adjustment for changes in capitalization for stock splits, stock dividends and similar events.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item regarding certain relationships and related transactions is incorporated by reference to the information set forth in the section titled Certain Relationships and Related Person Transactions and Director Independence in our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item regarding principal accounting fees and services is incorporated by reference to the information set forth in the section titled Principal Accounting Fees and Services in our Proxy Statement.

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PART IV

ITEM 15: EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K

(1) Financial Statements See Index to the Financial Statements at Item 8 of this Report on Form 10-K.

(2) The following financial statement schedule of Stereotaxis, Inc. is filed as part of this Report and should be read in conjunction with the financial statements of Stereotaxis, Inc.:

Schedule II: Valuation and Qualifying Accounts.

All other schedules have been omitted because they are not applicable, not required under the instructions, or the information requested is set forth in the consolidated financial statements or related notes thereto.

(3) Exhibits

See Exhibit Index appearing on page 86 herein.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

STEREOTAXIS, INC.

(Registrant)

Date: March 15, 2010

By: /s/ MICHAEL P. KAMINSKI

Michael P. Kaminski

President & Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael P. Kaminski and Daniel J. Johnston, and each of them, his true and lawful attorneys-in-fact and agents, with full Power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities to sign any and all amendments to this Annual Report on Form 10-K and any other documents and instruments incidental thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full Power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents and/or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ FRED A. MIDDLETON **Fred A. Middleton**	Chairman of the Board of Directors	March 15, 2010
/s/ MICHAEL P. KAMINSKI **Michael P. Kaminski**	President & Chief Executive Officer, Director (principal executive officer)	March 15, 2010
/s/ DANIEL J. JOHNSTON **Daniel J. Johnston**	Chief Financial Officer (principal financial officer and principal accounting officer)	March 15, 2010
/s/ CHRISTOPHER ALAFI **Christopher Alafi**	Director	March 15, 2010
/s/ DAVID W. BENFER **David W. Benfer**	Director	March 15, 2010
/s/ BEVIL J. HOGG **Bevil J. Hogg**	Director	March 15, 2010

/s/ William M. Kelley	Director	March 15, 2010
William M. Kelley		
/s/ Abhijeet J. Lele	Director	March 15, 2010
Abhijeet J. Lele		

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Signature	Title	Date
/s/ William C. Mills III **William C. Mills III**	Director	March 15, 2010
/s/ Robert J. Messey **Robert J. Messey**	Director	March 15, 2010
/s/ Eric N. Prystowsky **Eric N. Prystowsky**	Director	March 15, 2010

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SCHEDULE II

VALUATION AND QUALIFYING ACCOUNTS

FOR THE YEARS ENDED DECEMBER 31, 2009, 2008, AND 2007

	Balance at Beginning of Year	Additions Charged to Cost and Expenses	Deductions	Balance at the End of Year
Allowance for doubtful accounts and returns:				
Year ended December 31, 2009	$ 328,307	$ 353,532	$ (359,376)	$ 322,463
Year ended December 31, 2008	189,040	207,798	(68,531)	328,307
Year ended December 31, 2007	90,716	280,648	(182,324)	189,040
Allowance for inventories valuation:				
Year ended December 31, 2009	$ 583,278	$ 321,058	$ (91,868)	$ 812,468
Year ended December 31, 2008	595,105	87,391	(99,218)	583,278
Year ended December 31, 2007	211,455	2,170,606	(1,786,956)	595,105

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EXHIBIT INDEX

Number	Description
3.1	Restated Articles of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
3.2	Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
4.1	Form of Specimen Stock Certificate, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 4.1.
4.2	Fourth Amended and Restated Investor Rights Agreement, dated December 17, 2002 by and among Registrant and certain stockholders, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 4.3.
4.3	Joinder Agreement to Series D-2 Preferred Stock Purchase Agreement, Fourth Amended and Restated Investor Rights Agreement and Amendment to Second Amended and Restated Stockholders Agreement dated January 21, 2003 by and among Registrant and certain stockholders, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 4.4.
4.4	Joinder and Amendment to Second Amended and Restated Stockholders Agreement and Fourth Amended and Restated Investor Rights Agreement, dated May 27, 2003 by and among Registrant and certain stockholders incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 4.5.
4.5	Second Joinder and Amendment to Second Amended and Restated Stockholders Agreement and Fourth Amended and Restated Investor Rights Agreement, dated December 22, 2003 by and among Registrant and certain stockholders, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 4.6.
4.6	Third Joinder and Amendment to Second Amended and Restated Stockholders Agreement and Fourth Amended and Restated Investor Rights Agreement, dated January 28, 2004 by and among Registrant and certain stockholders, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 4.7.
4.7	Form of Warrant issued pursuant to that certain Note and Warrant Purchase Agreement, dated as of November 10, 2005, between the Registrant and the investors named therein, incorporated by reference to Exhibit 4.2 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2005.
4.8	Form of Warrant issued pursuant to that certain Note and Warrant Purchase Agreement effective February 7, 2008 between the Registrant and certain investors named therein (included in Exhibit 10.31a).
4.9	Form of Series A Warrant, issued pursuant to that certain Securities Purchase Agreement, dated December 29, 2008, incorporated by reference to Exhibit 4.1 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed December 29, 2008.
4.10	Form of Series B, C and D Warrants, issued pursuant to that certain Securities Purchase Agreement, dated December 29, 2008, incorporated by reference to Exhibit 4.2 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed December 29, 2008.

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Number	Description
4.11	Form of Warrant, issued pursuant to that certain Securities Purchase Agreement, dated December 29, 2008, incorporated by reference to Exhibit 4.3 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed December 29, 2008.
10.1#	1994 Stock Option Plan, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.1.
10.2a#	2002 Stock Incentive Plan, as amended and restated June 10, 2009, incorporated by reference to Exhibit 10.2 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2009.
10.2b#	Form of Incentive Stock Option Award Agreement under the 2002 Stock Incentive Plan, incorporated by reference to Exhibit 10.3 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed December 19, 2008.
10.2c#	Form of Non-Qualified Stock Option Award Agreement under the 2002 Stock Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed December 19, 2008.
10.2d#	Form of Restricted Stock Agreement under the 2002 Stock Incentive Plan, incorporated by reference to Exhibit 10.7 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2008.
10.2e#	Form of Performance Share Agreement under the 2002 Stock Incentive Plan, incorporated by reference to Exhibit 10.8 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2008.
10.2f#	Form of Stock Appreciation Right Award Agreement under the 2002 Stock Incentive Plan, incorporated by reference to Exhibit 10.2 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed December 19, 2008.
10.3#	2009 Employee Stock Purchase Plan, as adopted June 10, 2009, incorporated by reference to Exhibit 10.1 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2009.
10.4a#	2002 Non-Employee Directors Stock Plan, as amended and restated Mary 29, 2008, incorporated by reference to Exhibit 10.4 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2008.
10.4b#	Form of Non-Qualified Stock Option Agreement under the 2002 Non-Employee Directors Stock Plan, incorporated by reference to Exhibit 10.1 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2005.
10.5a#	Restated Employment Agreement dated February 22, 2006 between Bevil J. Hogg and the Registrant, incorporated by reference to Exhibit 10.5 of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2007.
10.5b#	Amended and Restated Employment Agreement dated November 25, 2008, between Bevil J. Hogg and the Registrant, incorporated by reference to Exhibit 10.5b of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2008.
10.6a#	Employment Agreement dated April 4, 2001 between Douglas M. Bruce and the Registrant, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.6.
10.6b#	Amendment to Employment Agreement dated August 6, 2009 between Douglas M. Bruce and the Registrant, incorporated by reference to Exhibit 10.4 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2009.

Number	Description
10.7a#	Employment Agreement dated February 16, 2001 between Melissa Walker and the Registrant, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.7.
10.7b#	Amendment to Employment Agreement dated August 6, 2009 between Melissa C. Walker and the Registrant, incorporated by reference to Exhibit 10.7 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2009.
10.8a#	Employment Agreement dated April 17, 2002 between Michael P. Kaminski and the Registrant, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.8.
10.8b#	First Amendment to Employment Agreement dated as of May 29, 2008, by and between the Registrant and Micheal P. Kaminski, incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed June 3, 2008.
10.8c#	Corrected Second Amendment to Employment Agreement dated August 6, 2009 by and between Michael P. Kaminski and the Registrant, incorporated by reference to Exhibit 10.3 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2009.
10.9a#	Letter Agreement and Employment Agreement dated May 26, 2004 between James M. Stolze and the Registrant, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.17.
10.9b#	Amendment to Employment Agreement dated August 6, 2009 between James M. Stolze and the Registrant, incorporated by reference to Exhibit 10.6 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2009.
10.10a#	Employment Agreement, dated June 2, 2008, between the Registrant and Louis T. Ruggiero, incorporated by reference to Exhibit 10.3 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2008.
10.10b#	Amendment to Employment Agreement dated August 6, 2009 between Louis T. Ruggiero and the Registrant, incorporated by reference to Exhibit 10.5 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2009.
10.11#	Employment Agreement dated August 5, 2009 between Dan Johnston and the Registrant, incorporated by reference to Exhibit 10.8 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2009.
10.12#	Summary of annual cash compensation of executive officers (filed herewith).
10.13#	Summary of Non-Employee Directors Compensation, incorporated by reference to Exhibit 10.5 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2008.
10.14	Stereotaxis Advisory Board and Consulting Agreement, dated February 25, 2009, between the Company and Eric N. Prystowsky, MD, incorporated by reference to Exhibit 10.3 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended March 31, 2009.
10.15	Collaboration Agreement dated June 8, 2001 between the Registrant and Siemens AG, Medical Solutions, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.9.
10.16	Extended Collaboration Agreement dated May 27, 2003 between the Registrant and Siemens AG, Medical Solutions, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.10.

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Number	Description
10.17	Amendment to Collaboration Agreement dated May 5, 2006 between the Company and Siemens Aktiengesellschaft, Medical Solutions, incorporated by reference to Exhibit 10.1 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2006.
10.18	Development and Supply Agreement dated May 7, 2002 between the Registrant and Biosense Webster, Inc., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.11.
10.19	Amendment to Development and Supply Agreement dated November 3, 2003 between the Registrant and Biosense Webster, Inc., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.12.
10.20	Alliance Expansion Agreement, dated as of May 4, 2007, between Biosense Webster, Inc. and the Registrant, incorporated by reference to Exhibit 10.1 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2007.
10.21	Second Amendment to Development Alliance and Supply Agreement, dated as of July 18, 2008, between the Registrant and Biosense Webster, Inc., incorporated by reference to Exhibit 10.1 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2008.
10.22	Third Amendment to the Development Alliance and Supply Agreement with Biosense Webster, Inc. (filed herewith)
10.23	Form of Indemnification Agreement between the Registrant and its directors and executive officers, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.14.
10.24	Letter Agreement, effective October 6, 2003, between the Registrant and Philips Medizin Systeme G.m.b.H., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.16.
10.25	Japanese Market Development Agreement dated May 18, 2004 between the Registrant, Siemens Aktiengesellschaft and Siemens Asahi Medical Technologies Ltd., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.32.
10.26	Office Lease dated November 15, 2004 between the Registrant and Cortex West Development I, LLC, incorporated by reference to Exhibit 10.39 of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2004.
10.27	Amendment to Office Lease dated November 30, 2007 between the Registrant and Cortex West Development I, LLC, incorporated by reference to Exhibit 10.22 of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2007.
10.28	Amended and Restated Loan and Security Agreement, dated March 12, 2009, between the Company and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant s Form 10-Q/A (File No. 000-50884) for the fiscal quarter ended March 31, 2009.
10.29	First Loan Modification Agreement (Domestic), by and between Silicon Valley Bank and Stereotaxis, Inc., dated December 15, 2009, incorporated by reference to Exhibit 10.1 of the Registrant s Form 8-K (File No. 000-50884) filed on December 21, 2009.
10.30	Export-Import Bank Loan and Security Agreement, dated March 12, 2009, between the Company, Stereotaxis International, Inc., and Silicon Valley Bank, incorporated by reference to Exhibit 10.2 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended March 31, 2009.

Number	Description
10.31a	Note and Warrant Purchase Agreement, effective February 7, 2008, between the Registrant and the investors named therein, incorporated by reference to Exhibit 10.31 of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2007.
10.31b	First Amendment to Note and Warrant Purchase Agreement, effective December 29, 2008, between the Registrant and the investors named therein, incorporated by reference to Exhibit 10.32 of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2008.
10.31c	Second Amendment to Note and Warrant Purchase Agreement, effective October 9, 2009, between the Registrant and the investors named therein (filed herewith).
21.1	List of Subsidiaries of the Registrant (filed herewith).
23.1	Consent of Ernst & Young LLP
31.1	Rule 13a-14(a)/15d-14(a) Certification (pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, executed by Chief Executive Officer).
31.2	Rule 13a-14(a)/15d-14(a) Certification (pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, executed by Chief Financial Officer).
32.1	Section 1350 Certification (pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Chief Executive Officer).
32.2	Section 1350 Certification (pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Chief Financial Officer)

\# Indicates management contract or compensatory plan

Confidential treatment granted as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission.