

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)

**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)

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**DELAWARE**  
(State or Other Jurisdiction of

**94-3120386**  
(I.R.S. Employer

Incorporation or Organization)

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

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

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  No

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

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.

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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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### **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, 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, estimates, 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

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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*<sup>®</sup> 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*<sup>®</sup> *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*<sup>®</sup> *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*<sup>®</sup> 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<sup>®</sup>RMT navigation and ablation system, CELSIUS<sup>®</sup> RMT, NAVISTAR<sup>®</sup> RMT, NAVISTAR<sup>®</sup> RMT DS, NAVISTAR<sup>®</sup> RMT THERMOCOOL<sup>®</sup> and CELSIUS<sup>®</sup> RMT THERMOCOOL<sup>®</sup> 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<sup>®</sup>2515 or LASSO<sup>®</sup>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<sup>®</sup> RMT THERMOCOOL<sup>®</sup> 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**

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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.