Stereotaxis, Inc.
Form 10-K
March 15, 2019

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, 2018

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 the 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: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $.001 Par Value

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 the 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 [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 OTCQX on June 30, 2018) was approximately $29.6 million.

The number of outstanding shares of the registrant's common stock on February 28, 2019 was 59,236,369

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2019 Annual Meeting of Shareholders are incorporated by reference in Part III, Items 10, 11, 12, 13 and 14.

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PART I

ITEM 1. BUSINESS

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

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

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

OVERVIEW

We design, manufacture and market robotic systems and instruments for use primarily by electrophysiologists for the treatment of abnormal heart rhythms known as cardiac arrhythmias. We offer our proprietary *Epoch* Solution, an advanced remote robotic navigation system, for use in a hospital's interventional surgical suite, or "interventional lab". We believe the *Epoch* Solution revolutionizes the treatment of arrhythmias and coronary artery disease by enabling enhanced safety, efficiency and efficacy for catheter-based, or interventional procedures.

The *Epoch* Solution is comprised of the *Niobe* ES Robotic Magnetic Navigation System ("*Niobe* ES system"), *Odyssey* Information Management Solution ("*Odyssey* Solution"), and the *Vdrive* Robotic Navigation System ("*Vdrive* system"), and related devices. We consider our technology to be 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 robotic magnetic system, are protected by an extensive patent portfolio, as well as substantial expertise and trade secrets.

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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 and equipment service costs beyond warranty period. 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, 2018, we had approximately $2.8 million of backlog, consisting of outstanding purchase orders and other commitments for these systems. We had backlog of approximately $1.5 million as of December 31, 2017. Of the December 31, 2018 backlog, we expect approximately 85.0% to be recognized as revenue over the course of 2019. 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 robotic magnetic system is lengthy and generally involves construction or renovation activities at customer sites. Consequently, revenues and/or orders resulting from sales of our robotic magnetic system can vary significantly from one reporting period to the next.

We have business arrangements with technology leaders in the global interventional market, including manufacturers of fluoroscopy systems, ablation catheters, and electrophysiology mapping systems. Through these arrangements, we provide compatibility between our technology and other equipment that is necessary to perform interventional procedures. The catheter arrangement also provides development and distribution of disposable interventional devices.

We were incorporated in Delaware in June, 1990 as Stereotaxis, Inc. Our principal executive offices are located at 4320 Forest Park Avenue, Suite 100, St. Louis, Missouri 63108, and our telephone number is (314) 678-6100.

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.

Our systems address the current challenges in the interventional lab by providing precise computerized control of the working tip of the interventional instrument and by integrating this control with the visualization 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.

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Enhance patient and physician safety. The clinical value of our robotic magnetic system has been demonstrated in over 350 publications and in more than 100,000 procedures. A systematic review of all peer-reviewed publications on our technology observed that robotic magnetic navigation reduced major complication rates by 62%, minor complications by 43% and patient radiation duration by 31% in comparison to traditional manual intervention. These safety benefits to patients are complemented by improved occupational safety for the physicians and nursing staff who are performing the procedures. Healthcare professionals face long term orthopedic and exposure risks which are mitigated by our robotic technology. 49% of professionals performing manual procedures suffer from orthopedic injury. 85% of brain tumors in interventional physicians present on the left side of the brain which is the side typically exposed to radiation when performing a manual procedure. Our robotic technology improves physician safety and reduces physician fatigue by enabling them to conduct procedures remotely from an adjacent control room, which reduces their exposure to harmful radiation, and the orthopedic burden of wearing lead.

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

Enhance hospital efficiency by reducing and standardizing procedure times, disposables utilization and staffing needs. Conventional interventional procedure times currently range from several minutes to many hours as physicians often engage in repetitive, “trial and error” maneuvers due to difficulties with manually controlling the working tip of disposable interventional devices. By reducing both navigation time and the time needed to carry out therapy at the target site, we believe that our robotic technology can reduce procedure times compared to manual procedures, especially in the most complex procedures such as the treatment of ventricular tachycardia. We believe the robotic magnetic 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, 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 robotic magnetic 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 our products, we believe hospitals will realize significant operational benefits when recruiting physicians to work in a more safe procedure environment, while attracting patients who desire to have safer procedures that lead to better long term outcomes.

OUR PRODUCTS

Niobe® ES Robotic Magnetic Navigation System

Our proprietary *Niobe* ES system is the latest generation of the *Niobe* system, which provides the physician with precise remote digital instrument control through user friendly “point and click” computer mouse control, in combination with sophisticated image integration and 3D reconstruction. It can be operated either from an adjacent room and outside the x-ray fluoroscopy field or beside the patient table, as in traditional interventional procedures. The robotic magnetic system allows the operator to navigate disposable interventional devices to the treatment site through complex paths in the blood vessels and chambers of the heart to deliver treatment by using computer controlled, externally applied magnetic fields to directly govern the motion of the working tip of these devices, each of which has a magnetically sensitive tip that predictably responds to magnetic fields generated by our system. Because the working tip of the disposable interventional device is directly controlled by these external magnetic fields, the physician has the same degree of control regardless of the number or type of turns, or the distance traveled by the working tip to arrive at its position in the blood vessels or chambers of the heart. This results in highly precise digital control of the working tip of the disposable interventional device while still giving the physician the option to manually advance the device.

Through our arrangements with fluoroscopy system manufacturers and providers of catheters and electrophysiology mapping systems, we provide compatibility between the robotic magnetic system and the visualization and information systems used during electrophysiology procedures in order to provide the physician with a comprehensive information and instrument control system. In addition, we have integrated the robotic magnetic system with 3D catheter location sensing technology to provide accurate real-time information as to the 3D location of the working tip of the instrument.

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The components of the robotic magnetic system are identified and described below:

Niobe® Robotic Magnetic Navigation System. Our robotic magnetic 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 robotic magnetic 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 robotic magnetic system magnets precisely steer the working tip of the device.

Odyssey® Solution

The *Odyssey* Solution offers a fully integrated, real-time information solution to manage, control, record and share procedures across networks or around the world. We believe that the *Odyssey* Solution enhances the physician workflow in interventional labs through a consolidated user interface of multiple systems on a single display to enable greater focus on the case and improve the efficiency of the lab. Through the use of a single mouse and keyboard, the *Odyssey* Solution allows the user to command multiple systems in the lab from a single point of control. In addition, the *Odyssey* Solution acquires a real-time, remote view of the lab capturing synchronized procedure data for review of important events during cases. The *Odyssey* Solution enables physicians to access recorded cases and create snapshots following procedures for enhanced clinical reporting, auditing and presentation. The *Odyssey* Solution enables physicians to establish a comprehensive master archive of procedures performed in the lab providing an excellent tool for training new staff on the standard practices. The *Odyssey* Solution further enables procedures to be observed remotely around the world with high speed Internet access over a hospital VPN even wirelessly using a standard laptop or Windows tablet computer. 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.

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 robotic magnetic system 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 up to two of the four available disposable options (*V-Loop*, *V-Sono, V-CAS, and V-CAS Deflect*).

Disposables and Other Accessories

Our robotic magnetic 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; and

Biosense Webster's CARTO® RMT navigation and ablation system, CELSIUS® RMT, NAVISTAR® RMT, NAVISTAR® RMT DS, NAVISTAR® RMT THERMOCOOL® and CELSIUS® RMT THERMOCOOL® Irrigated Tip Diagnostic/Ablation Steerable Tip Catheters co-developed by Biosense Webster and Stereotaxis, as described below, with sales of such magnetically-enabled catheters generating royalty payable from Biosense Webster to Stereotaxis.

We believe that we can adapt many of the applicable disposable interventional devices for use with our system by using our proprietary technology to add an inexpensive micro-magnet at their working tip. This micro-magnet is activated by an external magnetic field, which allows interventional devices with tip dimensions as small as 14 thousandths (0.014) of an inch to be oriented and positioned in a predictable and controllable fashion. We believe this approach to bringing digital control to disposable interventional devices using embedded magnets can simplify the overall design of these devices because mechanical controls are no longer required.

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

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

our *V-CAS* Deflect fully integrated catheter advancement system ("V-CAS Deflect system") with a robotic deflectable sheath for maximum integration and versatility, allowing users to advance and retract the magnetic catheter body at angles up to 210°;

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.

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Other Recurring Revenue

Other recurring revenue includes revenue from product maintenance plans, other post warranty maintenance, and the implied obligation to provide software enhancements if and when available for one year following installation. Revenue from services and software enhancements is deferred and amortized over the service or update period, which is typically one year. Revenue related to services performed on a time-and-materials basis is recognized when performed. Other recurring revenue represented 52% and 44% of revenue for the years ended December 31, 2018 and 2017, 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 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, Europe, 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 Europe. *The V-CAS Deflect* catheter advancement system has been CE Marked for sale in 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 strategic relationship 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 Relationships" below for a description of our arrangements with Biosense Webster.

FINANCIAL INFORMATION ABOUT CUSTOMERS

Revenue from Biosense Webster Inc. related to royalties and *Odyssey* system sales accounted for $2.9 million and $3.3 million, or 10% and 11%, of total net revenue for the years ended December 31, 2018 and 2017, respectively. No other single customer accounted for more than 10% of total revenue for the years ended December 31, 2018 and 2017.

CLINICAL APPLICATIONS

We have focused our clinical and commercial efforts on applications of our products 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.

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.

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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 the procedure growth rate is approximately 10% annually.

We believe that our robotic system is particularly well-suited for those electrophysiology procedures which are time consuming or which can only be performed by highly experienced physicians. These procedures include:

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.

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. Over 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 robotic magnetic 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.

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STRATEGIC RELATIONSHIPS

We have entered into business arrangements with technology leaders in the global interventional market, including manufacturers of fluoroscopy systems, ablation catheters, and electrophysiology mapping systems, that we believe aid us in commercializing our robotic magnetic system. These arrangements are important to us as they provide for the integration of our system with digital imaging and 3D catheter location sensing technology, as well as catheters compatible with our system.

Imaging

We have successfully integrated our robotic magnetic system with digital fluoroscopy systems to provide advanced interventional lab visualization and instrument control through user-friendly computerized interfaces. The maintenance of these arrangements, or the establishment of equivalent alternatives, is critical to our commercialization efforts. The commercial availability of currently compatible digital imaging fluoroscopy systems is unlikely to continue and efforts are being made to ensure the availability of integrated next generation systems and/or equivalent alternatives; however, we cannot provide assurance as to the timeline of the ongoing availability of such compatible systems or our ability to obtain equivalent alternatives on competitive terms or at all.

Disposables Devices

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 our robotic magnetic system. We have jointly developed associated location and non-location sensing electrophysiology mapping and ablation catheters that are navigable with our robotic magnetic 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.

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 10% of revenue for the years ended December 31, 2018 and 2017.

Biosense Webster's distribution rights for co-developed catheters are nonexclusive until December 31, 2022. Upon the expiration or termination of the agreement, other than due to a change of control of Stereotaxis, the agreement provides for a continuation of supply by Biosense Webster of the co-developed catheters to us or our customers for three years. 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 agreements with Biosense Webster, 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 agreement in certain specified "change of control" situations, although the termination would not be effective until one year after the change of control and then would be subject to a wind-down period during which Biosense Webster would continue to supply co-developed catheters to us or to our customers for three years (or, for non-location sensing mapping and ablation catheters, until our first sale of a competitive product after a change of control, if earlier than three years). If either party terminates the agreement under this provision, we must pay a termination fee to Biosense Webster equal to 5% of our total equity value in the change of control transaction, up to a maximum of $10 million. If a change of control of Stereotaxis occurs after Biosense Webster has received approval from the U.S. FDA for atrial fibrillation indication for the NAVISTAR® RMT THERMOCOOL® catheter, we would be required to pay an additional $10 million fee to Biosense Webster, and termination of the agreement by either party would not be effective until two years after the change of control. We also agreed to notify Biosense Webster if we reasonably believe that we are engaged in substantive discussions with respect to the sale of the Company or substantially all of our assets.

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 strategic third parties to integrate our robotic magnetic 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.

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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 employ service and support engineers with networking and medical equipment expertise, and outsource 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, *Odysse*y, and *Vdrive* Systems

Our manufacturing strategy for our *Niobe* system and *Odyssey* Solution is to sub-contract the manufacture of major subassemblies of our systems to maximize manufacturing flexibility and lower fixed costs. Our current manufacturing strategy for the *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 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 robotic magnetic 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 2016.

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, Biosense Webster distributes magnetically-enabled electrophysiology mapping and ablation catheters, co-developed pursuant to our agreement with them.

Our sales and marketing efforts include two important elements: (1) selling robotic magnetic systems, *Odyssey* Solutions, and *Vdrive* systems 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 compatible ablation catheters 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 robotic magnetic 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 Europe, 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 per procedure. 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.

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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, 2018, we had 74 issued U.S. patents, 1 co-owned U.S. patent and no licensed-in U.S. patents. In addition, we had 8 pending U.S. patent applications and 1 co-owned U.S. patent application. As of December 31, 2018 we had 36 issued foreign patents and 5 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 robotic magnetic system, which contains numerous complex algorithms that control our disposable devices inside the magnetic fields generated by the robotic magnetic 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 robotic magnetic 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 robotic magnetic system, which we maintain as trade secrets. This expertise centers around our proprietary magnet design, which is a critical aspect of our ability to design, manufacture and install a cost-effective magnetic navigation system that is small enough to be installed in a standard interventional lab. Our *Odyssey* Solution contains numerous complex algorithms and proprietary software and hardware configurations, and requires substantial knowledge to design and assemble, which we maintain as trade secrets. This 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 robotic magnetic system 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 robotic magnetic system.

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 robotic magnetic system is not currently compatible, as well as non-RF ablation devices including single-shot cryoablation devices and other 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 three companies that have commercialized endovascular catheter navigation systems which have been cleared by the FDA for mapping and/or ablation procedures. In addition, we are aware of two companies with an electromagnetic catheter navigation system that have received CE Mark approval in Europe. However, each of these companies has limited or no commercial activities.

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.

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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.

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. The majority 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 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 require 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.

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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.

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.

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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 robotic magnetic system. Many of the states in which we sell robotic magnetic systems have laws that require institutions located in those states to obtain a certificate of need in connection with the purchase of our system, and some of our purchase orders are conditioned upon our customer's receipt of necessary certificate of need approval.

Employees

As of December 31, 2018, we had 119 employees, 31 of whom were engaged directly in research and development, including those related to regulatory and clinical research, 53 in sales and marketing activities, 18 in manufacturing and service, and 17 in general administrative activities including finance, information systems, legal and general management. 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. 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.

Executive Officers

See Part III – Item 10 for information about our Executive Officers.

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:

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

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.

We may not be able to continue as a going concern if we do not improve the operating performance of the Company or raise additional capital.

The Company has sustained operating losses throughout its corporate history and expects that its 2019 expenses will exceed its 2019 gross margin. The Company expects to continue to incur operating losses and negative cash flows until revenues reach a level sufficient to support ongoing operations or expense reductions are in place. The Company's liquidity needs will be largely determined by the success of clinical adoption within the installed base of our robotic magnetic system as well as by new placements of capital systems. The Company's plans for improving the liquidity conditions primarily include its ability to control the timing and spending of its operating expenses and raising additional funds through debt or equity financing.

There can be no assurance that any of our plans will be successful or that additional capital will be available to us on reasonable terms, or at all, when needed. If we are unable to improve the operating performance of the Company or if we are unable to obtain sufficient additional capital, it may impair our ability to raise new capital, obtain new

customers, and hire and retain employees, which could force us to substantially revise our business plan or cease operations, which may reduce or negate the value of your investment.

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

We are highly dependent on the principal members of our management, as well as our scientific and sales staff. Attracting and retaining qualified personnel will be critical to our success, and competition for qualified personnel is intense. We may not be able to attract and retain personnel on acceptable terms given the competition for qualified personnel among technology and healthcare companies and universities. The loss of personnel 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 robotic magnetic system. The robotic magnetic 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 robotic magnetic system based on the disposable interventional devices that have received regulatory clearance or approval. Moreover, the robotic magnetic 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 robotic magnetic 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 robotic magnetic 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 purchasing our products.

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 robotic magnetic 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, a 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.

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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. Uncertainty about current global economic conditions and future 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. A credit crisis 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 becomes sluggish or deteriorates for a longer period than we anticipate, we may experience a material negative decrease on the demand for our products which may, in turn, have a material adverse effect on our revenue, profitability, financial condition, ability to raise additional capital and the market price of our stock.

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

We believe that physicians will not use our products unless they determine that the *Niobe* ES system and *Vdrive* system provide a safe, effective and preferable alternative to interventional methods in general use today. If longer-term patient studies or clinical experience indicate that treatment with our system or products is less effective, less efficient or less safe than our current data suggest, our sales would be harmed, and we could be subject to significant liability. Further, unsatisfactory patient outcomes or patient injury could cause negative publicity for our products, particularly in the early phases of product introduction. In addition, physicians may be slow to adopt our products if they perceive liability risks arising from the use of these new products. It is also possible that as our products become more widely used, latent defects could be identified, creating negative publicity and liability problems for us and adversely affecting demand for our products. If physicians do not use our products, we likely will not become profitable or generate sufficient cash to survive as a going concern.

Our collaborations with fluoroscopy system manufacturers and providers of catheters and electrophysiology mapping systems or other parties may fail, or we may not be able to enter into additional collaborations in the future.

We have collaborated with and are continuing to collaborate with fluoroscopy system manufacturers and providers of catheters and electrophysiology mapping systems and other parties to make our instrument control technology compatible with their respective imaging products or disposable interventional devices and to co-develop additional disposable interventional devices for use with our products. A significant portion of our revenue from system sales is derived from these integrated products. The maintenance of these collaborations, or the establishment of equivalent alternatives, is critical to our commercialization efforts. The commercial availability of currently compatible digital imaging fluoroscopy systems is unlikely to continue and efforts are being made to ensure the availability of integrated next generation systems and/or equivalent alternatives; however, we cannot assure as to the timeline of the ongoing availability of such compatible systems or our ability to obtain equivalent alternatives on competitive terms or at all.

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 robotic magnetic 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.

Some of our 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.

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

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

- our inability to recruit and retain adequate numbers of qualified sales and marketing personnel;
- our inability to accurately forecast future product sales and utilize resources accordingly;
- the inability of sales personnel to obtain access to or persuade adequate numbers of hospitals and physicians to purchase and use our products; and
- unforeseen costs associated with maintaining and expanding an independent sales and marketing organization.

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

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

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

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

In order for physicians to learn to use the robotic magnetic 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 three companies that have commercialized endovascular catheter navigation systems which have been cleared by the FDA for mapping and/or ablation procedures. In addition, we are aware of two 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.

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 robotic magnetic 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.

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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 the future 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 achieved operating profitability during certain quarters, 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.

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

Our current borrowing agreement contains various covenants, including financial covenants under our credit agreement with our primary lender. If we violate our covenants, it could impact our ability to borrow and we could be required to repay any related outstanding debt. We could be unable to make these payments, which could lead to insolvency. Even if we are able to make these payments, it will lead to the lack of availability for additional borrowings under our bank loan agreement due to our borrowing capacity. There can be no assurance that we will be able to maintain compliance with these covenants or that we could replace this source of liquidity if these covenants were to be violated and our loans and other borrowed amounts were forced to be repaid.

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

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

Our trade secrets, nondisclosure agreements and other contractual provisions to protect unpatented technology provide only limited and possibly inadequate protection of our rights. As a result, third parties may be able to use our unpatented technology, and our ability to compete in the market would be reduced. In addition, employees, consultants and others who participate in developing our products or in commercial relationships with us may breach

their agreements with us regarding our intellectual property, and we may not have adequate remedies for the breach.

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

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

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

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

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

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

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

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

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

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If we or the parties in our strategic collaborations 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 collaborations 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 collaborations 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 may rely on our distributors and strategic collaborations, in some instances, to assist us in this regulatory approval process in countries outside the U.S. and Europe, for example, in Japan.

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

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

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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 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 ISO 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. Furthermore, the European Union recently adopted new EN ISO 13485:2016 standards, with which we must comply no later than April 2019. We cannot assure you that we will be able to timely comply with EN ISO 13485:2016 standards. We cannot be certain that our facilities or those of our suppliers or subcontractors will comply with the FDA, EN ISO 13485:2003, or when applicable, EN ISO 13485:2016 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, EN ISO 13485:2003 or when applicable, EN ISO 13485:2016, 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 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;

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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 as well as the potential repeal or amendment of such legislation, 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 Trump 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, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA). Among other things, the law imposed 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 was enacted for 2016 and 2017, and extended for 2018 and

2019, the tax is currently scheduled to resume collection on January 1, 2020. We expect that the PPACA could have a material adverse effect on our industry generally and our ability to successfully commercialize our products or could limit or eliminate our spending on certain development projects.

On August 2, 2011, President Obama 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.

Changes to, or repeal of, the PPACA, which the administration and certain members of Congress have affirmatively indicated that they will pursue, could materially and adversely affect our business and financial position, and results of operations. Even if the PPACA is not amended or repealed, the administration could propose changes impacting implementation of the PPACA, which could materially and adversely affect our financial position or operations. However, we cannot currently predict the content, timing or impact that any such future legislation will have on our business.

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.

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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 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.

We are limited by our inability to use a short form registration statement on Form S-3, which may affect our ability to access the capital markets, if needed.

A Registration Statement on Form S-3 permits an eligible issuer to incorporate by reference its past and future filings and reports made under the Securities Exchange Act of 1934, as amended, or the Exchange Act. In addition, Form S-3 enables eligible issuers to conduct primary offerings “off the shelf” under Rule 415 of the Securities Act of 1933, as amended, or the Securities Act. The shelf registration process under Form S-3 combined with the ability to incorporate information on a forward basis, allows issuers to avoid additional delays and interruptions in the offering process and to access the capital markets in a more expeditious and efficient manner than raising capital in a standard offering on Form S-1.

To be eligible to use Form S-3 for a registered offering of our securities to investors, either (1) the aggregate market value of our common stock held by non-affiliates would have to exceed $75 million or (2) our common stock would have to be listed and registered on a national securities exchange. Currently, we do not meet either of those eligibility requirements and are therefore precluded from using a Form S-3 in connection with a registered offering of our securities to investors.

Due to our present inability to use Form S-3, if we wanted to conduct a registered offering of securities to investors, we will be required to use long form registration and may experience delays. In addition, our ability to undertake certain types of financing transactions may be limited or unavailable to us without the ability to use Form S-3. Furthermore, because of the delay associated with long form registration and the limitations on the financing transactions we may undertake, the terms of any financing transaction we are able to conduct may not be advantageous to us or may cause us not to obtain capital in a timely fashion to execute our business strategies and continue to operate as a going concern.

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.

As of December 31, 2018, we had 41.7 million shares of our common stock issuable upon conversion of our Series A Convertible Preferred Stock bearing dividends at a rate of six percent (6.0%) per annum, which are cumulative and accrue daily from the date of issuance on the $1,000 stated value. Such dividends will not be paid in cash, except in connection with any liquidation, dissolution or winding up of the Company or any redemption of the Series A Convertible Preferred Stock. Instead, the value of the accrued dividends is added to the liquidation preference of the Series A Convertible Preferred Stock and will increase the number of shares of common stock issuable upon conversion, which will dilute the ownership of our common stockholders.

In addition, a significant number of shares of our common stock are subject to warrants, stock options and stock appreciation rights, and we may request the ability to issue additional such securities. 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, including the Series A Convertible Preferred Shares), will dilute the ownership of our existing stockholders and that the perception that such sales could occur, will adversely affect prevailing market prices for our common stock.

Further, the Series A Convertible Preferred Shares rank senior to our common stock as to distributions and payments upon the liquidation, dissolution and winding up of the Company. No such distributions or payments upon the liquidation, dissolution and winding up of the Company may be made to holders of common stock unless and until the holders of the Series A Convertible Preferred Shares have received the stated value of $1,000 per share plus any accrued and unpaid dividends. Until all Series A Convertible Preferred Shares have been converted or redeemed, no dividends may be paid on the common stock without the express written consent of the holders of a majority of the outstanding Series A Convertible Preferred Shares. In the event that dividends or other distributions of assets are made or paid by the Company to the holders of the common stock, the holders of Series A Convertible Preferred Shares are entitled to participate in such dividend or distribution on an as-converted basis. Any such distributions or payments upon the liquidation, dissolution or winding up of the Company may dilute the ownership interests of our existing stockholders.

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 collaboration 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 collaboration agreement with Biosense Webster contains 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 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 strategic relationships with two multinational fluoroscopy system manufacturers and one provider of catheters and electrophysiology mapping systems;
- our ability to develop, introduce and market integrated next generation systems and/or alternatives to our current strategic relationships with fluoroscopy system manufacturers and the catheter and electrophysiology mapping system provider on a timely basis;
- 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.

Nasdaq delisted our common stock from The Nasdaq Capital Market and our common stock began trading on the OTCQX® Best Market in August 2016. Trading of our shares on the over-the-counter markets could negatively impact the liquidity of our common stock and our ability to access the capital markets and, in turn, could impair the value of your investment.

On August 4, 2016, trading in our common stock on The Nasdaq Capital Market ("Nasdaq") was suspended as a result of a determination from Nasdaq to delist our common stock due to our failure to meet certain applicable requirements.

On August 4, 2016, shares of our common stock commenced trading on the OTCQX® Best Market under the Company's existing ticker symbol of "STXS." Trading of our shares on the over-the-counter markets could negatively impact the liquidity of our common stock and our ability to access the capital markets, which could impair the value of your investment.

The trading of our common stock on the over-the-counter market, including the OTCQX® Best Market, may adversely affect the market liquidity of our common stock, limit our ability to issue additional securities (including pursuant to registration statements on Form S-3) 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.

Furthermore, our common stock may not continue to trade on the OTCQX® Best Market in the future, broker-dealers may cease to provide public quotes of our common stock on this market, or the trading volume of our common stock may be insufficient to provide for an efficient trading market. Any such developments could impair the value of your investment.

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 OTCQX® Best 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 2018, our common stock traded between $0.51 and $1.65 per share, on trading volume ranging from approximately 0 to 0.3 million shares per day. The market price of our common stock will be affected by a number of factors, including:

- actual or anticipated variations in our results of operations or those of our competitors;
- the receipt or denial of regulatory approvals;
- announcements of new products, technological innovations or product advancements by us or our competitors;
- developments with respect to patents and other intellectual property rights;
- changes in earnings estimates or recommendations by securities analysts or our failure to achieve analyst earnings estimates;
- developments in our industry; and
- participants in the market for our common stock may take short positions with respect to our common stock.

These factors, as well as general economic, credit, political and market conditions, may materially adversely affect the market price of our common stock. As with the stock of many other public companies, the market price of our common stock has been particularly volatile during the recent period of upheaval in the capital markets and world economy. This excessive volatility may continue for an extended period of time following the filing date of this report. Furthermore, the stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Volatility in the price of our common stock on the OTCQX® Best 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.

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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 2018 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 under a lease agreement through December 31, 2021.

In August 2016, the Company entered into an agreement to sublease approximately 11,000 square feet of office space immediately and an additional 16,000 square feet of office space beginning in January of 2017, with the term of the sublease ending on December 31, 2018. The term of the sublease was subsequently extended through December 31, 2021.

We lease approximately 2,200 square feet of office space in Maple Grove, Minnesota, under a lease agreement through October 30, 2021, and have leased office space in Amsterdam, The Netherlands through August 31, 2019. In addition, we lease an office space in Beijing, China under a lease agreement through September 8, 2020 and an office space in Japan through April 30, 2019.

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.

PART II

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. On August 4, 2016 our common stock was transferred to the OTCQX® Best Market. Any over-the-counter market quotations reflect inter-dealer prices, without mark-up, mark-down, or commission and may not necessarily represent actual transactions.

As of February 28, 2019, there were approximately 519 stockholders of record of our common stock, although we believe that there is a significantly larger number of beneficial owners of our common stock.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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.

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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* Robotic Magnetic Navigation System ("*Niobe* system"). This system is designed to enable physicians to complete more complex interventional procedures by providing image-guided delivery of catheters 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, resulting in improved navigation, efficient procedures and reduced x-ray exposure. The core components of the robotic magnetic system have received regulatory clearance in the U.S., Canada, Europe, China, Japan and various other countries. As of December 31, 2018, the Company had an installed base of 126 *Niobe* ES systems.

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 robotic magnetic 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.

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

We generate revenue from 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 royalties paid to the Company on the sale by Biosense Webster of co-developed catheters, and from other recurring revenue including ongoing software and service contracts. We market our products to a broad base of hospitals in the United States and internationally as detailed in Note 17 to the financial statements.

We have strategic relationships with technology leaders in the global interventional market. Through these strategic relationships we provide compatibility between our robotic magnetic system and 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. The maintenance of these strategic relationships, or the establishment of equivalent alternatives, is critical to our commercialization efforts. The commercial availability of currently compatible digital imaging fluoroscopy systems is unlikely to continue and efforts are being made to ensure the availability of integrated next generation systems and/or equivalent alternatives; however, we cannot provide assurance as to the timeline of the ongoing availability of such compatible systems or our ability to obtain equivalent alternatives on competitive terms or at all.

The Company believes the cash on hand at December 31, 2018 will be sufficient to meet its obligations as they become due in the ordinary course of business for at least 12 months following the date these financial statements are issued. The Company has sustained operating losses throughout its corporate history and expects that its 2019 expenses will exceed its 2019 gross margin. The Company expects to continue to incur operating losses and negative cash flows until revenues reach a level sufficient to support ongoing operations or expense reductions are in place. The Company’s liquidity needs will be largely determined by the success of clinical adoption within the installed base of robotic magnetic systems as well as by new placements of capital systems. The Company also may consider raising cash through capital transactions, which could include either debt or equity financing.

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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 Codification ("ASC") Topic 606 ("ASC 606"), *Revenue from Contracts with Customers,* on January 1, 2018 using the modified retrospective method. Upon adoption of the new revenue guidance, the Company recorded a cumulative-effect reduction to accumulated deficit of $0.3 million on January 1, 2018 relating primarily to the deferral of previously expensed costs to obtain a contract. The Company capitalized sales commissions paid in connection with multi-year service contracts and is amortizing such asset over the economic life of those contracts. Previously, sales commissions on multi-year service contracts were expensed as incurred. The impact of this change on operating expenses in any given period will depend, in part, on the amount of such commissions incurred and capitalized in relation to the amount of ongoing amortization expense. For the twelve months ended December 31, 2018, the Company recorded no material impact to commission expense as a result of adopting the new standard. The Company did not otherwise experience significant changes in the timing or method of revenue recognition for any of its material revenue streams.

We generate revenue from initial capital sales of systems as well as recurring revenue from the sale of our proprietary disposable devices, from royalties paid to the Company on the sale by Biosense Webster of co-developed catheters, and from other recurring revenue including ongoing software and service contracts.

We account for a contract with a customer when there is a legally enforceable contract between the Company and the customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. We record our revenue based on consideration specified in the contract with each customer, net of any taxes collected from customers that are remitted to government authorities.

For contracts containing multiple products and services the Company accounts for individual products and services as separate performance obligations if they are distinct, which is if a product or service is separately identifiable from other items in the bundled package, and if a customer can benefit from it on its own or with other resources that are

readily available to the customer. The Company recognizes revenues as the performance obligations are satisfied by transferring control of the product or service to a customer.

For multiple-element arrangements, revenue is allocated to each performance obligation based on its relative standalone selling price. Standalone selling prices are based on observable prices at which the Company separately sells the products or services. If a standalone selling price is not directly observable, then the Company estimates the standalone selling price considering market conditions and entity-specific factors including, but not limited to, features and functionality of the products and services and market conditions. The Company regularly reviews standalone selling prices and updates these estimates as necessary.

Systems:

Contracts related to the sale of systems typically contain separate obligations for the delivery of system(s), installation and an implied obligation to provide software enhancements if and when available for one year following installation. Revenue is recognized when the Company transfers control to the customer, which is generally at the point when acceptance occurs that indicates customer acknowledgment of delivery or installation, depending on the terms of the arrangement. Revenue from the implied obligation to deliver software enhancements if and when available is recognized ratably over the first year following installation of the system as the customer receives the right to software updates throughout the period. Revenue from this performance obligation is included in Other Recurring Revenue. The Company’s system contracts generally do not provide a right of return. Systems are generally covered by a one-year assurance type warranty; warranty costs were not material for the periods presented.

Disposables:

Revenue from sales of disposable products is recognized when control is transferred to the customers, which generally occurs at the time of shipment, but can also occur at the time of delivery depending on the customer arrangement. Disposable products are covered by an assurance type warranty that provides for the return of defective products. Warranty costs were not material for the periods presented.

Royalty:

The Company is entitled to royalty payments from Biosense Webster, payable quarterly based on net revenues from sales of the co-developed catheters.

Other Recurring Revenue:

Other recurring revenue includes revenue from product maintenance plans, other post warranty maintenance, and the implied obligation to provide software enhancements if and when available for one year following installation. Revenue from services and software enhancements is deferred and amortized over the service or update period, which is typically one year.

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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 between one and five 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 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 actual 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 utilized in calculating stock-based compensation have been prepared based on historical data. 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. The amount of expense to be recorded in future periods may decrease if the requisite service periods are not completed.

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.

Income Taxes

Deferred tax 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, 2018 and 2017

Revenue. Revenue decreased to $29.3 million for the year ended December 31, 2018, from $31.1 million for the year ended December 31, 2017, a decrease of approximately 6%. Revenue from sales of systems decreased to $1.6 million for the year ended December 31, 2018, from $4.3 million for the year ended December 31, 2017, a decrease of approximately 63%. We recognized a total of $1.6 million in revenue for *Odyssey* and *Odyssey Cinema* systems during the 2018 period. System revenue for the prior year included revenue on two *Niobe* ES systems and a total of $2.2 million for *Odyssey* and *Odyssey Cinema* systems. Revenue from sales of disposable interventional devices, service and accessories increased to $27.8 million for the year ended December 31, 2018, from $26.9 million for the year ended December 31, 2017, an increase of approximately 3%. The increase was primarily attributable to service revenue.

Cost of Revenue. Cost of revenue decreased to $5.7 million for the year ended December 31, 2018, from $10.8 million for the year ended December 31, 2017, a decrease of approximately 47%. As a percentage of our total revenue, overall gross margin increased from 65% for the year ended December 31, 2017, to 81% for the year ended December 31, 2018, primarily due to lower inventory-related charges and higher current year margins on disposable products and service contracts. Cost of revenue for systems sold decreased to $1.8 million for the year ended December 31, 2018, from $6.2 million for the year ended December 31, 2017 and gross margin for systems improved to (13%) for the year ended December 31, 2018 from (45%) for the year ended December 31, 2017 due to the 2017 inventory-related charge. Gross margin from systems was negative in 2018 due to low sales volumes and obsolescence charges on the receipt of committed inventory related to its *Niobe ES* product line. Cost of revenue for disposable interventional devices, service and accessories decreased to $3.9 million for the year ended December 31, 2018, from $4.6 million for the year ended December 31, 2017, resulting in an increase in gross margin to 86% from 83% driven by higher margins on disposables products and service contracts between these periods in the current year.

Research and Development Expense. Research and development expense increased to $8.2 million for the year ended December 31, 2018 from $6.7 million for the year ended December 31, 2017, an increase of approximately 23%. This increase was primarily due to higher project-based expenses.

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Sales and Marketing Expense. Sales and marketing expense decreased to $13.0 million for the year ended December 31, 2018, from $13.6 million for the year ended December 31, 2017, a decrease of approximately 5%. This decrease was primarily due to a more efficient distribution of clinical adoption and marketing resources which favorably impacted both headcount and contractor costs partially offset by higher commissions.

General and Administrative Expense. General and administrative expenses include finance, information systems, legal, and general management expenses. General and administrative expense decreased to $4.9 million for the year ended December 31, 2018, from $6.0 million for the year ended December 31, 2017, a decrease of approximately 18%. This decrease was primarily driven by reduced executive headcount costs and administrative expense.

Other Income (Expense). Other income (expense) represents the non-cash change in market value of certain warrants previously 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 was $2.6 million for the year ended December 31, 2018 and $0.2 million for the year ended December 31, 2017 due primarily to the adjustment in fair value of warrants. As of December 31, 2018, all such warrants have expired or been reclassified to equity.

Interest Expense. Interest expense in the current year period decreased approximately 90% from the twelve months ended December 31, 2017, due to lower loan commitment fees.

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, 2018, and December 31, 2017 to reflect these uncertainties. As of December 31, 2018, we had gross federal net operating loss carryforwards of approximately $100.3 million which will expire between 2030 and 2037. As of December 31, 2018, we had state net operating loss deferred tax assets of approximately $1.9 million which will expire at various dates between 2019 and 2037 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, 2018, our accumulated deficit was $476.7 million with cash and cash equivalents of $10.8 million. 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, 2018, our borrowing facility was comprised of a revolving line of credit with $3.3 million of unborrowed availability with our primary lender, Silicon Valley Bank.

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 maximum available under the line is $5.0 million subject to the value of collateralized 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.

On April 26, 2018, the Company entered into a First Amendment to Third Amended and Restated Loan and Security Agreement with Silicon Valley Bank to extend the maturity of the revolving line of credit to April 25, 2019. The maximum availability under the revolving line of credit remains at $5.0 million, and provides for an interest rate during a "streamline period" equal to the prime rate subject to a floor of 4.5%. A "streamline period" occurs when the Company has, for each consecutive day in the immediately preceding monthly period, maintained a liquidity ratio greater than 1.75:1.00, and continuing so long as the streamline period has been maintained. Upon the termination of a streamline period, the Company must maintain the streamline threshold each consecutive day for one fiscal quarter, prior to entering into a subsequent streamline period. During non-streamline periods, the interest rate is the prime rate plus 1.5%, subject to a floor of 4.5%. In addition, the amendment requires that the liquidity ratio shall at all times include not less than $1.5 million of the Borrower's unrestricted cash and cash equivalents maintained at the Bank prior to giving effect to any advance.

As of December 31, 2018, 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, 2018 the Company had a borrowing capacity of $3.3 million based on the Company's collateralized assets. The Company's total liquidity as of December 31, 2018, was $14.1 million which included cash and cash equivalents of $10.8 million.

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, 2018.

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Convertible Preferred Stock and Warrants

In September 2016, the Company issued 24,000 shares of Series A Convertible Preferred Stock, par value $0.001 with a stated value of $1,000 per share which are convertible into shares of the Company's common stock at an initial conversion rate of $0.65 per share and (ii) warrants to purchase an aggregate of 36,923,078 shares of common stock. The convertible preferred shares are entitled to vote on an as-converted basis with the common stock, subject to specified beneficial ownership issuance limitations. The convertible preferred shares bear dividends at a rate of six percent (6%) per annum, which are cumulative and accrue daily from the date of issuance on the $1,000 stated value. Such dividends will not be paid in cash except in connection with any liquidation, dissolution or winding up of the Company or any redemption of the convertible preferred shares. Each holder of convertible preferred shares has the right to require us to redeem such holder's convertible preferred shares upon the occurrence of specified events, which include certain business combinations, the sale of all or substantially all of the Company's assets, or the sale of more than 50% of the outstanding shares of the Company's common stock. In addition, the Company has the right to redeem the convertible preferred shares in the event of a defined change of control. The convertible preferred shares rank senior to our common stock as to distributions and payments upon the liquidation, dissolution, and winding up of the Company. Since the convertible preferred shares are subject to conditions for redemption that are outside the Company's control, the convertible preferred shares are presently reported in the mezzanine section of the balance sheet.

The warrants issued in conjunction with the convertible preferred stock (the "SPA Warrants") have an exercise price equal to $0.70 per share subject to adjustments as provided under the terms of the warrants. The warrants are exercisable through September 29, 2021, subject to specified beneficial ownership issuance limitations. Prior to their modification in February 2018, the warrants were puttable upon the occurrence of certain events outside of the Company's control, and were classified as liabilities under Accounting Standards Codification ("ASC") Topic 480-10. The calculated fair value of the warrants was periodically re-measured with any changes in value recognized in "Other income (expense)" in the Statements of Operations. See Note 10 for additional details.

The warrants were modified on February 28, 2018 to allow for a reduction in the exercise price from $0.70 per share to $0.28 per share for a period between March 1, 2018 and March 5, 2018. Additionally, the beneficial ownership limitation related to the warrants was modified and the right of holders to require the Company to redeem their SPA Warrants in exchange for cash in certain circumstances was eliminated. Following these modifications, the warrants were no longer subject to liability accounting and were reclassified to equity. During the restricted exercise period, Stereotaxis received exercise notices for 35,791,927 warrants and received an aggregate of $10.0 million in cash from the warrant exercise. As a result of these transactions, total stockholders' equity increased by $27 million and common shares outstanding increased by 35,791,927 shares. The Consent and Amendment and the Amended and Restated Form of Warrants are available in a Form 8-K filed with the Securities and Exchange Commission on March 6, 2018.

Liquidity

The following table summarizes our cash flow by operating, investing and financing activities for each of years ended December 31, 2018 and 2017 (in thousands):

	Twelve Months Ended December 31,	
	2018	2017
Cash flow used in operating activities	$(2,547)	$(4,675)
Cash flow used in investing activities	(265)	(82)
Cash flow (used in)/provided by financing activities	9,922	(59)

Net cash used in operating activities. We used approximately $2.5 million and $4.7 million of cash in operating activities during the years ended December 31, 2018 and 2017, respectively. The decrease in cash used in operating activities from 2017 to 2018 was driven by reduced operating losses after adjusting for large non-cash transactions in 2017 including inventory obsolescence and revenue recognized during the period for which cash had been collected in 2016.

Net cash used in investing activities. We used approximately $0.3 million and approximately $0.1 million during the years ended December 31, 2018 and December 31, 2017, respectively, for the purchase of property and equipment.

Net cash used in/provided by financing activities. We generated approximately $9.9 million of cash for the year ended December 31, 2018, compared to approximately $0.1 million used for the year ended December 31, 2017. The cash generated for the year ended December 31, 2018 was driven by proceeds from the warrant exercise. The cash used for the year ended December 31, 2017 was driven by payments of deferred financing costs offset by proceeds from issuance of stock.

At December 31, 2018, we had working capital of approximately $7.8 million, compared to a working capital deficit of $20.3 million at December 31, 2017. The increase in working capital was primarily driven by proceeds from the warrant modification and exercise.

As of December 31, 2018, 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, 2018, the Company had a borrowing capacity of $3.3 million based on the Company’s collateralized assets. The maturity date of the revolving line of credit is April 25, 2019.

The credit facility is 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, 2018, we are required to meet 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, 2018, we were in compliance with all financial covenants of this agreement.

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The Company believes the cash on hand at December 31, 2018 will be sufficient to meet its obligations as they become due in the ordinary course of business for at least 12 months following the date these financial statements are issued. The Company has sustained operating losses throughout its corporate history and expects that its 2019 expenses will exceed its 2019 gross margin. The Company expects to continue to incur operating losses and negative cash flows until revenues reach a level sufficient to support ongoing operations or expense reductions are in place. The Company's liquidity needs will be largely determined by the success of clinical adoption within the installed base of robotic magnetic systems as well as by new placements of capital systems. The Company also may consider raising cash through capital transactions, which could include either debt or equity financing.

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 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 because our common stock is no longer listed on a national securities exchange, or that such financing will not be dilutive to our stockholders. If adequate funds are not available to us, we could be required to delay development or commercialization of new products, to license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize ourselves or to reduce the sales, marketing, customer support or other resources devoted to our products, any of which could have a material adverse effect on our business, financial condition and results of operations. In addition, we could be required to cease operations.

Off-Balance Sheet Arrangements

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

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial Statements

Index To Financial Statements

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

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Stereotaxis, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Stereotaxis, Inc. (the Company) as of December 31, 2018 and 2017, the related statements of operations, convertible preferred stock and stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2018, and the related notes and financial statement schedule listed in the Index at Item 15(a) (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis

for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2002.

St. Louis, Missouri

March 15, 2019

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STEREOTAXIS, INC.

BALANCE SHEETS

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$10,796,072	$3,686,302
Accounts receivable, net of allowance of $398,847 and $361,350 in 2018 and 2017, respectively	5,021,111	4,287,255
Inventories, net	1,191,666	1,146,971
Prepaid expenses and other current assets	963,700	750,085
Total current assets	17,972,549	9,870,613
Property and equipment, net	343,693	592,688
Intangible assets, net	-	159,470
Other assets	198,365	44,432
Total assets	$18,514,607	$10,667,203
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$1,726,360	$1,654,101
Accrued liabilities	2,642,481	3,195,247
Deferred revenue	5,825,536	5,702,769
Warrants	-	19,574,977
Total current liabilities	10,194,377	30,127,094
Long-term deferred revenue	407,151	611,863
Other liabilities	641,461	535,369
Total liabilities	11,242,989	31,274,326
Convertible Preferred stock:		
Convertible Preferred stock, par value $0.001; 10,000,000 shares authorized, 23,900 shares outstanding at 2018 and 2017	5,960,475	5,960,475
Stockholders' equity (deficit):		
Common stock, par value $0.001; 300,000,000 shares authorized, 59,058,297 and 22,805,731 shares issued at 2018 and 2017, respectively	59,058	22,806
Additional paid in capital	478,179,574	450,748,403
Treasury stock, 4,015 shares at 2018 and 2017	(205,999)	(205,999)
Accumulated deficit	(476,721,490)	(477,132,808)
Total stockholders' equity (deficit)	1,311,143	(26,567,598)
Total liabilities and stockholders' equity (deficit)	$18,514,607	$10,667,203

See accompanying notes.

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STEREOTAXIS, INC.

STATEMENTS OF OPERATIONS

	Twelve Months Ended December 31,	
	2018	2017
Revenue:		
Systems	$1,582,053	$4,275,798
Disposables, service and accessories	27,764,564	26,868,302
Total revenue	29,346,617	31,144,100
Cost of revenue:		
Systems	1,788,658	6,199,643
Disposables, service and accessories	3,928,521	4,554,596
Total cost of revenue	5,717,179	10,754,239
Gross margin	23,629,438	20,389,861
Operating expenses:		
Research and development	8,219,387	6,704,200
Sales and marketing	12,965,920	13,627,724
General and administrative	4,901,170	5,977,534
Total operating expenses	26,086,477	26,309,458
Operating loss	(2,457,039)	(5,919,597)
Other income	2,590,361	212,031
Interest income (expense)	(16,566)	(179,844)
Net income (loss)	$116,756	$(5,887,410)
Cumulative dividend on convertible preferred stock	(1,434,000)	(1,432,259)
Net loss attributable to common stockholders	$(1,317,244)	$(7,319,669)
Net loss per share attributable to common stockholders:		
Basic	$(0.03)	$(0.32)
Diluted	$(0.03)	$(0.32)
Weighted average number of common shares and equivalents:		
Basic	52,082,618	22,614,248
Diluted	52,082,618	22,614,248

Certain prior year amounts have been reclassified to conform to the 2018 presentation.

See accompanying notes.

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STEREOTAXIS, INC.

STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Treasury	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	(Deficit)
Balance at December 31, 2016	23,900	$5,960,475	22,063,582	$22,064	$449,939,406	$(205,999)	$(471,245,398)	$(21,489,927)
Share-based compensation					768,682			768,682
Restricted stock vesting			675,473	675	(552)			123
Components of comprehensive loss: net loss							(5,887,410)	(5,887,410)
Employee stock purchase plan			66,676	67	40,867			40,934
Balance at December 31, 2017	23,900	$5,960,475	22,805,731	$22,806	$450,748,403	$(205,999)	$(477,132,808)	$(26,567,598)

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Treasury	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	(Deficit)
Balance at December 31, 2017	23,900	$5,960,475	22,805,731	$22,806	$450,748,403	$(205,999)	$(477,132,808)	$(26,567,598)
Issuance of common stock and warrants			35,792,593	35,793	26,813,524			26,849,317
Share-based compensation					561,115			561,115
Restricted stock vesting			385,606	385	(385)			
Components of comprehensive loss: net loss							116,756	116,756
			74,367	74	56,917			56,991

Employee stock purchase plan								
Cumulative Catchup for Adoption of ASC 606 [1]							294,562	294,562
Balance at December 31, 2018	23,900	$5,960,475	59,058,297	$59,058	$478,179,574	$(205,999)	$(476,721,490)	$1,311,143

[1] Represents the adjustments related to the adoption of new accounting standards. See Note 2 for details.

See accompanying notes.

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STEREOTAXIS, INC.

STATEMENTS OF CASH FLOWS

	Twelve Months Ended December 31,	
	2018	2017
Cash flows from operating activities		
Net income (loss)	$116,756	$(5,887,410)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	513,029	554,361
Amortization of intangibles	65,988	199,321
Amortization of deferred finance costs	24,657	99,998
Share-based compensation	560,973	768,682
Net impairments and loss on asset disposal	94,931	98,550
Adjustment of warrants	(2,590,361)	(212,030)
Provisions for obsolete inventory	320,447	3,948,726
Changes in operating assets and liabilities:		
Accounts receivable	(733,856)	378,704
Inventories	(365,142)	285,406
Prepaid expenses and other current assets	(124,419)	105,215
Other assets	26,775	(5,191)
Accounts payable	72,259	(968,909)
Accrued liabilities	(552,766)	(1,295,917)
Deferred revenue	(81,945)	(2,959,033)
Other liabilities	106,092	214,960
Net cash used in operating activities	(2,546,582)	(4,674,567)
Cash flows from investing activities		
Purchase of fixed assets	(265,482)	(81,577)
Net cash used in investing activities	(265,482)	(81,577)
Cash flows from financing activities		
Payments of deferred financing costs	-	(100,000)
Proceeds from issuance of stock, net of issuance costs	57,137	41,054
Proceeds from warrant exercise	9,864,697	-
Net cash provided by (used in) financing activities	9,921,834	(58,946)
Net increase (decrease) in cash and cash equivalents	7,109,770	(4,815,090)
Cash and cash equivalents at beginning of period	3,686,302	8,501,392
Cash and cash equivalents at end of period	$10,796,072	$3,686,302
Supplemental disclosures of cash flow information:		
Interest paid	-	-

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,™ V-CAS Deflect,™ QuikCAS™ and Cardiodrive® 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 Robotic 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 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 resulting in improved navigation, efficient procedures and reduced x-ray exposure. As of December 31, 2018, the Company had an installed base of 126 Niobe ES systems.

In addition to the robotic magnetic 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 robotic magnetic 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 and equipment service costs beyond warranty period. 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 Europe. *The V-CAS Deflect* catheter advancement system has been CE Marked for sale in Europe.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company believes the cash on hand at December 31, 2018 will be sufficient to meet its obligations as they become due in the ordinary course of business for at least 12 months following the date these financial statements are issued. The Company has sustained operating losses throughout its corporate history and expects that its 2019 expenses will exceed its 2019 gross margin. The Company expects to continue to incur operating losses and negative cash flows until revenues reach a level sufficient to support ongoing operations or expense reductions are in place. The Company’s liquidity needs will be largely determined by the success of clinical adoption within the installed base of robotic magnetic systems and placement of new robotic magnetic systems as well as by new placements of capital systems. The Company also may consider raising cash through capital transactions, which could include either debt or equity financing.

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, 2018 or 2017.

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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.

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.

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 11 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

Revenue Recognition

The Company adopted Accounting Standards Codification (“ASC”) Topic 606 (“ASC 606”), *Revenue from Contracts with Customers,* on January 1, 2018 using the modified retrospective method. As part of the Company's adoption of ASC 606, the Company elected to use the following practical expedients (i) applying the modified retrospective method only to open contracts as of December 31, 2017; (ii) not to adjust the promised amount of consideration for the effects of a significant financing component when the Company expects, at contract inception, that the period between the Company's transfer of a promised product or service to a customer and when the customer pays for that product or service will be one year or less; (iii) to expense costs as incurred for costs to obtain a contract when the amortization period would have been one year or less; and (iv) not to assess whether promised goods or services are performance

obligations if they are immaterial in the context of the contract with the customer.

Upon adoption of the new revenue guidance, the Company recorded a cumulative-effect reduction to accumulated deficit of $0.3 million on January 1, 2018 relating primarily to the deferral of previously expensed costs to obtain a contract. The Company capitalized sales commissions paid in connection with multi-year service contracts and is amortizing such asset over the economic life of those contracts. Previously, sales commissions on multi-year service contracts were expensed as incurred. The impact of this change on operating expenses in any given period will depend, in part, on the amount of such commissions incurred and capitalized in relation to the amount of ongoing amortization expense. For the twelve months ended December 31, 2018, the Company recorded no material impact to commission expense as a result of adopting the new standard. The Company did not otherwise experience significant changes in the timing or method of revenue recognition for any of its material revenue streams.

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We generate revenue from initial capital sales of systems as well as recurring revenue from the sale of our proprietary disposable devices, from royalties paid to the Company on the sale by Biosense Webster of co-developed catheters, and from other recurring revenue including ongoing software and service contracts.

We account for a contract with a customer when there is a legally enforceable contract between the Company and the customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. We record our revenue based on consideration specified in the contract with each customer, net of any taxes collected from customers that are remitted to government authorities.

For contracts containing multiple products and services the Company accounts for individual products and services as separate performance obligations if they are distinct, which is if a product or service is separately identifiable from other items in the bundled package, and if a customer can benefit from it on its own or with other resources that are readily available to the customer. The Company recognizes revenues as the performance obligations are satisfied by transferring control of the product or service to a customer.

For multiple-element arrangements, revenue is allocated to each performance obligation based on its relative standalone selling price. Standalone selling prices are based on observable prices at which the Company separately sells the products or services. If a standalone selling price is not directly observable, then the Company estimates the standalone selling price considering market conditions and entity-specific factors including, but not limited to, features and functionality of the products and services and market conditions. The Company regularly reviews standalone selling prices and updates these estimates as necessary.

Systems:

Contracts related to the sale of systems typically contain separate obligations for the delivery of system(s), installation and an implied obligation to provide software enhancements if and when available for one year following installation. Revenue is recognized when the Company transfers control to the customer, which is generally at the point when acceptance occurs that indicates customer acknowledgment of delivery or installation, depending on the terms of the arrangement. Revenue from the implied obligation to deliver software enhancements if and when available is recognized ratably over the first year following installation of the system as the customer receives the right to software updates throughout the period and is included in Other Recurring Revenue. The Company’s system contracts generally do not provide a right of return. Systems are generally covered by a one-year assurance type warranty; warranty costs were not material for the periods presented. Revenue from system delivery and installation represented 5% and 13% of revenue for the twelve months ended December 31, 2018 and 2017, respectively.

Disposables:

Revenue from sales of disposable products is recognized when control is transferred to the customers, which generally occurs at the time of shipment, but can also occur at the time of delivery depending on the customer arrangement. Disposable products are covered by an assurance type warranty that provides for the return of defective products. Warranty costs were not material for the periods presented. Disposable revenue represented 33% of revenue for the twelve months ended December 31, 2018 and 2017, respectively.

Royalty:

The Company is 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 10% of revenue for the twelve months ended December 31, 2018 and 2017.

Other Recurring Revenue:

Other recurring revenue includes revenue from product maintenance plans, other post warranty maintenance, and the implied obligation to provide software enhancements if and when available for one year following installation. Revenue from services and software enhancements is deferred and amortized over the service or update period, which is typically one year. Revenue related to services performed on a time-and-materials basis is recognized when performed. Other recurring revenue represented 52% and 44% of revenue for the twelve months ended December 31, 2018 and 2017, respectively.

	Twelve Months Ended December 31,	
	2018	2017
Systems	$1,582,053	$4,275,798
Disposables, service and accessories	27,764,564	26,868,302
Total revenue	$29,346,617	$31,144,100

Transaction price allocated to remaining performance obligations relates to amounts allocated to products and services for which the revenue has not yet been recognized. A significant portion of this amount relates to the Company's systems contracts and obligations that will be recognized as revenue in future periods. These obligations are generally satisfied within two years after contract inception but may occasionally extend longer. Transaction price representing revenue to be earned on remaining performance obligations on system contracts was approximately $2.8 million as of December 31, 2018. Performance obligations arising from contracts for disposables, royalty and service are generally expected to be satisfied within one year after entering into the contract.

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The following information summarizes the Company's contract assets and liabilities:

	December 31, 2018	December 31, 2017
Contract Assets - Unbilled Receivables	$251,867	$2,917
Customer deposits	487,086	—
Product shipped, revenue deferred	645,199	941,724
Deferred service and license fees	5,100,402	5,372,908
Total deferred revenue	6,232,687	6,314,632
Less: Long-term deferred revenue	(407,151)	(611,863)
Total current deferred revenue	$5,825,536	$5,702,769

The Company invoices its customers based on the billing schedules in its sales arrangements. Contract assets primarily represent the difference between the revenue that was earned but not billed on service contracts and revenue from system contracts that was recognized based on the relative selling price of the related performance obligations and the contractual billing terms in the arrangements. Deferred revenue is primarily related to service contracts, for which the service fees are billed up-front, generally quarterly or annually, and for amounts billed in advance for system contracts for which some performance obligations remain outstanding. For service contracts, the associated deferred revenue is generally recognized ratably over the service period. For system contracts, the associated deferred revenue is recognized when the remaining performance obligations are satisfied. The Company did not have any impairment losses on its contract assets for the periods presented.

Revenue recognized for the twelve months ended December 31, 2018 and 2017, that was included in the deferred revenue balance at the beginning of each reporting period was $5.5 million and $8.0 million, respectively.

The Company has determined that sales incentive programs for the Company's sales team meet the requirements to be capitalized as the Company expects to generate future economic benefits from the related revenue generating contracts after the initial capital sales transaction. The costs capitalized as contract acquisition costs included in prepaid expenses and other assets, in the Company's balance sheet was $0.3 million as of December 31, 2018. The Company did not incur any impairment losses during any of the periods presented.

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 relationships 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, 2018 or 2017 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 four years.

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.

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Net Earnings (Loss) per Common Share

Basic earnings (loss) per common share is computed by dividing the net earnings (loss) for the period by the weighted average number of common shares outstanding during the period. In periods where there is net income, we apply the two-class method to calculate basic and diluted net income (loss) per share of common stock, as our Convertible Preferred Stock is a participating security. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. In periods where there is a net loss, the two-class method of computing earnings per share does not apply as our Convertible Preferred Stock does not contractually participate in our losses. We compute diluted net income (loss) per common share using net income (loss) as the "control number" in determining whether potential common shares are dilutive, after giving consideration to all potentially dilutive common shares, including stock options, warrants, unvested restricted stock units outstanding during the period and potential issuance of stock upon the conversion of our Convertible Preferred Stock issued and outstanding during the period, except where the effect of such securities would be antidilutive.

The Company did not include any portion of unearned restricted shares, outstanding options, stock appreciation rights, warrants or convertible preferred stock 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, 2018, the Company had 1,165,086 shares of common stock issuable upon the exercise of outstanding options and stock appreciation rights at a weighted average exercise price of $2.54 per share, 1,131,151 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $0.70 per share, and 41,743,654 shares of our common stock issuable upon conversion of our Series A Convertible Preferred Stock. The Company had no unearned restricted shares outstanding for the period ended December 31, 2018.

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.

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 government provided insurance on such deposits.

Revenue from Biosense Webster Inc. related to royalties and *Odyssey* system sales accounted for $2.9 million and $3.3 million, or 10% and 11%, of total net revenue for the years ended December 31, 2018, and 2017, respectively. No other single customer accounted for more than 10% of total revenue for the year ended December 31, 2018. No single country other than the U.S. accounted for more than 10% of total revenue for the years ended December 31, 2018 and 2017.

Reclassifications

In 2018, we adjusted our operating expense categories to improve our alignment with common industry reporting practice, and as a result, certain amounts in prior periods have been reclassified to conform to the current period presentation. For the year ended December 31, 2017, approximately $1.9 million of regulatory and clinical research expenses previously included in General and Administrative expense have been reclassified to Research and Development expense, and approximately $0.6 million of international training expense previously included in General and Administrative expense has been reclassified to Sales and Marketing expense. These reclassifications had no effect on reported income or losses.

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2016-02 ("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 substantially complete with our evaluation of the impact of adopting ASU 2016-02 on its consolidated financial statements and will adopt ASU 2016-02 during the first quarter of 2019 using the alternative modified transition method. Under this method, the cumulative-effect adjustment to the opening balance of retained earnings is recognized on the date of adoption with prior periods not restated.

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The new standard provides a number of optional practical expedients in transition. The Company expects to elect the 'package of practical expedients', which permits it not to reassess under the new standard its prior conclusions about lease identification, lease classification, and initial direct costs. In addition, the new standard provides practical expedients for an entity's ongoing accounting that the Company anticipates making, such as the (1) the election for certain classes of underlying asset to not separate non-lease components from lease components and (2) the election for short-term lease recognition exemption for all leases that qualify.

As a lessee, the Company believes the largest impact will be on its consolidated balance sheets for the accounting of facilities-related leases, which represents the majority of the operating leases it has entered into as a lessee. These leases will be recognized under the new standard as Right of Use ("ROU") assets and operating lease liabilities. The Company will also be required to provide expanded disclosures for its leasing arrangements. As of December 31, 2018, the Company had between $6.0 million and $7.0 million of operating lease commitments that are not recognized on its consolidated balance sheets as determined under the current standard. For a lessee, the results of operations are not expected to significantly change after adoption of the new standard.

In addition, from time to time, the Company has sublet a portion of its operating facilities. Under the existing standard, the Company recorded any sub-lease proceeds as a reduction to its operating expenses. Under the new standard, as a lessor, the Company will record these amounts as Other Income. The Company does not expect this change to have a material impact on its consolidated financial statements.

While substantially complete, the Company is still finalizing its adoption of ASC 842 and the related impact on the Company's financial statements and disclosures. As the Company completes its evaluation of this new standard during the first quarter of 2019, new information may arise that could change the Company's current assessment of the impact to existing accounting. Additionally, the Company will continue to monitor industry activities and any additional guidance provided by regulators, standards setters, or the accounting profession, and adjust the Company's assessment and implementation plans accordingly.

3. Inventory

Inventory consists of the following:

	December 31, 2018	December 31, 2017
Raw materials	$2,686,870	$2,528,270
Work in process	2,594	4,836

Finished goods	2,963,013	2,515,637
Reserve for obsolescence	(4,460,811)	(3,901,772)
Total inventory	$1,191,666	$1,146,971

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31, 2018	December 31, 2017
Prepaid expenses	$401,972	$575,501
Prepaid commissions	304,585	-
Deferred financing costs	-	24,658
Deposits	455,508	194,358
Total prepaid expenses and other assets	1,162,065	794,517
Less: Noncurrent prepaid expenses and other assets	(198,365)	(44,432)
Total current prepaid expenses and other assets	$963,700	$750,085

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5. Property and Equipment

Property and equipment consist of the following:

	December 31, 2018	December 31, 2017
Equipment	$6,831,665	$7,295,698
Leasehold improvements	2,592,339	2,592,339
	9,424,004	9,888,037
Less: Accumulated depreciation	(9,080,311)	(9,295,349)
Net property and equipment	$343,693	$592,688

6. Intangible Assets

As of December 31, 2018 and 2017, the Company had total intangible assets of $3,049,810 and $3,143,291, respectively. Accumulated amortization at December 31, 2018 and 2017 was $3,049,810 and $2,983,821, respectively. Amortization expense for 2018 and 2017 was $65,988 and $199,321, respectively, as determined under the straight-line method. For the twelve months ended December 31, 2018 and 2017, the Company also recognized impairment charges of $93,482 and $77,778, respectively in research and development expense related to certain intellectual property rights. The impairment is the result of an analysis that indicated it was probable the undiscounted cash flows derived from the intellectual property would not exceed its book value during its remaining useful life.

7. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2018	December 31, 2017
Accrued salaries, bonus, and benefits	$1,491,844	$1,641,491
Accrued rent	69,826	441,417
Accrued licenses and maintenance fees	576,598	581,672
Accrued warranties	149,464	164,365
Accrued taxes	251,988	234,668

Accrued professional services	430,088	367,072
Other	314,134	299,931
Total accrued liabilities	3,283,942	3,730,616
Less: Long term accrued liabilities	(641,461)	(535,369)
Total current accrued liabilities	$2,642,481	$3,195,247

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8. Long-Term Debt and Credit Facilities

As of December 31, 2018 and 2017, there were no contractual principal maturities of debt.

The revolving line of credit is 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 maximum available under the line is $5.0 million subject to the value of collateralized 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.

On April 26, 2018, the Company entered into a First Amendment to Third Amended and Restated Loan and Security Agreement with Silicon Valley Bank to extend the maturity of the revolving line of credit to April 25, 2019. The maximum availability under the revolving line of credit remains at $5.0 million, and provides for an interest rate during a "streamline period" equal to the prime rate subject to a floor of 4.5%. A "streamline period" occurs when the Company has, for each consecutive day in the immediately preceding monthly period, maintained a liquidity ratio greater than 1.75:1.00, and continuing so long as the streamline period has been maintained. Upon the termination of a streamline period, the Company must maintain the streamline threshold each consecutive day for one fiscal quarter, prior to entering into a subsequent streamline period. During non-streamline periods, the interest rate is the prime rate plus 1.5%, subject to a floor of 4.5%. In addition, the amendment requires that the liquidity ratio shall at all times include not less than $1.5 million of the Borrower's unrestricted cash and cash equivalents maintained at the Bank prior to giving effect to any advance.

As of December 31, 2018, 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, 2018 the Company had a borrowing capacity of $3.3 million based on the Company's collateralized assets. The Company's total liquidity as of December 31, 2018, was $14.1 million, which included cash and cash equivalents of $10.8 million. As of December 31, 2018, we were in compliance with all financial covenants of this agreement and we anticipate continued compliance throughout the remainder of 2019.

9. Lease Obligations

The Company leases its facilities under operating leases. For the years ended December 31, 2018 and 2017 rent expense was $718,736 and $588,197, respectively. The rent expense for the years ended December 31, 2018 and 2017 is net of sublease income of $837,949 and $812,660, respectively.

The lease for the Company's principal executive office space and manufacturing facilities expired on December 31, 2018. On January 10, 2019, the company exercised its remaining renewal option to extend the term of the lease by three years. The lease contains an escalating rent provision which the Company has straight-lined over the term of the lease.

The future minimum lease payments under non-cancelable leases as of December 31, 2018 are as follows (excluding any potential sublease income):

Year	Operating Lease Payments
2019	$2,334,382
2020	2,364,408
2021	2,404,565
Total minimum lease payments	7,103,355

10. Convertible Preferred Stock and 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, 2018.

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Convertible Preferred Stock and Warrants

In September 2016, the Company issued 24,000 shares of Series A Convertible Preferred Stock, par value $0.001 with a stated value of $1,000 per share which are convertible into shares of the Company's common stock at an initial conversion rate of $0.65 per share and (ii) warrants to purchase an aggregate of 36,923,078 shares of common stock. The convertible preferred shares are entitled to vote on an as-converted basis with the common stock, subject to specified beneficial ownership issuance limitations. The convertible preferred shares bear dividends at a rate of six percent (6%) per annum, which are cumulative and accrue daily from the date of issuance on the $1,000 stated value. Such dividends will not be paid in cash except in connection with any liquidation, dissolution or winding up of the Company or any redemption of the convertible preferred shares. Each holder of convertible preferred shares has the right to require us to redeem such holder's convertible preferred shares upon the occurrence of specified events, which include certain business combinations, the sale of all or substantially all of the Company's assets, or the sale of more than 50% of the outstanding shares of the Company's common stock. In addition, the Company has the right to redeem the convertible preferred shares in the event of a defined change of control. The convertible preferred shares rank senior to our common stock as to distributions and payments upon the liquidation, dissolution, and winding up of the Company. Since the convertible preferred shares are subject to conditions for redemption that are outside the Company's control, the convertible preferred shares are presently reported in the mezzanine section of the balance sheet.

The warrants issued in conjunction with the convertible preferred stock have an exercise price equal to $0.70 per share subject to adjustments as provided under the terms of the warrants. The warrants are exercisable through September 29, 2021, subject to specified beneficial ownership issuance limitations. Prior to their modification in February 2018, the warrants were puttable upon the occurrence of certain events outside of the Company's control, and were classified as liabilities under ASC 480-10. The calculated fair value of the warrants was periodically re-measured with any changes in value recognized in "Other income (expense)" in the Statements of Operations. See Note 11 for additional details.

The warrants were modified on February 28, 2018 to allow for a reduction in the exercise price from $0.70 per share to $0.28 per share for a period between March 1, 2018 and March 5, 2018. Additionally, the beneficial ownership limitation related to the warrants was modified and the right of holders to require the Company to redeem their SPA Warrants in exchange for cash in certain circumstances was eliminated. Following these modifications, the warrants were no longer subject to liability accounting and were reclassified to equity. During the restricted exercise period, Stereotaxis received exercise notices for 35,791,927 warrants and received an aggregate of $10.0 million in cash from the warrant exercise. As a result of these transactions, total stockholders' equity increased by $27.0 million and common shares outstanding increased by 35,791,927 shares.

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

	December 31, 2018	December 31, 2017
Warrants	1,131,151	38,779,119
Series A Convertible Preferred Stock Series	47,844,562	47,844,562
Stock award plans	4,438,503	5,573,046
Employee Stock Purchase Plan	51,251	125,618
	53,465,467	92,322,345

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.

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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-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 equity awards to new directors generally vest over a two year period. Annual grants to directors generally vest between one and five years following grant.

A summary of the option and stock appreciation rights activity for the year ended December 31, 2018 is as follows:

	Number of Options/SARs	Range of Exercise Price	Weighted Average Exercise Price per Share
Outstanding, December 31, 2017	413,301	$0.62 - $54.90	$ 9.04
Granted	950,500	$0.74 - $1.07	$ 0.76
Exercised	(2,916)	$0.62	$ 0.62
Forfeited	(195,799)	$0.62 - $54.90	$ 7.66
Outstanding, December 31, 2018	1,165,086	$0.74 - $43.90	$ 2.54

As of December 31, 2018, the weighted average remaining contractual life of the options and stock appreciation rights outstanding was 8.18 years. Of the 1,165,086 options and stock appreciation rights that were outstanding as of December 31, 2018, 291,679 were vested and exercisable with a weighted average exercise price of $7.83 per share and a weighted average remaining term of 5.16 years.

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

	Year Ended December 31, 2018				
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 - $1.00	818,500	9.18	$ 0.75	-	$ -
$1.01 - $2.00	101,500	7.86	$ 1.48	51,718	$ 1.86
$2.01- $4.00	115,791	6.11	$ 2.15	110,666	$ 2.15
$4.01 - $10.00	86,500	5.24	$ 4.04	86,500	$ 4.04

$10.01 - $20.00	-	-	$ -	-	$ 0.00
$30.01 - $40.00	30,545	1.92	$ 34.74	30,545	$ 34.74
$40.01 - $50.00	12,250	0.44	$ 43.90	12,250	$ 43.90
	1,165,086	8.18	$ 2.54	291,679	$ 7.83

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, 2018. The intrinsic value of the options and stock appreciation rights outstanding at December 31, 2018 was approximately $0.3 million based on a closing share price of $1.08 on December 31, 2018. There were no fully vested options or stock appreciation rights outstanding at December 31, 2018 with an exercise price less than the closing stock price on December 31, 2018. During the year ended December 31, 2018 the aggregate intrinsic value of options and stock appreciation rights exercised under the Company's stock option plans was less than $0.1 million. No options or stock appreciation rights were exercised under the Company's stock option plans during the year-ended December 31, 2017, and the Company realized no proceeds during that period. The weighted average grant date fair value of options and stock appreciation rights granted during the year ended December 31, 2018 was $0.76 per share.

A summary of the restricted stock unit activity for the year ended December 31, 2018 is as follows:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value per Unit
Outstanding, December 31, 2017	680,363	$ 1.11
Granted	422,167	$ 0.80
Vested	(385,606)	$ 1.24
Forfeited	(69,275)	$ 1.12
Outstanding, December 31, 2018	647,649	$ 0.83

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The intrinsic value of restricted stock units outstanding at December 31, 2018 was $0.7 million based on a closing share price of $1.08 as of December 31, 2018. During the year ended December 31, 2018, the aggregate intrinsic value of restricted stock units vested was $0.3 million determined at the date of vesting.

As of December 31, 2018, 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 $0.6 million. This cost will be amortized over a period of up to four years over the underlying estimated service periods and will be adjusted for subsequent changes in actual forfeitures and anticipated vesting periods.

2009 Employee Stock Purchase Plan

In 2009, the Company adopted its 2009 Employee Stock Purchase Plan ("ESPP"). In June 2014, our shareholders approved an amendment of 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, 2018, there were 51,251 remaining shares available for issuance under the Employee Stock Purchase Plan.

11. 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.

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.

	Fair Value Measurement Using			
	Total	Quoted Prices in Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities at December 31, 2018				
Warrants issued August 2013	$—	$ —	$ —	$ —
Warrants issued September 2016	—	—	—	—
Total liabilities at fair value:	$ —	$ —	$ —	$ —
Liabilities at December 31, 2017:				
Warrants issued August 2013	$ 5,746	$ —	$ —	$ 5,746
Warrants issued September 2016	19,569,231	—	—	19,569,231
Total liabilities at fair value:	$ 19,574,977	$ —	$ —	$ 19,574,977

Level 1

The Company does not have any financial assets or liabilities classified as Level 1.

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Level 2

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

Level 3

In conjunction with the Company's August 2013 and September 2016 financing transactions, the Company issued warrants to purchase shares of the Company's common stock. Due to the provisions included in the warrant agreements at the time of issuance, the warrants did not meet the exemptions for equity classification and as such, the Company accounted for these warrants as derivative instruments. The calculated fair value of the warrants issued in conjunction with the August 2013 financing transactions was classified as a liability and periodically re-measured with any changes in value recognized in "Other income (expense)" in the Statements of Operations until their expiration in November 2018. As detailed in Note 10, the remaining warrants from the September 2016 transaction were modified on February 28, 2018 and reclassified to equity.

The remaining warrants from the August 2013 transaction (Exchange Warrants) expired November 2018 and were last revalued as of September 30, 2018 using the following assumptions: 1) volatility of 70.17%; 2) risk-free interest rate of 2.19%; and 3) a closing stock price of $1.21.

Using the same option pricing model, the Exchange warrants were valued as of December 31, 2017 using the following assumptions: 1) volatility of 70.56%; 2) risk-free interest rate of 1.76%; and 3) a closing stock price of $0.80.

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, 2018:

	Warrants issued	Warrants issued	Total Liabilities

	August 2013	September 2016	
Balance at beginning of period	$ 5,746	$ 19,569,231	$ 19,574,977
Issues	-	-	-
Settlements	-	(16,984,616)	(16,984,616)
Revaluation	(5,746)	(2,584,615)	(2,590,361)
Balance at end of period	$ -	$ -	$ -

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.

12. Income Taxes

The provision for income taxes consists of the following:

	Year Ended December 31,	
	2018	2017
Deferred:		
Federal	$ (236,779)	$ 13,308,196
State and local	(238,946)	(263,860)
	(475,725)	13,044,336
Valuation allowance	475,725	(13,044,336)
	$ —	$ —

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,			
	2018		2017	
U.S. statutory income tax rate	21.0	%	34.0	%
State and local taxes, net of federal tax benefit	(42.8	)%	1.8	%
Permanent differences between book and tax	(390.5	)%	(1.5	)%
Deferred tax adjustments	293.5	%	(6.1	)%
Tax cuts & jobs act	0.0	%	(244.9	)%
State rate adjustments	(292.9	)%	(4.0	)%
Prior year return-to-provision adjustment	4.3	%	0.0	%
Valuation allowance	407.4	%	220.7	%

Effective income tax rate	—	%	—	%

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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 and stock compensation shortfalls. The deferred state rate adjustments are a result of changes in apportionment and various state rate law changes. The deferred tax adjustments are primarily attributable to the write-off of deferred tax assets associated with the unexercised stock compensation awards that expired during the current year.

The components of the deferred tax asset are as follows:

	December 31,	
	2018	2017
Current accruals	$1,746,094	$1,718,808
Deferred revenue	605	30,648
Depreciation and amortization	1,279,973	1,311,718
Deferred compensation	471,143	633,303
Net operating loss carryovers	22,933,668	22,359,693
Deferred tax assets	26,431,483	26,054,170
Valuation allowance	(26,359,083)	(25,955,759)
Net deferred tax assets before deferred tax liabilities	72,400	98,411
Accounting method changes	—	(98,411)
Capitalized compensation costs	(72,400)	—
Net deferred tax assets	$—	$—

On December 22, 2017, the Tax Cuts and Jobs Act (“TCJA”) was enacted, which made significant changes to the Internal Revenue Code (“IRC” or “Code”). The TCJA lowered the U.S. federal income tax rate to 21%, beginning on January 1, 2018. Additionally, among other changes, the TCJA imposes a one-time transition tax on the mandatory repatriation of unremitted foreign earnings, as well as a minimum tax on global intangible low-taxed income (“GILTI”) of foreign subsidiaries. As required by SEC Staff Accounting Bulletin 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act, we finalized our accounting analysis with the filing of our 2017 tax returns. We have recorded the impacts of the TCJA in our effective tax rate and have elected to treat taxes due on future U.S. inclusions in taxable income related to GILTI using the period cost method. The Company will continue to monitor the forthcoming regulations and additional guidance of the GILTI, FDII, and BEAT provisions under the TCJA, which are complex and subject to continuing regulatory interpretation by the IRS.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, 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 a large portion of the Company's 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 as reflected in the net operating loss carryovers in the table above. 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 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.

As of December 31, 2018, we had gross federal net operating loss carryforwards of approximately $100.3 million. The federal net operating loss carryforwards reflect accumulated book losses reduced for the 2013 IRC Section 382 ownership change limitation of $284.7 million and approximately $92.0 million of book/tax differences and expiration of unused carryforwards. The federal net operating loss carryforwards generated prior to the 2018 tax year will expire between 2030 and 2037. The federal net operating loss generated during 2018 will be carried forward indefinitely as a result to changes in the law following TCJA. As of December 31, 2018, we had state net operating loss deferred tax assets of approximately $1.9 million which will expire at various dates between 2019 and 2037 if not utilized.

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As a result of stock issuances which occurred during the year, the Company believes that an ownership change may have occurred under Section 382 of the Code. Any change could significantly limit the value of the existing net operating loss carryforward. The Company is currently evaluating the impact of the warrant exercise on the availability of its U.S. net operating loss carryforward. Refer to Note 10 for a full discussion of the Company's equity transactions.

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, 1999 forward, all tax years from 1999 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.

At December 31, 2018 and 2017, the Company had less than $0.1 million in reserves for uncertain tax positions. 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, 2018, accrued interest and penalties were less than $0.1 million.

13. 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:

	Twelve months ended December 31,	
	2018	2017
Net income (loss)	$116,756	$(5,887,410)
Deemed dividend on convertible preferred stock	—	—
Cumulative dividend on convertible preferred stock	(1,434,000)	(1,432,259)
Net loss attributable to common stockholders	$(1,317,244)	$(7,319,669)
Weighted average number of common shares and equivalents:	52,082,618	22,614,248
Basic EPS	$(0.03)	$(0.32)
Diluted EPS	$(0.03)	$(0.32)

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,	
	2018	2017
Shares issuable upon vesting/exercise of:		
Options to purchase common stock	1,165,086	413,301
Series A Convertible Preferred Stock and Accumulated Dividends	41,743,654	39,537,501
Restricted stock units	647,649	680,363
Warrants	1,131,151	38,779,119
	44,687,540	79,410,284

14. Employee Benefit Plan

The Company offers employees the opportunity to participate in a 401(k) plan. For 2018, the Company recognized expense of approximately $0.2 million to match employee contributions up to 3% of each participating employee's salary. The Company did not match employee contributions made in 2017.

15. 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.

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

	December 31, 2018	December 31, 2017
Warranty accrual, beginning of the fiscal period	$164,365	$222,845
Accrual adjustment for product warranty	34,253	32,679
Payments made	(49,154)	(91,159)
Warranty accrual, end of the fiscal period	$149,464	$164,365

16. 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.

17. 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, 2018 and 2017 were as follows:

	Year Ended December 31,	
	2018	2017
United States	$18,611,676	$18,038,638
International	10,734,941	13,105,462
Total	$29,346,617	$31,144,100

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.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Report on Internal Control Over Financial Reporting

As of December 31, 2018, 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, 2018. 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, 2018.

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 30, 2019, 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

We intend to promptly disclose any amendments to, or waivers from, any provision of the Code of Business Conduct and Ethics 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:

David L. Fischel

Chief Executive Officer and Chairman of the Board since February 2017

Director since September 2016

Mr. Fischel, 32, was named Chief Executive Officer and Chairman of the Board on February 3, 2017. He has served as a director of Stereotaxis since leading the equity investment and positive strategic initiatives announced in September 2016. He has served for over nine years as Principal and portfolio manager for medical device investments at DAFNA Capital Management, LLC. In addition to his research responsibilities, Mr. Fischel has been deeply involved in all aspects of DAFNA Capital's operations including legal, accounting, IT, compliance, human resources and marketing. Prior to joining DAFNA Capital, he was a research analyst at SCP Vitalife, a healthcare venture capital fund. Mr. Fischel completed his B.S. magna cum laude in Applied Mathematics with a minor in Accounting at the University of California at Los Angeles and received his MBA from Bar-Ilan University in Tel Aviv. He is a Certified Public Accountant, Chartered Financial Analyst and Chartered Alternative Investment Analyst.

Kevin Barry

Chief Legal Officer, Chief Compliance Officer, and Corporate Secretary

Officer since 2018

Mr. Barry, 55, was appointed as the Chief Legal Officer, Chief Compliance Officer, and Corporate Secretary in November 2018. He has 20 years of experience representing life sciences companies. Prior to joining Stereotaxis, he served as Vice President of Legal Affairs & Chief Compliance Officer for BioFire Diagnostics, a bioMerieux company, and previously held senior legal roles with Sonova Holding, AG, CareFusion, and Cardinal Health. Mr. Barry received his J.D. from Duke University and holds a B.S. from St. Louis University.

Martin C. Stammer

Chief Financial Officer

Officer since February 2013

Mr. Stammer, 38, 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.

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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.

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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.:

~~Se~~hedule II: Valuation and Qualifying Accounts.

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 60 herein.

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SCHEDULE II

VALUATION AND QUALIFYING ACCOUNTS

FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017

	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, 2018	$ 361,350	64,294	(26,797)	$ 398,847
Year ended December 31, 2017	$ 379,817	$ (18,467)	$ —	$ 361,350
Allowance for inventories valuation:				
Year ended December 31, 2018	$ 3,901,772	320,446	238,593	$ 4,460,811
Year ended December 31, 2017	$ 272,614	$ 3,948,726	$ (319,568)	$ 3,901,772

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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	Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on September 30, 2016.
3.3	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 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.
4.3b	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.).
4.3c	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).
4.3d	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.
4.3e	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.

4.3f	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.
4.3g	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.
4.4	Form of Warrant issued pursuant to that certain Exchange Agreement, dated August 7, 2013, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K (File No. 000-50884) filed on August 8, 2013.
4.5	Form of Warrant issued pursuant to that certain Securities Purchase Agreement, dated September 26, 2016, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K (file No. 001-36159) filed on September 28, 2016.
4.6	Form of Amended and Restated Warrant of Stereotaxis, Inc. issued pursuant to that certain Consent and Amendment, dated as of February 28, 2018, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on March 6, 2018.
10.1a#	Amended and Restated Stereotaxis, Inc. 2012 Stock Incentive Plan, effective February 22, 2017, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 001-36159) for the fiscal quarter ended June 30, 2017.
10.1b#	Amended and Restated Stereotaxis, Inc. 2012 Stock Incentive Plan, effective February 9, 2016, incorporated by reference to Exhibit 10.2 of the Registrant's Form 10-Q (File No. 001-36159) for the fiscal quarter ended June 30, 2016.
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.

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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.
10.1e#	Form of Restricted Share Unit Terms of Award Under Stereotaxis, Inc. 2012 Stock Incentive Plan, Director Award, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 001-36159) for the fiscal quarter ended March 31, 2017.
10.1f#	Form of Incentive Stock Option Terms of Award Under Stereotaxis, Inc. 2012 Stock Incentive Plan, incorporated by reference to Exhibit 10.1f of the Registrant's Form 10-K (File No. 001-36159) filed on March 20, 2018 for the fiscal year ended December 31, 2017.
10.1g#	Form of Non-Qualified Stock Option Terms of Award Under Stereotaxis, Inc. 2012 Stock Incentive Plan, incorporated by reference to Exhibit 10.1g of the Registrant's Form 10-K (File No. 001-36159) filed on March 20, 2018 for the fiscal year ended December 31, 2017.
10.1h#	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.
10.2#	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.
10.4a#	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.
10.4b#	Severance Agreement and Release dated February 3, 2017, between the Company 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 February 6, 2017.
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 effective January 1, 2017, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 001-36159) for the fiscal quarter ended March 31, 2017.
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.
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.

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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 10.13i of the Registrant's Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2011.
10.10j	Eighth Amendment to the Development Alliance and Supply Agreement effective June 19, 2018, among the Company and Biosense Webster, Inc., incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K (File No. 001-36159) filed on June 25, 2018.
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.
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, incorporated by reference to Exhibit 10.13e of the

	Registrant's Form 10-K (File No. 001-36159) for the fiscal year ending December 31, 2015.
10.13f	Fifth Amendment to Office Lease, effective January 10, 2019, between Registrant and VTR LS 4320 FOREST PARK, LLC successor to Cortex West Development I, LLC, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on January 10, 2019.
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 the 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.

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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.
offi10.15g	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.
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.
10.15l	Eleventh Loan Modification Agreement (Domestic), dated May 10, 2016, between the Company, Stereotaxis International, Inc., and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 001-36159) filed on May 11, 2016.
10.15m	Third Amended and Restated Loan and Security Agreement, effective November 7, 2017, among the Company, Stereotaxis International, Inc., and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 001-36159) for the fiscal quarter ended September 30, 2017.
10.15n	First Amendment to Third Amended and Restated Loan and Security Agreement, dated April 26, 2018, 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 April 30, 2018.
10.16a	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 Current

	Report on Form 8-K (File No. 000-50884) filed on April 2, 2012.
10.16b	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.
10.16c	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.
10.16d	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.
10.16e	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.
10.17	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.
10.18a	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.

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10.18b	Second Amendment, dated June 2, 2016, to Consulting Agreement, dated June 4, 2014, between Stereotaxis, Inc. and Eric N. Prystowsky, M.D., incorporated by reference to Exhibit 10.19(B) of the Registrant's Form 10-K (File No. 001-36159) for the fiscal year ended December 31, 2016.
10.19	Securities Purchase Agreement, dated September 26, 2016, between the Company and certain investors named therein, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on September 28, 2016.
10.20	Registration Rights Agreement, dated September 26, 2016, between the Company and certain purchasers named therein, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on September 28, 2016.
10.21	Letter Agreement, dated February 3, 2017, between the Company and David Fischel, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on February 6, 2017.
10.22	Consent and Amendment, dated as of February 28, 2018, by and between Stereotaxis, Inc. and the holders identified on the signature pages thereto, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8–K (File No. 001-36159) filed on March 6, 2018.
10.23	Form of Lock-up Agreement between Stereotaxis, Inc. and the holders exercising the Amended and Restated Warrant, dated as of March 5, 2018, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8–K (File No. 001-36159) filed on March 6, 2018.
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.

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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 15, 2019 By:*/s/ David L. Fischel*
David L. Fischel
Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David L. Fischel 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/ David L. Fischel **David L. Fischel**	Chairman of the Board of Directors and Chief Executive Officer (principal executive officer)	March 15, 2019
/s/ Martin C. Stammer **Martin C. Stammer**	Chief Financial Officer (principal financial officer and principal accounting officer)	March 15, 2019
/s/ David W. Benfer **David W. Benfer**	Director	March 15, 2019
/s/ Nathan Fischel **Nathan Fischel**	Director	March 15, 2019

/s/ Joe Kiani **Joe Kiani**	Director	March 15, 2019
/s/ Arun Menawat **Arun Menawat**	Director	March 15, 2019
/s/ Robert J. Messey **Robert J. Messey**	Director	March 15, 2019
/s/ Ross B. Levin **Ross B. Levin**	Director	March 15, 2019