Stereotaxis, Inc.
Form 10-K
March 27, 2014

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, 2013

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 001-36159

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

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, 2013) was approximately $6.8 million.

The number of outstanding shares of the registrant s common stock on February 28, 2014 was 19,308,125.

DOCUMENTS INCORPORATED BY REFERENCE

STEREOTAXIS, INC.

INDEX TO ANNUAL REPORT ON FORM 10-K

ITEM 1. BUSINESS

In this report, Stereotaxis, the Company, Registrant, we, us, and our refer to Stereotaxis, Inc. and its wholly-owned subsidiaries. *Epoch Odyssey*®, *Odyssey Cinema* , *Vdrive* , *Vdrive Duo* , *V-CAS* , *V-Loop* , *V-Sono* , *QuikCAS* , *QuikDrive* , *CardioAssert* , *Titan*® and *Pegasus* 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 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;

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;

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 robotic systems and instruments for use primarily by electrophysiologists for the treatment of abnormal heart rhythms known as cardiac arrhythmias. We offer our proprietary *Epoch* Solution, an advanced remote robotic navigation system for use in a hospital s interventional surgical suite, or interventional lab . We believe the *Epoch* Solution 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 (*Vdrive* 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 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 expertise 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.

The *Niobe* system is designed primarily for use by interventional electrophysiologists in the treatment of arrhythmias and approximately 1% 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.

The *Niobe* system has been used in more than 66,000 procedures and is supported by more than 200 peer-reviewed publications in leading medical journals such as PACE, Europace, the Journal of the American College of Cardiology and the Journal of Interventional Cardiac Electrophysiology. *Niobe* system revenue represented 23%, 26%, and 19% of revenue for the years ended December 31, 2013, 2012, and 2011, respectively.

Stereotaxis has also developed the *Odyssey* Solution which provides an innovative enterprise solution for integrating, recording and networking interventional lab information within hospitals. The *Odyssey* Solution consists of two lab solutions including *Odyssey* Vision and the *Odyssey Cinema* system. *Odyssey* Vision consolidates all of the lab information from multiple sources, freeing doctors from managing complex interfaces during patient therapy for optimal procedural and clinical efficiency. 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* 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 10%, 14%, and 18% of revenue for the years ended December 31, 2013, 2012, and 2011, respectively.

Our *Vdrive* system provides navigation and stability for diagnostic and therapeutic devices designed to improve interventional procedures. The *Vdrive* 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 (*V-Loop*, *V-Sono*, *V-CAS*, and *V-CAS* Deflect) 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. 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, 2013, we had approximately $6.8 million of backlog, consisting of outstanding purchase orders and other commitments for these systems. We had backlog of approximately $8.9 million and $20 million as of December 31, 2012 and 2011, respectively. Of the December 31, 2013 backlog, we expect approximately 75% to be recognized as revenue over the course of 2014. 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 *Epoch* Solution is lengthy and generally involves construction or renovation activities at customer sites. Consequently, revenues and/or orders resulting from sales of our *Epoch* Solution can vary significantly from one reporting period to the next.

We have alliances with Siemens AG Medical Healthcare, Philips Healthcare and Biosense Webster, a subsidiary of Johnson & Johnson. Through these alliances, we integrate our *Niobe* system with Siemens and Philips market-leading cath lab imaging systems 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-marketing of integrated systems.

BACKGROUND

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.

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. 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 electrophysiology and interventional cardiology persist. 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. 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.

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 that the *Odyssey* Solution will provide physicians the ability to enhance procedure workflow, more effectively manage their interventional procedures, and collaborate with other physicians. We believe the *Vdrive* system will provide physicians with the ability to navigate and control diagnostic catheters and sheaths from either the procedure room or the nearby control room, which will facilitate the performance of procedures remotely while further improving efficiency and efficacy of the procedure.

CURRENT CHALLENGES IN INTERVENTIONAL MEDICINE

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

Limitations of Instrument Control

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

Lack of Integration of Information Systems

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

real-time x-ray fluoroscopy 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. 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 atrial fibrillation, ventricular tachycardia and cardiac chronic total occlusions 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. Conversely, 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.

Enhance patient and physician safety. The *Niobe* system has been used in more than 66,000 procedures and the incidence of all reported major adverse cardiac events associated with the use of the system for all procedures is approximately 0.3%. 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.

Improve clinical workflow and information management. Complex ablation procedures involve several sources of information, which conventionally require a physician to mentally integrate and process large quantities of information from different sources in real time, often from separate user interfaces. Sources of information include real time x-ray and/or ultrasound images, real time location sensing systems providing the 3-D location of a catheter tip, pre-operative map of the electrical activity of the heart, real time recording of electrical activity of the heart, and temperature feedback from an ablation catheter. The *Odyssey* Solution improves 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 and keyboard control.

Enhance hospital efficiency by reducing and standardizing procedure times, disposables utilization and staffing needs. Conventional 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.

Improve 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.

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.

OUR PRODUCTS

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

Our proprietary *Niobe* ES system is the latest generation of the *Niobe* system, which 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 an adjacent room and outside the x-ray fluoroscopy field. The *Niobe* 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* system with Siemens and with Philips digital x-ray fluoroscopy systems. In addition, we have integrated the *Niobe* system with Biosense Webster s 3D catheter location sensing technology 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® Robotic Magnetic Navigation System. Our *Niobe* system utilizes two permanent magnets mounted on articulating and pivoting arms that are enclosed within a stationary housing, with one magnet on either side of the patient table. These magnets generate magnetic navigation fields that are less than 10% of the strength of fields typically generated by MRI equipment and therefore require significantly less shielding, and cause significantly less interference, than MRI equipment. The *Niobe* system is indicated for use in cardiac, peripheral and neurovascular applications.

Cardiodrive® Automated Catheter Advancement System. As the physician conducts the procedure from the adjacent control room, the *Cardiodrive Automated Catheter Advancement System (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. 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.

***Vdrive* Robotic Navigation System**

The *Vdrive* system reaches further into the evolution of electrophysiology robotic navigation technologies than any platform before it. More than a robotic catheter manipulator, the *Vdrive* system and *Niobe* ES robotic system provide independent remote manipulation of diagnostic catheters and magnetic ablation catheters in a single interface. The *Vdrive* 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 with 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 any two of the four available disposable options (*V-Loop*, *V-Sono, V-CAS, and V-CAS* Deflect).

Disposables and Other Accessories

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

- our *QuikCAS* automated catheter advancement disposables designed to provide precise remote advancement of proprietary electrophysiology catheters;

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; and

Our suite of *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.

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 (*V-CAS* system) that controls both the magnetic catheter body and a standard fixed-curve sheath;

our *V-CAS* Deflect fully integrated catheter advancement system (*V-CAS* Deflect 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°;

our *V-Loop* circular catheter manipulator (*V-Loop* device), which allows the user to control certain circular mapping catheters, such as Biosense Webster s LASSO®2515 or LASSO®2515 NAV Circular Mapping Catheter, advance, retract, rotate, deflect and adjust loop radius, and hold the catheter position against the tissue to optimize electrograms; and

our *V-Sono* ICE catheter manipulator (*V-Sono* device) that allows a single physician to manipulate BWI SoundStar and AcuNav catheters and CARTO 3 System from the control room, store and recall previous positions and automatically sweep over an area of interest with adjustable speed and angle all without leaving the control room.

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* system, the *Cardiodrive*, and various disposable interventional devices in the U.S., Canada, Europe, China, Japan, 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, China 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* and *Vdrive Duo* systems with the *V-CAS, V-CAS* Deflect, *V-Loop* and *V-Sono* devices in Europe. In addition, we have received licensing to market the *Vdrive* and *Vdrive Duo* systems with the *V-CAS, V-CAS* Deflect, and *V-Loop* devices in Canada and have applied for a license of the *V-Sono* device. We have received regulatory clearance that allows us to market the *Vdrive* with *V-Sono* device in the United States. 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 *Titan* and *Pegasus* coronary peripheral guidewires in the U.S. and Europe.

Biosense Webster has received FDA approval, Chinese CFDA 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. Our alliance with Biosense Webster provides for co-development of 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 $24.0 million, $27.0 million, and $23.9 million for the years ended December 31, 2013, 2012, and 2011, respectively. Our total international revenue was $14.0 million, $19.5 million and $18.0 million for the years ended December 31, 2013, 2012, and 2011, 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 three million people in the United States and over seven 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 600,000 electrophysiology procedures are performed annually worldwide, and procedure growth rate is 10% 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. 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.

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 catheter contact to be consistently 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 of 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.

Imaging Alliances

Siemens and Philips Alliances. We have successfully integrated our *Niobe* system with both Siemens and Philips digital fluoroscopy systems to provide advanced interventional lab visualization and instrument control through user-friendly computerized interfaces. We also coordinate our sales efforts with Siemens and Philips to co-market integrated systems at leading hospital sites in the U.S., Europe and in Asia. 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.

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 net revenues from sales of the co-developed catheters. These royalties are used to make payments under the debt agreement with Healthcare Royalty Partners II, L.P. (formerly 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 of magnetically enabled interventional disposable devices in 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 either party terminates the agreement under this provision, we must pay a termination fee to Biosense Webster equal to 5% of our total equity value in the change of control transaction, up to a maximum of $10 million. If a change of control of Stereotaxis occurs after Biosense Webster has received approval from the U.S. FDA for atrial fibrillation indication for the NAVISTAR® RMT THERMOCOOL® catheter, we 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 Biosense Webster and us on an exclusive basis until December 31, 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. The catheter most recently developed under the collaboration activities with Biosense Webster was approved for sale in Japan on March 22, 2013. 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, we entered into a new agreement, under which we 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* system, *Odyssey* Solution, and *Vdrive* system 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 teaching hospitals, which serve to increase our access to world class physicians and to expand our name recognition in the medical community. Our research and development expenses for the years ending December 31, 2013, 2012, and 2011, were $5.7 million, $8.4 million, and $12.9 million, respectively.

CUSTOMER SERVICE AND SUPPORT

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

Our back-up technical support includes a combination of on-line, telephone and on-site technical assistance services 24 hours a day, seven days a week. We have also hired service and support engineers with networking and medical equipment expertise, and have outsourced a portion of our installation and support services. We offer 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 customers worldwide.

MANUFACTURING

***Niobe*, *Odyssey*, and *Vdrive* Systems**

Our manufacturing strategy for our *Niobe* system, *Vdrive* system and *Odyssey* Solution is to sub-contract the manufacture of major subassemblies of our system to maximize manufacturing flexibility and lower fixed costs. Our current manufacturing strategy for *Vdrive* system is to build all subassemblies in-house. We maintain quality control for all of our systems 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 work closely with our contract manufacturers and have strong relationships with component suppliers. We have entered into manufacturing agreements to provide high volume capability for devices other than catheters.

Software

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

General

Our manufacturing facilities operate under processes that meet the FDA s requirements under the Quality System Regulation, or QSR. 2011 FDA Establishment Inspections of our Maple Grove, Minnesota facility noted no observations. Our ISO registrar and European notified body has audited our facilities annually since 2001 and found the facilities to be in compliance with requirements. The initial ISO 9001 certification was issued in January 2002 and the most recent ISO 13485 certificate was issued in 2013.

SALES AND MARKETING

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

Our sales and marketing efforts include two important elements: (1) selling *Niobe* system, *Odyssey* Solution, and *Vdrive* system directly and through distributors; and (2) leveraging our installed base of systems to drive recurring sales of disposable interventional devices, software and service.

REIMBURSEMENT

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

In countries outside the United States, reimbursement is obtained from various sources, including governmental authorities, private health insurance plans, and labor unions. In most foreign countries, private insurance systems may also offer payments for some therapies. Additionally, health maintenance organizations are emerging in certain European countries. In the European Union, we believe that substantially all of the procedures, whether commercial or in clinical trials, conducted with the *Niobe* system or *Vdrive* system has been reimbursed to date. In Japan, the Ministry of Health, Labor and Welfare (MHLW) has classified the *Niobe* system as a C2 medical device (the highest reimbursement category) on an interim basis. The MHLW will establish a permanent technical fee for procedures using the *Niobe* system during its biennial review of insurance reimbursement pricing for C2 devices which is estimated to occur around April 1, 2014. In other foreign countries, we may need to seek international reimbursement approvals, and we do not know if these required approvals will be obtained in a timely manner or at all.

See Item 1A Risk Factors for a discussion of various risks associated with reimbursement from third-party payors.

INTELLECTUAL PROPERTY

Our strategy is to patent the technology, inventions and improvements that we consider important to the development of our business. As a result, we have an extensive patent portfolio that we believe protects the fundamental scope of our technology, including our magnet technology, navigational methods, procedures, systems, disposable interventional devices and our 3D integration technology. As of December 31, 2013, we had 114 issued U.S. patents, 3 co-owned U.S. patents and 4 licensed-in U.S. patents. In addition, we had 22 pending U.S. patent applications and 2 co-owned U.S. patent applications. As of December 31, 2013 we had 34 issued foreign patents and 19 owned Foreign Patent Applications. We also have a number of invention disclosures under consideration and several applications that are being prepared for filing.

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

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

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

We seek to protect our proprietary information by requiring our employees, consultants, contractors, outside parties and other advisers who are engaged in development work for us to execute nondisclosure and assignment of invention agreements upon commencement of their employment or engagement, through which we seek to protect our intellectual property. These agreements to protect our unpatented technology provide only limited and possibly inadequate protection of our rights. Third parties may therefore be able to use our unpatented technology, reducing our ability to compete. In addition, employees, consultants and other parties to these agreements may breach them and adequate remedies may not be available to us for their breaches. Many of our employees were previously employed at universities or other medical device companies, including potential competitors. We could in the future be subject to claims that these employees or we have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and divert the attention of management and key personnel from our business operations. We also generally seek confidentiality agreements from third parties that receive our confidential data or materials.

Intellectual property risks and uncertainties are further discussed in Item 1A Risk Factors in this annual report.

COMPETITION

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

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

We also face competition from companies that are developing new approaches and products for use in interventional procedures, including robotic approaches that are directly competitive with our technology. Some of these companies may have an established presence in the field of interventional cardiology, including the major imaging, capital equipment and disposables companies that are currently selling products in the interventional lab. We are aware of one public company that has commercialized a catheter delivery system which has been cleared by the FDA for mapping procedures only. In addition, we are aware of one private company with an electro-magnetic catheter delivery system that has received CE Mark approval in Europe. We also face competition from companies who currently market or are developing non-radio frequency ablation therapy, drugs, gene or cellular therapies to treat the conditions for which our products are intended.

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

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

GOVERNMENT REGULATION

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

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

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

U.S. Food and Drug Administration Regulation

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

Our medical devices are categorized under the statutory framework described in the FD&C Act. This framework is a risk-based system which classifies medical devices into three classes from lowest risk (Class I) to highest risk (Class III). In general, Class I and II devices are either exempt from the need for FDA clearance or cleared for marketing through a premarket notification, or 510(k), process. Our Class II devices subject to 510(k) requirements provide diagnostic information or are considered to be general tools, such as our *Niobe* system and our suite of guidewires, which have utility in a variety of interventional procedures. Our Class III therapeutic devices are subject to the premarket approval, or PMA, process. If clinical data are needed to support clearance, approval or a marketing application for our devices, generally, an investigational device exemption, or IDE, is assembled and submitted to the FDA. The FDA reviews and must approve the IDE before the study can begin. In addition, the study must be approved by an Institutional Review Board covering each clinical site involved in the study. When all approvals are obtained, we initiate a clinical study to evaluate the device. Following completion of the study, we collect, analyze and present the data in an appropriate submission to the FDA (i.e. in support of either a 510(k) or PMA).

Under the 510(k) process, the FDA determines whether or not the device is substantially equivalent to a previously marketed predicate device. In making this determination, the FDA compares the new device to the predicate device and if the two devices are substantially equivalent , the device may be cleared for marketing and introduction into domestic commerce. To establish substantial equivalence, the applicant must show that the new device has the same intended use as the predicate device, and it either has the same technological characteristics or has been shown to be equally safe and effective and does not raise different questions of safety and effectiveness as compared to the predicate device.

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

Further, we are subject to, at any time, periodic and routine inspection by the FDA to ensure compliance with the QSR requirements. Companies deemed non-compliant with the QSR in part or in full may receive a Warning Letter and/or be subject to other enforcement actions.

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

For our 510(k) devices, we design the submission to cover multiple models or variations in order to minimize the number of submissions. For our PMA devices, we often rely upon the PMA approvals of our strategic partners to utilize the PMA supplement regulatory path rather than pursue an original PMA. Because of the differences in the amount of data and numbers of patients in clinical trials, a PMA supplement process is often much simpler than that required for approval of an original PMA.

After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR, labeling regulations, the FDA s general prohibition against promoting products for unapproved or off-label uses, the Medical Device Reporting regulation (which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and the Reports of Corrections and Removals regulation (which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act). FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

fines, injunctions, and civil penalties;

recall or seizure of products;

operating restrictions, partial suspension or total shutdown of production;

refusing requests for 510(k) clearance or PMA approval of new products;

withdrawing 510(k) clearance or PMA approvals already granted; and

criminal prosecution.

International Regulation

In order for us to market our products in other countries, we must obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. These regulations, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. Failure to obtain regulatory approval in a timely manner and to meet all local requirements including language and specific safety standards in any foreign country in which we plan to market our products could prevent us from marketing products in such countries, limit our ability to generate revenue, or subject us to sanctions and fines.

The primary regulatory environment in Europe is that of the European Union, which consists of 28 countries encompassing most of the major countries in Europe. The European Union requires that manufacturers of medical products obtain the right to affix the CE Mark to their products before selling them in member countries of the European Union. The CE Mark is an international symbol of adherence to quality assurance standards and compliance with applicable medical device directives. In order to obtain the right to affix the CE Mark to products, a manufacturer must obtain certification that its processes meet certain quality standards. Compliance with the Medical Device Directive, as certified by a recognized European Notified Body, permits the manufacturer to affix the CE Mark on its products and commercially distribute those products throughout the European Union.

If we modify existing products or develop new products in the future, including new devices, we will need to apply for permission to affix the CE Mark to such products. We will be subject to regulatory audits, currently conducted annually, in order to maintain any CE Mark permissions we have already obtained.

To be sold in Japan, most medical devices must undergo thorough safety examinations and demonstrate medical efficacy before they receive regulatory (Shonin) approval. In March 2013, we received Shonin approval from the Japanese Ministry of Health, Labor, and Welfare (MHLW) for our *Niobe* System in Japan.

Anti-Kickback Statute

The federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The definition of remuneration has been broadly interpreted to include anything of value, including for example gifts, discounts,

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the furnishing of supplies or equipment, credit arrangements, payments of cash and waivers of payments. Several courts have interpreted the statute s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Moreover, the intent element has been amended so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it.

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

Government officials have focused their enforcement efforts on marketing of healthcare services and products, among other activities, and recently have brought cases against sales personnel who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business. As part of our compliance program, we have established healthcare compliance policies and procedures and appointed a Clinical Compliance Officer to help ensure compliance with the Anti-Kickback Statute and similar state laws and we train our employees on our healthcare compliance policies.

Beginning in 2013, under the Physician Payment Sunshine Act, we were required to track all transfers of value between Stereotaxis and US physicians and/or teaching hospitals and other relevant healthcare professionals. The first report is due to the federal government in March 2014. This information will be published by the federal government on a searchable website in September 2014.

HIPAA and Other Privacy Laws

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created two federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors.

A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

In addition to creating the two new federal healthcare crimes, HIPAA also establishes uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses. Two standards have been promulgated under HIPAA: the Standards for Privacy of Individually Identifiable Health Information, which restrict the use and disclosure of certain individually identifiable health information, and the Standards for Electronic Transactions, which establish standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures. In addition, these security standards require covered entities to implement certain security measures to safeguard certain electronic health information. In parallel with HIPAA, Stereotaxis is also subject to the Privacy and Security Standards as those Standards are applicable to it under HITECH, the Health Information Technology for Economic and Clinical Health Act, which is Title XIII of the American Recovery and Reinvestment Act.

In addition to federal regulations issued under HIPAA, some states and foreign countries have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. In those cases, it may be necessary to modify our operations and procedures to comply with the more

stringent state and foreign laws, which may entail significant and costly changes for us. We believe that we are in compliance with such state and applicable foreign laws and regulations. However, if we fail to comply with applicable state or foreign laws and regulations, we could be subject to additional sanctions.

Federal False Claims Act

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

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

Certificate of Need Laws

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

Employees

As of December 31, 2013, we had 123 employees, 22 of whom were engaged directly in research and development, 48 in sales and marketing activities, 22 in manufacturing and service, 5 in regulatory, clinical affairs and quality activities, 6 in training activities and 20 in general administrative and accounting activities. A significant majority of our employees is not covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

Availability of Information

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

ITEM 1A. RISK FACTORS

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

We may not generate cash from operations or be able to raise the necessary capital to continue operations.

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

- service our debt obligations and meet our financial covenants;
- maintain customer and vendor relationships;
- hire, train and retain employees;
- maintain or expand our operations;
- enhance our existing products or develop new ones; or
- respond to competitive pressures.

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

Our auditors have expressed substantial doubt regarding our ability to continue as a going concern. If we are unable to continue as a going concern, we may be required to substantially revise our business plan or cease operations.

As of December 31, 2013, we had cash and cash equivalents of $13.8 million and working capital of $4.4 million. We incurred operating losses of $8.8 million, $10.6 million, and $31.9 million in 2013, 2012 and 2011, respectively. As a result, our auditors have expressed substantial doubt about our ability to continue as a going concern. Our auditors included an explanatory paragraph regarding our ability to continue as a going concern in their auditors report on our 2011 and 2012 financial statements as well. We cannot assure you that we will be able to obtain sufficient funds from our operating or financing activities to support our continued operations. If we cannot continue as a going concern, we may need to substantially revise our business plan or cease operations, which may reduce or negate the value of your investment. In addition, our continued receipt of an opinion from our auditors that expresses doubt about our ability to continue as a going concern may impair our ability to raise new capital, obtain new customers, and hire and retain employees.

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

We have financed our operations through equity transactions, a financing of our catheter royalty stream under the Healthcare Royalty Partners II, L.P. (formerly Cowen Healthcare Royalty Partners II, L.P.) facility entered into in November 2011, as well as bank and other borrowings. In the third quarter of 2013, we extended our revolving line of credit, which matures on March 31, 2014. In addition, our current borrowing agreements contain various covenants, including financial covenants under our credit agreement with our primary lender. The covenants in these various agreements are similar, but are not identical in all respects. If we violate our covenants, we could be required to repay the indebtedness as to which that default relates. In addition, as a result of various cross-default provisions in these agreements, a violation of the covenants under one or more of such agreements could trigger our obligation to repay all of our existing indebtedness. We could be unable to make these payments, which could lead to insolvency. Even if we are able to make these payments, it will lead to the lack of availability for additional borrowings under our bank loan agreement due to our borrowing capacity. There can be no assurance that we will be able to maintain compliance with these covenants or that we could replace this source of liquidity if these covenants were to be violated and our loans and other borrowed amounts were forced to be repaid.

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

We are highly dependent on the principal members of our management, as well as our scientific and sales staff. Attracting and retaining qualified personnel will be critical to our success, and competition for qualified personnel is intense. We may not be able to attract and retain personnel on acceptable terms given the competition for qualified personnel among technology and healthcare companies and universities. The loss of personnel, in particular senior executives, or our inability to attract and retain other qualified personnel could harm our business and our ability to compete. In addition, the loss of members of our scientific staff may significantly delay or prevent product development and other business objectives. A loss of key sales personnel could result in a reduction of revenue. In addition, if we outsource certain employee functions that were formerly handled in-house, our personnel costs could increase.

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

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

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

Our backlog, which consists of purchase orders and other commitments, is considered by some investors to be a significant indicator of future performance. Consequently, negative changes to this backlog or its failure to grow commensurate with expectations could negatively impact our future operating results or our share price. Our backlog includes those outstanding purchase orders and other commitments that management believes will result in recognition of revenue upon delivery or installation of our systems. We cannot assure you that we will recognize revenue in any particular period or at all because some of our purchase orders and other commitments are subject to contingencies that are outside our control. In addition, these orders and commitments may be revised, modified or cancelled, either by their express terms, as a result of negotiations or by project changes or delays. System installation is by its nature subject to the interventional lab construction or renovation process which comprises multiple stages, all of which are outside of our control. Although the actual installation of our *Niobe* ES system requires only a few weeks, and can be accomplished by either our staff or by subcontractors, successful installation of our system can be subjected to delays related to the overall construction or renovation process. If we experience any failures or delays in completing the installation of these systems, our reputation would suffer and we may not be able to sell additional systems. We have experienced situations in which our purchase orders and other commitments did not result in recognizing revenue from placement of a system with a customer. In addition to construction delays, there are risks that an institution will attempt to cancel a purchase order as a result of subsequent project review by the institution or the departure from the institution of physicians or physician groups who have expressed an interest in the *Epoch* Solution.

In 2013, 2012 and 2011, we experienced decreases in our backlog. These, or similar events, have occurred in the past and are likely to occur in the future, causing delays in revenue recognition or even removal of orders and other commitments from our backlog. Such events would have a negative effect on our revenue and results of operations.

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

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

The rate of technological innovation of our products might not keep pace with the rest of the market.

The rate of innovation for the market in which our products compete is fast-paced and requires significant resources and innovation. If other products and technologies are developed that compete with, or may compete with, the *Niobe*, *Odyssey* and *Vdrive* systems, it could be difficult for us to maintain our advantages associated with being an early developer of this technology. In addition, connectivity with other devices in the electrophysiology lab is a key driver of value. If the Company is not able to continue to commit sufficient resources to ensure that its products are compatible with other products within the electrophysiology lab, this could have a negative impact on revenue.

General economic conditions could materially adversely impact us.

Our operating performance is dependent upon economic conditions in the United States and in other countries in which we operate. The recent economic downturn or the lack of a robust recovery in the United States and in other countries in which we sell our products may cause customers to delay purchasing or installation decisions or cancel existing orders. The *Niobe* ES system, *Odyssey* Solution and *Vdrive* system are typically purchased as part of a larger overall capital project and an economic downturn or the lack of a robust recovery might make it more difficult for our customers, including distributors, to obtain adequate financing to support the project or to obtain requisite approvals. Any delay in purchasing decisions or cancellation of purchasing commitments may result in a decrease in our revenues. Another credit crisis similar to the credit crisis that began in 2008 could further affect our business if key suppliers are unable to obtain financing to manufacture our products or become insolvent and we are unable to manufacture product to meet customer demand. If the United States and global economy continues to be sluggish or deteriorates further for a longer period than we anticipate, we may experience a material negative decrease on the demand for our products which may, in turn, have a material adverse effect on our revenue, profitability, financial condition, ability to raise additional capital and the market price of our stock.

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

We believe that physicians will not use our products unless they determine that the *Niobe* ES system and *Vdrive* system provide a safe, effective and preferable alternative to interventional methods in general use today. If longer-term patient studies or clinical experience indicate that treatment with our system or products is less effective, less efficient or less safe than our current data suggest, our sales would be harmed, and we could be

subject to significant liability. Further, unsatisfactory patient outcomes or patient injury could cause negative publicity for our products, particularly in the early phases of product introduction. In addition, physicians may be slow to adopt our products if they perceive liability risks arising from the use of these new products. It is also possible that as our products become more widely used, latent defects could be identified, creating negative publicity and liability problems for us and adversely affecting demand for our products. If physicians do not use our products, we likely will not become profitable or generate sufficient cash to survive as a going concern.

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

We have collaborated with and are continuing to collaborate with Siemens, Philips, Biosense Webster and other parties to integrate our instrument control technology with their respective imaging products or disposable interventional devices and to co-develop additional disposable interventional devices for use with our *Niobe* system. A significant portion of our revenue from system sales is derived from these integrated products.

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

- we fail to or are unable to maintain adequate compatibility of our products with the most prevalent imaging products or disposable interventional devises expected by our customers for their clinical practice;
- any of our collaboration partners delays or fails in the integration of its technology with our *Niobe* system;
- any of our collaboration partners fails to develop or commercialize the integrated products in a timely manner; or
- we become involved in disputes with one or more of our collaboration partners regarding our collaborations.

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

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

The complexity associated with selling, marketing, and distributing products could impair our ability to increase revenue.

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

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

our inability to accurately forecast future product sales and utilize resources accordingly;

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

unforeseen costs associated with maintaining and expanding an independent sales and marketing organization.

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

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

Our research and development efforts and our marketing strategy depend heavily on obtaining support, physician training assistance, and collaboration from highly regarded physicians at leading commercial and research hospitals, particularly in the U.S. and Europe. If we are unable to gain and/or maintain such support, training services, and collaboration or if the reputation or standing of these physicians is impaired or otherwise adversely affected, our ability to market our products and, as a result, our financial condition, results of operations and cash flow could be materially and adversely affected.

Physicians may not commit enough time to sufficiently learn our system.

In order for physicians to learn to use the *Niobe* system, they must attend structured training sessions in order to familiarize themselves with a sophisticated user interface and they must be committed to learning the technology. Further, physicians must utilize the technology on a regular basis to ensure they maintain the skill set necessary to use the interface. Continued market acceptance could be delayed by lack of physician willingness to attend training sessions, by the time required to complete this training, or by state or institutional restrictions on our ability to provide training. An inability to train a sufficient number of physicians to generate adequate demand for our products could have a material adverse impact on our financial condition and cash flow.

Customers may choose to purchase competing products and not ours.

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

We also face competition from companies that are developing drugs or other medical devices or procedures to treat the conditions for which our products are intended. The medical device and pharmaceutical industries make significant investments in research and development, and innovation is rapid and continuous. Other companies in the medical device industry continue to develop new devices and technologies for manual intervention methods. We are aware of one public company that has commercialized a catheter delivery system which has been cleared by the FDA for mapping procedures only. In addition, we are aware of one private company with an electro-magnetic catheter delivery system that has received CE Mark approval in Europe. We also face competition from companies who currently market or are developing drugs, gene or cellular therapies to treat the conditions for which our products are intended. If these or other new products or technologies emerge that provide the same or superior benefits as our products at equal or lesser cost, it could render our products obsolete or unmarketable. In addition, the presence of other competitors may cause potential customers to delay their purchasing decisions, resulting in a longer than expected sales cycle, even if they do not choose our competitors products. We cannot be certain that physicians will use our products to replace or supplement established treatments or that our products will be competitive with current or future products and technologies.

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

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

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

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

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

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

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

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

We have incurred substantial net losses since inception, and we expect to incur net losses into 2014 as we continue the commercialization of our products. We are still in the process of realizing the full potential of the commercialization of our technology, and will need to continue to make improvements to that technology. Moreover, the extent of our future losses and the timing of profitability are highly uncertain, and we may never achieve profitable operations. If we require more time than we expect to generate significant revenue and achieve profitability, we may not be able to continue our operations. Our failure to achieve profitability could negatively impact the market price of our common stock. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Furthermore, even if we achieve significant revenue, we may choose to pursue a strategy of increasing market penetration and presence or expand or accelerate new product development or clinical research activities at the expense of profitability.

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

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

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

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

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

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

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

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

We purchase the permanent magnets for our *Niobe* ES system from a manufacturer that uses material produced in Japan, and we anticipate that certain of the production work for these magnets will be performed for this manufacturer in China. In addition, our subcontractor purchases magnets for our disposable interventional devices directly from a manufacturer in Japan. Any event causing a significant increase in price or a disruption of imports, including the imposition of import restrictions, could adversely affect our business. The flow of

components from our vendors could also be adversely affected by financial or political instability in any of the countries in which the goods we purchase are manufactured, if the instability affects the production or export of product components from those countries. Trade restrictions in the form of tariffs or quotas, or both, could also affect the importation of those product components and could increase the cost and reduce the supply of products available to us. In addition, decreases in the value of the U.S. dollar against foreign currencies could increase the cost of products we purchase from overseas vendors.

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

We subcontract the manufacture and assembly of components of our *Niobe* ES system, *Odyssey* Solution, and *Vdrive* system, and all of our disposable devices. The products we design may not satisfy all of the performance requirements of our customers and we may need to improve or modify the design or ask our subcontractors to modify their production process in order to do so. In addition, we or our subcontractors may experience quality problems, substantial costs and unexpected delays related to efforts to upgrade and expand manufacturing, assembly and testing capabilities. If we incur delays due to quality problems or other unexpected events, our revenue may be impacted.

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

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

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

Our trade secrets, nondisclosure agreements and other contractual provisions to protect unpatented technology provide only limited and possibly inadequate protection of our rights. As a result, third parties may be

able to use our unpatented technology, and our ability to compete in the market would be reduced. In addition, employees, consultants and others who participate in developing our products or in commercial relationships with us may breach their agreements with us regarding our intellectual property, and we may not have adequate remedies for the breach.

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

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

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

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

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

We may not be able to maintain all the licenses or rights from third parties necessary for the development, manufacture, or marketing of new and existing products.

As we develop additional products and improve or maintain existing products, we may find it advisable or necessary to seek licenses or otherwise make payments in exchange for rights from third parties who hold patents covering certain technology. If we cannot obtain or maintain the desired licenses or rights for any of our products, we could be forced to try to design around those patents at additional cost or abandon the product altogether, which could adversely affect revenue and results of operations. If we have to abandon a product, our ability to develop and grow our business in new directions and markets would be adversely affected. If we do not maintain licenses or exclusivity with suppliers of certain components of our *Odyssey* Solution, competitors may enter the market, negatively impacting our ability to develop and commercialize the *Odyssey* Solution.

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

The *Niobe* system is designed to have the potential for expanded applications beyond electrophysiology and interventional cardiology, including congestive heart failure, structural heart repair, interventional neurosurgery,

interventional neuroradiology, peripheral vascular, pulmonology, urology, gynecology and gastrointestinal medicine. We continue to develop the *Odyssey* Solution and *Vdrive* system for interventional labs that have a *Niobe* system installed as well as those standard interventional labs that do not have a *Niobe* system installed. However, we have limited financial and managerial resources and therefore may be required to focus on products in selected industries and sites and to forego efforts with regard to other products and industries. Our decisions may not produce viable commercial products and may divert our resources from more profitable market opportunities. Moreover, we may devote resources to developing products in these additional areas but may be unable to justify the value proposition or otherwise develop a commercial market for products we develop in these areas, if any. In that case, the return on investment in these additional areas may be limited, which could negatively affect our results of operations.

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

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

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

Our products are medical devices that are subject to extensive regulation in the U.S. and in foreign countries where we do business. Unless an exemption applies, each medical device that we wish to market in the U.S. must be designated as Class I, exempt from premarket approval or notification or first receive either a 510(k) clearance or a pre-market approval, or PMA, from the U.S. FDA pursuant to the Federal Food, Drug, and Cosmetic Act, or FD&C Act. The FDA s 510(k) clearance process usually takes from four to 12 months, but it can take longer. The process of obtaining PMA approval is much more costly, lengthy, and uncertain, generally taking from one to three years or even longer. Although we have 510(k) clearance for many of our products, including disposable interventional devices, and we are able to market these products commercially in the U.S., our business model relies significantly on revenue from disposable interventional devices, some of which may not achieve FDA clearance or approval. We cannot assure you that any of our devices will not be required to undergo the lengthier and more burdensome PMA process. We cannot commercially market any disposable interventional devices in the U.S. until the necessary clearances or approvals from the FDA have been received. In addition, we are working with third parties to co-develop disposable products. In some cases, these companies are responsible for obtaining appropriate regulatory clearance or approval to market these disposable devices. If these clearances or approvals are not received or are substantially delayed or if we are not able to offer a sufficient array of approved disposable interventional devices, we may not be able to successfully market our system to as many institutions as we currently expect, which could have a material adverse impact on our financial condition, results of operations and cash flow.

Furthermore, obtaining 510(k) clearances, PMAs or PMA supplement approvals, from the FDA could result in unexpected and significant costs for us and consume management s time and other resources. The FDA could ask us to supplement our submissions, collect non-clinical data, conduct clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain a 510(k) clearance or PMA or PMA supplement approval, the clearance or approval could be revoked or other restrictions imposed if post-market data demonstrates safety issues or lack of effectiveness. We cannot predict with certainty how, or

when, the FDA will act on our marketing applications. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be adversely affected. Also, a failure to obtain approvals may limit our ability to grow domestically and internationally.

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

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

We may fail to comply with continuing regulatory requirements of the FDA and other authorities and become subject to enforcement action, which may include substantial penalties.

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

Additionally, any modification to an FDA 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance. Modifications to a PMA approved device or its labeling may require either a new PMA or PMA supplement approval, which could be a costly and lengthy process. In addition, if we are unable to obtain on-label approval for key applications, we may face product market adoption barriers that we cannot overcome. In the future, we may modify our products after they have received clearance or approval, and we may determine that new clearance or approval is unnecessary. We cannot assure you that the FDA would agree with any of our decisions not to seek new clearance or approval. If the FDA requires us to seek clearance or approval for any modification, we could be subject to enforcement sanctions and we also may be required to cease marketing or recall the modified product until we obtain FDA clearance or approval which could also limit product sales, delay product shipment and harm our profitability.

In many foreign countries in which we market our products, we are subject to regulations affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. Many of these regulations are similar to those of the FDA or other U.S. regulations. In addition, in many countries the national health or social security organizations require our products to be qualified before procedures performed using our products become eligible for reimbursement. Failure to receive or delays in the receipt of, relevant foreign qualifications could have a material adverse effect on our business, financial condition and results of operations. Due to the movement toward harmonization of standards in the European Union, we expect a changing regulatory environment in Europe characterized by a

shift from a country-by-country regulatory system to a European Union-wide single regulatory system. We cannot predict the timing of this harmonization and its effect on us. Adapting our business to changing regulatory systems could have a material adverse effect on our business, financial condition, and results of operations. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension, or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

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

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

Our manufacturing processes must comply with the FDA s quality system regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging and shipping of our products. The FDA enforces the QSR through inspections. We cannot assure you that we or our suppliers or subcontractors would pass such an inspection. If we or our suppliers or subcontractors fail to remain in compliance with the FDA or EN 13485:2003 standards, we or they may be required to cease all or part of our operations for some period of time until we or they can demonstrate that appropriate steps have been taken to comply with such standards or face other enforcement action, such as a public warning letter. We cannot be certain that our facilities or those of our suppliers or subcontractors will comply with the FDA or EN 13485:2003 standards in future audits by regulatory authorities. Failure to pass such an inspection could force a shutdown of manufacturing operations, a recall of our products or the imposition of other enforcement sanctions, which would significantly harm our revenue and profitability. Further, we cannot assure you that our key component suppliers are or will continue to be in compliance with applicable regulatory requirements and quality standards and will not encounter any manufacturing difficulties. Any failure to comply with the FDA s QSR or EN 13485:2003 by us or our suppliers could significantly harm our available inventory and product sales. Further, any failure to comply with FDA s QSR by us or our suppliers could result in FDA refusing requests for and/or delays in 510(k) clearance or PMA approval of new products.

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

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

loss of revenue;

delay in market acceptance of our products;

damage to our reputation;

additional regulatory filings;

product recalls;

increased service or warranty costs; and/or

product liability claims relating to the software defects.

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

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

- the federal healthcare program Anti-Kickback Law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us if we provide coding and billing advice to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any health care benefit program or making false statements relating to health care matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and the applicable Privacy and Security Standards of HITECH, the Health Information Technology for Economic and Clinical Health Act, which is Title XIII of the American Recovery and Reinvestment Act;

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;

- federal self-referral laws, such as the Stark Anti-Referral Law, which prohibits a physician from making a referral to a provider of certain health services with which the physician or the physician s family member has a financial interest;

- federal and state Sunshine laws, which require manufacturers of certain medical devices to collect and report information on payments or transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members; and

- regulations pertaining to receipt of CE mark for our products marketed outside of the United States and submission to periodic regulatory audits in order to maintain these regulatory approvals.

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

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Healthcare policy changes, including legislation enacted in 2010, may have a material adverse effect on us.

In response to perceived increases in health care costs in recent years, there have been and continue to be proposals by the Obama administration, members of Congress, state governments, regulators and third-party payors to control these costs and, more generally, to reform the U.S. healthcare system.

In March 2010, the President signed into law the Patient Protection and Affordable Care Act (PPACA). Among other things, the law imposes a tax on medical device manufacturers and producers equal to 2.3% of the sales price for all sales beginning January 1, 2013. This excise tax applies to the majority of our products sold within the United States. We expect that the PPACA could have a material adverse effect on our industry generally and our ability to successfully commercialize our products or could limit or eliminate our spending on certain development projects.

On August 2, 2011, the President signed into law the Budget Control Act of 2011, which created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee was charged with identifying a reduction of at least $1.2 trillion for the years 2013 through 2021. The Committee did not achieve this target by the imposed deadline, triggering the legislation s automatic reduction to several government programs. Included in the automatic reduction are aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013.

The taxes imposed by the PPACA, the expansion in the government s role in the U.S. healthcare industry, and other healthcare reform measures at the federal and state level that may be adopted in the future could have a material, negative impact on our results of operations and our cash flows.

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

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

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

We expect that U.S. hospitals will continue to bill various third-party payors, such as Medicare, Medicaid and other government programs and private insurance plans, for procedures performed with our products, including the costs of the disposable interventional devices used in these procedures. If in the future our disposable interventional devices do not fall within U.S. reimbursement categories and our procedures are not reimbursed, or if the reimbursement is insufficient to cover the costs of purchasing our system and related disposable interventional devices, the adoption of our systems and products would be significantly slowed or halted, and we may be unable to generate sufficient sales to support our business. Our success in international markets also depends upon the eligibility of our products for reimbursement through government-sponsored

health care payment systems and third-party payors. In both the U.S. and foreign markets, health care cost-containment efforts are prevalent and are expected to continue. These efforts could reduce levels of reimbursement available for procedures involving our products and, therefore, reduce overall demand for our products as well. A failure to generate sufficient sales could have a material adverse impact on our financial condition, results of operations and cash flow.

Our growth will place a significant strain on our resources, and if we fail to manage our growth, our ability to develop, market, and sell our products will be harmed.

Our business plan contemplates a period of substantial growth and business activity. This growth and activity will likely result in new and increased responsibilities for management personnel and place significant strain upon our operating and financial systems and resources. To accommodate our growth and compete effectively, we will be required to improve our information systems, create additional procedures and controls and expand, train, motivate and manage our work force. We cannot be certain that our personnel, systems, procedures, and controls will be adequate to support our future operations. Any failure to effectively manage our growth could impede our ability to successfully develop market and sell our products.

We face currency and other risks associated with international operations.

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

currency fluctuations that could impact the demand for our products or result in currency exchange losses;

export restrictions, tariff and trade regulations and foreign tax laws;

customs duties, export quotas or other trade restrictions;

economic and political instability; and

shipping delays.

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

Our continuing ability to use Form S-3 may be limited.

As of the date of the filing of this Form 10-K, our public float is slightly above $75 million. As a result, any reduction in our market capitalization could limit our ability to file new shelf registration statements on SEC Form S-3 and/or to fully use the remaining capacity on our existing registration statements on SEC Form S-3. We have relied significantly on shelf registration statements on SEC Form S-3 for many of our financings in recent years, so any such limitations may harm our ability to raise the capital we need. In addition, if we are unable to remain compliant with our bank financing covenants, or if we are not able to timely file and make effective registration statements prior to the dates required under the federal securities laws, we would be ineligible to use Form S-3 for a 12-month period. Under those circumstances, until we are again eligible to use Form S-3, we would be required to use a registration statement on Form S-1 to register securities with the SEC or issue such securities in a private placement, which could increase the cost of raising capital.

Risks Related To Our Common Stock

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

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

Future issuances of our securities could dilute current stockholders ownership.

We have outstanding warrants to purchase 3.0 million shares of the Company s common stock at a weighted average exercise price of $14.21, with prices ranging from $1.55 to $46.40. A significant number of shares of our common stock are subject to stock options and stock appreciation rights, and we may request the ability to issue additional such securities to our employees. We may also decide to raise additional funds through public or private debt or equity financing to fund our operations. While we cannot predict the effect, if any, that future exercises of warrants or future sales of debt, our common stock, other equity securities or securities convertible into our common stock or other equity securities or the availability of any of the foregoing for future sale, will have on the market price of our common stock, it is likely that sales of substantial amounts of our common stock (including shares issued upon the exercise of warrants, stock options, stock appreciation rights or the conversion of any convertible securities outstanding now or in the future), or the perception that such sales could occur, will adversely affect prevailing market prices for our common stock.

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

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

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

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

- discourage, delay or prevent a change in the control of our company or a change in our management;
- adversely affect the voting power of holders of common stock; and
- limit the price that investors might be willing to pay in the future for shares of our common stock.

In addition, our alliance agreement with Biosense Webster and our debt agreement with Healthcare Royalty Partners II, L.P. contain provisions that may similarly discourage a takeover and negatively affect our share price as described above.

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

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the new SEC regulations such as the Dodd-Frank Wall Street Reform and Consumer Protection Act, and NASDAQ Capital Market rules have in the past created uncertainty for public companies. We continue to evaluate and monitor developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional compliance costs we may incur or the timing of such costs. These new or changed laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by courts and regulatory and governing bodies. This could result in uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Maintaining appropriate standards of corporate governance and public disclosure may result in increased general and administrative expense and a diversion of management time and attention from revenue-generating activities to compliance activities. In addition, if we fail to comply with new or changed laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business and reputation may be harmed.

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

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

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

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

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

Our common stock is traded on the NASDAQ Capital Market and trading volume may be limited or sporadic. The market price of our common stock has experienced, and may continue to experience, substantial volatility. During 2013, our common stock traded between $1.21 and $10.85 per share, on trading volume ranging from approximately 4,500 to 21 million shares per day. The market price of our common stock will be affected by a number of factors, including:

- actual or anticipated variations in our results of operations or those of our competitors;

the receipt or denial of regulatory approvals;

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

developments with respect to patents and other intellectual property rights;

changes in earnings estimates or recommendations by securities analysts or our failure to achieve analyst earnings estimates;

developments in our industry; and

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

These factors, as well as general economic, credit, political and market conditions, may materially adversely affect the market price of our common stock. As with the stock of many other public companies, the market price of our common stock has been particularly volatile during the recent period of upheaval in the capital markets and world economy. This excessive volatility may continue for an extended period of time following the filing date of this report. Furthermore, the stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Volatility in the price of our common stock on the NASDAQ Capital Market may depress the trading price of our common stock, which could, among other things, allow a potential acquirer of the Company to purchase a significant amount of our common stock at low prices.

We and certain of our current and former executive officers and directors, are defendants in a federal securities class action lawsuit and a federal shareholder derivative lawsuit. These lawsuits are described in Part I Item 3 Legal Proceedings in this Annual Report on Form 10-K. Our attention may be diverted from our ordinary business operations by these lawsuits and we may incur significant expenses associated with the defense of these lawsuits (including substantial fees of lawyers and other professional advisors and potential obligations to indemnify officers and directors and our underwriters who may be parties to such action). Depending on the outcome of these lawsuits, we may be required to pay material damages and fines, consent to injunctions on future conduct, or suffer other penalties, remedies or sanctions. The ultimate resolution of these matters could have a material adverse effect on our results of operations, financial condition, liquidity, our ability to meet our debt obligations and, consequently, negatively impact the trading price of our common stock. In addition, the volatility of our stock price could lead to similar class action securities litigation being filed against us in the future, which could result in substantial costs and a diversion of our management resources, which could significantly harm our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

We have not received any written comments regarding our periodic or current reports from the staff of the SEC that were issued 180 days or more preceding the end of our 2013 fiscal year and that remain unresolved.

ITEM 2. PROPERTIES

Our primary company facilities are located in St. Louis, Missouri where we currently lease approximately 52,000 square feet of office and 12,000 square feet of demonstration and assembly space. In the third quarter of 2013, the Company modified the existing lease agreement to terminate approximately 13,000 square feet of unimproved space. This space is leased under an agreement through 2018.

We lease approximately 3,900 square feet of office space in Maple Grove, Minnesota, under a lease agreement through October 31, 2014, and have leased office space in Amsterdam, The Netherlands through August 31, 2014. In addition, we lease an office space in Beijing, China on a month by month basis.

ITEM 3. LEGAL PROCEEDINGS

On October 7, 2011, a purported securities class action was filed against the Company and two of the Company s past executive officers in the U.S. District Court for the Eastern District of Missouri by Kevin Pound, a purported shareholder of the Company. On December 29, 2011, the court granted an unopposed motion appointing Local 522 Pension Fund as Lead Plaintiff in the action and granting Lead Plaintiff leave to file an Amended Complaint, which Lead Plaintiff filed on March 19, 2012. The Amended Complaint alleges that, during the period from February 28, 2011 through August 9, 2011, the Company and certain of its officers made materially false and misleading statements regarding the Company s financial condition and future business prospects, in violation of sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended. The Amended Complaint seeks unspecified damages, costs, attorneys fees and such other relief as the Court may deem appropriate. On May 18, 2012, the Company filed a motion to dismiss the Amended Complaint. On July 24, 2012, Lead Plaintiff filed its response to the motion to dismiss, and on August 30, 2012, the Company filed its reply brief in support of the motion to dismiss. On March 18, 2014, the Court granted the Company s motion to dismiss and entered judgment in favor of the defendants and against the plaintiffs. The plaintiffs have thirty days, or until April 17, 2014, to file a notice of appeal. The Company believes the complaint is without merit and, in the event of an appeal by the plaintiffs, intends to vigorously defend against it. In addition, the Company has obligations, under certain circumstances, to indemnify the individual defendants with respect to claims asserted against them and otherwise to the fullest extent permitted under Delaware law and the Company s bylaws and certificate of incorporation.

On December 2, 2011, a purported shareholder derivative action was filed in the U.S. District Court for the Eastern District of Missouri by Carl Zorn, a purported shareholder of the Company, against the directors of the Company and the Company as a nominal defendant. The Complaint in this action alleges that the individual defendants breached their fiduciary duties to the Company, engaged in gross mismanagement and caused waste of corporate assets of the Company by allowing the Company and certain of its officers to make the same allegedly false and misleading statements regarding the Company s financial condition and future business prospects that are at issue in the purported class action. The Complaint seeks unspecified damages, restitution and other equitable relief, as well as costs and attorneys fees from the named defendants on behalf of the Company. At the request of all parties, on March 22, 2012, the Court entered an order staying the case pending resolution of the motion to dismiss in the securities class action. The Company believes the complaint is without merit and intends to vigorously defend against it. However, litigation is inherently uncertain and it is too early in this proceeding to predict the outcome of this lawsuit or to reasonably estimate possible losses, if any, related thereto. In addition, the Company has obligations, under certain circumstances, to indemnify the individual defendants with respect to claims asserted against them and otherwise to the fullest extent permitted under Delaware law and the Company s bylaws and certificate of incorporation.

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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

PRICE RANGE OF COMMON STOCK

Our common stock began trading on the NASDAQ Global Market under the symbol STXS on August 12, 2004 and was transferred to the NASDAQ Capital Market effective August 19, 2013. The following table sets forth the high and low sales prices of our common stock for the periods indicated and reported by NASDAQ.

	High	Low
Year Ended December 31, 2013		
First Quarter	$ 3.28	$ 1.77
Second Quarter	2.07	1.31
Third Quarter	10.85	1.21
Fourth Quarter	6.24	3.10
Year Ended December 31, 2012		
First Quarter	$ 9.30	$ 6.50
Second Quarter	6.80	2.00
Third Quarter	2.44	1.37
Fourth Quarter	3.39	1.01

As of February 28, 2014, there were approximately 292 stockholders of record of our common stock, although we believe that there is a significantly larger number of beneficial owners of our common stock.

DIVIDEND POLICY

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

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

STOCK PRICE PERFORMANCE GRAPH

The following graph shows the total stockholder return from December 31, 2008 through December 31, 2013 for a $100 investment in Stereotaxis, Inc., the NASDAQ OMX Global Index, and the NASDAQ Medical Device Index. As a result of change in the total return data made available to us through our vendor provider, our performance graphs going forward will be using a comparable index provided by NASDAQ OMX Global Indexes. Please note, information for the NASDAQ Medical Device Manufacturer s Index is provided only from December 31, 2008 through December 31, 2013, the last day this data was available by our third-party index provider. All values assume reinvestment of the full amount of all dividends although dividends have never been declared on Stereotaxis common stock. The stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.

Comparison of Cumulative Total Return

Among Stereotaxis, Inc, The NASDAQ OMX Global Index,

and The NASDAQ Medical Device Manufacturer s Index

ITEM 6. SELECTED FINANCIAL DATA

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

	Year Ended December 31,				
	2013	2012	2011	2010	2009
Consolidated Statements of Operations Data:					
Revenue	$ 38,031,081	$ 46,562,434	$ 41,987,432	$ 54,051,237	$ 51,149,555
Cost of revenue	11,001,301	14,781,055	12,498,081	15,564,687	17,021,633
Gross margin	27,029,780	31,781,379	29,489,351	38,486,550	34,127,922
Operating costs and expenses:					
Research and development	5,672,058	8,405,086	12,886,488	12,244,163	14,260,854
Sales and marketing	17,132,093	20,607,999	31,635,415	30,178,818	28,694,540
General and administrative	13,066,103	13,394,556	16,908,656	15,022,689	15,010,490
Total operating expenses	35,870,254	42,407,641	61,430,559	57,445,670	57,965,884
Operating loss	(8,840,474)	(10,626,262)	(31,941,208)	(18,959,120)	(23,837,962)
Interest and other income (expense), net [1] [2]	(59,917,115)	1,387,835	(89,967)	(964,367)	(3,656,495)
Net loss	$ (68,757,589)	$ (9,238,427)	$ (32,031,175)	$ (19,923,487)	$ (27,494,457)
Basic and diluted net loss per common share	$ (5.95)	$ (1.33)	$ (5.84)	$ (3.94)	$ (6.34)
Shares used in computing basic and diluted net loss per common share	11,554,566	6,944,928	5,482,627	5,052,200	4,334,432
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 13,775,130	$ 7,777,718	$ 13,954,919	$ 35,248,819	$ 30,546,550
Working capital	4,351,694	(5,715,760)	(6,596,218)	12,395,426	12,878,277
Total assets	31,076,396	32,165,944	39,931,832	65,761,792	56,120,516
Long-term debt, less current maturities	18,481,478	16,824,736	17,290,531	8,000,000	10,346,655
Accumulated deficit	(453,403,462)	(384,645,873)	(375,407,446)	(343,376,271)	(323,452,784)
Total stockholders equity	(11,701,995)	(18,790,226)	(18,828,895)	10,475,246	7,641,343

(1) Other income recorded in 2010 includes $1.5 million in grants under the Qualifying Therapeutic Discovery Project Program.

(2) Other income (expense) recorded in 2013, 2012, 2011, 2010, and 2009 includes ($47.3) million, $8.2 million, $3.4 million, $0.6 million, and $0.9 million in warrant and other mark-to-market adjustments, respectively.

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

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

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

Overview

Stereotaxis designs, manufactures and markets the *Epoch* Solution, which is an advanced cardiology instrument control system for use in a hospital s interventional surgical suite to enhance the treatment of arrhythmias and coronary artery disease. The *Epoch* Solution is comprised of the *Niobe* ES robotic system, *Odyssey* Solution, and the *Vdrive* system. We believe that the *Epoch* Solution represents a revolutionary technology in the interventional surgical suite, or interventional lab , and has the potential to become the standard of care for a broad range of complex cardiology procedures. We also believe that our technology represents an important advance in the ongoing trend toward digital instrumentation in the interventional lab and provides substantial, clinically important improvements and cost efficiencies over manual interventional methods, which require years of physician training and often result in long and unpredictable procedure times and sub-optimal therapeutic outcomes.

The *Niobe* ES robotic system is the latest generation of the *Niobe* Robotic Magnetic Navigation System (*Niobe* system). This system is designed to enable physicians to complete more complex interventional procedures by providing image guided delivery of catheters and guidewires through the blood vessels and chambers of the heart to treatment sites. This is achieved using externally applied magnetic fields that govern the motion of the working tip of the catheter or guidewire, resulting in improved navigation, efficient procedures and reduced x-ray exposure. The core components of the *Niobe* system have received regulatory clearance in the U.S., Canada, Europe, China, Japan and various other countries.

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

Our *Vdrive* system provides navigation and stability for diagnostic and therapeutic devices designed to improve interventional procedures. The *Vdrive* 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 (*V-Loop*, *V-Sono*, *V-CAS*, and *V-CAS* Deflect) which can be manipulated by these systems.

We generate revenue from both the initial capital sales of the *Niobe*, *Odyssey* and *Vdrive* systems as well as recurring revenue from the sale of our proprietary disposable devices, from ongoing license and service contracts, and from royalties paid to the Company on the sale by Biosense Webster of co-developed catheters. We market our products to a broad base of hospitals in the United States and internationally as detailed in Note 18 to the financial statements.

We have alliances with each of Siemens AG Medical Solutions, Philips Medical Systems and Biosense Webster, Inc., through which we integrate our *Niobe* system with market leading digital imaging and 3D catheter location sensing technology, as well as disposable interventional devices, in order to continue to develop new solutions in the interventional lab. Each of these alliances provides for coordination of our sales and marketing activities with those of our partners.

Since our inception, we have generated significant losses. As of December 31, 2013, we had incurred cumulative net losses of approximately $453.4 million. As of December 31, 2013, the Company had an installed base of 100 *Niobe* ES systems and has received positive feedback from the physicians at these sites. We expect to incur additional losses and to have negative cash flow from operations into 2014 as we continue the development and commercialization of our products, conduct our research and development activities and advance new products into clinical development from our existing research programs and fund additional sales and marketing initiatives. Our existing cash, cash equivalents and borrowing facilities may not be sufficient to fund our operating expenses and capital equipment requirements through the next 12 months, which would require us to obtain additional financing before that time.

The Company s independent registered public accounting firm s report issued in this Annual Report on Form 10-K included an explanatory paragraph describing the existence of conditions that raise substantial doubt about the Company s ability to continue as a going concern, including recurring operating losses and the net capital deficiency. The financial statements do not include any adjustments relating to the recoverability and classification of assets carrying amounts or the amount of and classification of liabilities that may result should the Company be unable to continue as a going concern.

Critical Accounting Policies and Estimates

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

Revenue Recognition

The Company adopted Accounting Standards Update 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU 2009-13) in the fourth quarter of 2009, effective as of January 1, 2009.

ASU 2009-13 permits management to estimate the selling price of undelivered components of a bundled sale for which it is unable to establish vendor-specific objective evidence (VSOE) or third-party evidence

(TPE). This requires management to record revenue for certain elements of a transaction even though it might not have delivered other elements of the transaction, for which it was unable to meet the requirements for establishing VSOE or TPE. The Company believes that the guidance significantly improves the reporting of these types of transactions to more closely reflect the underlying economic circumstances. This guidance also prohibits the use of the residual method for allocating revenue to the various elements of a transaction and requires that the revenue be allocated proportionally based on the relative estimated selling prices.

Under our revenue recognition policy, a portion of revenue for *Niobe* systems, *Vdrive* systems and certain types of *Odyssey* systems is recognized upon delivery, provided that title has passed, there are no uncertainties regarding acceptance, persuasive evidence of an arrangement exists, the sales price is fixed and determinable, and collection of the related receivable is reasonably assured. Revenue is recognized for other types of *Odyssey* systems upon completion of installation, since there are no qualified third party installers. When installation is the responsibility of the customer, revenue from system sales is recognized upon shipment since these arrangements do not include an installation element or right of return privileges. We do not recognize revenue in situations in which inventory remains at a Stereotaxis warehouse or in situations in which title and risk of loss have not transferred to the customer. However, we may deliver systems to a non-hospital site at the customer s request as outlined in the terms and conditions of the sales agreement, in which case we evaluate whether the substance of the transaction meets the delivery and performance requirements for revenue recognition under bill and hold guidance. Amounts collected prior to satisfying the above revenue recognition criteria are reflected as deferred revenue. Revenue from services and license fees, whether sold individually or as a separate unit of accounting in a multi-element arrangement, is deferred and amortized over the service or license fee period, which is typically one year. Revenue from services is derived primarily from the sale of annual product maintenance plans. We recognize revenue from disposable device sales or accessories upon shipment and establish an appropriate reserve for returns. The return reserve, which is applicable only to disposable devices, is estimated based on historical experience which is periodically reviewed and updated as necessary. In the past, changes in estimate have had only a de minimus effect on revenue recognized in the period. We believe that the estimate is not likely to change significantly in the future.

Stock-based Compensation

Stock compensation expense, which is a non-cash charge, results from stock option and stock appreciation rights grants made to employees, and directors at the fair value of the option granted, and from grants of restricted shares and units to employees, directors, and third-party consultants. The fair value of options and stock appreciation rights granted was determined using the Black-Scholes valuation method which gives consideration to the estimated value of the underlying stock at the date of grant, the exercise price of the option, the expected dividend yield and volatility of the underlying stock, the expected life of the option and the corresponding risk-free interest rate. The fair value of the grants of restricted shares and units was determined based on the closing price of our stock on the date of grant. Stock compensation expense for options, stock appreciation rights and for time-based restricted share grants is amortized on a straight-line basis over the vesting period of the underlying issue, generally over four years except for grants to directors which generally vest over one to two years and restricted stock units which generally vest over a period of 18 months to four years. Stock compensation expense for performance-based restricted shares is amortized on a straight-line basis over the anticipated vesting period and is subject to adjustment based on the actual achievement of objectives. Compensation expenses related to option grants to non-employees are re-measured quarterly through the vesting date. Compensation expense is recognized only for those options expected to vest, net of estimated forfeitures. Estimates of the expected life of options have been based on the average of the vesting and expiration periods, which is the simplified method under general accounting principles for share-based payments. Estimates of volatility and forfeiture rates utilized in calculating stock-based compensation have been prepared based on historical data and future expectations. Actual experience to date has been consistent with these estimates.

The amount of compensation expense to be recorded in future periods may increase if we make additional grants of options, stock appreciation rights or restricted shares or if we determine that actual forfeiture rates are

less than anticipated. The amount of expense to be recorded in future periods may decrease if the requisite service periods are not completed or if the actual forfeiture rates are greater than anticipated.

Valuation of Inventory

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

Deferred Income Taxes

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

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

Results of Operations

Comparison of the Years ended December 31, 2013 and 2012

Revenue. Revenue decreased to $38.0 million for the year ended December 31, 2013, from $46.6 million for the year ended December 31, 2012, a decrease of approximately 18%. Revenue from sales of systems decreased to $12.7 million for the year ended December 31, 2013, from $19.7 million for the year ended December 31, 2012, a decrease of approximately 35%. We recognized revenue on nine *Niobe* ES systems, a total of $0.9 million for *Niobe* ES upgrades, $3.7 million for *Odyssey* and *Odyssey Cinema* systems, and a total of $0.3 million for *Vdrive* systems during the 2013 reporting period compared to nine *Niobe* systems, and a total of $3.3 million for *Niobe* ES upgrades, $6.5 million for *Odyssey* and *Odyssey Cinema* systems, and $1.1 million for *Vdrive* systems during the 2012 reporting period. Revenue from sales of disposable interventional devices, service and accessories decreased to $25.3 million for the year ended December 31, 2013, from $26.9 million for the year ended December 31, 2012, a decrease of approximately 6%. The decrease was attributable to lower disposable sales volume as a result of lower utilization.

Cost of Revenue. Cost of revenue decreased to $11.0 million for the year ended December 31, 2013, from $14.8 million for the year ended December 31, 2012, a decrease of approximately 26%. As a percentage of our total revenue, overall gross margin increased from 68% for the year ended December 31, 2012, to 71% for the year ended December 31, 2013, due to a shift in mix from system revenue to disposable, service, and accessories revenue. Cost of revenue for systems sold decreased to $6.9 million for the year ended December 31, 2013, from $9.9 million for the year ended December 31, 2012, a decrease of approximately 31%. This decrease was primarily due to decreased system sales volumes across *Odyssey*, *Odyssey Cinema* and *Vdrive* product lines. Gross margin for systems was 46% for the year ended December 31, 2013, compared to 50% for year ended December 31, 2012. The decrease is primarily attributable to lower production volumes and related cost

absorption as well as lower gross margin on *Niobe* ES systems. Cost of revenue for disposable interventional devices, service and accessories decreased to $4.1 million for the year ended December 31, 2013, from $4.9 million for the year ended December 31, 2012, resulting in an increase in gross margin to 84% from 82% between these periods. The increase is due to higher margins on service in the current year period due to fewer ES upgrades provided in exchange for extended service contracts.

Research and Development Expense. Research and development expense decreased to $5.7 million for the year ended December 31, 2013 from $8.4 million for the year ended December 31, 2012, a decrease of approximately 33%. The decrease is primarily due to reduced headcount expenses and a reduction in consulting, contract research, and material expenses as part of the Company s efforts to reduce operating expenses.

Sales and Marketing Expense. Sales and marketing expense decreased to $17.1 million for the year ended December 31, 2013, from $20.6 million for the year ended December 31, 2012, a decrease of approximately 17%. The decrease was due to primarily due to reduced headcount and related travel expenses as well as decreased marketing and consulting expenses.

General and Administrative Expense. General and administrative expenses include regulatory, clinical, general management and training expenses. General and administrative expense decreased to $13.1 million for the year ended December 31, 2013, from $13.4 million for the year ended December 31, 2012, a decrease of approximately 2%. The decrease was primarily due to reduced headcount, partially offset by increased consulting expenses, lease exit activities and medical device excise tax.

Other Income (Expense). Other expense represents the non-cash change in market value of certain warrants classified as a derivative and recorded as a current liability under general accounting principles for determining whether an instrument (or embedded feature) is indexed to an entity s own stock. Other expense also includes the adjustment in fair value of the derivative asset and liability related to the conversion features embedded in the subordinated convertible debentures. Other expense increased to $47.3 million for the year ended December 31, 2013, due primarily to the adjustment of warrants and convertible debt features in connection with the third quarter capital transactions with convertible note holders and other equity investors.

Interest Expense. Interest expense increased to $12.6 million for the year ended December 31, 2013 from $6.9 million for the year ended December 31, 2012, due primarily to the write-off of the unamortized debt discount in connection with the third quarter capital transactions with convertible note holders and other equity investors.

Comparison of the Years ended December 31, 2012 and 2011

Revenue. Revenue increased to $46.6 million for the year ended December 31, 2012 from $42.0 million for the year ended December 31, 2011, an increase of approximately 11%. Revenue from sales of systems increased to $19.7 million for the year ended December 31, 2012 from $15.6 million for the year ended December 31, 2011, an increase of approximately 26%, primarily due to an increase in the number of *Niobe* systems and *Niobe* ES upgrades sold. The number of units recognized to revenue was 9 *Niobe* systems and a total of $3.3 million for *Niobe* ES upgrades and $6.5 million for *Odyssey* systems during the 2012 reporting period compared to 7 *Niobe* systems, and a total of $0.5 million for *Niobe* ES upgrades and $7.4 million for *Odyssey* systems during the 2011 reporting period. Revenue from sales of disposable interventional devices, service and accessories increased to $26.9 million for the year ended December 31, 2012 from $26.4 million for the year ended December 31, 2011, an increase of approximately 2%. The increase was attributable to improved utilization due to *Niobe* ES upgrades and to a lesser extent the increased base of installed systems, the resulting disposable sales, offset by lower royalty income resulting from a reduction in the royalty rate effective January 1, 2012.

Cost of Revenue. Cost of revenue increased to $14.8 million for the year ended December 31, 2012 from $12.5 million for the year ended December 31, 2011, an increase of approximately 18%. As a percentage of our

total revenue, overall gross margin decreased from 70% for the year ended December 31, 2011, to 68% for the year ended December 31, 2012, due to a shift in mix from disposable, service, and accessories revenue to systems revenue. Cost of revenue for systems sold increased to $9.9 million for the year ended December 31, 2012 from $8.6 million for the year ended December 31, 2011, an increase of approximately 15%. This increase was primarily due to an increase in the number of *Niobe* units sold in 2012 compared to 2011. Gross margin for systems was 50% for the year ended December 31, 2012, compared to 45% for year ended December 31, 2011. The improvement is primarily attributable to higher production volumes and related cost absorption. Cost of revenue for disposable interventional devices, service and accessories increased to $4.9 million for the year ended December 31, 2012 from $3.9 million for the year ended December 31, 2011, resulting in a decrease in gross margin to 82% from 85% between these periods. The decrease in gross margin is due to a higher mix of lower margin disposables revenue, lower royalties and providing *Niobe* ES upgrades in exchange for new or extended premium service contracts

Research and Development Expense. Research and development expense decreased to $8.4 million for the year ended December 31, 2012 from $12.9 million for the year ended December 31, 2011, a decrease of approximately 35%. The decrease is primarily due to the completion of major development efforts of the *Epoch* Solution and *Odyssey* system upgrades in 2011, as well as reduced headcount expenses.

Sales and Marketing Expense. Sales and marketing expense decreased to $20.6 million for the year ended December 31, 2012, from $31.6 million for the year ended December 31, 2011, a decrease of approximately 35%. The decrease was due to primarily due to reduced headcount and related travel and relocation expenses as well as lower marketing and consulting expenses.

General and Administrative Expense. General and administrative expenses include regulatory, clinical, general management and training expenses. General and administrative expense decreased to $13.4 million for the year ended December 31, 2012, from $16.9 million for the year ended December 31, 2011, a decrease of approximately 21%. The decrease was primarily due to reduced headcount and related travel and relocation expenses, lower spending on registrations in Japan as our products approach the end of clinical trials, and decreased bad debt expense and consulting costs.

Other Income. Other income increased to $8.3 million for the year ended December 31, 2012 from $3.4 million for the year ended December 31, 2011. Other income represents the change in market value of certain warrants classified as a derivative and recorded as a current liability under general accounting principles for determining whether an instrument (or embedded feature) is indexed to an entity s own stock. Other income also includes the adjustment in fair value of the derivative asset and liability related to the conversion features embedded in the subordinated convertible debentures. The primary drivers of fluctuations in this balance are changes in the Company s stock price from one period to the next.

Interest Expense. Interest expense increased to $6.9 million for the year ended December 31, 2012 from $3.5 million for the year ended December 31, 2011, due to the Healthcare Royalty Partners II, L.P. (formerly Cowen Healthcare Royalty Partners II, L.P.) financing in November 2011 and additional $2.5 million borrowing in August 2012, and the issuance of $8.5 million in Debentures in May 2012. Interest expense also includes the amortization of the debt discount on the Debentures totaling $1.0 million for the year ended December 31, 2012.

Income Taxes

Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. Accordingly, net deferred tax assets have been fully offset by valuation allowances as of December 31, 2013, 2012 and 2011 to reflect these uncertainties. As of December 31, 2013, we had federal net operating loss carryforwards of approximately $75.8 million which will expire between 2018 and 2033. As of December 31, 2013, we had state net operating loss carryforwards of approximately $2.3 million which will expire at various dates between 2014 and 2033 if not utilized. We may not be able to utilize all of these loss carryforwards prior to their expiration.

Capital Resources

As of December 31, 2013, our borrowing facilities were comprised of a revolving line of credit with $3.0 million of unborrowed availability with our primary lender, Silicon Valley Bank, as well as the Healthcare Royalty Partners debt discussed in the following sections.

Biosense Webster Advance

In July 2008, the Company and Biosense Webster entered into an amendment to their existing agreements relating to the development and sale of catheters. Pursuant to the amendment, Biosense Webster agreed to pay to the Company $10.0 million as an advance on royalty amounts that were owed at the time the amendment was executed or would be owed in the future by Biosense Webster to the Company pursuant to the royalty provisions of one of the existing agreements. The Company and Biosense Webster also agreed that an aggregate of up to $8.0 million of certain agreed upon research and development expenses that were owed at the time the amendment was executed or may be owed in the future by the Company to Biosense Webster pursuant to the existing agreement would be deferred and would be due, together with any unrecouped portion of the $10.0 million royalty advance, no later than December 31, 2011. Interest on the outstanding and unrecouped amounts of the royalty advance and deferred research and development expenses accrued at an interest rate of the prime rate plus 0.75%. Outstanding royalty advances and deferred research and development expenses and accrued interest thereon were recouped by Biosense Webster by deductions from royalty amounts otherwise owed to the Company from Biosense Webster pursuant to the existing agreement. Approximately $18.0 million had been advanced by Biosense Webster to the Company pursuant to the amendment. As of December 31, 2011, these amounts plus interest accrued thereon had been repaid in full, in accordance with the agreement. The Company recorded research and development expenses of $1.1 million, and disposables, service and accessories revenue of $3.6 million for the year ended December 31, 2011, related to this agreement.

Revolving line of credit

In November 2010, the Company received from stockholders, who at the time were affiliates of two members of our board of directors, (the Lenders), an extension of their commitment to provide $10 million in either direct loans to the Company or loan guarantees to the Company s primary bank lender through the earlier of March 31, 2012 or the date the Company received $30 million of third party, non-bank financing, coincidental with the proposed maturity of the bank line of credit, as amended. The Company granted to the Lenders warrants to purchase 80,000 shares in exchange for their extension. The warrants are exercisable at $40.15 per share, beginning on March 1, 2011 and expiring on February 28, 2016. The fair value of these warrants of $1,747,392, calculated using the Black-Scholes method, will be deferred and amortized to interest expense ratably. As the previous guarantee was no longer in effect, the Company expensed in 2010 the entire balance on the warrants issued to the Lenders in October 2009.

In December 2010, the Company further amended its agreement with its primary lender to extend the maturity of the current working capital line of credit from March 31, 2011 to March 31, 2012, retaining the $30 million total availability under the line per the 2009 amendment. The revised agreement retained the $10 million sublimit for borrowings supported by guarantees from the Lenders. Under the revised facility the Company was required to maintain a minimum tangible net worth and liquidity ratio as defined in the agreement. Interest on the facility accrued at the rate of prime plus 0.5% subject to a floor of 6% for the amount under guarantee and prime plus 1.75% subject to a floor of 7% for the remaining amounts.

On September 30, 2011, we entered into a fourth loan modification agreement with our primary lender to reduce the total availability amount of all credit extensions under the Original Agreement, other than the term loan, from $30 million to $20 million. The Agreement also modified the interest rate applicable to the term loan under the Original Agreement from the bank s prime rate plus 3.50% to the Bank s prime rate plus 5.50%.

On November 30, 2011, the Company entered into a Second Amended and Restated Loan and Security Agreement with its primary lender (Amended Loan Agreement). Under the Amended Loan Agreement, the

Company agreed to revised tangible net worth and liquidity ratio covenants. Further, certain intellectual property assets of the Company were added to the collateral which secures repayment of the loan. Finally, the Amended Loan Agreement permits the Company to repay Healthcare Royalty Partners II, L.P. (Healthcare Royalty Partners), formerly Cowen Healthcare Royalty Partners II, L.P. , with the royalties due to the Company under the Biosense Agreement (the Biosense Agreement), as described below.

On March 30, 2012, the Company amended its agreement with its primary lender. The amendment extended the maturity date of the working capital line of credit from March 31, 2012 to April 30, 2012 and reduced the Company s borrowing availability by $3,333,333. The Company also received from the Lenders an extension of their commitment to provide $10 million in loan guarantees until April 30, 2012. As a result of this extension, the Company issued the Lenders warrants to purchase 75,735 shares of common stock at $6.60 per share.

On May 1, 2012, the Company and its primary lender entered into an agreement in which the lender extended the maturity of the revolving line of credit from April 30, 2012 to May 15, 2012. The Company and the Lenders also agreed to amend their agreement to extend the $10 million loan guarantee through May 15, 2012. The Company granted warrants to purchase an aggregate of 60,976 shares of common stock at $4.10 per share in exchange for the extension of the guarantee.

On May 10, 2012, upon closing of financing transactions for gross proceeds of $18.5 million, the Company entered into the Third Loan Modification Agreement with its primary lender. The amendment extended the revolving credit facility maturity to March 31, 2013 and revised the financial covenants. Additionally, the revolving line of credit was decreased from $20 million to $13 million. The reduction was as a result of the pay down of $7 million of the guarantees provided by the Lenders. In addition the Company and the Lenders agreed to decrease the $10 million guarantee to $3 million and to further extend the loan guarantee through March 31, 2013. The Company granted warrants to purchase an aggregate of 234,305 shares of common stock at $3.361 per share in exchange for the extension of the guarantee.

On March 29, 2013, the Company amended its agreement with its primary lender. The amendment extended the maturity date of the working capital line of credit from March 31, 2013 to June 30, 2013. The Company and the Lenders also agreed to extend until June 30, 2013 the $3 million guarantee. As a result of this extension, the Company issued the Lenders warrants to purchase 113,636 shares of common stock at $1.98 per share.

On June 28, 2013, the Company amended its agreement with its primary lender. The amendment extended the maturity date of the working capital line of credit from June 30, 2013 to July 31, 2013, and decreased the amount of available advances from $13 million to $6 million. In addition, the Bank waived the testing of the tangible net worth and liquidity ratio financial covenants under the Amended Loan Agreement for the period ended June 30, 2013. The Company and the Lenders also agreed to extend until July 31, 2013 the $3 million guarantee. As a result of this extension, the Company issued the Lenders warrants to purchase 48,387 shares of common stock at $1.55 per share.

On July 31, 2013, the Company amended its agreement with its primary lender. The amendment extended the maturity date of the working capital line of credit from July 31, 2013 to August 31, 2013. In addition, the Bank waived the testing of the liquidity ratio financial covenant under the Amended Loan Agreement for the period ended July 31, 2013. The Company and the Lenders also agreed to extend until August 31, 2013 the $3 million guarantee. As a result of this extension, the Company issued the Lenders warrants to purchase 14,313 shares of common stock at $5.24 per share.

On August 30, 2013, the Company amended its agreement with its primary lender. The amendment extended the maturity date of the working capital line of credit from August 31, 2013 to March 31, 2014. In addition, the Company and the Bank agreed to a reduction in the revolving credit line from $6.0 million to $3.0 million, the elimination of the $3.0 million sublimit guaranteed by the Lenders, and release of the guarantees by the Lenders in favor of the Bank. The amendment eliminated the prepayment premium for the prepayment of the term loan and modified the financial covenants to (a) eliminate the minimum tangible net worth covenant,

(b) substitute in lieu thereof an EBITDA (Earnings Before Interest, Taxes, Depreciation and Amortization) test, requiring the Company to maintain a minimum EBITDA of no less than (no worse than) (i) negative $4.0 million for the trailing three-month period ending September 30, 2013 and (ii) negative $3.0 million for the trailing three-month period ending December 31, 2013, in each case tested quarterly on a trailing three month basis, and (c) revise the liquidity ratio covenant to require the Company to maintain a liquidity ratio of greater than 2:1, excluding certain short term advances from the calculation.

Term note

Under the 2010 amendment to the loan agreement, the Company entered into a $10 million term loan maturing on December 31, 2013, with $2 million of principal due in 2011 and $4 million of principal due in each of 2012 and 2013. Interest on the term loan accrued at the rate of prime plus 3.5%. Under this agreement, the Company provided its primary lender with warrants to purchase 11,111 shares of common stock. The warrants are exercisable at $36.00 per share, beginning on December 17, 2010 and expiring on December 17, 2015. The fair value of these warrants of $228,332, calculated using the Black-Scholes method, was deferred and amortized to interest expense ratably over the life of the term loan. The term note was paid in full in September 2013.

Healthcare Royalty Partners Debt

In November 2011, the Company entered into a loan agreement with Healthcare Royalty Partners (formerly Cowen Healthcare Royalty Partners II, L.P.). Under the agreement the Company borrowed from Healthcare Royalty Partners $15 million. The Company was permitted to borrow up to an additional $5 million in the aggregate based on the achievement by the Company of certain milestones related to *Niobe* system sales in 2012. On August 8, 2012, the Company borrowed an additional $2.5 million based upon achievement of a milestone related to *Niobe* system sales for the nine months ended June 30, 2012. On January 31, 2013, the Company borrowed an additional $2.5 million based upon achievement of a milestone related to *Niobe* system sales for the twelve months ended December 31, 2012. The loan will be repaid through, and secured by, royalties payable to the Company under its Development, Alliance and Supply Agreement with Biosense Webster, Inc. The Biosense Agreement relates to the development and distribution of magnetically enabled catheters used with Stereotaxis *Niobe* system in cardiac ablation procedures. Under the terms of the Agreement, Healthcare Royalty Partners will be entitled to receive 100% of all royalties due to the Company under the Biosense Agreement until the loan is repaid. The loan is a full recourse loan, matures on December 31, 2018, and bears interest at an annual rate of 16% payable quarterly with royalties received under the Biosense Agreement. If the payments received by the Company under the Biosense Agreement are insufficient to pay all amounts of interest due on the loan, then such deficiency will increase the outstanding principal amount on the loan. After the loan obligation is repaid, the royalties under the Biosense Agreement will again be paid to the Company. The loan is also secured by certain assets and intellectual property of the Company. The Agreement also contains customary affirmative and negative covenants. The use of payments due to the Company under the Biosense Agreement was approved by our primary lender under the Amended Loan Agreement described above.

Subordinated Convertible Debentures

In May 2012, the Company entered into a securities purchase agreement with certain institutional investors whereby the Company agreed to sell an aggregate of approximately $8.5 million in aggregate principal amount of unsecured, subordinated, convertible debentures (the Debentures), which became convertible into shares of the Company s common stock at a conversion price of $3.361 per share (or approximately 2.5 million shares in the aggregate), on July 10, 2012, the date that the Company received shareholder approval for the transaction. The purchasers of the Debentures also received warrants, which were scheduled to expire in November 2018, to purchase an aggregate of approximately 2.5 million shares of the Company s common stock at an exercise price of $3.361 per share (Convert Warrants). The Debentures bear interest at 8% per year and were scheduled to mature on May 7, 2014. In addition, the Company had the ability to issue shares of its common stock in lieu of cash interest payments under certain circumstances, and following the registration of the shares for resale, the Company issued shares in lieu of cash interest payments.

The Company recorded the Debentures on the balance sheet net of the debt discount. The debt discount of $7.6 million was due to warrants issued in conjunction with the Debentures and the debt conversion features. Upon issuance of the Debentures, the fair value of the warrants and derivative liability were $4.1 million and $3.5 million, respectively. The debt discount was amortized over the life of the loan using the effective interest method and the warrants and derivative liability were recorded at fair value on each reporting period. Refer to Note 12 for additional discussion of the fair value of the warrants and conversion features.

On August 7, 2013, holders of Convert Warrants exercised all of their Convert Warrants for an aggregate of approximately $2.5 million shares of our common stock, resulting in cash proceeds of approximately $8.5 million. In addition, holders of all of the Debentures exchanged the balance of their unconverted Debentures for an aggregate of approximately 2.7 million shares of the Company s common stock and additional warrants (the Exchange Warrants) to purchase approximately 2.5 million shares, having an exercise price of $3.361 per share. On August 8, 2013, certain former holders of the Debentures exercised Exchange Warrants to purchase an aggregate of 1.4 million shares of common stock in cashless net exercises as provided for in the Exchange Warrants, which resulted in the issuance to such funds of an aggregate of 0.8 million shares of common stock, but no net proceeds to the Company. The Company is relying on the exemption from registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended, based on representations to the Company made by the warrant holders.

The mark-to-market expense associated with the adjustment of warrants and convertible debt features in connection with the third quarter capital transactions are included in other expense for the year ended December 31, 2013. The write-off of the unamortized debt discount is included in interest expense for the year ended December 31, 2013.

Listing Transfer to NASDAQ Capital Market

On August 15, 2013, the NASDAQ Listing Qualifications Panel (the Panel) granted approval of the Company s request to transfer its listing to The NASDAQ Capital Market from The NASDAQ Global Market. The Company s securities began trading on the NASDAQ Capital Market effective August 19, 2013.

Reverse Stock Split

On July 10, 2012, the Company filed a Certificate of Amendment to our Amended and Restated Certificate of Incorporation to implement a one-for-ten reverse split of our common stock (the Reverse Stock Split). The ratio for the Reverse Stock Split was determined by our Board of Directors pursuant to the approval of the stockholders at the Company s special meeting of stockholders held on July 10, 2012, authorizing the Board to effect a reverse stock split within a range of one-for-four to one-for-ten shares of the Company s common stock. The Reverse Stock Split was effective as of July 10, 2012, and the Company s common stock began trading on the NASDAQ Global Market on a post-split basis on July 11, 2012.

As a result of the Reverse Stock Split, each ten shares of the Company s issued and outstanding common stock were automatically combined and converted into one issued and outstanding share of common stock. The Reverse Stock Split affected all issued and outstanding shares of the Company s common stock, as well as common stock underlying stock options, stock appreciation rights, restricted stock, restricted stock units, warrants and convertible debentures outstanding immediately prior to the effectiveness of the Reverse Stock Split. The Reverse Stock Split reduced the number of shares of the Company s common stock outstanding from approximately 78 million to 7.8 million at the time of the Reverse Stock Split. In addition, the Amendment increased the number of authorized shares of the Company s common stock from 100 million to 300 million. The Reverse Stock Split did not alter the par value of common stock, which remained $0.001 per share, or modify any voting rights or other terms of the Company s common stock. Unless otherwise indicated, all information set forth herein gives effect to such Reverse Stock Split.

Common Stock

In May 2012, the Company entered into a Stock and Warrant Purchase Agreement with certain institutional investors whereby it agreed to sell an aggregate of approximately 2.17 million shares of the Company s common stock (the PIPE Common Stock) at a price of $3.361 per share, together with six-year warrants at a price of $1.25 per share to purchase an aggregate of approximately 2.17 million shares of common stock having an exercise price of $3.361 per share (the PIPE Warrants). Each purchaser received a PIPE Warrant to purchase one share of common stock for every share of PIPE Common Stock purchased. Net proceeds from the sale of the securities were approximately $9.1 million, after placement agent fees and other offering expenses. The Company used the funds to repay $7 million of the revolving credit facility guaranteed by the Lenders.

On August 7, 2013, venture funds affiliated with Sanderling Ventures received an aggregate of 183,478 shares of common stock based upon the cashless exercise of warrants to purchase an aggregate of 262,450 shares of common stock. These warrants were comprised of 75,758 warrants with an exercise price of $1.98 per share, 156,204 warrants with an exercise price of $3.361 per share and 30,488 warrants with an exercise price of $4.10 per share. The warrants were issued by the Company in private placements in 2012 and 2013 in connection with the extension of previously disclosed guarantees.

On August 13, 2013, venture funds affiliated with Sanderling Ventures exercised PIPE Warrants to purchase an aggregate of 650,619 shares of common stock in a cashless net exercise as provided for in the PIPE Warrants, which resulted in the issuance to such funds of an aggregate of 308,194 shares of common stock. As a result, there were no net proceeds to the Company.

On August 16, 2013, certain affiliates of Franklin Templeton exercised PIPE Warrants to purchase an aggregate of 650,618 shares of common stock for cash. The Company received an aggregate of $2,186,727 gross proceeds from the sale.

On August 16, 2013, Alafi Capital Company exercised PIPE Warrants to purchase an aggregate of 261,241 shares of common stock for cash. The Company received an aggregate of $878,031 gross proceeds from the sale.

On November 27, 2013, the Company announced the results of its previously announced offering of subscription rights to purchase shares of its common stock, par value $0.001 per share. Pursuant to the rights offering, subscription rights to purchase approximately 3.4 million shares of common stock were exercised, resulting in gross proceeds to Stereotaxis of approximately $10.2 million.

The holders of common stock are entitled one vote for each share held and to receive dividends whenever funds are legally available and when declared by the Board of Directors subject to the prior rights of holders of all classes of stock having priority rights as dividends and the conditions of the Revolving Credit Agreement. No dividends have been declared or paid as of December 31, 2013.

Liquidity

The following table summarizes our cash flow by operating, investing and financing activities for each of years ended December 31, 2013, 2012, and 2011 (in thousands):

	2013	2012	2011
Cash flow used in operating activities	$ (6,332)	$ (12,118)	$ (31,569)
Cash flow used in investing activities		(131)	(1,032)
Cash flow provided by financing activities	12,329	6,071	11,307

Net cash used in operating activities. We used approximately $6.3 million, $12.1 million, and $31.6 million of cash in operating activities during the years ended December 31, 2013, 2012, and 2011, respectively. The decrease in cash used in operating activities from December 31, 2011, to December 31, 2013, is primarily a result of reduction in operating losses from 2011 to 2012 and changes in working capital from 2012 to 2013.

Net cash used in investing activities. There were no purchases of equipment during the year ended December 31, 2013. We used approximately $0.1 million and $1.0 million to fund investing activities during the years ended December 31, 2012, and 2011, respectively, for the purchase of property and equipment.

Net cash provided by financing activities. We generated approximately $12.3 million from financing activities during the year ended December 31, 2013 compared to $6.1 million generated for the year ended December 31, 2012 and $11.3 million generated for the year ended December 31, 2011. The increase in cash generated from 2012 to 2013 was primarily driven by increased stock transactions, including warrant exercises, of $12.2 million compared to 2012 offset by reduced debt financing of $5.9 million in 2013 compared to 2012. The decrease from 2011 to 2012 cash generated was primarily due to $7.7 million from the issuance of subordinated convertible debentures and warrants, $9.1 million from stock and warrants and $2.5 million in additional borrowing from Healthcare Royalty Partners partially offset by $8.0 million net payments under our revolving line of credit, $4.0 million related to the term note, and $1.3 million for the Healthcare Royalty Partners debt.

At December 31, 2013, we had working capital of approximately $4.4 million, compared to a working capital deficit of $5.7 million at December 31, 2012.

As of December 31, 2013, the Company had no outstanding debt under the revolving line of credit. Draws on the line of credit are made based on the borrowing capacity one week in arrears. As of December 31, 2013, the Company had a borrowing capacity of $3.0 million based on the Company s collateralized assets. As such, the Company had ability to borrow $3.0 million under the revolving line of credit at December 31, 2013. The maturity date of the revolving line of credit is March 31, 2014.

These credit facilities are secured by substantially all of our assets. The credit agreements include customary affirmative, negative and financial covenants. For example, we are restricted from incurring additional debt, disposing of or pledging our assets, entering into merger or acquisition agreements, making certain investments, allowing fundamental changes to our business, ownership, management or business locations, and from making certain payments in respect of stock or other ownership interests, such as dividends and stock repurchases. Under our loan arrangements, as in effect at December 31, 2013 and as modified in August 2013, we are required to meet EBITDA and liquidity covenants as defined in the loan agreement. We are also required under the credit agreements to maintain our primary operating account and the majority of our cash and investment balances in accounts with our primary lending bank. As of the amendment date and as of December 31, 2013, we were in compliance with all covenants of this agreement.

We expect to have negative cash flow from operations into 2014. Throughout 2014, we expect to continue the development and commercialization of our existing products, our research and development programs and the advancement of new products into clinical development. During 2014, we expect operating expenses to be generally consistent with 2013 with additional investment in certain targeted areas.

We may be required to raise capital or pursue other financing strategies to continue our operations. Until we can generate significant cash flow from our operations, we expect to continue to fund our operations with cash resources primarily generated from the proceeds of our past and future public offerings, private sales of our equity securities and working capital and equipment financing loans. In the future, we may finance cash needs through the sale of other equity securities or non-core assets, strategic collaboration agreements, debt financings or through distribution rights. We cannot accurately predict the timing and amount of our utilization of capital, which will depend on a number of factors outside of our control. Our existing cash, cash equivalents and borrowing facilities may not be sufficient to fund our operating expenses and capital equipment requirements through the next 12 months, which would require us to obtain additional equity or other financing before that time. We cannot assure that such additional financing will be available on a timely basis on terms acceptable to us or at all, or that such financing will not be dilutive to our stockholders. If adequate funds are not available to us, we could be required to delay development or commercialization of new products, to license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize ourselves or to reduce the sales, marketing, customer support or other resources devoted to our products, any of which could

have a material adverse effect on our business, financial condition and results of operations. In addition, we could be required to cease operations.

Off-Balance Sheet Arrangements

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

Contractual Obligations

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

	Payments by Period (In thousands)				
	Under 1 Year	1 3 Years	3 5 Years	Over 5 Years	Total
Long-term debt	$ 50	$ 99	$ 18,382	$	$ 18,531
Operating leases	$ 1,594	$ 3,493	$ 3,990	$	$ 9,077
Total	$ 1,644	$ 3,592	$ 22,372	$	$ 27,608

Commercial Commitments

In 2012, we entered into a letter of credit to support a commitment in the amount of approximately $0.1 million. This letter of credit is valid through 2015.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

Foreign Exchange Risk

We operate mainly in the U.S., Europe and Asia and we expect to continue to sell our products both within and outside of the U.S. Although the majority of our revenue and expenses are transacted in U.S. dollars, a portion of our operations are conducted in Euros and to a lesser extent, in other currencies. As such, we have foreign exchange exposure with respect to non-U.S. dollar revenues and expenses as well as cash balances, accounts receivable, accounts payable and other asset and liability balances denominated in non-US dollar currencies. Our international operations are subject to risks typical of international operations, including, but not limited to, differing economic conditions, changes in political climate, differing tax structures, other regulations and restrictions, and foreign exchange rate volatility. Future fluctuations in the value of these currencies may affect the price competitiveness of our products. In addition, because we have a relatively long installation cycle for our systems, we will be subject to risk of currency fluctuations between the time we execute a purchase order and the time we deliver the system and collect payments under the order, which could adversely affect our operating margins. As of December 31, 2013 we have not hedged exposures in foreign currencies or entered into any other derivative instruments.

For the year ended December 31, 2013, sales denominated in foreign currencies were approximately 15.3% of total revenue. For the year ended December 31, 2013, our revenue would have decreased by approximately $0.6 million if the U.S. dollar exchange rate used would have strengthened by 10%. For the year ended December 31, 2013, expenses denominated in foreign currencies were approximately 13.5% of our total expenses. For the year ended December 31, 2013, our operating expenses would have decreased by approximately $0.5 million if the U.S. dollar exchange rate used would have strengthened by 10%. In addition,

we have assets and liabilities denominated in foreign currencies. A 10% strengthening of the U.S. dollar exchange rate against all currencies with which we have exposure at December 31, 2013 would have resulted in a $0.1 million decrease in the carrying amounts of those net assets.

Interest Rate Risk

We have exposure to interest rate risk related to our investment portfolio. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing the risk of loss. Our interest income is sensitive to changes in the general level of U.S. interest rates, particularly since the majority of our investments are in short-term debt instruments. We invest our excess cash primarily in U.S. government securities and marketable debt securities of financial institutions and corporations with strong credit ratings. These instruments generally have maturities of two years or less when acquired. We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions. Accordingly, we believe that while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments.

We have exposure to market risk related to any investments we might hold. Market liquidity issues might make it impossible for the Company to liquidate its holdings or require that the Company sell the securities at a substantial loss. As of December 31, 2013, the Company did not hold any investments other than those held in money market funds.

We have exposure to interest rate risk related to our borrowings as the interest rates for certain of our outstanding loans are subject to increase should the interest rate increase above a defined percentage. Because certain issuances of our outstanding debt are subject to minimum interest rates ranging from 5.75% to 7.0%, a hypothetical increase in interest rates of 100 basis points would have no impact on interest expense due to interest rate floors on our floating rate debt.

Inflation Risk

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial Statements

Index To Financial Statements

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

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Stereotaxis, Inc.

We have audited the accompanying balance sheets of Stereotaxis, Inc. (the Company) as of December 31, 2013 and 2012, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2013. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Stereotaxis, Inc. at December 31, 2013 and 2012, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles**.** Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth herein.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred recurring operating losses and has a net capital deficiency. These conditions raise substantial doubt about the Company s ability to continue as a going concern. Management s plans in regard to these matters also are described in Note 1. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty regarding the Company s ability to continue as a going concern.

/s/ Ernst & Young LLP

St. Louis, Missouri

March 27, 2014

STEREOTAXIS, INC.

BALANCE SHEETS

	December 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 13,775,130	$ 7,777,718
Accounts receivable, net of allowance of $383,077 and $640,183 in 2013 and 2012, respectively	7,558,152	11,570,489
Inventories	4,879,039	5,098,241
Prepaid expenses and other current assets	1,945,206	3,492,067
Total current assets	28,157,527	27,938,515
Property and equipment, net	1,184,589	2,141,923
Intangible assets, net	1,679,486	1,979,320
Long-term receivables	20,431	73,199
Other assets	34,363	32,987
Total assets	$ 31,076,396	$ 32,165,944
Liabilities and stockholders deficit		
Current liabilities:		
Short-term debt and current maturities of long-term debt	$ 49,733	$ 12,264,490
Accounts payable	3,512,339	3,556,688
Accrued liabilities	7,079,381	5,361,810
Deferred revenue	7,519,754	9,502,939
Warrants and debt conversion features	5,644,626	2,968,348
Total current liabilities	23,805,833	33,654,275
Long-term debt, less current maturities	18,481,478	16,824,736
Long-term deferred revenue	491,080	477,159
Other liabilities		
Stockholders deficit:		
Preferred stock, par value $0.001; 10,000,000 shares authorized, none outstanding at 2013 and 2012		
Common stock, par value $0.001; 300,000,000 shares authorized, 19,311,390 and 8,018,615 shares issued at 2013 and 2012, respectively	19,311	8,019
Additional paid in capital	441,888,155	366,053,627
Treasury stock, 4,015 shares at 2013 and 2012	(205,999)	(205,999)
Accumulated deficit	(453,403,462)	(384,645,873)
Total stockholders deficit	(11,701,995)	(18,790,226)
Total liabilities and stockholders deficit	$ 31,076,396	$ 32,165,944

See accompanying notes.

STEREOTAXIS, INC.

STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2013	**2012**	**2011**
Revenue:			
Systems	$ 12,743,218	$ 19,672,983	$ 15,585,538
Disposables, service and accessories	25,287,863	26,889,451	26,401,894
Total revenue	38,031,081	46,562,434	41,987,432
Cost of revenue:			
Systems	6,870,954	9,905,528	8,576,283
Disposables, service and accessories	4,130,347	4,875,527	3,921,798
Total cost of revenue	11,001,301	14,781,055	12,498,081
Gross margin	27,029,780	31,781,379	29,489,351
Operating expenses:			
Research and development	5,672,058	8,405,086	12,886,488
Sales and marketing	17,132,093	20,607,999	31,635,415
General and administrative	13,066,103	13,394,556	16,908,656
Total operating expenses	35,870,254	42,407,641	61,430,559
Operating loss	(8,840,474)	(10,626,262)	(31,941,208)
Other income (expense)	(47,349,378)	8,265,507	3,416,383
Interest income	5,800	7,361	9,052
Interest expense	(12,573,537)	(6,885,033)	(3,515,402)
Net loss	$ (68,757,589)	$ (9,238,427)	$ (32,031,175)
Net loss per common share:			
Basic	$ (5.95)	$ (1.33)	$ (5.84)
Diluted	$ (5.95)	$ (1.33)	$ (5.84)
Weighted average shares used in computing net loss per common share:			
Basic	11,554,566	6,944,928	5,482,627
Diluted	11,554,566	6,944,928	5,482,627

See accompanying notes.

STEREOTAXIS, INC.

STATEMENTS OF STOCKHOLDERS EQUITY

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders Equity (Deficit)
Balance at December 31, 2010	5,474,624	$ 5,475	$ 354,052,041	$ (205,999)	$ (343,376,271)	$ 10,475,246
Issuance of common stock	8,400	8	(8)			
Share-based compensation			2,487,441			2,487,441
Issuance of stock under stock purchase plan	8,449	9	232,382			232,391
Exercise of stock options	468		7,202			7,202
Grant of restricted shares, net of forfeitures	51,216	51	(51)			
Net Loss					(32,031,175)	(32,031,175)
Balance at December 31, 2011	5,543,157	$ 5,543	$ 356,779,007	$ (205,999)	$ (375,407,446)	$ (18,828,895)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders Equity (Deficit)
Balance at December 31, 2011	5,543,157	$ 5,543	$ 356,779,007	$ (205,999)	$ (375,407,446)	$ (18,828,895)
Issuance of common stock and warrants	2,415,339	2,415	10,409,260			10,411,675
Share-based compensation			2,293,731			2,293,731
Issuance of stock under stock purchase plan	10,315	10	73,543			73,553
Grant of restricted shares, net of forfeitures	19,885	20	(20)			
Restricted stock vestings	29,919	31	(31)			
Reclassification of warrants to liability			(3,501,863)			(3,501,863)
Net Loss					(9,238,427)	(9,238,427)
Balance at December 31, 2012	8,018,615	$ 8,019	$ 366,053,627	$ (205,999)	$ (384,645,873)	$ (18,790,226)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders Equity (Deficit)
Balance at December 31, 2012	8,018,615	$ 8,019	$ 366,053,627	$ (205,999)	$ (384,645,873)	$ (18,790,226)
Issuance of common stock and warrants	7,742,717	7,743	64,586,770			64,594,513
Share-based compensation			1,050,260			1,050,260
Rights offering	3,400,349	3,400	10,197,647			10,201,047
Grant of restricted shares, net of forfeitures	(61,910)	(62)	62			
Restricted stock vestings	211,619	211	(211)			
Net Loss					(68,757,589)	(68,757,589)
Balance at December 31, 2013	19,311,390	$ 19,311	$ 441,888,155	$ (205,999)	$ (453,403,462)	$ (11,701,995)

See accompanying notes.

STEREOTAXIS, INC.

STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2013	**2012**	**2011**
Cash flows from operating activities			
Net loss	$ (68,757,589)	$ (9,238,427)	$ (32,031,175)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation	919,136	1,300,188	1,462,238
Amortization of intangibles	299,833	299,833	299,833
Amortization of deferred finance costs and debt discount	7,703,336	2,977,119	1,331,549
Share-based compensation	1,050,260	2,293,731	2,487,441
Non-cash royalty (income), net			(2,353,718)
Gain on debt conversion		(75,612)	
Loss on asset disposal	36,103	12,444	86,278
Adjustment of warrants and convertible debt features	47,450,066	(8,189,895)	(3,416,383)
Interest due from issuance of stock	551,296	192,128	
Changes in operating assets and liabilities:			
Accounts receivable	4,013,279	(447,613)	2,811,531
Other receivables	51,827	19,534	28,495
Inventories	219,202	937,810	(594,576)
Prepaid expenses and other current assets	429,025	(760,474)	827,297
Other assets	(1,376)	7,773	(2,223)
Accounts payable	(44,349)	(2,053,493)	(3,186,001)
Accrued liabilities	1,717,571	(514,689)	(1,090,072)
Deferred revenue	(1,969,264)	1,125,079	1,775,856
Other liabilities		(3,094)	(5,648)
Net cash used in operating activities	(6,331,644)	(12,117,658)	(31,569,278)
Cash flows from investing activities			
Purchase of equipment		(130,699)	(1,031,749)
Net cash used in investing activities		(130,699)	(1,031,749)
Cash flows from financing activities			
Payments of term loan	(4,000,000)		