Stereotaxis, Inc.
Form 10-K
March 13, 2009
Table of Contents

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, 2008

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 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 Exchange Act). Yes ¨ No x

The aggregate market value of the registrants 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, 2008) was approximately $149 million.

The number of outstanding shares of the registrant s common stock on February 28, 2009 was 42,046,241.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Registrant s next Annual Meeting of Stockholders to be held on May 21, 2009 are incorporated by reference into Part III of this Form 10-K.

Table of Contents

STEREOTAXIS, INC.

INDEX TO ANNUAL REPORT ON FORM 10-K

Table of Contents

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;
- 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.

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 new therapeutic solutions and enhancing the efficiency and efficacy of existing catheter-based, or interventional, procedures. Our Niobe® system allows physicians to more effectively navigate proprietary catheters, guidewires and other delivery devices, both our own and those we are co-developing with strategic partners, through the blood vessels and chambers of the heart to treatment sites in order to effect treatment. This is achieved using computer-controlled, externally applied

Table of Contents

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. Our Odyssey Total Information 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 and represents an important advance supporting efficient and effective information management and physician collaboration.

Enhancements to the Odyssey Total Information Solution currently in development would allow physicians to record, archive and review procedures and collaborate with other Odyssey users either with or without a Niobe system. We believe that our Odyssey Total Information 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. As of December 31, 2008, we had recognized revenue on 118 Niobe systems and 14 Odyssey systems and had approximately $69 million of backlog, consisting of outstanding purchase orders and other commitments for these systems. As of December 31, 2007, we had backlog of approximately $58 million. Of the December 31, 2008 backlog, we expect approximately 50% to be recognized as revenue over the course of 2009. 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 preponderance of the Stereotaxis installations worldwide are intended for use in electrophysiology.

Our Niobe system consists of the following proprietary components:

- our Niobe Magnetic Navigation System, which utilizes permanent magnets to navigate catheters, guidewires and other delivery devices through complex paths in the blood vessels and chambers of the heart to carry out treatment;

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

- our Cardiodrive® automated catheter advancement system, which is used to remotely advance and retract the catheter in the patient s heart; and

In addition to the Niobe system and its components, Stereotaxis also has developed the Odyssey Total Information Solution, which consolidates the multiple sources of diagnostic and imaging information found in the interventional lab into a large-screen user interface with single mouse control, which can be connected via a

Table of Contents

private network line to other interventional labs or to a remote clinical call center. The system also features a remote viewing and recording capability, called Odyssey Cinema , that simultaneously captures procedure data from multiple sources. This tool includes an archiving capability that will allow 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 Total Information 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 often desire the benefits of Odyssey s consolidated large screen single mouse control, and potential real-time access to networked call center support that we believe can improve clinical workflows and related efficiencies.

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

We currently have regulatory clearance to market our Niobe Magnetic Navigation System, our Navigant advanced user interface, our Cardiodrive automated catheter advancement system, our Odyssey workstation 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.

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 initially 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. Over four 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 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.

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,

Table of Contents

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 Total Information 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 THE CATH LAB

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. Manual control of the working tip becomes increasingly difficult as more turns are required to navigate the instrument to the treatment site, as the blood vessels to be navigated become smaller and less accessible or more obstructed, and as greater precision is required to safely carry out therapy at 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;

Table of Contents

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 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 enabling new treatments for major diseases and enhancing the treatment of more complex existing cases. 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. To treat congestive heart failure, precise navigation within the coronary venous system for optimal placement of pacemaker leads is required. 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 treatments once these sites are reached.

Improve clinical workflow and information management. The Odyssey Total Information Solution will improve clinical workflow and information management efficiency by consolidating 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 workstation. Odyssey Cinema will 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 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

Table of Contents

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 the Niobe system can reduce complex interventional 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 interventional 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 interventionalists, 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 18,000 procedures and the incidence of all reported major adverse cardiac events associated with the use of the system for all procedures is less than 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 physician, who stands 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.

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, which 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 interventional cardiology and 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

Table of Contents

x-ray fluoroscopy systems. In addition, we have integrated the Niobe 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 system are identified and described below:

Niobe Magnetic Navigation System. Our Niobe Magnetic Navigation System utilizes two permanent magnets mounted on articulating or pivoting arms that are enclosed within a stationary housing, with one magnet on either side of the patient table, inside the interventional lab. 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 interventional cardiologists and electrophysiologists and allows these 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 designed for interventional cardiology or electrophysiology, or both, as well as optional application software tailored for specific clinical procedures.

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

Odyssey Total Information Solution.

The Odyssey Total Information Solution consolidates the multiple sources of diagnostic and imaging information found in the interventional labs into a networked large-screen user interface with single mouse control. Odyssey Cinema is designed to simultaneously capture procedure data from multiple sources and includes an archiving capability that will allow clinicians to store and replay procedures. This information will be accessible from locations throughout the hospital local area network via Odyssey Connect and over the global Odyssey network providing physicians with a tool for clinical collaboration, remote consultation and training.

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 received regulatory marketing clearance, licensing and CE Mark approvals necessary for us to market the Odyssey workstation in the U.S. and Europe and are in the process of obtaining necessary approvals for Odyssey Cinema and Odyssey Connect in the U.S. and Europe and for all of our products in various other countries.

Table of Contents

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 automated catheter advancement disposable used to provide precise remote advancement of proprietary 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 biventricular pacing leads used in cardiac resynchronization therapy for treating congestive heart failure as well as stents and angioplasty balloons;
- our Tangent® electrophysiology mapping catheter used to locate aberrant electrical signals in the heart;
- our Helios II® electrophysiology ablation catheter used for certain arrhythmia treatments; 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. In addition, we have received FDA clearance for our Tangent mapping catheter in the U.S. 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. We are also developing disposable interventional devices for other applications. 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 initially 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. Over four million people in the U.S. currently suffer from the resulting abnormal

8

Table of Contents

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 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,

Table of Contents

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. If the blockage is in an easy to reach location, it can typically be treated by pushing a guidewire through the portion of the vessel that is blocked with plaque, expanding a small balloon to compress the plaque against the artery walls in order to open the artery, and then finally deploying a stent, which is a small metal scaffold, to help keep the artery open. If a blockage is located within tortuous vasculature, however, the physician must navigate the guidewire through a series of sharp turns, making the blockage very difficult to reach. Even if such lesions are reached, delivering a balloon or stent to the treatment site through tortuous anatomy can be difficult. In addition, 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 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. Complex partial occlusions, complex non-chronic total occlusions and chronic total occlusions. Treatment of these complex lesions is generally more problematic due to the difficulty in steering and pushing a guidewire through them. 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. The ability to cross complex lesions such as chronic total occlusions has grown increasingly important due to the effectiveness of drug eluting stents in treating 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. Some interventional procedures require physicians to navigate a disposable interventional device through a series of sharp turns in the patient s vasculature. Navigating through

Table of Contents

tortuous anatomy using manual interventional techniques can be very time consuming and physicians often cannot reach the lesion or manipulate the balloon or stent across the lesion once it is reached. Each turn in the vessel diminishes the control the physician has over the steering of the wire tip. 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.

Stent Placement. The likelihood of restenosis, or re-blockage of cleared arteries, is greatly increased in multi-vessel diseased patients whose blockages are typically more diffusely distributed throughout longer lengths of the vessel. As a result, these patients are often referred to invasive bypass surgery. We expect that drug-eluting stents, which reduce the likelihood of restenosis, may enable patients with more complex lesions to be treated interventionally rather than with bypass surgery. In order to treat this new group of patients, however, physicians will need to place stents in more challenging or remote locations. By using externally applied magnetic fields to precisely place a stent through a patient s vasculature, we believe that our system allows these devices to be more easily deployed in these difficult to reach treatment sites.

Small Vessels. Based on our interpretation of various medical studies, we have determined that diabetic patients usually comprise about 20 to 30% of U.S. hospital s interventional procedure volume. These patients generally have smaller vessels, which often contain longer lesions with more diffusely distributed blockages, as well as tortuous anatomy, making guidewire navigation and stent delivery extremely difficult. We believe that these patients can benefit significantly from the improved disposable interventional device navigation enabled by our system.

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 estimated that PAD currently affects 8 to 12 million Americans, making it the third most prevalent disease in the U.S. This number is expected to grow to over 17 million in 2010 and 22 million in 2020. It is primarily a disease of the elderly; roughly 20% of people over the age of 70 suffer from it. With people living longer and increasingly indulging in unhealthy dietary habits, it is not difficult to account for the heightened prevalence of this disease.

PAD is associated with several significant co-morbidities. Atherosclerosis is a systemic condition; therefore, it affects the coronary arteries as well. A significant number of people with PAD also suffer from Coronary Artery Disease, which means that they are at serious risk of myocardial infarction (heart attack), in addition to the consequences of PAD. Stroke is also a common morbidity for people with PAD. If the carotid artery (the artery that supplies blood to the brain) becomes occluded, stroke can occur, leading to serious disability and possibly, death. Diabetes mellitus is a very serious co-morbidity for PAD and diabetics are significantly more likely to have PAD compared with the general population. Additionally, having diabetes correlates to a poorer prognosis for PAD. PAD can progress to Critical Limb Ischemia (CLI), in which significant tissue death is taking place. Rest pain, ulcerations, and gangrene can result, requiring amputation of the affected limb.

Chronic Total Occlusions (CTO) 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. These blockages consist largely of plaque that has been deposited on the lining of the artery wall, and which over time has become calcified. The calcification makes the blockage very rigid, and causes the artery to lose elasticity. The artery s ability to contract and expand is thus diminished, resulting in a narrowing of the artery lumen and a reduction in the amount of blood that can flow through it. CTOs, which are often a factor in peripheral vascular disease, pose a

Table of Contents

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 CTOs, by providing precise magnetic tip control in combination with 3-D image reconstruction of these complex vascular lesions.

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. Traditional treatment for brain aneurysms involves highly invasive open brain surgery. Interventional procedures have evolved for filling the aneurysm with platinum micro-coils delivered to the site in order to reduce blood flow within the aneurysm. We believe that the Niobe system has the potential to be adapted for use in the interventional treatment of brain aneurysms, by enabling physicians to reach a broader range of aneurysm targets, and by making procedure times for these cases more predictable.

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 have successfully conducted what we believe to be the first human surgical procedures ever conducted using computerized control in our neurosurgery program by navigating complex pathways through brain tissue to multiple target sites. The Niobe system also has applicability in the respiratory, gastro-intestinal and genito-urinary systems, for diagnosis and treatment of diseases affecting the lungs, prostate, kidneys, colon and small intestine. 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 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, most 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,

Table of Contents

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 each 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 the Company and Biosense Webster amended their agreement 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.

Our agreement with Biosense Webster relating to exclusive integration with their 3D localization system expires in May 2009 and our agreement relating to exclusive development and sale of magnetically enabled

Table of Contents

non-irrigated catheters expires in December 2009. The Company is in discussion with Biosense Webster to determine the ongoing relationship between Stereotaxis and Biosense Webster as it relates to future co-development, integration, and distribution of the 3D localization system and non-irrigated magnetically enabled mapping and ablation catheters.

In July 2008, the Company and Biosense Webster reached an agreement under which Biosense Webster advanced the Company $10 million and allowed the Company 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 the Company on the sale of magnetically enabled co-developed catheters. If not fully recouped, any remaining advances will be due to Biosense on December 31, 2011.

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 has contracted with Siemens to provide worldwide maintenance and support services to our customers for our integrated products. This allows us to leverage Siemens extensive maintenance and support infrastructure for direct, on-site technical support activities, including its call center, customer support engineers and service parts logistics and delivery. It also provides a single point of contact for the customer and 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.

Table of Contents

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.

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