Stereotaxis, Inc.
Form 10-K
March 11, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(MARK ONE)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2015

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 Capital Market on June 30, 2015) was approximately $27.7 million.

The number of outstanding shares of the registrant s common stock on February 29, 2016 was 21,622,856.

DOCUMENTS INCORPORATED BY REFERENCE

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STEREOTAXIS, INC.

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ITEM 1. BUSINESS

In this report, Stereotaxis , the Company , Registrant , we , us , and our refer to Stereotaxis, Inc. and its wholly owned subsidiaries. Epoch®, Niobe®, Odyssey®, Odyssey Cinema , Vdrive®, Vdrive Duo , V-CAS , V-Loop , V-Sono , QuikCAS , CardioDrive®, and Pegasus are trademarks of Stereotaxis, Inc. All other trademarks that 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 , estim potential , or continue , or the negative of such terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. These

statements are only predictions.

Factors that may cause our actual results to differ materially from our forward-looking statements include, among others, changes in general economic and business conditions and the risks and other factors set forth in Item 1A Risk Factors and elsewhere in this annual report on Form 10-K.

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

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OVERVIEW

We design, manufacture and market 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 Remote Magnetic Navigation System (*Niobe* ES system), *Odyssey* Information Management Solution (*Odyssey* Solution), and the *Vdrive* Robotic Navigation System (*Vdrive* system), and related devices. We consider our technology an important advancement in the ongoing trend toward fully digitized, integrated and automated interventional labs. We believe our technology provides substantial, clinically important improvements over manual interventional methods, which often result in long and unpredictable procedure times with suboptimal therapeutic outcomes. We believe our products also support 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.

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, 2015, we had approximately $6.0 million of backlog, consisting of outstanding purchase orders and other commitments for these systems. We had backlog of approximately $5.7 million and $6.8 million as of December 31, 2014 and 2013, respectively. Of the December 31, 2015 backlog, we expect approximately 79% to be recognized as revenue over the course of 2016. 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 and distribution 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 in certain countries such as the United States. 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.

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THE STEREOTAXIS VALUE PROPOSITION

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.

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 electrophysiology and interventional cardiology procedures, on a cost-justified basis.

We believe that our systems will:

Improve patient 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. Maintaining this precision and contact can be very challenging, especially in the most complex procedures, such as those for the treatment of ventricular tachycardia. 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 affecting more precise, safe, treatments once these sites are reached.

Expand the market by enhancing the treatment of more complex cases. Treatment of a number of major diseases, including ventricular tachycardia, atrial fibrillation, congenital heart diseases, 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 ventricular tachycardia and atrial fibrillation are often referred to other more invasive or less curative therapies because of the difficulty in precisely and safely controlling the working tip of disposable interventional devices used to treat these complex cases interventionally. Because our robotic technology provides precise, computerized control of the working tip of disposable interventional devices, we believe that it will potentially enable difficult ventricular tachycardia, atrial fibrillation, and congenital heart diseases to be treated interventionally on a much broader scale than today.

Enhance patient and physician safety. The *Niobe* system has been used in more than 85,000 procedures and the incidence of 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 through reduced usage of fluoroscopy during procedures with the *Niobe* system due to enhanced and more fully integrated mapping capabilities of the *Niobe* software. Our robotic technology can further improve physician safety and reduce physician fatigue by enabling them to conduct

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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 procedure times compared to manual procedures, especially in the most complex procedures such as the treatment of ventricular tachycardia. 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 can result from decreased use of multiple catheters, high-end deflectable sheaths, 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 Remote 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 an adjacent room and outside the x-ray fluoroscopy field or beside the patient table, as in traditional interventional procedures. 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

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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 initially launched in 2005 and continues to develop significantly as the various systems advance.

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

Niobe® Remote 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)* in conjunction with the *QuikCAS* automated catheter advancement system is used to remotely advance and retract the electrophysiology catheter in the patient s heart while the *Niobe* magnets precisely steer the working tip of the device.

Niobe system revenue represented 19% and 12% of revenue for the years ended December 31, 2015 and 2014, respectively.

***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. 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.

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Vdrive **Robotic Navigation System**

The *Vdrive* system provides 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 three available disposable options (*V-Loop*, *V-Sono* and*, V-CAS*).

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, with sales of such magnetically-enabled catheters generating royalty payable from Biosense Webster to Stereotaxis; and

- The *Pegasus* coronary guidewire 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-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 from the control room, store and recall previous positions and automatically sweep over an area of interest with adjustable speed and angle, and automatically track a 3.5mm NAVISTAR® RMT THERMOCOOL® Irrigated Tip Catheter all without leaving the control room.

Disposable revenue including royalties represented 34% and 39% of revenue for the years ended December 31, 2015 and 2014, respectively.

Other Recurring Revenue

Other recurring revenue includes revenue from software licenses, product maintenance plans, and other post warranty maintenance. Revenue from services and license fees is deferred and amortized over the service or

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license fee period, which is typically one year. Other recurring revenue represented 37% and 38% of revenue for the years ended December 31, 2015 and 2014, respectively.

Regulatory Approval

We have received regulatory clearance, licensing and/or CE Mark approvals necessary for us to market the *Niobe* system, *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, Japan and other selected countries and we are in the process of obtaining necessary approvals for extending our markets in other countries.

We have received regulatory clearance, licensing and/or CE Mark approvals necessary for us to market the *Vdrive* and *Vdrive Duo* systems with the *V-CAS, V-Loop* and *V-Sono* devices in the U.S., Canada and European Union.

We have received Food and Drug Administration (FDA) clearance and the CE Mark necessary for us to market the *Pegasus* coronary peripheral guidewires in the U.S. and Europe.

Biosense Webster has received FDA approval, and CE Mark for the CARTO® RMT navigation system for use with the *Niobe* system, the 4mm CELSIUS® RMT Diagnostic/Ablation Steerable Tip Catheter, the 4mm NAVISTAR® RMT Diagnostic/Ablation Steerable Tip Catheter, the 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. Biosense Webster also received China CFDA approval and Japan PMDA approval for the CARTO® RMT navigation system for use with the *Niobe* system, and the 3.5mm NAVISTAR® 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 AND CUSTOMERS

Our total U.S. revenue was $19.8 million and $21.6 million for the years ended December 31, 2015 and 2014, respectively. Our total international revenue was $17.9 million and $13.4 million for the years ended December 31, 2015 and 2014, respectively. No single country other than the U.S. accounted for more than 10% of total revenue for the years ended December 31, 2015 and 2014. Biosense Webster Inc. accounted for $3.5 million, and $4.7 million, or 9%, and 13% of total net revenue for the years ended December 31, 2015 and 2014, respectively. No other single customer accounted for more than 10% of total revenue for the years ended December 31, 2015 and 2014.

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 some of our patents may be applicable in these areas as well.

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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 5.0 million people in the U.S. currently suffer from the resulting abnormal heart rhythms, which are known as arrhythmias. The prevalence of arrhythmias is expected to continue to rise as the population ages and life expectancy continues to increase. These conditions are a major physical and economic burden and are 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 arrhythmias a major economic factor in healthcare. We believe payors are very interested in therapies that may reduce the financial impact of these diseases.

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. Nearly one million electrophysiology procedures are performed annually worldwide, and procedure growth rate is over 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:

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.

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. 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 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.

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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.

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, 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 approximately 11,000 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. We believe 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;

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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. Through our alliance with Biosense Webster, we have successfully integrated 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 the *Niobe* system. We have jointly developed associated location and non-location sensing electrophysiology mapping and ablation catheters that are navigable with the *Niobe* system. We believe that these integrated products 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 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. Additionally, Biosense Webster has non-exclusive rights until May 2016 to resell Stereotaxis *Odyssey* products, including *Odyssey* Vision and *Odyssey Cinema* systems in most countries.

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. Royalty revenue from the co-developed catheters represented 8% and 9% of revenue for the years ended December 31, 2015 and 2014, respectively. 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.

Biosense Webster s distribution rights for co-developed catheters were exclusive through December 31, 2015 and currently are nonexclusive until December 31, 2018. Biosense Webster s right to distribute such products in Japan is exclusive until March 22, 2018 and nonexclusive until March 22, 2021. The agreement provides an opportunity to expand the product offering covered by the agreement to include a next generation irrigated magnetic catheter, subject to mutually agreeable terms including exclusive distribution rights.

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. These restrictions are no longer applicable after December 31, 2015. Additionally, 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

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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.

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, 2015, 2014, and 2013, were $6.3 million, $5.2 million, and $5.7 million, respectively.

CUSTOMER SERVICE AND SUPPORT

We provide worldwide maintenance and support services to our customers for our integrated products directly or with the assistance of outsourced product and service 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 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

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manufacturing strategy for *Vdrive* system is to build all subassemblies in-house using sub-contract manufactured components. We maintain quality control for all of our systems by completing final system assembly and inspection in-house.

We purchase both custom and off-the-shelf components from a large number of suppliers and subject them to quality specifications and processes. Some of the components necessary for the assembly of our products are currently provided to us by sole-sourced suppliers (the only recognized supply source available to us) or single-sourced suppliers (the only approved supply source for us among other sources). We purchase the majority of our components and major assemblies through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of finished goods.

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 facility operates under processes that meet the FDA s requirements under the Quality System Regulation (QSR). Our ISO registrar and European notified British Standard Institution (BSI) has audited our facility annually since 2001 and found the facility to be in compliance with relevant 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 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

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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 have 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), and has established a technical fee of Japanese Yen 50,000. 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

The proprietary nature of, and protection for, our products, processes and know-how are important to our business. We seek patent protection in the United States and internationally for our systems and other technology where available and when appropriate.

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, 2015, we had 89 issued U.S. patents, 1 co-owned U.S. patent and no licensed-in U.S. patents. In addition, we had 13 pending U.S. patent applications and 1 co-owned U.S. patent application. As of December 31, 2015 we had 44 issued foreign patents and nine owned foreign patent applications. The key patents that protect our *Niobe* system extend until 2022 and beyond. We also have a number of invention disclosures under consideration and several applications that are being prepared for filing. We cannot be certain that any patents will be issued from any of our pending patent applications, nor can we be certain that any of our existing patents or any patents that may be granted in the future will provide us with protection.

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 in the U.S. 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

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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.

In addition, we seek to protect our proprietary information by entering into confidentiality, assignment of invention or license agreements with our employees, consultants, contractors, advisers and other third parties. However, we believe that these measures afford only limited protection.

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.

In electrophysiology we consider the primary competition to our *Epoch* Solution to be traditional catheter-based electrophysiology ablation approaches including RF (radiofrequency) ablation and non-RF therapies. To our knowledge, we are the only company that has commercialized remote, digital and direct control of the working tip of catheters for use in RF ablation procedures. Our success depends in part on convincing hospitals and physicians to convert traditional interventional procedures to procedures using our *Epoch* Solution.

We face competition from companies that are developing and marketing new products for use in electrophysiology. These products include next generation mapping systems and RF ablation devices with which our *Epoch* Solution is not currently compatible, as well as new products for use in other interventional therapies. Some of these products are marketed by companies that may have an established presence in the field of electrophysiology, including major imaging, capital equipment and disposables companies that are currently selling products in the interventional lab. In addition, we face competition from companies that currently market or are developing drugs, gene or cellular therapies to treat the conditions for which our products are intended.

We also face competition from companies that are developing remote interventional techniques. We are aware of one public company and two private companies that have commercialized electrophysiology catheter navigation systems which have been cleared by the FDA for mapping procedures only. In addition, we are aware of two private companies with an electromagnetic catheter navigation system that have received CE Mark approval in Europe.

We face direct competition to certain products in our *Odyssey* Solution, such as the *Odyssey* Vision system. These competitors include established imaging companies as well as dedicated solution providers. 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

Our products are medical devices that are subject to extensive regulation in the U.S. and in foreign countries where we do business. The U.S. FDA regulates the development, testing, manufacturing, labeling, storage, recordkeeping, promotion, marketing, distribution and service of medical devices in the U.S. to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical devices manufactured in the U.S. to international markets and the importation of medical devices manufactured abroad.

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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, our products must meet the requirements of a large and growing body of international standards which govern the design, manufacture, materials content and sourcing, testing, certification, packaging, installation, use and disposal of our products. Failure to meet these standards could limit the ability to market our products in those regions which require compliance to such standards. Examples of groups of such standards are electrical safety standards such as those of the International Electrotechnical Commission and composition standards such as the Reduction of Hazardous Substances (RoHS) and Waste Electrical and Electronic Equipment (WEEE) Directives.

U.S. Food and Drug Administration

Unless an exemption applies, each medical device we wish to commercially market in the United States will require 510(k) clearance, de novo approval, or pre-market approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risks are placed in either Class I or II, which requires the manufacturer to submit to the FDA a pre-market notification requesting permission to commercially distribute the device, known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, or life-supporting, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III, requiring pre-market approval, or PMA. All of our current products are Class II devices requiring 510(k) clearances. Biosense Webster s compatible catheters used with our *Niobe* system are Class III therapeutic devices and are subject to the PMA process.

If U.S. 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 a 510(k), de novo, or PMA).

When a 510(k) clearance is required, we must submit a pre-market notification demonstrating that our proposed device is substantially equivalent to a previously cleared and legally marketed 510(k) device, de novo approved device, or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of pre-market approval applications. 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. The FDA may require further information, including clinical trial results or product test data, to make a determination regarding substantial equivalence. The FDA s 510(k) clearance process usually takes from four to 12 months, but can take longer.

If a device is not eligible for the 510(k) clearance process, but the product is low or moderate risk, we may be able to obtain de novo review. The de novo process allows FDA to classify a low- to moderate-risk device not previously classified into Class I or II. If the device is not eligible for either the 510(k) or de novo processes, a PMA must be submitted to the FDA. A PMA must be supported by extensive data, including but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate reasonable evidence of the device s safety and efficacy to the FDA s satisfaction. The PMA process is much more costly, lengthy and uncertain than the 510(k) clearance process, and it generally takes from one to three years, but can take longer. We cannot be sure that the FDA will ever grant 510(k) clearance, de novo approval or pre-market approval for any product we propose to market in the United States.

After a device receives 510(k) clearance or de novo approval, any modification that could significantly affect its safety or effectiveness, or that would constitute a significant change in its intended use, will require a

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new clearance. Modification 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.

After a device is placed on the market, numerous regulatory requirements apply. These include for example:

- The Quality System Regulation, or QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, documentation and other quality assurance procedures during product design and throughout the manufacturing process;

- Labeling requirements and the FDA prohibitions against promoting products for uncleared, unapproved or off-label uses;

- Medical device reporting regulations, 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 the malfunction were to recur; and

- 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.

The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA to determine our compliance with the QSR and other regulations. If we fail to comply with the QSR or other regulatory requirements, we may receive a warning or untitled letter from the FDA or be subject to other enforcement actions, including fines, injunctions, civil penalties, seizures, operating restrictions, partial suspension or total shutdown of production, refusing requests for 510(k) clearance, de novo petitions, or PMA approval of new products, withdrawing 510(k) clearance, de novo approvals, or PMA approvals already granted, and criminal prosecution. The FDA also has the authority to require us to repair, replace or refund the cost of any medical device that we have manufactured or distributed, if there is a reasonable probability that the device would cause serious, adverse health consequences or death.

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 and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries may differ from that required to obtain FDA clearance or approval.

The primary regulatory environment in Europe is that of the European Union, which encompasses most of the major countries in Europe. The European Union, along with other member countries of the European Economic Area, or EEA, 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 EEA. The CE Mark is an international symbol of adherence to quality assurance standards and compliance with applicable 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 medical device manufacturer to affix the CE Mark on its products and commercially distribute those products throughout the EEA. We are subject to annual surveillance audits and periodic re-certification audits in order to maintain our CE Mark permissions.

To be sold in Japan, most medical devices must undergo thorough safety examinations and demonstrate medical efficacy before they receive regulatory (Shonin) approval. We are subject to additional regulations in other foreign countries, including, but not limited to, Canada, Taiwan, China, Korea, and Russia, in order to sell our products. We intend that either we or our distributors will receive any necessary approvals or clearance prior to marketing our products in these international markets.

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Please refer to Regulatory Approval in Item 1 of this annual report for a description of the regulatory clearance, licensing and/or approvals we currently have or are pursuing.

Anti-Kickback and False Claims Laws

We are subject to various federal and state laws relating to healthcare fraud and abuse, including anti-kickback and false claims laws. The U.S. 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, the furnishing of supplies or equipment, credit arrangements, payments of cash and waivers of payments, and providing anything of value at less than fair market value. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws

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

Transparency Laws

Under the Physician Payments Sunshine Act, or the Sunshine Act, which was enacted by Congress as part of the Patient Protection and Affordable Care Act, we are required to track and report to the federal government on an annual basis, subject to certain exceptions, all payments and other transfers of value to U.S. physicians and teaching hospitals, as well as ownership interests held by physicians. Such data are made available by the government on a publicly searchable website. In addition, we are subject to similar state laws related to the tracking and reporting of certain payments and other transfers of value to healthcare professionals.

HIPAA and Other Privacy Laws

We are subject to laws and regulations protecting the privacy and integrity of patient medical information, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which 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. HIPAA also prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. 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.

Certificate of Need Laws

In a number of states in the U.S., 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. Many of the states in which we sell *Niobe* systems have laws that require institutions located in those states to

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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.

Employees

As of December 31, 2015, we had 126 employees, 22 of whom were engaged directly in research and development, 57 in sales and marketing activities, 19 in manufacturing and service, 6 in regulatory, clinical affairs and quality activities, 5 in training activities and 17 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.

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ITEM 1A. RISK FACTORS

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

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, 2015, we had cash and cash equivalents of $5.6 million and working capital of $1.1 million. We incurred operating losses of $5.4 million, $5.4 million, and $8.8 million in 2015, 2014 and 2013, 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 2013 and 2014 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 have recently received a notice from Nasdaq advising that we do not meet the continued listing standards of The Nasdaq Capital Market. If we are unable to maintain a listing on a national securities exchange, it could negatively impact the price and liquidity of our common stock and our ability to access the capital markets, which could impair the value of your investment.

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain that listing, we must satisfy minimum financial and other listing requirements. On August 5, 2015, the Nasdaq Listing Qualifications Department (the Staff) notified us that we did not comply with the rule regarding the minimum market value of listed securities, because the Company did not maintain a minimum market value of listed securities of $35 million for the 30 consecutive business days prior to the date of the letter, and that if we were unable to demonstrate compliance with this requirement during the applicable grace period, our common stock would be subject to delisting after that time.

On February 2, 2016, we received a determination letter from the Staff notifying us that because we did not regain compliance with the market value of listed securities rule by the applicable deadline, our common stock

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would be subject to delisting from Nasdaq unless the Company requests a hearing before the Nasdaq Listing Qualifications Panel (the Panel). The Company submitted a timely request for a hearing before the Panel, at which we will present our plan to achieve compliance with the continued listing requirements for The Nasdaq Capital Market. The delisting of our common stock is automatically stayed pending the issuance of the Panel s decision following the hearing and the expiration of any extension period granted by the Panel. Under the Nasdaq Listing Rules, the Panel may, in its discretion, determine to continue the Company s listing pursuant to an exception for a maximum of 180 calendar days from the date of the Staff s determination letter, or through July 31, 2016.

The Staff has also informed us that if we are subject to a compliance period for another deficiency under the Nasdaq Listing Rules, at the hearing, we must also address our plan for regaining compliance with that particular requirement within the applicable compliance period. On January 20, 2016, we received notice from the Staff that our common stock had not met the $1.00 per share minimum bid price requirement for 30 consecutive business days prior to the date of the notice, and we were provided 180 calendar days, or until July 18, 2016, to regain compliance with that requirement. We would regain compliance with the minimum bid price requirement if the bid price of our common stock closes at $1.00 per share or more for a minimum of 10 consecutive business days at any time before July 18, 2016. However, we may be unable to do so in that time frame or at all. Further, our common stock may be delisted from The Nasdaq Stock Market prior to July 18, 2016, if the Panel does not accept our plan to regain compliance with the market value of listed securities requirement or if the additional time to regain compliance granted by the Panel expires before July 18, 2016 and we are not able to achieve compliance by the end of the extension period.

There is no assurance that the Panel will accept our compliance plan. Even if the Panel accepts our compliance plan and we are granted additional time to regain compliance with The Nasdaq Capital Market listing standards, there can be no assurance that we will be able to evidence compliance by the deadline established by the Panel. If the Panel does not accept our compliance plan, or if it accepts our compliance plan and we are not able to achieve compliance by the established deadline, then our common stock will be delisted. If our common stock is delisted from The Nasdaq Stock Market, we anticipate that our common stock will be immediately eligible for quotation on the OTC Market.

The delisting of our common stock from The Nasdaq Stock Market could adversely affect the market liquidity of our common stock, limit or prohibit the use of our Controlled Equity Offering, and adversely affect our ability to obtain financing for the continuation of our operations which could harm our business or cause us to cease operations. In addition, the delisting of our common stock from The Nasdaq Stock Market could result in other negative implications, including the potential loss of confidence by suppliers, customers and employees, the loss of institutional investor interest and fewer business development opportunities. Any such developments could impair the value of your investment.

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 first quarter of 2015, we extended our revolving line of credit, which matures on March 31, 2018. 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

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replace this source of liquidity if these covenants were to be violated and our loans and other borrowed amounts were forced to be repaid.

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.

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Decreases in our backlog have occurred in the past and could 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. Since 2008, the global economy has been impacted by the effects of an ongoing global financial crisis. This global financial crisis continues to cause disruption in the financial markets, including diminished liquidity and credit availability. Uncertainty about current global economic conditions 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.

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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 devices expected by our customers for their clinical practice;
- any of our collaboration partners delays or fails in the integration of its technology or new products 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

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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 traditional 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 pharmaceuticals or other medical devices and procedures. Many of these alternative treatments are also widely accepted in the medical community and have a long history of use.

We are aware of one public company and two private companies that have commercialized electrophysiology catheter navigation systems which have been cleared by the FDA for mapping procedures only. In addition, we are aware of two private companies with an electromagnetic catheter navigation system that has received CE Mark approval in Europe.

We face competition from companies that are developing drugs, gene or cellular therapies 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 traditional interventional methods.

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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 losses into 2016 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. Although we have

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achieved operating profitability during one quarter, we may not achieve profitable operations on an annual basis, and if we achieve profitable operations, we may not sustain or increase profitability on a quarterly or annual basis. If we require more time than we expect to generate significant revenue and achieve annual profitability, or if we are unable to sustain profitability once achieved, we may not be able to continue our operations. Our failure to achieve annual profitability or sustain profitability on an annual or quarterly basis could negatively impact the market price of our common stock. 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.

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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 all or part of 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.

Security breaches and other disruptions to our information technology infrastructure could interfere with our operations, compromise confidential information, and expose us to liability which could materially adversely impact our business and reputation.

Security breaches and other disruptions to our information technology infrastructure could interfere with our operations; compromise information belonging to us, our employees, customers, and suppliers; and expose us to liability which could adversely impact our business and reputation. In the ordinary course of business, we rely on information technology networks and systems, some of which are managed by third parties, to process, transmit, and store electronic information, and to manage or support a variety of business processes and activities. Additionally, we collect and store certain data, including proprietary business information and customer and employee data, and may have access to confidential or personal information in certain of our businesses that is subject to privacy and security laws, regulations, and customer-imposed controls. Despite our cyber security measures (including employee and third-party training, monitoring of networks and systems, and maintenance of backup and protective systems) which are continuously reviewed and upgraded, our information technology networks and infrastructure may still be vulnerable to damage, disruptions, or shutdowns due to attack by hackers, breaches, employee error or malfeasance, power outages, computer viruses, telecommunication or utility failures, systems failures, natural disasters, or other catastrophic events. Any such events could result in legal claims or proceedings, liability or penalties under privacy laws, disruption in operations, and damage to our reputation, which could materially adversely affect our business. While we have experienced, and expect to continue to experience, these types of threats to our information technology networks and infrastructure, to date none of these threats has had a material impact on our business or operations.

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

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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

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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

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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. Each medical device that we wish to market in the U.S. must be designated as exempt from premarket approval or notification, or first receive either a 510(k) clearance, de novo approval, 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 new 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, de novo approvals, 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, de novo approvals, 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 alliances 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.

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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 or its policies in a way to make ongoing regulatory compliance more burdensome and difficult.

Additionally, any modification to an FDA 510(k) cleared or de novo-approved 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 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 that we determined to not require clearance or approval in the first instance, 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 or other quality standards.

Our manufacturing processes must comply with the FDA s QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging and shipping of

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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 comply with the FDA regulation 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, untitled letter, fines, injunctions, civil penalties, seizures, operating restrictions, partial suspension or total shutdown of production, refusing requests for 510(k) clearance, de novo petitions, or PMA approval of new products, withdrawing 510(k) clearance, de novo approvals, or PMA approvals already granted, and/or criminal prosecution. 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, de novo approval, 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 Statute, 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

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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.

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 continues 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. Although a two-year moratorium on the excise tax has been enacted for 2016 and 2017, the tax is currently scheduled to resume collection on January 1, 2018. 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.

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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 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 may 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

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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 below $75 million. As a result, we are limited in 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.

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Future issuances of our securities could dilute current stockholders ownership.

We have outstanding warrants to purchase 2.1 million shares of the Company s common stock at a weighted average exercise price of $4.82, with prices ranging from $1.55 to $40.15. 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.

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

The revenue and income potential of our products and our business model are unproven, and we may be unable to generate significant 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 alliances 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 2015, our common stock traded between $0.65 and $2.97 per share, on trading volume ranging from approximately 9,700 to 9.4 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

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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. In addition, the volatility of our stock price could lead to class action securities litigation being filed against us, 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 2015 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 December 31, 2018. The Company entered a sublease agreement in October 2015 to sublease 3,152 rentable square feet on the first floor of the building through December 31, 2018.

We lease approximately 2,200 square feet of office space in Maple Grove, Minnesota, under a lease agreement through October 31, 2018, and have leased office space in Amsterdam, The Netherlands through August 31, 2016. In addition, we lease an office space in Beijing, China under a lease agreement through September 8, 2017 and an office space in Japan through April 30, 2016.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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

PRICE RANGE OF COMMON STOCK

Our common stock 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, 2015		
First Quarter	$ 2.97	$ 1.43
Second Quarter	2.36	1.44
Third Quarter	2.53	0.65
Fourth Quarter	1.40	0.73
Year Ended December 31, 2014		
First Quarter	$ 6.34	$ 3.60
Second Quarter	4.74	3.10
Third Quarter	3.61	2.30
Fourth Quarter	2.35	1.32

As of February 29, 2016, there were approximately 373 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.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

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

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

Overview

Stereotaxis designs, manufactures and markets 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 system is the latest generation of the *Niobe* Remote 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 the *Odyssey* Solution that we believe can improve clinical workflows and related efficiencies.

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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*, and *V-CAS*) 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, 2015, we had incurred cumulative net losses of approximately $466.0 million. As of December 31, 2015, the Company had an installed base of 125 *Niobe* ES systems. In 2016, the Company plans to continue developing the *Niobe* ES system with the goal of furthering clinical adoption. We expect to have negative cash flow from operations into 2016 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 included 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 ongoing 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.

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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. 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 and units is amortized on a straight-line basis over the vesting period of the underlying issue, generally over four years except for grants to directors which generally vest over one to two years. Stock compensation expense for performance-based restricted shares, if any, 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

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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.

Long-Lived and Intangible Assets

In accordance with accounting rules for the impairment or disposal of long-lived assets, including intangible assets, such assets are reviewed at least quarterly to determine whether any events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. For long-lived assets to be held and used, we base our evaluation on impairment indicators such as the nature of the assets, the future economic benefit of the assets, any historical or future profitability measurements and other external market conditions or factors that may be present. If impairment indicators are present or other factors exist that indicate the carrying amount of the asset may not be recoverable, the Company determines whether an impairment has occurred through the use of an undiscounted cash flow analysis of the asset at the lowest level for which identifiable cash flows exist. Management s assumptions related to future cash flows require significant judgment as actual operating levels have fluctuated in the past and are expected to continue to do so in the future. If the carrying value of the asset exceeds the total anticipated undiscounted future cash flows generated by that asset, the asset is impaired and an impairment charge is incurred. The loss on impairment is recognized for the difference between the asset s carrying amount and the asset s discounted fair value, which in most cases is estimated based upon Level 2 or Level 3 inputs.

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, 2015 and 2014

Revenue. Revenue increased to $37.7 million for the year ended December 31, 2015, from $35.0 million for the year ended December 31, 2014, an increase of approximately 8%. Revenue from sales of systems increased to $10.6 million for the year ended December 31, 2015, from $7.8 million for the year ended December 31, 2014,

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an increase of approximately 36%. We recognized revenue on seven *Niobe* ES systems, a total of $2.8 million for *Odyssey* and *Odyssey Cinema* systems, and $0.8 million for *Vdrive* systems during the 2015 period. System revenue for the prior year included three *Niobe* ES systems, a total of $1.8 million for system installation revenue, two *Niobe* ES system upgrades and a customer deposit for a previously cancelled *Niobe* system order. In addition, in the prior year, we recognized revenue on a total of $2.8 million for *Odyssey* and *Odyssey Cinema* systems and a total of $0.8 million for *Vdrive* systems. Revenue from sales of disposable interventional devices, service and accessories decreased slightly to $27.0 million for the year ended December 31, 2015, from $27.2 million for the year ended December 31, 2014, a decrease of approximately 1%. The decrease was attributable to the impact of the stronger U.S. dollar on European sales partially offset by higher service revenue in the current year period.

Cost of Revenue. Cost of revenue increased to $10.4 million for the year ended December 31, 2015, from $8.2 million for the year ended December 31, 2014, an increase of approximately 27%. As a percentage of our total revenue, overall gross margin decreased from 77% for the year ended December 31, 2014, to 72% for the year ended December 31, 2015, due to a shift in mix from disposable, service, and accessories revenue to system revenue. Cost of revenue for systems sold increased to $6.1 million for the year ended December 31, 2015, from $4.2 million for the year ended December 31, 2014, an increase of approximately 44%. This increase was primarily due to increased *Niobe* system sales volumes. Gross margin for systems decreased to 43% for the year ended December 31, 2015 from 46% for the year ended December 31, 2014 due to increased system costs. Cost of revenue for disposable interventional devices, service and accessories increased to $4.4 million for the year ended December 31, 2015, from $4.0 million for the year ended December 31, 2014, resulting in a decrease in gross margin to 84% from 85% between these periods driven by higher expenses incurred under service contracts in the current year period.

Research and Development Expense. Research and development expense increased to $6.3 million for the year ended December 31, 2015 from $5.2 million for the year ended December 31, 2014, an increase of approximately 21%. The increase is primarily due to a one time impairment charge on certain intangible assets as well as higher headcount expenses and project spending. See Note 6 for additional detail on the asset impairment charge.

Sales and Marketing Expense. Sales and marketing expense increased to $15.9 million for the year ended December 31, 2015, from $15.2 million for the year ended December 31, 2014, an increase of approximately 4%. This increase was primarily due to the addition of sales employees leading to increased headcount and travel related expenses.

General and Administrative Expense. General and administrative expenses include regulatory, clinical, general management and routine training expenses. General and administrative expense decreased to $10.5 million for the year ended December 31, 2015, from $11.8 million for the year ended December 31, 2014, a decrease of approximately 11%. This decrease was primarily due to decreased regulatory expenses associated with our Japanese license and reduced legal and consulting expenses.

Other Income. Other income 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. The primary drivers of fluctuations in this balance are changes in the Company s stock price from one period to the next. Other income decreased to $1.3 million for the year ended December 31, 2015 from $3.5 million for the year ended December 31, 2014 due primarily to the adjustment in fair value of warrants.

Interest Expense. Interest expense has remained relatively consistent at $3.3 million for the year ended December 31, 2015 and for the year ended December 31, 2014.

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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, 2015 and 2014 to reflect these uncertainties. As of December 31, 2015, we had gross federal net operating loss carryforwards of approximately $92.7 million which will expire between 2017 and 2035. As of December 31, 2015, we had state net operating loss deferred tax assets of approximately $1.2 million which will expire at various dates between 2016 and 2035 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, 2015, our accumulated deficit was $466.0 million with cash and cash equivalents of $5.6 million, and $18.4 million debt principal outstanding. Since inception, we have financed our operations primarily through cash generated by operations, borrowings on our revolving line of credit and proceeds from our debt and stock offerings. As of December 31, 2015, our borrowing facilities were comprised of a revolving line of credit with $5.2 million of unborrowed availability with our primary lender, Silicon Valley Bank, as well as the Healthcare Royalty Partners debt discussed in the following sections.

Revolving line of credit

The Company has had a working capital line of credit with its primary lender, Silicon Valley Bank, since 2004. The revolving line of credit is secured by substantially all of the Company s assets. The Company is required under the revolving line of credit to maintain its primary operating account and the majority of its cash and investment balances in accounts with its primary lender. The facility was last amended on March 27, 2015, extending the maturity date three years to March 31, 2018 and maintaining the maximum amount available under the line of $10 million subject to the value of collateralized assets. The current agreement requires the Company to maintain a minimum tangible net worth of not less than (no worse than) negative $22.5 million, with such minimum requirement subject to increase under certain circumstances as described in the agreement, and to maintain a liquidity ratio of greater than 1.50:1.00, excluding certain short term advances from the calculation.

As of December 31, 2015, 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, 2015 the Company had a borrowing capacity of $5.2 million based on the Company s collateralized assets.

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

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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.

Common Stock

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 certain conditions of our agreement with our primary lender. No dividends have been declared or paid as of December 31, 2015.

Issuances of Common Stock

Controlled Equity Offering

In May 2014, the Company entered into a Controlled Equity Offering[SM] sales agreement (the Sales Agreement), with Cantor Fitzgerald & Co. (Cantor), as agent and/or principal, pursuant to which the Company could issue and sell, from time to time, shares of its common stock having an aggregate gross sales price of up to $18.0 million. The Company will pay Cantor a commission of 3.0% of the gross proceeds from any common stock sold through the Sales Agreement.

During the twelve months ended December 31, 2015, the Company sold an aggregate of 542,996 shares of common stock under the Sales Agreement, at an average price of approximately $1.98 per share for gross proceeds of $1,072,743 and net proceeds of $1,040,561, after deducting Cantor s commission. As of December 31, 2015, $13.8 million of common stock remained available to be sold under this facility, subject to certain conditions as specified in the Sales Agreement.

Warrant Offering

On October 8, 2015 the Company completed its offering (the Warrants Offering) of transferable subscription warrants to holders of record of the Company s common stock. Under the terms of the Warrants Offering shareholders of record on September 9, 2015 and holders of certain of the Company s warrants (pursuant to the terms of their respective warrants) were entitled to one subscription warrant to purchase one share of common stock at a price of $1.10 per share for every four common shares held up to an aggregate of 5,755,775 shares of common stock. Pursuant to the Warrants Offering, subscription warrants to purchase 267,256 shares of common stock were exercised, resulting in gross proceeds to the Company of $293,982.

Liquidity

The following table summarizes our cash flow by operating, investing and financing activities for each of years ended December 31, 2015 and 2014 (in thousands):

	2015	2014
Cash flow used in operating activities	$ (2,529)	$ (9,092)
Cash flow used in investing activities	(153)	(124)
Cash flow provided by financing activities	1,005	2,711

Net cash used in operating activities. We used approximately $2.5 million and $9.1 million of cash in operating activities during the years ended December 31, 2015 and 2014, respectively. The decrease in cash used in operating activities from 2014 to 2015 is the result of changes in cash generated by working capital.

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Net cash used in investing activities. We used approximately $0.2 million and $0.1 million during the years ended December 31, 2015 and December 31, 2014, respectively, for the purchase of property and equipment.

Net cash provided by financing activities. We generated approximately $1.0 million from financing activities during the year ended December 31, 2015 compared to $2.7 million generated for the year ended December 31, 2014. The decrease from 2014 to 2015 in cash generated was primarily due to lower proceeds from equity transactions including the controlled equity offering.

At December 31, 2015, we had working capital of approximately $1.1 million, compared to working capital of $4.8 million at December 31, 2014.

As of December 31, 2015, 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, 2015, the Company had a borrowing capacity of $5.2 million based on the Company s collateralized assets. The maturity date of the revolving line of credit is March 31, 2018.

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, 2015, we are required to meet minimum tangible net worth 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 December 31, 2015, we were in compliance with all covenants of this agreement.

We expect to have negative cash flow from operations into 2016. Throughout 2016, 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 2016, we expect operating expenses to be generally consistent with 2015 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 you that such additional financing will be available on a timely basis on terms acceptable to us or at all, that we will be able to engage in equity financings if our common stock is delisted from NASDAQ, 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.

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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.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial Statements

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

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Stereotaxis, Inc.

We have audited the accompanying balance sheets of Stereotaxis, Inc. (the Company) as of December 31, 2015 and 2014, and the related statements of operations, stockholders equity, and cash flows for each of the two years in the period ended December 31, 2015. 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, 2015 and 2014, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2015, 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 discussed in Note 1 to the financial statements, the Company has incurred recurring losses from operations and has a net capital deficiency that raise substantial doubt about the Company s ability to continue as a going concern. Management s plans in regard to these matters are also 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 11, 2016

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STEREOTAXIS, INC.

BALANCE SHEETS

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 5,593,582	$ 7,270,301
Accounts receivable, net of allowance of $93,478 and $131,464 in 2015 and 2014, respectively	6,376,470	6,480,499
Inventories	4,504,282	6,371,903
Prepaid expenses and other current assets	785,211	1,094,837
Total current assets	17,259,545	21,217,540
Property and equipment, net	1,067,321	894,728
Intangible assets, net	635,889	1,379,653
Other assets	264,159	388,850
Total assets	$ 19,226,914	$ 23,880,771
Liabilities and stockholders deficit		
Current liabilities:		
Accounts payable	$ 1,840,135	$ 2,353,133
Accrued liabilities	6,058,390	5,259,694
Deferred revenue	7,445,935	6,658,170
Warrants and debt conversion features	794,130	2,134,187
Total current liabilities	16,138,590	16,405,184
Long-term debt	18,429,177	18,388,764
Long-term deferred revenue	2,009,198	976,165
Other liabilities	275,603	660,376
Total liabilities	36,852,568	36,430,489
Stockholders deficit:		
Preferred stock, par value $0.001; 10,000,000 shares authorized, none outstanding at 2015 and 2014		
Common stock, par value $0.001; 300,000,000 shares authorized, 21,551,173, and 20,480,874 shares issued at 2015 and 2014, respectively	21,551	20,481
Additional paid in capital	448,517,472	446,241,703
Treasury stock, 4,015 shares at 2015 and 2014	(205,999)	(205,999)
Accumulated deficit	(465,958,678)	(458,605,903)
Total stockholders deficit	(17,625,654)	(12,549,718)
Total liabilities and stockholders deficit	$ 19,226,914	$ 23,880,771

See accompanying notes.

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STEREOTAXIS, INC.

STATEMENTS OF OPERATIONS

	Year Ended December 31, 2015	2014
Revenue:		
Systems	$ 10,640,584	$ 7,839,006
Disposables, service and accessories	27,033,940	27,172,270
Total revenue	37,674,524	35,011,276
Cost of revenue:		
Systems	6,052,241	4,204,719
Disposables, service and accessories	4,385,917	4,018,661
Total cost of revenue	10,438,158	8,223,380
Gross margin	27,236,366	26,787,896
Operating expenses:		
Research and development	6,252,791	5,158,331
Sales and marketing	15,850,362	15,168,940
General and administrative	10,543,741	11,845,289
Total operating expenses	32,646,894	32,172,560
Operating loss	(5,410,528)	(5,384,664)
Other income	1,340,057	3,510,439
Interest income	1,864	7,084
Interest expense	(3,284,168)	(3,335,300)
Net loss	$ (7,352,775)	$ (5,202,441)
Net loss per common share:		
Basic	$ (0.35)	$ (0.26)
Diluted	$ (0.35)	$ (0.26)
Weighted average shares used in computing net loss per common share:		
Basic	21,113,203	19,945,038
Diluted	21,113,203	19,945,038

See accompanying notes.

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STEREOTAXIS, INC.

STATEMENTS OF STOCKHOLDERS EQUITY

	Common Stock		Additional Paid-In			Total Stockholders
	Shares	Amount	Capital	Treasury Stock	Accumulated Deficit	Equity (Deficit)
Balance at December 31, 2013	19,311,390	$ 19,311	$ 441,888,155	$ (205,999)	$ (453,403,462)	$ (11,701,995)
Issuance of common stock	878,077	879	2,852,794			2,853,673
Share-based compensation			1,501,045			1,501,045
Grant of restricted shares, net of forfeitures	259					
Restricted stock vestings	291,148	291	(291)			
Net loss					(5,202,441)	(5,202,441)
Balance at December 31, 2014	20,480,874	$ 20,481	$ 446,241,703	$ (205,999)	$ (458,605,903)	$ (12,549,718)

	Common Stock		Additional Paid-In	Treasury	Accumulated	Total Stockholders Equity
	Shares	Amount	Capital	Stock	Deficit	(Deficit)
Balance at December 31, 2014	20,480,874	$ 20,481	$ 446,241,703	$ (205,999)	$ (458,605,903)	$ (12,549,718)
Issuance of common stock	809,822	809	940,545			941,354
Share-based compensation			1,312,319			1,312,319
Restricted stock vestings	241,775	242	(242)			
Net loss					(7,352,775)	(7,352,775)
Employee stock purchase plan	18,702	19	23,147			23,166
Balance at December 31, 2015	21,551,173	$ 21,551	$ 448,517,472	$ (205,999)	$ (465,958,678)	$ (17,625,654)

See accompanying notes.

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STEREOTAXIS, INC.

STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2015	2014
Cash flows from operating activities		
Net loss	$ (7,352,775)	$ (5,202,441)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	320,301	413,773
Amortization of intangibles	299,833	299,833
Amortization of deferred finance costs	222,682	240,601
Share-based compensation	1,312,319	1,501,045
Impairment of intangible asset	443,931	
Loss on asset disposal	5,883	
Adjustment of warrants	(1,340,057)	(3,510,439)
Changes in operating assets and liabilities:		
Accounts receivable	104,029	1,098,084
Inventories	1,521,995	(1,492,864)
Prepaid expenses and other current assets	86,944	144,518
Other assets	124,691	110,763
Accounts payable	(512,998)	(1,159,206)
Accrued liabilities	798,696	(1,634,850)
Deferred revenue	1,820,798	(376,499)
Other liabilities	(384,773)	475,539
Net cash used in operating activities	(2,528,501)	(9,092,143)
Cash flows from investing activities		
Purchase of equipment	(153,151)	(123,912)
Net cash used in investing activities	(153,151)	(123,912)
Cash flows from financing activities		
Proceeds (payments) from Healthcare Royalty Partners debt	40,413	(142,447)
Proceeds from issuance of stock and warrants, net of issuance costs	964,520	2,853,673
Net cash provided by financing activities	1,004,933	2,711,226
Net increase (decrease) in cash and cash equivalents	(1,676,719)	(6,504,829)
Cash and cash equivalents at beginning of period	7,270,301	13,775,130
Cash and cash equivalents at end of period	$ 5,593,582	$ 7,270,301
Supplemental disclosures of cash flow information:		
Interest paid	2,974,345	3,028,884

See accompanying notes.

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STEREOTAXIS, INC.

NOTES TO FINANCIAL STATEMENTS

Notes to Financial Statements

In this report, Stereotaxis, the Company, Registrant, we, us, and our refer to Stereotaxis, Inc. and its wholly owned subsidiaries. Epoch®, Niobe®, Odyssey®, Odyssey Cinema, Vdrive®, Vdrive Duo, V-CAS, V-Loop, V-Sono, QuikCAS, Cardiodrive®, and Pegasus are trademarks of Stereotaxis, Inc. All other trademarks that appear in this report are the property of their respective owners.

1. Description of Business

Stereotaxis designs, manufactures and markets the *Epoch* Solution, which is an advanced remote robotic navigation system for use in a hospital s interventional surgical suite, or interventional lab, that we believe revolutionizes the treatment of arrhythmias and coronary artery disease by enabling enhanced safety, efficiency and efficacy for catheter-based, or interventional, procedures. The *Epoch* Solution is comprised of the *Niobe* ES Remote Magnetic Navigation System (*Niobe* ES system), *Odyssey* Information Management Solution (*Odyssey* Solution), and the *Vdrive* Robotic Navigation System (*Vdrive* system), and related devices.

The *Niobe* system is designed to enable physicians to complete more complex interventional procedures by providing image-guided delivery of catheters and guidewires through the blood vessels and chambers of the heart to treatment sites. This is achieved using externally applied magnetic fields that govern the motion of the working tip of the catheter or guidewire, resulting in improved navigation, efficient procedures and reduced x-ray exposure.

In addition to the *Niobe* system and its components, 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.

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 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.

The core components of Stereotaxis systems, such as *Niobe* system, *Odyssey* Solution, *Cardiodrive* and various disposable interventional devices have received regulatory clearance in the U.S., Europe, Canada, China, Japan and various other countries. We have received the regulatory clearance, licensing and/or CE Mark approvals that allow us to market the *Vdrive* and *Vdrive Duo* systems with the *V-CAS*, *V-Loop* and *V-Sono* devices in the U.S., Canada and European Union.

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Since our inception, we have generated significant losses. As of December 31, 2015, we had incurred cumulative net losses of approximately $466.0 million. In May 2011, the Company introduced the *Niobe* ES system and as of December 31, 2015, the Company had an installed base of 125 *Niobe* ES systems. In 2016, the Company plans to continue developing the *Niobe* ES system with the goal of furthering clinical adoption. Between 2011 and 2015, the Company implemented a wide ranging plan to rebalance and reduce operating expenses by 15% to 20% on an annual run rate basis. We expect to incur additional losses into 2016 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. During 2016, we will continue to monitor operating expenses and make 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 financing before that time. Further, our revolving line of credit with Silicon Valley Bank matures on March 31, 2018 subject to continuing compliance with our covenants. We cannot assure you that additional financing will be available on a timely basis on terms acceptable to us or at all, that we will be able to engage in equity financings if our common stock is delisted from NASDAQ, 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. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability of assets or the amounts of liabilities that may result should the Company be unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

The Company considers all short-term investments purchased with original maturities of three months or less to be cash equivalents. The Company places its cash with high-credit-quality financial institutions and invests primarily in money market accounts. No cash was restricted at December 31, 2015 or 2014.

Accounts Receivable and Allowance for Uncollectible Accounts

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

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Financial Instruments

Financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable and debt. The carrying value of such amounts reported at the applicable balance sheet dates approximates fair value. See Note 9 for disclosure of the fair value of debt.

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including warrants. General accounting principles for fair value measurement established a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets and liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). See Note 12 for disclosure of fair value measurements.

Inventory

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

Property and Equipment

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

Long-Lived Assets

If facts and circumstances suggest that a long-lived asset may be impaired, the carrying value is reviewed. If this review indicates that the carrying value of the asset will not be recovered, as determined based on projected undiscounted cash flows related to the asset over its remaining life, the carrying value of the asset is reduced to its estimated fair value, which in most cases is estimated based upon Level 2 or Level 3 inputs.

Intangible Assets

Intangible assets consist of purchased technology and intellectual property rights valued at cost on the acquisition date and amortized over their estimated useful lives of 10-15 years. If facts and circumstances suggest that an intangible asset may be impaired, the carrying value is reviewed. If this review indicates that the carrying value of the asset will not be recovered, as determined based on projected undiscounted cash flows related to the asset over its remaining life, the carrying value of the asset is reduced to its estimated fair value, which in most cases is estimated based upon Level 2 or Level 3 inputs.

Use of Estimates

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

Revenue and Costs of Revenue

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

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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 *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. The Company does 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. 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 multiple-deliverable arrangement, is deferred and amortized over the service or license fee period, which is typically one year. Revenue from services is derived primarily from the sale of annual product maintenance plans. We recognize revenue from disposable device sales or accessories upon shipment and establish an appropriate reserve for returns. The return reserve, which is applicable only to disposable devices, is estimated based on historical experience which is periodically reviewed and updated as necessary. In the past, changes in estimate have had only a de minimus effect on revenue recognized in the period. We believe that the estimate is not likely to change significantly in the future.

Costs of systems revenue include direct product costs, installation labor and other costs, estimated warranty costs, and initial training and product maintenance costs. These costs are recorded at the time of sale. Costs of disposable revenue include direct product costs and estimated warranty costs and are recorded at the time of sale. Cost of revenue from services and license fees are recorded when incurred.

Research and Development Costs

Internal research and development costs are expensed in the period incurred. Amounts receivable from strategic alliances under research reimbursement agreements are recorded as a contra-research and development expense in the period reimbursable costs are incurred. There were no material receivables at December 31, 2015 or 2014 under these types of agreements. Advance receipts or other unearned reimbursements are included in accrued liabilities on the accompanying balance sheet until earned.

Share-Based Compensation

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

The Company utilized the Black-Scholes valuation model to determine the fair value of share-based payments at the date of previously issued grant using risk-free interest rate based on the Treasury yield on the date of the grant and expected volatility based on the Company s historical volatility over the expected term of the option. The resulting compensation expense is recognized over the requisite service period, generally one to

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four years. Compensation expense is recognized only for those awards expected to vest, with forfeitures estimated based on the Company s historical experience and future expectations.

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

Shares purchased by employees under the 2004 Employee Stock Purchase Plan were considered to be compensatory and were accounted for in accordance with general accounting principles for share-based payments. Shares purchased by employees under the 2009 Employee Stock Purchase Plan are considered to be non-compensatory.

Net Earnings (Loss) per Common Share

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

The Company did not include any portion of unearned restricted shares, outstanding options, stock appreciation rights or warrants in the calculation of diluted loss per common share because all such securities are anti-dilutive for all periods presented. The application of the two-class method of computing earnings per share under general accounting principles for participating securities is not applicable during these periods because those securities do not contractually participate in its losses.

As of December 31, 2015, the Company had 706,494 shares of common stock issuable upon the exercise of outstanding options and stock appreciation rights at a weighted average exercise price of $9.34 per share and 2,120,365 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $4.82 per share. The Company had no unearned restricted shares outstanding for the period ended December 31, 2015.

Income Taxes

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

Product Warranty Provisions

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

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Patent Costs

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

Concentrations of Risk

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

Biosense Webster Inc. accounted for $3,514,897 and $4,651,490, or 9%, and 13%, of total net revenue for the years ended December 31, 2015, and 2014, respectively. No other single customer accounted for more than 10% of total revenue for the year ended December 31, 2015.

Reclassifications

Certain amounts in the prior period financial statements have been reclassified to conform to the current period presentation. These reclassifications had no effect on reported losses.

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (FASB) issued ASU 2016-02 *Leases* (ASC 842), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases, direct financing leases and operating leases. ASC 842 supersedes the previous leases standard, ASC 840 *Leases.* The standard is effective for interim and annual periods beginning after December 31, 2018 (January 1, 2019 for the Company), with early adoption permitted. The Company is in the process of evaluating the impact of this accounting standard update.

In November 2015, the FASB issued Accounting Standards Update (ASU or Update) No. 2015-17, Income Taxes (Topic 740): To simplify the presentation of deferred income taxes . The amendments in this Update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments in this Update apply to all entities that present a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in this Update. This standard is effective for public companies for financial statements issued for annual periods beginning after December 15, 2016 (January 1, 2017 for the Company), and interim periods within those annual periods. We have adopted this accounting standard update and there was no impact to the results of operations or cash flows.

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory regarding the subsequent measurement of inventory as part of its Simplification Initiative. This standard is effective for public companies for fiscal years beginning after December 15, 2016 (January 1, 2017 for the Company), including interim periods within those fiscal years. This Update should be applied prospectively, and early application is permitted as of the beginning of an interim or annual reporting period. We

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are currently evaluating the impact of adopting this accounting standard update but do not expect this to significantly impact the results of operations, financial conditions, cash flows, or financial statement presentation.

In April 2015, the FASB issued ASU No. 2015-03, Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs . To simplify the presentation of debt issuance costs, the amendments in this Update require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from that debt liability, consistent with the presentation of a debt discount. In August 2015, the FASB issued ASU 2015-15, Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements Amendments to SEC Paragraphs Pursuant to Staff Announcement at June 18, 2015 EITF Meeting (SEC Update), which adds the SEC staff s guidance on the presentation of debt issuance costs associated with lines of credit to the Codification. The SEC staff stated it will not object to an entity presenting the costs of securing line-of-credit arrangements as an asset, regardless of whether there are any outstanding borrowings. The Standard is effective for financial statements issued for fiscal years beginning after December 15, 2015 (January 1, 2016 for the Company), and interim periods within those fiscal years. Early adoption of the amendments in this Update is permitted for financial statements that have not been previously issued. We have evaluated the impact of adopting this accounting standard update on our financial statements. The Company s audited consolidated balance sheets as of December 31, 2015 and 2014 includes $349,018 and $465,251, respectively, of deferred financing cost assets (excluding $25,960 and $27,134, respectively, related to line-of-credit arrangements) that would, under the new guidance be presented as a direct reduction to liabilities.

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU or Update) No. 2014-15, to communicate amendments to FASB Account Standards Codification Subtopic 205-40, Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern. The ASU requires management to evaluate relevant conditions, events and certain management plans that are known or reasonably knowable as of the evaluation date when determining whether substantial doubt about an entity s ability to continue as a going concern exists. Management will be required to make this evaluation for both annual and interim reporting periods. Management will have to make certain disclosures if it concludes that substantial doubt exists or when it plans to alleviate substantial doubt about the entity s ability to continue as a going concern. The standard is effective for annual periods ending after December 15, 2016 and for interim reporting periods starting in the first quarter of 2017 (December 31, 2016 for the Company). Early adoption is permitted. We are currently evaluating the impact of adopting this accounting standard update on our financial statement disclosures and have not concluded on an adoption method.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which converges the FASB s and the International Accounting Standards Board s current standards on revenue recognition. The standard provides companies with a single model to use in accounting for revenue arising from contracts with customers and supersedes current revenue guidance. The standard is effective for annual and interim periods beginning after December 15, 2017 (January 1, 2018 for the Company). Early adoption is not permitted. The standard permits companies to either apply the adoption to all periods presented, or apply the requirements in the year of adoption through a cumulative adjustment. We are currently evaluating the impact of adopting this accounting standard update on our financial statements and disclosures and have not concluded on an adoption method.

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3. Inventory

Inventory consists of the following:

	December 31, 2015	December 31, 2014
Raw materials	$ 2,065,676	$ 2,746,926
Work in process	24,758	374,236
Finished goods	2,433,819	3,310,375
Reserve for obsolescence	(19,971)	(59,634)
Total inventory	$ 4,504,282	$ 6,371,903

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31, 2015	December 31, 2014
Prepaid expenses	$ 454,822	$ 679,740
Deferred financing costs	374,978	492,385
Deposits	136,583	311,562
Deferred cost of revenue	82,987	
Total prepaid expenses and other assets	1,049,370	1,483,687
Less: Noncurrent prepaid expenses and other assets	(264,159)	(388,850)
Total prepaid expenses and other current assets	$ 785,211	$ 1,094,837

5. Property and Equipment

Property and equipment consist of the following:

	December 31, 2015	December 31, 2014
Equipment	$ 8,496,636	$ 8,264,804
Equipment held for lease	303,412	303,412
Leasehold improvements	2,320,368	2,328,381
	11,120,416	10,896,597
Less: Accumulated depreciation	(10,053,095)	(10,001,869)
Net property and equipment	$ 1,067,321	$ 894,728

6. Intangible Assets

As of December 31, 2015 and 2014, the Company had total intangible assets of $3,221,069 and $3,665,000. Accumulated amortization at December 31, 2015 and 2014 was $2,585,180 and $2,285,347, respectively. Amortization expense for the years 2015 and 2014 was $299,833

per year, as determined under the straight-line method. The estimated future amortization of intangible assets is $199,320 annually through July 2018, decreasing thereafter to $143,765 in 2018, $65,988 in 2019 and $27,496 through May 2020.

The Company also recognized impairment charges of $443,931 during 2015 on certain 2010 intellectual property rights relating to the Company s *Odyssey* Solution due to uncertainty around forecasted revenue under the *Odyssey* system distribution agreement beyond May, 2016. The impairment is the result of a decline in

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forecasted revenue attributable to this intellectual property that indicated it was probable the undiscounted future cash flows would not exceed the book value of the intellectual property. As a result, the book value of the intellectual property was reduced to its fair value as estimated using a discounted cash flow analysis. The Company evaluated the discount rate in the fair value calculation with the assistance of a third party valuation specialist (Level 3).

7. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2015	December 31, 2014
Accrued salaries, bonus, and benefits	$ 3,053,012	$ 2,557,557
Accrued rent	1,361,379	1,407,740
Accrued licenses and maintenance fees	666,373	661,766
Accrued interest	494,703	493,616
Accrued warranties	316,835	364,548
Accrued taxes	324,226	332,364
Other	117,465	102,479
Total accrued liabilities	6,333,993	5,920,070
Less: Long term accrued liabilities	(275,603)	(660,376)
Total current accrued liabilities	$ 6,058,390	$ 5,259,694

Certain prior year amounts have been reclassified to conform to the 2015 presentation.

8. Deferred Revenue

Deferred revenue consists of the following:

	December 31, 2015	December 31, 2014
Product shipped, revenue deferred	$ 366,388	$ 457,348
Customer deposits	2,505,000	1,065,371
Deferred service and license fees	6,583,745	6,111,616
	9,455,133	7,634,335
Less: Long-term deferred revenue	(2,009,198)	(976,165)
Total current deferred revenue	$ 7,445,935	$ 6,658,170

9. Long-Term Debt and Credit Facilities

Debt outstanding consists of the following:

	December 31, 2015		December 31, 2014	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
Healthcare Royalty Partners debt	$ 18,429,177	$ 18,429,177	$ 18,388,764	$ 18,388,764

Less current maturities				
Total long term debt	$ 18,429,177	$ 18,429,177	$ 18,388,764	$ 18,388,764

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Contractual principal maturities of debt at December 31, 2015 are as follows:

2016	$
2017	
2018	18,429,177
2019	
2020	
2021 and Beyond	
	$ 18,429,177

In accordance with general accounting principles for fair value measurement, the Company s debt and credit facilities were measured at fair value as of December 31, 2015 and December 31, 2014. Long-term debt fair value estimates are based on estimated borrowing rates to discount the cash flows to their present value (Level 3).

The revolving line of credit and the Company s obligations with Healthcare Royalty Partners II, L.P. (collectively, the Credit Agreements) are secured by substantially all of the Company s assets. The Company is required under the Credit Agreements to maintain its primary operating account and the majority of its cash and investment balances in accounts with the primary lender.

Revolving line of credit

The Company has had a working capital line of credit with its primary lender, Silicon Valley Bank, since 2004. The revolving line of credit is secured by substantially all of the Company s assets. The Company is also required under the revolving line of credit to maintain its primary operating account and the majority of its cash and investment balances in accounts with its primary lender. The facility was last amended on March 27, 2015 extending the maturity date three years to March 31, 2018. The current agreement requires the Company to maintain a minimum tangible net worth of not less than (no worse than) negative $22.5 million, with such minimum requirement subject to increase under certain circumstances as described in the agreement, and to maintain a liquidity ratio of greater than 1.50:1.00, excluding certain short term advances from the calculation.

As of December 31, 2015, 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, 2015 the Company had a borrowing capacity of $5.2 million based on the Company s collateralized assets.

Healthcare Royalty Partners Debt

In November 2011, the Company entered into a loan agreement with Healthcare Royalty Partners II, L.P. (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

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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.

10. Lease Obligations

The Company leases its facilities under operating leases. For the years ended December 31, 2015 and 2014 rent expense was $1,205,338 and $1,068,972, respectively. The rent expense for the year ended December 31, 2015 is net of sublease income of $18,912.

In January 2006, the Company moved its primary operations into its current facilities. The facility is subject to a lease which expires in December 31, 2018. Under the terms of the lease, the Company has options to renew for up to three additional years. The lease contains an escalating rent provision which the Company has straight-lined over the term of the lease.

In the third quarter of 2013, the Company modified the existing lease agreement to terminate approximately 13,000 square feet of unimproved space. The costs associated with the termination were $515,138, and were accrued as a rent liability as of September 30, 2013. As of December 31, 2015, the remaining accrued costs associated with the termination were $284,793.

In the fourth quarter of 2015, the Company entered a sublease agreement to sublease 3,152 square feet of the first floor office space through December 31, 2018.

The future minimum lease payments under non-cancelable leases as of December 31, 2015 are as follows:

Year	Operating Lease Payments
2016	$ 1,968,006
2017	1,975,514
2018	2,026,362
Total minimum lease payments	5,969,882
Less amounts representing sublease receipts	(233,248)
	$ 5,736,634

11. Stockholders Equity

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, 2015.

Controlled Equity Offering

The Company entered into a Controlled Equity Offering[SM] sales agreement (the Sales Agreement) in May 2014, as amended on March 26, 2015, with Cantor Fitzgerald & Co. (Cantor), as agent and/or principal, pursuant to which the Company could issue and sell, from time to time, shares of its common stock having an aggregate gross sales price of up to $18.0 million. The Company will pay Cantor a commission of 3.0% of the gross proceeds from any common stock sold through the Sales Agreement.

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During the twelve months ended December 31, 2015, the Company sold an aggregate of 542,996 shares of common stock under the Sales Agreement, at an average price of approximately $1.98 per share for gross proceeds of $1,072,743 and net proceeds of $1,040,561, after deducting Cantor s commission. As of December 31, 2015, $13.8 million of common stock remained available to be sold under this facility, subject to certain conditions as specified in the Sales Agreement.

Warrant Offering

On October 8, 2015 the Company completed an offering (the Warrants Offering) of transferable subscription warrants to holders of record of the Company s common stock. Under the terms of the Warrants Offering shareholders of record on September 9, 2015 and holders of certain of the Company s warrants (pursuant to the terms of their respective warrants) were entitled to one subscription warrant to purchase one share of common stock at a price of $1.10 per share for every four common shares held up to an aggregate of 5,755,775 shares of common stock. Pursuant to the Warrants Offering, subscription warrants to purchase 267,256 shares of common stock were exercised, resulting in gross proceeds to the Company of $293,982.

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

	December 31, 2015	December 31, 2014
Warrants	2,120,365	2,197,883
Stock award plans	731,442	1,297,389
Employee Stock Purchase Plan	231,298	250,000
	3,083,105	3,745,272

Stock Award Plans

The Company has various stock plans that permit the Company to provide incentives to employees and directors of the Company in the form of equity compensation. In August 2012, the Board of Directors adopted a stock incentive plan (the 2012 Stock Incentive Plan) which was subsequently approved by the Company s stockholders. This plan replaces the 2002 Stock Incentive Plan which expired on March 25, 2012.

The 2012 Stock Incentive Plan allows for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted shares and restricted share units to employees, directors, and consultants. Options granted under the 2012 Stock Incentive Plan expire no later than ten years from the date of grant. The exercise price of each incentive stock option shall not be less than 100% of the fair value of the stock subject to the option on the date the option is granted. The vesting provisions of individual options may vary, but incentive stock options generally vest 25% on the first anniversary of each grant and 1/48 per month over the next three years. Stock appreciation rights are rights to acquire a calculated number of shares of the Company s common stock upon exercise of the rights. The number of shares to be issued is calculated as the difference between the exercise price of the right and the aggregate market value of the underlying shares on the exercise date divided by the market value as of the exercise date. Stock appreciation rights granted under the 2012 Stock Incentive Plan generally vest 25% on the first anniversary of such grant and 1/48 per month over the next three years and expire no later than ten years from the date of grant. The Company generally issues new shares upon the exercise of stock options and stock appreciation rights.

Restricted share grants are either time-based or performance-based. Time-based restricted shares generally cliff vest three years after grant. Performance-based restricted shares vest upon the achievement of performance objectives which are determined by the Company s Board of Directors.

Restricted stock unit grants are time-based and generally vest over a period of four years. Options granted to non-employee directors expire no later than ten years from the date of grant. The exercise price of options to non-

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employee directors shall not be less than 100% of the fair value of the stock subject to the option on the date the option is granted. Initial grants of options to new directors generally vest over a two year period. Annual grants to directors generally vest upon the earlier of one year or the next stockholder meeting.

A summary of the option and stock appreciation rights activity for the year ended December 31, 2015 is as follows:

	Number of Options/SARs	Range of Exercise Price	Weighted Average Exercise Price per Share
Outstanding, December 31, 2014	487,146	$1.69 - $116.40	$ 17.21
Granted	353,350	$1.45 - $2.15	$ 2.07
Exercised			
Forfeited	(134,002)	$1.45 - $91.90	$ 18.81
Outstanding, December 31, 2015	706,494	$1.45 - $116.40	$ 9.34

As of December 31, 2015, the weighted average remaining contractual life of the options and stock appreciation rights outstanding was 8.00 years. Of the 706,494 options and stock appreciation rights that were outstanding as of December 31, 2015, 235,572 were vested and exercisable with a weighted average exercise price of $22.43 per share and a weighted average remaining term of 6.42 years.

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

	Year Ended December 31, 2015				
Range of Exercise Prices	Options Outstanding	Weighted Average Remaining Life	Weighted Average Exercise Price	Number of Options Currently Exercisable	Weighted Average Exercise Price Per Vested Share
$0.00 - $10.00	607,749	8.67 years	$ 3.07	136,827	$ 4.07
$30.01 - $40.00	61,495	4.95 years	$ 34.89	61,495	$ 34.89
$40.01 - $50.00	12,250	3.44 years	$ 43.90	12,250	$ 43.90
$50.01 - $60.00	12,250	2.41 years	$ 54.90	12,250	$ 54.90
$90.01+	12,750	0.95 years	$ 107.59	12,750	$ 107.59
	706,494	8.00 years	$ 9.34	235,572	$ 22.43

The intrinsic value of options and stock appreciation rights is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company s common stock for the options and stock appreciation rights that were in-the-money at December 31, 2015. The intrinsic value of the options and stock appreciation rights outstanding at December 31, 2015 and the intrinsic value of fully vested options and stock appreciation rights outstanding at December 31, 2015 were zero based on a closing share price of $0.74 on December 31, 2015. No options or stock appreciation rights were exercised under the Company s stock option plans during the years ended December 31, 2014 or 2015 and the Company realized no proceeds during these periods. The weighted average grant date fair value of options and stock appreciation rights granted during the year ended December 31, 2015 was $2.07 per share.

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A summary of the restricted stock unit activity for the year ended December 31, 2015 is as follows:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value per Unit
Outstanding, December 31, 2014	697,751	$ 3.14
Granted	391,200	$ 2.04
Vested	(241,775)	$ 3.06
Forfeited	(95,168)	$ 2.82
Outstanding, December 31, 2015	752,008	$ 2.63

The intrinsic value of restricted stock units outstanding at December 31, 2015 was $0.6 million based on a closing share price of $0.74 as of December 31, 2015. During the year ended December 31, 2015, the aggregate intrinsic value of restricted stock units vested was $0.4 million determined at the date of vesting.

During the fourth quarter of 2015, the Company made an adjustment to its forfeiture rate based on historical information, which resulted in an increase to share-based compensation of approximately $0.2 million for the year ended December 31, 2015.

As of December 31, 2015, the total compensation cost related to options, stock appreciation rights and non-vested stock granted to employees under the Company s stock award plans but not yet recognized was approximately $2.1 million, net of estimated forfeitures of approximately $0.8 million. This cost will be amortized over a weighted average period of approximately two years on a straight-line basis over the underlying estimated service periods and will be adjusted for subsequent changes in estimated forfeitures.

2009 Employee Stock Purchase Plan

In 2009, the Company adopted its 2009 Employee Stock Purchase Plan (ESPP). In June 2014, our shareholders approved a proposal to amend the ESPP to increase the number of shares authorized for issuance under the ESPP by 250,000 shares. Eligible employees have the opportunity to participate in a new purchase period every 3 months. Under the terms of the plan, employees can purchase up to 15% of their compensation of the Company s common stock, subject to an annual maximum of $25,000, at 95% of the fair market value of the stock at the end of the purchase period, subject to certain plan limitations. As of December 31, 2015, there were 231,298 remaining shares available for issuance under the Employee Stock Purchase Plan.

12. Fair Value Measurements

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

Level 1:	Values are based on unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
Level 2:	Values are based on quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or other model-based valuation techniques for which all significant assumptions are observable in the market.
Level 3:	Values are generated from model-based techniques that use significant assumptions not observable in the market.

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The following table sets forth the Company s assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy. As required by the Fair Value Measurements and Disclosures topic of the Accounting Standards Codification, assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

	Total	Fair Value Measurement Using Quoted Prices in Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets at December 31, 2015:				
Cash equivalents	$ 524,083	524,083		
Total assets at fair value	$ 524,083	524,083		
Liabilities at December 31, 2015:				
Warrants issued May 10, 2012	$ 143,681			143,681
Warrants issued August 2013	$ 650,449			650,449
Total liabilities at fair value:	$ 794,130			794,130
Assets at December 31, 2014:				
Cash equivalents	$ 5,361,053	5,361,053		
Total assets at fair value	$ 5,361,053	5,361,053		
Liabilities at December 31, 2014:				
Warrants issued May 10, 2012	$ 728,712			728,712
Warrants issued August 2013	$ 1,405,475			1,405,475
Total liabilities at fair value:	$ 2,134,187			2,134,187

Level 1

The Company s financial assets consist of cash equivalents invested in money market funds in the amount of $524,083 and $5,361,053 at December 31, 2015 and December 31, 2014, respectively. These assets are classified as Level 1 as described above and total interest income recorded for these investments was insignificant during both the years ended December 31, 2015 and December 31, 2014. There were no transfers in or out of Level 1 during the year ended December 31, 2015.

Level 2

The Company does not have any financial assets or liabilities classified as Level 2.

Level 3

Due to provisions included in the warrant agreements, outstanding warrants related to the Company s May 2012 Stock and Warrant Purchase Agreement (PIPE warrants) do not meet the exemptions for equity classification and as such, the Company accounts for these PIPE warrants as derivative instruments. The PIPE warrants are periodically remeasured with any changes in value recognized in Other income (expense) in the Statement of Operations.

The remaining PIPE warrants expire in May 2018 and were valued using an option pricing model as of December 31, 2014 using the following assumptions: 1) volatility of 165.27%; 2) risk-free interest rate of 1.10%; and 3) a closing stock price of $1.48.

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The PIPE warrants were revalued using an option pricing model as of December 31, 2015 using the following assumptions: 1) volatility of 113.4%; 2) risk-free interest rate of 1.06%; and 3) a closing stock price of $0.74.

Due to the provisions included in the warrant agreements, warrants outstanding in conjunction with the Company s August 7, 2013 transaction (the Exchange warrants) also do not meet the exemptions for equity classification and as such, the Company accounts for these warrants as derivative instruments.

The remaining Exchange warrants expire in November 2018 and were valued using an option pricing model as of December 31, 2014 using the following assumptions: 1) volatility of 158.08%; 2) risk-free interest rate of 1.10%; and 3) a closing stock price of $1.48.

The Exchange warrants were revalued using an option pricing model as of December 31, 2015 using the following assumptions: 1) volatility of 182.94%; 2) risk-free interest rate of 1.31%; and 3) a closing stock price of $0.74.

The significant unobservable input used in the fair value measurement of the Company s warrants is volatility. Significant increases (decreases) in the volatility in isolation would result in a significantly higher (lower) liability fair value measurement.

The following table sets forth a summary of changes in the fair value of the Company s Level 3 financial liabilities for the year ended December 31, 2015:

	Warrants issued May 2012	Warrants issued August 2013	Total Liabilities
Balance at beginning of period	$ 728,712	$ 1,405,475	$ 2,134,187
Issues			
Settlements			
Revaluation	(585,031)	(755,026)	(1,340,057)
Balance at end of period	$ 143,681	$ 650,449	$ 794,130

The Company currently does not have derivative instruments to manage its exposure to currency fluctuations or other business risks. The Company evaluates all of its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. All derivative financial instruments are recognized in the balance sheet at fair value.

13. Income Taxes

The provision for income taxes consists of the following:

	Year Ended December 31, 2015	2014
Deferred:		
Federal	$ (2,529,455)	$ (894,506)
State and local	169,266	(1,582,500)
	(2,360,189)	(2,477,006)
Valuation allowance	2,360,189	2,477,006
	$	$

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

	Year Ended December 31,	
	2015	2014
U.S. statutory income tax rate	34.0%	34.0%
State and local taxes, net of federal tax benefit	1.9%	2.4%
Permanent differences between book and tax	5.6%	17.1%
Deferred tax adjustments	(9.3)%	(71.9)%
State rate adjustments	(0.1)%	(29.2)%
Valuation allowance	(32.1)%	47.6%
Effective income tax rate	%	%

Included in permanent differences between book and tax in the above table are the impacts of the non-deductible mark-to-market activity associated with convertible debt and warrants as well as permanent differences such as nondeductible meals and entertainment. The deferred tax adjustment for the year ended December 31, 2014 is a write-off of a portion of the deferred tax asset related to stock compensation. The state rate adjustments are a result of changes in apportionment and various state rate law changes.

The components of the deferred tax asset are as follows:

	December 31,	
	2015	2014
Current accruals	$ 1,687,951	$ 1,416,823
Deferred revenue	269,797	
Depreciation and amortization	2,269,341	2,302,685
Deferred compensation	1,389,832	1,589,935
Net operating loss carryovers	32,744,557	30,246,136
Deferred tax assets	38,361,478	35,555,579
Valuation allowance	(37,912,693)	(35,555,579)
Net deferred tax assets before deferred tax liabilities	448,785	
Accounting method changes	(448,785)	
Net deferred tax assets	$	$

Under Section 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code , if a corporation undergoes an ownership change, the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. In general, an ownership change will occur if there is a cumulative change in our ownership by 5-percent shareholders that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. Following significant ownership changes during 2013, the Company initiated a review of the availability of its U.S. net operating loss carryforwards. As a result of this review, it was determined that approximately $290 million of the Company s federal net operating loss carryovers would expire unused due to the limitation under IRC Section 382. The Company reduced the net operating loss carryover and corresponding valuation allowance as a result of these limitations. The remaining net operating loss carryforwards following the ownership change have been assigned a full valuation allowance against all deferred tax assets.

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary

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differences become deductible. The Company considers projected future taxable income and tax planning strategies in making this assessment. Based upon the level of historical taxable losses, and projections for future periods over which the deferred tax assets are deductible, the Company determined that a 100% valuation allowance of deferred tax assets was appropriate. The valuation allowance for deferred tax assets includes amounts for which subsequently recognized tax benefits will be applied directly to the contributed capital.

As of December 31, 2015, we had gross federal net operating loss carryforwards of approximately $92.7 million. The federal net operating loss carryforwards will expire between 2017 and 2035. As of December 31, 2015, we had state net operating loss deferred tax assets of approximately $1.2 million which will expire at various dates between 2016 and 2035 if not utilized.

The Company files income tax returns in the U.S. federal jurisdiction and various state and local jurisdictions. As the Company has a federal net operating loss carryforward from the year ended December 31, 1997 forward, all tax years from 1997 forward are subject to examination. As states have varying carryforward periods, and the Company has recently entered into additional states, the states are generally subject to examination for the previous 10 years or less.

The Company recognizes interest accrued, if any, net of tax and penalties, related to unrecognized tax benefits as components of income tax provision as applicable. As of December 31, 2015 accrued interest and penalties were less than $0.1 million.

At December 31, 2015 and 2014, the Company had approximately $0.3 million and $0.2 million, respectively, in reserves for uncertain tax positions.

14. Net Loss per Share

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

	2015	2014
Numerator:		
Numerator for basic EPS	$ (7,352,775)	$ (5,202,441)
Numerator for diluted EPS	$ (7,352,775)	$ (5,202,441)
Denominator:		
Denominator for basic EPS weighted average shares	21,113,203	19,945,038
Denominator for diluted EPS	21,113,203	19,945,038
Basic EPS	$ (0.35)	$ (0.26)
Diluted EPS	$ (0.35)	$ (0.26)

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

	December 31,	
	2015	2014
Shares issuable upon vesting/exercise of:		
Options to purchase common stock	706,494	487,146
Restricted stock units	752,008	697,751
Warrants	2,120,365	2,197,883
	3,578,867	3,382,780

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15. Employee Benefit Plan

The Company offers employees the opportunity to participate in a 401(k) plan. Employer contributions are discretionary under the 401(k) plan. Currently the Company does not match employee contributions.

16. Product Warranty Provisions

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

Accrued warranty, which is included in other accrued liabilities, consists of the following:

	December 31, 2015	December 31, 2014
Warranty accrual, beginning of the fiscal period	$ 364,548	$ 501,212
Accrual adjustment for product warranty	171,384	84,402
Payments made	(219,097)	(221,066)
Warranty accrual, end of the fiscal period	$ 316,835	$ 364,548

17. Commitments and Contingencies

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

18. Segment Information

The Company considers reporting segments in accordance with general accounting principles for disclosures about segments of an enterprise and related information. The Company s system and disposable devices are developed and marketed to a broad base of hospitals in the United States and internationally. The Company considers all such sales to be part of a single operating segment. Geographic revenues for the years ended December 31, 2015 and 2014 were as follows:

	Year Ended December 31, 2015	2014
United States	$ 19,757,986	$ 21,626,788
International	17,916,538	13,384,488
Total	$ 37,674,524	$ 35,011,276

All of the Company s long-lived assets are located in the United States. Revenues are attributed to countries based on the location of the customer.

19. Subsequent Events

None.

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

None.

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ITEM 9A. CONTROLS AND PROCEDURES

Report on Internal Control Over Financial Reporting

As of December 31, 2015, the Company s management, with the participation of the Company s Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company s disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act)). Based on such evaluation, the Company s Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, the Company s disclosure controls and procedures were effective.

The Company s management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act. The Company s internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. The Company s management assessed the effectiveness of our internal control over financial reporting as of December 31, 2015. In making the assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) in Internal Control Integrated Framework. Based on our assessment, our management has concluded that our internal control over financial reporting is effective as of December 31, 2015.

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

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

ITEM 9B. OTHER INFORMATION

None.

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PART III

Certain information required by Part III is omitted from this Report on Form 10-K since we intend to file our definitive Proxy Statement for our next Annual Meeting of Stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended (the Proxy Statement), no later than April 29, 2016, and certain information to be included in the Proxy Statement is incorporated herein by reference.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Information required by this item concerning our directors is incorporated by reference to the information set forth in the section titled Information About the Board of Directors in our Proxy Statement. Information regarding Section 16 reporting compliance is incorporated by reference to the information set forth in the section titled Section 16(a) Beneficial Ownership Reporting Compliance in our Proxy Statement. Information about our audit committee members and audit committee financial expert is incorporated by reference to the information set forth in the section titled Board Meetings and Committees in our Proxy Statement.

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

Stereotaxis, Inc.
Attn: Martin C. Stammer
4320 Forest Park Avenue, Suite 100
St. Louis, MO 63108
314-678-6100

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

The following is information with respect to our executive officers:

William C. Mills III

Chief Executive Officer since April 2013, Chairman of the Board since May 2012

Director since June 2000

Mr. Mills, 60, has served as our Chief Executive Officer since April 2013 and as the Chairman of our Board of Directors since May 2012. From 2004 until 2009, Mr. Mills was a managing member of a management company conceived by EGS Healthcare Capital Partners to manage EGS Private Healthcare Partnership III. Earlier, Mr. Mills was a Partner in the Boston office of Advent International, a private equity and venture capital firm, for five years. At Advent, he was co-responsible for healthcare venture capital investments and focused on investments in the medical technology and biopharmaceutical sectors. Before joining Advent, Mr. Mills spent more than 11 years with the Venture Capital Fund of New England where he was a General Partner. Prior to that, he spent seven years at PaineWebber Ventures/Ampersand Ventures as Managing General Partner. He currently serves as Chairman of the Board of Managers of Ascension Ventures III, L.P., a strategic healthcare venture fund focused on the medical device, healthcare information technology, and service sectors, and he is a member of the board of directors of Interleukin Genetics, Inc. (OTC MKTS: ILIU), a publicly traded company that develops and markets genetic tests. Mr. Mills received an S.M. in Chemistry from the Massachusetts Institute of Technology, an M.S. in Management from the Massachusetts Institute of Technology Sloan School of Management, and an A.B. cum laude in Chemistry from Princeton University.

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Paul A. Brathwaite, Ph.D.

Vice President, Research and Development

Officer since July 2015

Dr. Brathwaite, 46, was appointed Vice President of Research and Development in 2012 and was named an officer in 2015. He joined Stereotaxis in September 2003 as a software engineer and has held several positions within the Company with increasing responsibility, including Software Project Manager, Director of Clinical Adoption Engineering, and Senior Director of Research and Development. Prior to joining Stereotaxis, Dr. Brathwaite was employed as a software engineer at AutoQuant Imaging, Inc. Dr. Brathwaite holds a Doctorate in biomedical engineering and a Master of Science in electrical engineering from the University of Iowa. He also holds a Bachelor of Science in computer engineering from Queen s University, Canada.

Frank J. Cheng

Senior Vice President, Marketing and Business Development

Officer since April 2010

Mr. Cheng, 48, joined Stereotaxis in April 2010 as Senior Vice President and currently has executive responsibility in Marketing, Training, Clinical Research, Business Development and Asia Business. He has over 20 years of experience in the medical technology industry leading marketing, business development, and P&L general management. Prior to joining Stereotaxis, Mr. Cheng was President and Chief Executive Officer of Perfinity Biosciences, Inc. (previously Quadraspec, Inc.), from 2009 to 2010. He served as a director of Perfinity Biosciences, Inc. from 2009 to 2011. From 2005 to 2009, Mr. Cheng was President and Chief Executive Officer of OBS Medical. For four years prior to that, he was Vice President of Business Development for Roche Diagnostics. Earlier in his career, Mr. Cheng held marketing and strategic planning positions at GE Medical Systems for three years and Hillenbrand Industries (including its subsidiary, Hill-Rom Company) for four years. Mr. Cheng has an MBA from Vanderbilt University and a BBA from Wuhan University.

Karen W. Duros

Senior Vice President, General Counsel and Secretary

Officer since October 2010

Ms. Duros, 61, joined Stereotaxis in 2010. She has over 30 years of business and corporate legal experience in large and small companies. Prior to joining Stereotaxis, she was Senior Counsel for Monsanto Company from 2005 to 2010. From 1998 to 2005, Ms. Duros held several legal positions of increasing responsibility with Great Lakes Chemical Corporation, including Vice President and Secretary from 2004 to 2005, and General Counsel of Great Lakes Industrial Products division from 1999 to 2005. Previously, she was Vice President, General Counsel and Secretary of Tastemaker, a joint venture of Mallinckrodt, Inc. and Hercules, Inc., and prior to that, she held several legal positions with Mallinckrodt, Inc. Ms. Duros began her legal career with the St. Louis law firm, Thompson & Mitchell. She earned a law degree from Washington University School of Law and a B.A., Political Science, from Benedictine College.

David A. Giffin

Vice President, Human Resources

Officer since May 2010

Mr. Giffin, 67, joined Stereotaxis in January 2007. He was named an officer in 2010. Mr. Giffin has over 40 years of human resources experience. Prior to joining Stereotaxis, from 2001 to 2006, Mr. Giffin was Vice President, Human Resources and Social Enterprise at Provident, Inc., a St. Louis based social service agency. Prior to that position, he was Vice President, Human Resources at Huttig Building Products from 1991 to 2001. He also has held positions as Vice President, Human Resources at St. Johns Medical Center in St. Louis; and Consultant at The Bannon Consulting Group. He spent the early years of his career with Monsanto Company where he held a variety of human resources positions with increasing responsibility. Mr. Giffin earned his M.B.A. and a B.S. in Psychology from Purdue University.

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Martin C. Stammer

Chief Financial Officer

Officer since February 2013

Mr. Stammer, 35, was appointed as the Chief Financial Officer in February 2013. He previously served as Vice President, Controller since August 2012 and as Corporate Controller from July 2011 to August 2012. He joined the Company as Senior Manager, Financial Reporting in October 2009. Prior to joining the Company, from 2003 to 2009, Mr. Stammer was employed in various roles and capacities at Deloitte & Touche LLP, including most recently as Audit Manager. Mr. Stammer received his M.S. and B.S. in Accountancy from the University of Illinois and is a Certified Public Accountant.

ITEM 11. EXECUTIVE COMPENSATION

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

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

The information required by this item regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth in the section titled Security Ownership of Certain Beneficial Owners and Management in our Proxy Statement. The information required by this item regarding securities authorized for issuance under equity plans is incorporated by reference to the information set forth in the section titled Executive Compensation in our Proxy Statement.

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

The information required by this item regarding certain relationships and related transactions is incorporated by reference to the information set forth in the section titled Certain Relationships and Related Party Transactions in our Proxy Statement. The information required by this item regarding director independence is incorporated by reference to the information set forth in the section titled Corporate Governance Information in our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

Part IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

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

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

Schedule II: Valuation and Qualifying Accounts.

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

(3) Exhibits

See Exhibit Index appearing on page 81 herein.

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SIGNATURES

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

STEREOTAXIS, INC.

(Registrant)

Date: March 11, 2016

By: /s/ WILLIAM C. MILLS III
William C. Mills III

Chief Executive Officer

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

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

Signature	Title	Date
/s/ WILLIAM C. MILLS III **William C. Mills III**	Chairman of the Board of Directors and Chief Executive Officer (principal executive officer)	March 11, 2016
/s/ MARTIN C. STAMMER **Martin C. Stammer**	Chief Financial Officer (principal financial officer and principal accounting officer)	March 11, 2016
/s/ DAVID W. BENFER **David W. Benfer**	Director	March 11, 2016
/s/ DUANE DESISTO **Duane Desisto**	Director	March 11, 2016
/s/ JOSEPH D. KEEGAN **Joseph D. Keegan**	Director	March 11, 2016
/s/ FRED A. MIDDLETON **Fred A. Middleton**	Director	March 11, 2016
/s/ ROBERT J. MESSEY **Robert J. Messey**	Director	March 11, 2016

/s/ Eric N. Prystowsky	Director	March 11, 2016
Eric N. Prystowsky		
/s/ Euan S. Thomson	Director	March 11, 2016
Euan S. Thomson		

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SCHEDULE II

VALUATION AND QUALIFYING ACCOUNTS

FOR THE YEARS ENDED DECEMBER 31, 2015 AND 2014

	Balance at Beginning of Year	Additions Charged to Cost and Expenses	Deductions	Balance at the End of Year
Allowance for doubtful accounts and returns:				
Year ended December 31, 2015	$ 131,464	$ (9,463)	$ (28,523)	$ 93,478
Year ended December 31, 2014	$ 383,077	$ 48,742	$ (300,355)	$ 131,464
Allowance for inventories valuation:				
Year ended December 31, 2015	$ 59,634	$ 42,258	$ (81,921)	$ 19,971
Year ended December 31, 2014	$ 80,213	$ 6,970	$ (27,549)	$ 59,634

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EXHIBIT INDEX

Number	Description
3.1a	Restated Articles of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
3.1b	Certificate of Amendment to Amended and Restated Certificate of Incorporation, incorporated by reference to Exhibit 3.1 of the Registrant s Form 8-K (File No. 000-50884) filed on July 10, 2012.
3.2	Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
4.1	Form of Specimen Stock Certificate, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 4.1.
4.2	Form of PIPE Warrant issued pursuant to that certain Stock and Warrant Purchase Agreement dated May 7, 2012, between the Company and certain purchasers named therein, incorporated by reference to Exhibit 4.1 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed on May 8, 2012.
4.3a	Form of Warrant issued pursuant to that certain Third Amendment to Note and Warrant Purchase Agreement effective November 10, 2010, between the Registrant and certain investors named therein (included in Exhibit 10.16d).
4.3b	Form of Warrant Issued Pursuant to that Certain Fourth Amendment to Note and Warrant Purchase Agreement dated March 30, 2012, incorporated by reference to Exhibit 4.1 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended March 31, 2012.
4.3c	Form of Warrant issued pursuant to that certain Fifth Amendment to Note and Warrant Purchase Agreement, dated May 1, 2012, between the Company and certain investors named therein (included in Exhibit 10.3 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed on May 2, 2012.).
4.3d	Form of Warrant issued pursuant to that certain Sixth Amendment to Note and Warrant Purchase Agreement, dated May 7, 2012, between the Company and certain investors named therein (included in Exhibit 10.77 of the Registrant s Registration Statement on Form S-1 (File No. 000-50884) filed May 23, 2012).
4.3e	Amendment to Warrants of Stereotaxis, Inc., dated May 10, 2012, by and between the Company and the Warrant Holders, incorporated by reference to Exhibit 4.7 of the Registrant s Registration Statement on Form S-1 (File No. 000-50884) filed May 23, 2012.
4.3f	Form of Warrant issued pursuant to that certain Seventh Amendment to Note and Warrant Purchase Agreement dated March 29, 2013, between the Company and certain investors named therein, incorporated by reference to Exhibit 4.5i of the Registrant s Form 10-K (File No. 001-36159) for the fiscal year ended December 31, 2013.
4.3g	Form of Warrant issued pursuant to that certain Eighth Amendment to Note and Warrant Purchase Agreement dated June 28, 2013, between the Company and certain investors named therein, incorporated by reference to Exhibit 4.1 of the Registrant s Form 10-Q (File No. 001-36159) filed for the fiscal quarter ended June 30, 2013.
4.3h	Form of Warrant issued to certain investors in connection with extensions of loan guarantees by such investors, incorporated by reference to Exhibit 4.5k of the Registrant s Form 10-K (File No. 001-36159) for the fiscal year ended December 31, 2013.

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Number	Description
4.4	Form of Warrant issued pursuant to that certain Exchange Agreement, dated August 7, 2013, incorporated by reference to Exhibit 10.2 of Registrant s Current Report on Form 8-K (File No. 000-50884) filed on August 8, 2013.
10.1a#	Amended and Restated Stereotaxis, Inc. 2012 Stock Incentive Plan, as adopted March 27, 2014, incorporated by reference to Exhibit 10.4 of the Registrant s Form 10-Q (File No. 001-36159) for the fiscal quarter ended June 30, 2014.
10.1b#	Form of Restricted Share Unit Terms of Award under Stereotaxis, Inc. 2012 Stock Incentive Plan, incorporated by reference to Exhibit 10.2 of Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2012.
10.1c#	Form of Restricted Share Unit Terms of Award Under Stereotaxis, Inc. 2012 Stock Incentive Plan, Director Award, incorporated by reference to Exhibit 10.1c of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2012.
10.1d#	Form of Restricted Share Unit Terms of Award Under Stereotaxis, Inc. 2012 Stock Incentive Plan, March 5, 2013, incorporated by reference to Exhibit 10.1d of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2012.
10.2#	2002 Stock Incentive Plan, as amended and restated June 10, 2009, incorporated by reference to Exhibit 10.2 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2009.
10.3a#	Amended and Restated Stereotaxis, Inc. Employee Stock Purchase Plan, as adopted March 27, 2014, incorporated by reference to Exhibit 10.5 of the Registrant s Form 10-Q (File No. 001-36159) for the fiscal quarter ended June 30, 2014.
10.3b#	Amendment to Stereotaxis, Inc. 2009 Employee Stock Purchase Plan, as adopted February 27, 2015, incorporated by reference to Exhibit 10.3 of the Registrant s Form 10-Q (File No. 001-36159) for the fiscal quarter ended March 31, 2015.
10.4#	Executive Employment Agreement dated May 30, 2014, between Stereotaxis, Inc. and William C. Mills III, incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K (File No. 001-36159) filed on June 2, 2014.
10.5#	Form of Amended and Restated Executive Employment Agreement, 2013, between certain executive officers and the Company, incorporated by reference to Exhibit 10.6 of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2012.
10.6#	Summary of Management Bonus Plan adopted as of February 24, 2015, incorporated by reference to Exhibit 10.4 of the Registrant s Form 10-Q (File No, 001-36159) for the fiscal quarter ended March 31, 2015.
10.7#	Description of compensation of named executive officers, incorporated by reference to Exhibit 10.9 of the Registrant s Form 10-K (File No. 001-36159) for the fiscal year ending December 31, 2013.
10.8#	Summary of Non-Employee Director Compensation Program, incorporated by reference to Exhibit 10.2 of the Registrant s Form 10-Q (File No. 001-36159) for the fiscal quarter ended March 31, 2014.
10.9a	Collaboration Agreement dated June 8, 2001, between the Registrant and Siemens AG, Medical Solutions, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.9.
10.9b	Extended Collaboration Agreement dated May 27, 2003, between the Registrant and Siemens AG, Medical Solutions, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.10.

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Number	Description
10.9c	Amendment to Collaboration Agreement dated May 5, 2006, between the Company and Siemens Aktiengesellschaft, Medical Solutions, incorporated by reference to Exhibit 10.1 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2006.
10.10a	Development and Supply Agreement dated May 7, 2002, between the Registrant and Biosense Webster, Inc., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.11.
10.10b	Amendment to Development and Supply Agreement dated November 3, 2003, between the Registrant and Biosense Webster, Inc., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.12.
10.10c	Alliance Expansion Agreement, dated as of May 4, 2007, between Biosense Webster, Inc. and the Registrant, incorporated by reference to Exhibit 10.1 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2007.
10.10d	Second Amendment to Development Alliance and Supply Agreement, dated as of July 18, 2008, between the Registrant and Biosense Webster, Inc., incorporated by reference to Exhibit 10.1 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2008.
10.10e	Third Amendment to Development Alliance and Supply Agreement with Biosense Webster, Inc. effective as of December 21, 2009, incorporated by reference to Exhibit 10.22 of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2009.
10.10f	Fourth Amendment to Development Alliance and Supply Agreement with Biosense Webster, Inc., effective May 1, 2010, incorporated by reference to Exhibit 10.1 of the Registrant s Form 10-Q (File No. 000-50884) for the fiscal quarter ended March 31, 2010.
10.10g	Fifth Amendment to Development Alliance and Supply Agreement with Biosense Webster, Inc., dated as of July 30, 2010, incorporated by reference to Exhibit 10.1 of the Registrant s Form 8-K/A (File No. 000-50884) filed on August 3, 2010.
10.10h	Sixth Amendment and Catheter and Mapping System Extension to Development Alliance and Supply Agreement with Biosense Webster, Inc., dated January 3, 2011, effective as of December 17, 2010, incorporated by reference to Exhibit 10.13h of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2010.
10.10i	Seventh Amendment to the Development Alliance and Supply Agreement with Biosense Webster, Inc., effective December 5, 2011, incorporated by reference to Exhibit 10.19f of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2011.
10.11	Form of Indemnification Agreement between the Registrant and its directors and executive officers, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.14.
10.12	Letter Agreement, effective October 6, 2003, between the Registrant and Philips Medizin Systeme G.m.b.H., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.16.
10.13a	Office Lease dated November 15, 2004, between the Registrant and Cortex West Development I, LLC, incorporated by reference to Exhibit 10.39 of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2004.
10.13b	Amendment to Office Lease dated November 30, 2007, between the Registrant and Cortex West Development I, LLC, incorporated by reference to Exhibit 10.22 of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2007.

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Number	Description
10.13c	Second Amendment to Office Lease dated May 1, 2013, between Registrant and Wexford 4320 Forest Park, LLC, successor to Cortex West Development I, LLC, incorporated by reference to Exhibit 10.17c of the Registrant s Form 10-K (File No. 001-36159) for the fiscal year ending December 31, 2013.
10.13d	Third Amendment to Office Lease dated August 14, 2013, between Registrant and Wexford 4320 Forest Park, LLC, successor to Cortex West Development I, LLC, incorporated by reference to Exhibit 10.17d of the Registrant s Form 10-K (File No. 001-36159) for the fiscal year ending December 31, 2013.
10.13e	Fourth Amendment to Office Lease, effective October 1, 2015, between Registrant and Wexford 4320 Forest Park, LLC, successor to Cortex West Development I, LLC, filed herewith.
10.14a	Securities Purchase Agreement, dated May 7, 2012, between the Company and each purchaser identified on the signature page thereto, incorporated by reference to Exhibit 10.4 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed on May 8, 2012.
10.14b	Form of Convertible Debt Registration Rights Agreement incorporated by reference to Exhibit 10.5 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed on May 8, 2012.
10.14c	Form of Amendment and Exchange Agreement between Company and each of the holders of its convertible debentures participating in the exchange, incorporated by reference to Exhibit 10.1 of Registrant s Current Report on Form 8-K (File No. 000-50884) filed on August 8, 2013.
10.15a	Second Amended and Restated Loan and Security Agreement, effective November 30, 2011, by and among the Company, Stereotaxis International, Inc. and Silicon Valley Bank incorporated by reference to Exhibit 10.19f of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2011.
10.15b	First Loan Modification Agreement (Domestic), between the Company, Stereotaxis International, Inc. and Silicon Valley Bank, dated March 30, 2012, incorporated by reference to Exhibit 10.1 of the Registrant s Form 8-K (File No. 000-50884) filed on April 2, 2012.
10.15c	Second Amendment to the Amended and Restated Loan and Security Agreement (Domestic) dated May 1, 2012, between the Company, Stereotaxis International, Inc. and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed on May 2, 2012.
10.15d	Third Amendment to Amended and Restated Loan and Security Agreement (Domestic), dated May 7, 2012, between the Company, Stereotaxis International, Inc. and Silicon Valley Bank, incorporated by reference to Exhibit 10.75 of the Registrant s Registration Statement on Form S-1 (File No. 000-50884) filed May 23, 2012.
10.15e	Fourth Loan Modification Agreement (Domestic), dated December 28, 2012, between the Company, Stereotaxis International, Inc. and Silicon Valley Bank incorporated by reference to Exhibit 10.19f of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2012.
10.15f	Fifth Loan Modification Agreement (Domestic) dated March 29, 2013 between the Company, Stereotaxis International, Inc. and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed on April 1, 2013.
10.15g	Sixth Loan Modification and Waiver Agreement (Domestic), dated June 28, 2013, between the Company, Stereotaxis International, Inc., and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed on July 1, 2013.
10.15h	Seventh Loan Modification and Waiver Agreement (Domestic), dated July 31, 2013, between the Company, Stereotaxis International, Inc. and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed on August 2, 2013.

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Number	Description
10.15i	Eighth Loan Modification Agreement (Domestic), dated August 30, 2013, between the Company, Stereotaxis International, Inc. and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed on September 3, 2013.
10.15j	Ninth Loan Modification Agreement (Domestic), dated March 28, 2014, between the Company, Stereotaxis International, Inc. and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K (File No. 001-36159) filed on March 31, 2014.
10.15k	Tenth Loan Modification Agreement (Domestic), dated March 27, 2015, between Silicon Valley Bank, the Company, and Stereotaxis International, Inc., incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K (File No. 001-36159) filed on March 30, 2015.
10.16a	Note and Warrant Purchase Agreement, effective February 7, 2008, between the Registrant and the investors named therein, incorporated by reference to Exhibit 10.31 of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2007.
10.16b	First Amendment to Note and Warrant Purchase Agreement, effective December 29, 2008, between the Registrant and the investors named therein, incorporated by reference to Exhibit 10.32 of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2008.
10.16c	Second Amendment to Note and Warrant Purchase Agreement, effective October 9, 2009, between the Registrant and the investors named therein, incorporated by reference to Exhibit 10.31c of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2009.
10.16d	Third Amendment to Note and Warrant Purchase Agreement, effective November 10, 2010, between the Registrant and the investors named therein incorporated by reference to Exhibit 10.21d of the Registrant s Form 10-K (File No. 000-50884) filed for the fiscal year ended December 31, 2010.
10.16e	Fourth Amendment to the Note and Warrant Purchase Agreement between the Registrant and the investors named therein, dated March 30, 2012, incorporated by reference to Exhibit 10.3 of the Registrant s Form 8-K (File No. 000-50884) filed on April 2, 2012.
10.16f	Fifth Amendment to Note and Warrant Purchase Agreement, dated May 1, 2012, between the Registrant and the investors named therein, incorporated by reference to Exhibit 10.3 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed on May 2, 2012.
10.16g	Sixth Amendment to Note and Warrant Purchase Agreement, dated May 7, 2012, between the Registrant and the investors named therein, incorporated by reference to Exhibit 10.77 of the Registrant s Registration Statement on Form S-1 (File No. 000-50884) filed May 23, 2012.
10.16h	Seventh Amendment to Note and Warrant Purchase Agreement, dated March 29, 2013, between the Registrant and the investors named therein, incorporated by reference to Exhibit 10.3 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed on April 1, 2013.
10.16i	Eighth Amendment to Note and Warrant Purchase Agreement, dated June 28, 2013, between the Registrant and the investors named therein, incorporated by reference to Exhibit 10.3 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed on July 1, 2013.
10.17a	Loan Agreement dated as of November 30, 2011, by and among the Company, Stereotaxis International, Inc. and Healthcare Royalty Partners II, L.P. f/k/a Cowen Healthcare Royalty Partners II LLC incorporated by reference to Exhibit 10.22a of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2011.
10.17b	Intercreditor Agreement dated as of December 5, 2011, by and among the Company, Stereotaxis International, Inc., Healthcare Royalty Partners II, L.P. f/k/a Cowen Healthcare Royalty Partners II LLC and Silicon Valley Bank incorporated by reference to Exhibit 10.22a of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2011.

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Number	Description
10.18	Stock and Warrant Purchase Agreement, effective May 7, 2012, between the Company, and certain purchasers named therein, incorporated by reference to Exhibit 10.1 of the Registrant s Current Report on Form 8-K (File No. 000-50884) filed on May 8, 2012.
10.19a	Controlled Equity Offering[SM] Sales Agreement dated May 16, 2014, by and between Stereotaxis, Inc. and Cantor Fitzgerald & Co., incorporated by reference to Exhibit 1.1 of the Registrant s Current Report on Form 8-K (File No. 001-36159) filed on May 16, 2014.
10.19b	Amendment No. 1, dated March 26, 2015, to Sales Agreement, dated March 16, 2014, between Stereotaxis, Inc. and Cantor Fitzgerald & Co., incorporated by reference to Exhibit 1.1 of the Registrant s Current Report on Form 8-K (File No. 001-36159) filed on March 26, 2015.
10.20a	Consulting Agreement effective June 4, 2014, between Stereotaxis, Inc. and Eric N. Prystowsky, M.D., incorporated by reference to Exhibit 10.3 of the Registrant s Form 10-Q (File No. 001-36159) for the fiscal quarter ended June 30, 2014.
10.20b	Amendment No. 1, dated June 3, 2015, to Consulting Agreement, dated June 4, 2014, between Stereotaxis, Inc. and Eric N. Prystowsky, M.D., filed herewith.
21.1	List of Subsidiaries of the Registrant, incorporated by reference to Exhibit 21.1 of the Registrant s Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2009.
23.1	Consent of Ernst & Young LLP.
31.1	Rule 13a-14(a)/15d-14(a) Certification (pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, executed by Chief Executive Officer).
31.2	Rule 13a-14(a)/15d-14(a) Certification (pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, executed by Chief Financial Officer).
32.1	Section 1350 Certification (pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Chief Executive Officer).
32.2	Section 1350 Certification (pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Chief Financial Officer)
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

# Indicates management contract or compensatory plan.
Confidential treatment granted as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission.
Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission.