Stereotaxis, Inc.
Form 10-K
March 15, 2012
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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, 2011

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 x 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. x

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, 2011) was approximately $161 million.

The number of outstanding shares of the registrant s common stock on February 29, 2012 was 56,289,853.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Registrant s 2012 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

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STEREOTAXIS, INC.

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PART I

ITEM 1. BUSINESS

In this report, Stereotaxis, the Company, Registrant, we, us, and our refer to Stereotaxis, Inc. and its wholly-owned subsidiaries. *Epiphan*®, *Niobe*®, *Odyssey* , *Odyssey Cinema* , *Cardiodrive*®, *Cronus*®, *Assert*®, *PowerAssert* , *Titan*®, *Pegasus* , *Navigant* , *Vdrive* , *V-CAS* , *V-loop* , *Vdrive Duo* , *QuikCAS* are trademarks of Stereotaxis, Inc. All other trademarks that may appear in this report are the property of their respective owners.

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;
- our ability to fund operations;
- our ability to convert backlog to revenue;
- the timing and prospects for regulatory approval of our additional disposable interventional devices;
- the success of our business partnerships and strategic alliances;
- our estimates regarding our capital requirements;
- the ability of physicians to perform certain medical procedures with our products safely, effectively and efficiently;
- the adoption of our products by hospitals and physicians;
- the market opportunity for our products, including expected demand for our products;
- our plans for hiring additional personnel; and
- any of our other plans, objectives, expectations and intentions contained in 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.

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OVERVIEW

We design, manufacture and market the *Epoch* Solution, which is an advanced remote robotic navigation system for use in a hospital s interventional surgical suite, or interventional lab , that we believe revolutionizes the treatment of arrhythmias and coronary artery disease by enabling enhanced safety, efficiency and efficacy for catheter-based, or interventional, procedures. The *Epoch* Solution is comprised of the *Niobe* ES Robotic Magnetic Navigation System (*Niobe* ES system), *Odyssey* Information Management Solution (*Odyssey* Solution), and the *Vdrive* Robotic Navigation System. We believe that our technology represents an important advance in the ongoing trend toward fully digitized, integrated and automated interventional labs 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. The core elements of our technology, especially the *Niobe* ES system, are protected by an extensive patent portfolio, as well as substantial know-how and trade secrets.

Our *Niobe* ES system is the latest generation of the *Niobe* Robotic Magnetic Navigation System (*Niobe* system), which allows physicians to more effectively navigate proprietary catheters, guidewires and other delivery devices, both our own and those we are co-developing through strategic alliances, 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 devices. We believe that our *Niobe* ES 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. *Niobe* system revenue represented 19%, 40%, and 54% of revenue for the years ended December 31, 2011, 2010, and 2009, respectively.

The *Niobe* system is designed primarily for use by interventional electrophysiologists in the treatment of abnormal heart rhythms known as arrhythmias and approximately 3% of usage is 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. 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.

Stereotaxis has also developed the *Odyssey* Solution which provides an innovative enterprise solution for integrating, recording and networking interventional lab information within hospitals and around the world. The *Odyssey* Solution consists of several lab solutions including *Odyssey* Vision to consolidate all of the lab information from multiple sources, freeing doctors from managing complex interfaces during patient therapy for optimal procedural and clinical efficiency. In addition, we offer two lower cost alternatives which consolidate the lab information without providing a large display and an interface for connecting partner large display systems known as *Odyssey* Link and *Odyssey* Interface, respectively. The *Odyssey* Solution also includes a remote procedure viewing and recording capability in a basic *Odyssey Cinema* LT or premium *Odyssey Cinema* Studio offering (*Odyssey Cinema* system). The *Odyssey Cinema* system is an innovative solution delivering synchronized content targeted to improve care, enhance performance, increase referrals and market services. 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 Internet from anywhere with sufficient bandwidth. The *Odyssey Cinema* Studio offering includes a production console, Studio, to facilitate Internet broadcasting, collaboration and presentation editing. The Studio console leverages a global *Odyssey* Network enabling hospitals to broadcast to anyone or collaborate between hospitals that use the *Odyssey* system. The *Odyssey* Solution may be acquired either as part of the *Epoch* Solution or on a stand-alone basis for installation in interventional labs and other locations where clinicians desire improved clinical workflows and related efficiencies. *Odyssey* system revenue represented 18%, 18%, and 10% of revenue for the years ended December 31, 2011, 2010, and 2009, respectively.

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Our *Vdrive* Robotic Navigation System provides navigation and stability for diagnostic and therapeutic devices designed to improve interventional procedures. The *Vdrive* Robotic Navigation System complements the *Niobe* ES system control of therapeutic catheters for fully remote procedures and enables single-operator workflow and is sold as two options, the *Vdrive* System and the *Vdrive Duo* System. In addition to the *Vdrive* System and the *Vdrive Duo* System, we also manufacture and market various disposable components which can be manipulated by these systems.

We promote the full *Epoch* Solution in a typical hospital implementation, subject to regulatory approvals or clearances. The full *Epoch* Solution implementation requires a hospital to agree to an upfront capital payment and recurring payments. The upfront capital payment typically includes equipment and installation charges. The recurring payments typically include disposable costs for each procedure, equipment service costs beyond warranty period, and software licenses and *Odyssey* Network fees. In hospitals where the full *Epoch* Solution has not been implemented, equipment upgrade or expansion can be implemented upon purchasing of the necessary upgrade or expansion.

Not all products have and/or require regulatory clearance in all of the markets we serve. Please refer to Regulatory Approval in Item 1 for a description of our regulatory clearance, licensing, and/or approvals we currently have or are pursuing.

As of December 31, 2011, we had approximately $20 million of backlog, consisting of outstanding purchase orders and other commitments for these systems. We had backlog of approximately $43 million and $37 million as of December 31, 2010 and 2009, respectively, using the same active backlog criteria. Of the December 31, 2011 backlog, we expect approximately 82% to be recognized as revenue over the course of 2012. 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.

We have alliances with 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. The Biosense alliance also provides development of disposable interventional devices, coordination of marketing and sales efforts in order to continue to introduce new enhancements around the *Niobe* system, and non-exclusive commercialization of the *Odyssey* Solution to Biosense customers in the electrophysiology field. The Siemens and Philips alliances provide for coordination of our sales and marketing efforts with those of our alliance partners to facilitate co-placement of integrated systems. In addition, Siemens provides worldwide service for certain of our integrated systems. Sales to Siemens accounted for 5% of total net revenue for the year ended December 31, 2011.

BACKGROUND

We have focused our clinical and commercial efforts on applications of the *Epoch* Solution 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 generation and 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. Over 4.3 million people in the U.S. currently suffer from the resulting abnormal heart rhythms, which are known as arrhythmias. Electrophysiology is a fast-growing clinical specialty focused on the treatment of cardiac arrhythmias which can occur in any chamber of the heart.

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Electrophysiologists typically treat patients suffering from cardiac arrhythmias with a combination of drug therapy and/or interventional catheter ablation of cardiac tissue to interrupt aberrant electrical signals. Reimbursement for interventional catheter ablation has been stable in most markets with increasing governmental awareness of the impact of the disease state upon national healthcare programs.

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 advanced imaging techniques and sophisticated catheter and wire-based devices and techniques, the number of potential patients who can benefit from non-surgical interventional 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, 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 *Epoch* Solution represents a revolutionary step compared to manual techniques 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 the *Vdrive* Robotic Navigation System will provide physicians with the ability to navigate and control diagnostic catheters and sheaths from the procedure room, which will facilitate the performance of procedures remotely while further improving efficiency and efficacy of the procedure. We believe that the *Odyssey* Solution will provide physicians the ability to enhance procedure workflow, more effectively manage their interventional procedures, collaborate with other physicians, broadcast their clinical expertise and provide the capability to record and review segments or entire procedures to facilitate quality improvement.

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.

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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 and/or ultrasound images;
- a real-time location-sensing system providing the 3D location of the catheter tip;
- 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 can require a separate user interface, which further reduces the efficiency of the procedure.

THE STEREOTAXIS VALUE PROPOSITION

The *Epoch* Solution addresses 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 technology and information systems used during interventional cardiology and electrophysiology procedures, on a cost-justified basis.

We believe that our systems will:

Expand the market by enhancing the treatment of more complex cases and potentially enabling new treatments for major diseases. Treatment of a number of major diseases, including atrial fibrillation, ventricular tachycardia, cardiac chronic total occlusions, and critical limb ischemia due to chronic total occlusions of peripheral arteries, 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 and ventricular tachycardia, 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 our robotic technology provides precise, computerized control of the working tip of disposable interventional devices, we believe that it will potentially enable difficult total occlusions, atrial fibrillation, and ventricular tachycardia 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 can lead to sub-optimal results in many procedures. Additionally, the precise control of multiple complex diagnostic and therapeutic devices by a single physician can lead to better outcomes for the patient. 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 our robotic technology 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.

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Improve clinical workflow and information management. The *Odyssey* 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 Cinema* Studio is an information management solution which enables hospitals to view live and recorded procedures throughout hospital networks and while traveling abroad. This product also includes a Studio console to facilitate collaboration, broadcasting and presentation editing. An *Odyssey* Broadcast and *Odyssey* Connect network service is available to enable collaboration between hospitals using the *Odyssey* system and Internet broadcasting around the world.

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 the time needed to carry out therapy at the target site, we believe that our robotic technology 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 robotics 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 who are skilled in performing more complex procedures. We believe that our robotic technology 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 robotic systems 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. We believe the *Odyssey* Solution can allow advanced training online thereby accelerating learning.

Improve patient and physician safety. The *Niobe* system has been used in more than 45,000 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 2-6% for complex ablations, and significantly higher for new physicians and fellows. 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. Our robotic technology can further improve physician safety and reduce physician fatigue 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.

Help hospitals recruit physicians and attract patients. Due to the clinical benefits of the *Epoch* Solution, we believe hospitals will realize significant operational benefits when recruiting physicians to work in a more safe procedure environment, while attracting patients who desire to have safer procedures that lead to better long term outcomes.

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OUR PRODUCTS

***Niobe*® ES Robotic Magnetic Navigation System**

Our proprietary *Niobe* ES robotic 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* ES robotic system allows the operator to navigate disposable interventional devices to the treatment site through complex paths in the blood vessels and chambers of the heart to deliver treatment by 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* ES robotic system with Siemens and with Philips digital x-ray fluoroscopy systems. In addition, we have integrated the *Niobe* ES robotic system with Biosense Webster s 3D catheter location sensing technology 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* ES robotic system are identified and described below:

Niobe® Robotic Magnetic Navigation System. Our *Niobe* Robotic 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* ES robotic system is indicated for use in cardiac, peripheral and neurovascular applications.

Cardiodrive® Automated Catheter Advancement System. As the physician conducts the procedure from the adjacent control room, the *Cardiodrive* or *QuikCAS* automated catheter advancement systems are 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* Solution**

The *Odyssey* Solution offers a fully integrated, real-time information solution to manage, control, record and share procedures across networks or around the world. We believe that the *Odyssey* Solution enhances the physician workflow in interventional 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. Through the use of a single mouse and keyboard, the *Odyssey* Solution allows the user to command multiple systems in the lab from a single point of control. In addition, the *Odyssey* Solution acquires a real-time, remote view of the lab capturing synchronized procedure data for review of important events during cases. The *Odyssey* Solution enables physicians to access recorded cases and create snapshots following procedures for enhanced clinical reporting, auditing and presentation. The *Odyssey* Solution 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.

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The *Odyssey* Solution further enables procedures to be observed remotely around the world with high speed Internet access over a hospital VPN even wirelessly using a standard laptop or Windows tablet computer. In addition, physicians are able to utilize the Studio console to deliver Internet broadcasts to drive referrals, collaborate with other *Odyssey* hospitals to share best practices and efficiently build presentations saving considerable time.

Vdrive **Robotic Navigation System**

The *Vdrive* Robotic Navigation System reaches further into the evolution of robotic navigation technologies than any platform before it. More than a robotic catheter manipulator, the *Vdrive* Robotic Navigation System and *Niobe* ES robotic system provide independent remote manipulation of diagnostic catheters and magnetic ablation catheters in a single interface. The *Vdrive* Robotic Navigation System provides breakthrough navigation and stability for diagnostic and ablation devices designed with key features to assist in the delivery of better ablations. Important features include complementing the *Niobe* ES control of catheters for fully remote procedures; enabling fully remote, single operator workflow; and providing robotic control of diagnostic devices independent of magnetic navigation. The *Vdrive Duo* system is an optional expansion of the *Vdrive* hardware that allows control of the *V-loop* device and either *V-CAS* or *V-CAS* Deflect devices in the same procedure, with a single user interface.

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 disposables designed to provide precise remote advancement of proprietary electrophysiology catheters;
- our suite of *Cronus*, *Assert*, *Titan* and *Pegasus* coronary guidewires designed for use in interventional cardiology procedures for the introduction and placement of over-the-wire therapeutic devices, such as stents and angioplasty balloons; and
- Biosense Webster s CARTO® RMT navigation and ablation system, CELSIUS® RMT, NAVISTAR® RMT, NAVISTAR® RMT DS, NAVISTAR® RMT THERMOCOOL® and CELSIUS® RMT THERMOCOOL® Irrigated Tip Diagnostic/Ablation Steerable Tip Catheters co-developed by Biosense Webster and Stereotaxis, as described below.

We believe that we can adapt many of the applicable 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.

In addition to the *Vdrive* and *Vdrive Duo* systems, we also manufacture and market various disposable components which can be manipulated by these systems. These include:

- our *V-CAS* catheter advancement system that controls both the magnetic catheter body and a standard fixed-curve sheath;
- our *V-loop* circular catheter manipulator, which allows the user to control certain circular mapping catheters, such as Biosense Webster s LASSO®2515 or LASSO®2515 NAV Circular Mapping Catheter, and advance, retract, rotate, deflect and adjust loop radius all without leaving the control room; and
- our *V-CAS* Deflect fully integrated catheter advancement system with a robotic deflectable sheath for maximum integration and versatility, allowing users to advance and retract the magnetic catheter body at angles up to 270°.

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Regulatory Approval

We began commercial shipments of our *Niobe* system in 2003, following U.S. and European regulatory clearance of its core components. We have received regulatory clearance, licensing and/or CE Mark approvals necessary for us to market the *Niobe* Robotic Magnetic Navigation System, the *Cardiodrive* automated catheter advancement system, and various disposable interventional devices in the U.S., Canada, Europe, China, and various other countries.

We have received regulatory clearance, licensing and/or CE Mark approvals necessary for us to market the *Odyssey* Solution in the U.S., Canada, European Union and some other countries and we are in the process of obtaining necessary approvals for extending our markets in other countries.

We have received the CE Mark that allows us to market the *Vdrive Duo*, *V-loop*, *V-CAS* and the *V-CAS* Deflect devices in Europe. In addition, we have received licensing to market the *V-loop* and *V-CAS* devices in Canada. We are in the process of obtaining the necessary clearance for the *V-loop* device in the United States.

We have received Food and Drug Administration (FDA) clearance and the CE Mark necessary for us to market our suite of *Cronus*, *Assert*, *Titan* and *Pegasus* coronary and RF *PowerAssert* Peripheral guidewires in the U.S. and Europe. We continue to seek approvals and clearances to market our products as appropriate.

Biosense Webster has received FDA approval, Chinese SFDA 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 8mm Navistar RMT DS Diagnostic/Ablation Steerable Tip Catheter, and the 3.5mm NAVISTAR® RMT THERMOCOOL® Irrigated Tip Catheter. In addition, Biosense Webster has received FDA approval and CE Mark for the 3.5mm CELSIUS® 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. See Strategic Alliances Disposable Devices Alliance below for a description of our arrangements with Biosense Webster.

FINANCIAL INFORMATION ABOUT GEOGRAPHIC AREAS

Our total U.S. revenue was $23.9 million, $28.8 million, and $22.3 million for the years ended December 31, 2011, 2010, and 2009, respectively. Our total international revenue was $18.0 million, $25.2 million and $28.8 million for the years ended December 31, 2011, 2010, and 2009, respectively.

CLINICAL APPLICATIONS

We have focused our clinical and commercial efforts on applications of the *Epoch* Solution primarily in electrophysiology procedures for the treatment of arrhythmias and secondarily in complex interventional cardiology procedures for the treatment of coronary artery disease. Our system potentially has broad applicability in other areas, such as structural heart repair, interventional neurosurgery, interventional neuroradiology, peripheral vascular, renal denervation, 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. Over 4.3 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

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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 payors 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 more than 3,000 interventional labs around the world are currently capable of conducting electrophysiology procedures. Approximately 500,000 electrophysiology procedures are performed annually worldwide, and procedure growth rate is 9% annually.

We believe the *Epoch* Solution 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.

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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

More than 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 one half 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 believe well over 10,000 interventional labs worldwide are currently capable of conducting interventional cardiology. Approximately 4 million interventional cardiology procedures are performed annually in the U.S. alone. 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.

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 fetal interventions.

STRATEGIC ALLIANCES

We have entered into strategic alliances with technology leaders in the global interventional market, including Siemens, Philips, and Biosense Webster, that we believe 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 strategic alliance 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 alliances; and
- enable operational flexibility by not requiring us to provide any the parties in our strategic alliances with a right of first refusal in the event that another party wants to acquire us or with board representation where a strategic alliance has made a debt or equity investment in us.

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Imaging Alliances

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 equipment maintenance and support services for our products directly to our customers. 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 advanced user interface for the *Niobe* ES system.

In December 2010, Siemens Healthcare was named a non-exclusive, global reseller starting in the U.S., EU and Canada for Stereotaxis *Odyssey* Interface with Cinema. Siemens can promote and sell *Odyssey* Interface with Cinema connected to Siemens large display labs, delivering a fully integrated, real-time information management solution. The combined offering enables consolidated information from Siemens large display labs to be remotely viewed live or played back after procedures from a comprehensive case archive enhancing staff training and patient care.

Philips Alliance. We have successfully integrated our *Niobe* system with Philips digital x-ray fluoroscopy system. We also have an agreement under which we 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 Alliance

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. Under an amendment to this agreement in 2008, 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. These amounts plus interest accrued thereon had been repaid as of December 31, 2011.

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. These royalties are used to make payments under the debt agreement with Cowen Healthcare Royalty Partners II, L.P. as discussed in Item 7. Under the alliance with Biosense Webster, we agreed to certain restrictions on our ability to co-develop and distribute catheters competitive with those we are developing with Biosense Webster and we 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.

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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. If a change of control of the Company occurs after Biosense Webster has received approval from the U.S. FDA for atrial fibrillation indication for the NAVISTAR® RMT THERMOCOOL® catheter, the Company would be required to pay an additional $10 million fee to Biosense Webster, and termination of the agreement by either party would not be effective until two years after the change of control. 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 January 2011, we executed an amendment, effective December 2010, to our agreement with Biosense Webster to extend the development and distribution alliance related to certain catheters that have been developed under previous collaboration activities between the Company and Biosense Webster on an exclusive basis until December 15, 2015 and thereafter on a nonexclusive basis until December 31, 2018. Biosense Webster s rights to distribute such products in Japan is extended on an exclusive basis to the later of December 31, 2017 or five years after the date of approval of the applicable product for sale in Japan and on a nonexclusive basis to the later of December 31, 2020 or eight years after the date of approval of the applicable product for sale in Japan. Additionally, both companies agreed to expand the product offering covered by the agreement to include a next generation irrigated magnetic catheter, which will integrate technological advancements from both companies.

In May 2011, the Company entered into a new agreement, under which the Company has granted Biosense Webster global, non-exclusive rights to resell Stereotaxis *Odyssey* products, including *Odyssey* Vision and *Odyssey Cinema* systems.

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*, *Odyssey*, and *Vdrive* systems through ongoing product and software development; and