Stereotaxis, Inc.
Form 10-K
March 20, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(MARK ONE)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2017

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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, smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

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

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant on the last business day of the registrant s most recently completed second fiscal quarter (based on the closing sales prices on the OTCQX on June 30, 2017) was approximately $11.2 million.

The number of outstanding shares of the registrant s common stock on March 13, 2018 was 58,865,036.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant s 2018 Annual Meeting of Shareholders are incorporated by reference in Part III, Items 10, 11, 12, 13 and 14.

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STEREOTAXIS, INC.

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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 , estim potential , or continue , or the negative of such terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. These statements are only predictions.

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

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

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OVERVIEW

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

The *Epoch* Solution is comprised of the *Niobe* ES Remote Magnetic Navigation System (*Niobe* ES system), *Odyssey* Information Management Solution (*Odyssey* Solution), and the *Vdrive* Robotic Navigation System (*Vdrive* system), and related devices. We consider our technology an important advancement in the ongoing trend toward fully digitized, integrated and automated interventional labs. We believe our technology provides substantial, clinically important improvements over manual interventional methods, which often result in long and unpredictable procedure times with suboptimal therapeutic outcomes. We believe our products also support efficient and effective information management and physician collaboration. The core elements of our technology, especially the *Niobe* ES system, are protected by an extensive patent portfolio, as well as substantial expertise and trade secrets.

We promote the full *Epoch* Solution in a typical hospital implementation, subject to regulatory approvals or clearances. The full *Epoch* Solution implementation requires a hospital to agree to an upfront capital payment and recurring payments. The upfront capital payment typically includes equipment and installation charges. The recurring payments typically include disposable costs for each procedure, equipment service costs beyond warranty period, and software licenses. In hospitals where the full *Epoch* Solution has not been implemented, equipment upgrade or expansion can be implemented upon purchasing of the necessary upgrade or expansion.

Not all products have and/or require regulatory clearance in all of the markets we serve. Please refer to Regulatory Approval in Item 1 for a description of our regulatory clearance, licensing, and/or approvals we currently have or are pursuing.

As of December 31, 2017, we had approximately $1.5 million of backlog, consisting of outstanding purchase orders and other commitments for these systems. We had backlog of approximately $4.5 million and $6.0 million as of December 31, 2016 and 2015, respectively. Of the December 31, 2017 backlog, we expect approximately 68.0% to be recognized as revenue over the course of 2018. There can be no assurance that we will recognize such revenue in any particular period or at all because some of our purchase orders and other commitments are subject to contingencies that are outside our control. These orders and commitments may be revised, modified or canceled, either by their express terms, as a result of negotiations or by project changes or delays. In addition, the sales cycle for the *Epoch* Solution is lengthy and generally involves construction or renovation activities at customer sites. Consequently, revenues and/or orders resulting from sales of our *Epoch* Solution can vary significantly from one reporting period to the next.

We have business arrangements with technology leaders in the global interventional market, including two multinational fluoroscopy system manufacturers and one provider of catheters and electrophysiology mapping systems. Through these arrangements, we integrate our *Niobe* system with market-leading cath lab imaging systems and catheter location sensing technology. 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.

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THE STEREOTAXIS VALUE PROPOSITION

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

The *Epoch* Solution addresses the current challenges in the interventional lab by providing precise computerized control of the working tip of the interventional instrument and by integrating this control with the visualization technology and information systems used during electrophysiology and interventional cardiology procedures, on a cost-justified basis.

We believe that our systems will:

Improve patient outcomes by optimizing therapy. Difficulty in controlling the working tip of disposable interventional devices can lead to sub-optimal results in many procedures. Conversely, the precise control of multiple complex diagnostic and therapeutic devices by a single physician can lead to better outcomes for the patient. Precise instrument control is necessary for treating a number of cardiac conditions. To treat arrhythmias, precise placement of an ablation catheter against a beating inner heart wall is necessary. Maintaining this precision and contact can be very challenging, especially in the most complex procedures, such as those for the treatment of ventricular tachycardia. For coronary artery disease, precise and correct navigation and placement of expensive stents also have a significant impact on procedure costs and outcomes. We believe our robotic technology can enhance procedure results by improving navigation of disposable interventional devices to treatment sites, and by affecting more precise, safe, treatments once these sites are reached.

Expand the market by enhancing the treatment of more complex cases. Treatment of a number of major diseases, including ventricular tachycardia, atrial fibrillation, congenital heart diseases, and critical limb ischemia due to chronic total occlusions of peripheral arteries, is highly problematic using conventional wire and/or catheter-based techniques. Additionally, many patients with multi-vessel disease and certain complex arrhythmias, such as ventricular tachycardia and atrial fibrillation are often referred to other more invasive or less curative therapies because of the difficulty in precisely and safely controlling the working tip of disposable interventional devices used to treat these complex cases interventionally. Because our robotic technology provides precise, computerized control of the working tip of disposable interventional devices, we believe that it will potentially enable difficult ventricular tachycardia, atrial fibrillation, and congenital heart diseases to be treated interventionally on a much broader scale than today.

Enhance patient and physician safety. The *Niobe* system has been used in more than 100,000 procedures and the incidence of reported major adverse cardiac events associated with the use of the system for all procedures is approximately 0.76%. This represents what we believe to be a clinically significant improvement in major complication rates over conventional procedures, which can range as high as 5.46% for complex ablations, and significantly higher for new physicians and fellows. Additionally, during conventional catheter-based procedures, each of the physicians who stand by the patient table to manually control the catheter, the nursing staff assisting with the procedure, and the patient are exposed to the potentially harmful x-ray radiation from the fluoroscopy field. This exposure can be minimized through reduced usage of fluoroscopy during procedures with the *Niobe* system due to enhanced and more fully integrated mapping capabilities of the *Niobe* software. Our robotic technology can further improve physician safety and reduce physician fatigue by enabling them to conduct procedures remotely from an adjacent control room, which reduces their exposure to harmful radiation, and the orthopedic burden of wearing lead.

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

Enhance hospital efficiency by reducing and standardizing procedure times, disposables utilization and staffing needs. Conventional interventional procedure times currently range from several minutes to many hours as physicians often engage in repetitive, trial and error maneuvers due to difficulties with manually controlling the working tip of disposable interventional devices. By reducing both navigation time and the time needed to carry out therapy at the target site, we believe that our robotic technology can reduce procedure times compared to manual procedures, especially in the most complex procedures such as the treatment of ventricular tachycardia. We believe the *Niobe* system can also reduce the variability in procedure times compared to manual methods. Greater standardization of procedure times allows for more efficient scheduling of interventional cases including staff requirements. We also believe that additional cost savings from robotics can result from decreased use of multiple catheters, high-end deflectable sheaths, and contrast media in procedures compared with manual methods further enhancing the rate of return to hospitals.

Improve physician skill levels in order to improve the efficacy of complex cardiology procedures. Training required for physicians to safely and effectively carry out manual interventional procedures typically takes years, over and above the training required to become a specialist in cardiology. This has led to a shortage of physicians who are skilled in performing more complex procedures. We believe that our robotic technology can allow procedures that previously required the highest levels of manual dexterity and skill to be performed effectively by a broader range of interventional physicians, with more standardized outcomes. In addition, interventional physicians can learn to use robotic systems in a relatively short period of time. The *Niobe* system can also be programmed to carry out sequences of complex navigation automatically further enhancing ease of use. We believe the *Odyssey* Solution can allow advanced training online thereby accelerating learning.

Help hospitals recruit physicians and attract patients. Due to the clinical benefits of the *Epoch* Solution, we believe hospitals will realize significant operational benefits when recruiting physicians to work in a more safe procedure environment, while attracting patients who desire to have safer procedures that lead to better long term outcomes.

OUR PRODUCTS

***Niobe*® ES Remote Magnetic Navigation System**

Our proprietary *Niobe* ES system is the latest generation of the *Niobe* system, which provides the physician with precise remote digital instrument control through user friendly point and click computer mouse control, in combination with sophisticated image integration and 3D reconstruction. It can be operated either from an adjacent room and outside the x-ray fluoroscopy field or beside the patient table, as in traditional interventional procedures. The *Niobe* system allows the operator to navigate disposable interventional devices to the treatment site through complex paths in the blood vessels and chambers of the heart to deliver treatment by using computer controlled, externally applied magnetic fields to directly govern the motion of the working tip of these devices, each of which has a magnetically sensitive tip that predictably responds to magnetic fields generated by our 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.

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Through our arrangements with two multinational fluoroscopy system manufacturers and one provider of catheters and electrophysiology mapping systems, the *Niobe ES* system has been integrated with the visualization and information systems used during electrophysiology procedures in order to provide the physician with a fully-integrated and automated information and instrument control system. We have integrated our *Niobe* system with market-leading digital x-ray fluoroscopy systems. In addition, we have integrated the *Niobe* 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.

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

Niobe® Remote Magnetic Navigation System. Our *Niobe* system utilizes two permanent magnets mounted on articulating and pivoting arms that are enclosed within a stationary housing, with one magnet on either side of the patient table. These magnets generate magnetic navigation fields that are less than 10% of the strength of fields typically generated by MRI equipment and therefore require significantly less shielding, and cause significantly less interference, than MRI equipment. The *Niobe* system is indicated for use in cardiac, peripheral and neurovascular applications.

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

***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 *Niobe* ES control of catheters with fully remote, single operator workflow; and providing robotic control of diagnostic devices independent of magnetic navigation. The *Vdrive Duo* system is an optional expansion of the *Vdrive* hardware that allows control of up to two of the four available disposable options (*V-Loop*, *V-Sono, V-CAS, and V-CAS Deflect*).

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Disposables and Other Accessories

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

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

Disposable revenue including royalties represented 42% and 40% of revenue for the years ended December 31, 2017 and 2016, respectively.

Other Recurring Revenue

Other recurring revenue includes revenue from software licenses, product maintenance plans, and other post warranty maintenance. Revenue from services and license fees is deferred and amortized over the service or license fee period, which is typically one year. Other recurring revenue represented 44% and 42% of revenue for the years ended December 31, 2017 and 2016, 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.

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We have received regulatory clearance, licensing and/or CE Mark approvals necessary for us to market the *Odyssey* Solution in the U.S., Canada, European Union, China, Japan and other selected countries and we are in the process of obtaining necessary approvals for extending our markets in other countries.

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

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 GEOGRAPHIC AREAS AND CUSTOMERS

Our total U.S. revenue was $18.0 million and $19.4 million for the years ended December 31, 2017 and 2016, respectively. Our total international revenue was $13.1 million and $12.8 million for the years ended December 31, 2017 and 2016, respectively. No single country other than the U.S. accounted for more than 10% of total revenue for the years ended December 31, 2017 and 2016. Revenue from Biosense Webster Inc. related to royalties and *Odyssey* system sales accounted for $3.3 million, and $4.1 million, or 11%, and 13% of total net revenue for the years ended December 31, 2017 and 2016, respectively. No other single customer accounted for more than 10% of total revenue for the years ended December 31, 2017 and 2016.

CLINICAL APPLICATIONS

We have focused our clinical and commercial efforts on applications of the *Epoch* Solution primarily in electrophysiology procedures for the treatment of arrhythmias and secondarily in complex interventional cardiology procedures for the treatment of coronary artery disease. Our system potentially has broad applicability in other areas, such as structural heart repair, interventional neurosurgery, interventional neuroradiology, peripheral vascular, renal denervation, pulmonology, urology, gynecology and gastrointestinal medicine, and some of our patents may be applicable in these areas as well.

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.

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Drug therapies for arrhythmias often fail to adequately control the arrhythmia and may have significant side effects. Consequently, physicians have increasingly sought more permanent, non-pharmacological, solutions for arrhythmias. The most common interventional treatment for arrhythmias, and in particular tachyarrhythmias, where the patient s heart rate is too high or irregular, is an ablation procedure in which the diseased tissue giving rise to the arrhythmia is isolated or destroyed. Prior to performing an electrophysiology ablation, a physician typically performs a diagnostic procedure in which the electrical signal patterns of the heart wall are mapped to identify the heart tissue generating the aberrant electrical signals. Following the mapping procedure, the physician may then use an ablation catheter to eliminate the aberrant signal or signal path, restoring the heart to its normal rhythm. In cases where an ablation is anticipated, physicians will choose an ablation catheter and perform both the mapping and ablation with the same catheter. In February 2009 the FDA approved the Biosense Webster NAVISTAR® THERMOCOOL® irrigated catheter to be labeled for the treatment of atrial fibrillation. This is the first device approved by the FDA to be labeled for the interventional treatment of this arrhythmia.

We believe 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 over 10% annually.

We believe the *Epoch* Solution is particularly well-suited for those electrophysiology procedures which are time consuming or which can only be performed by highly experienced physicians. These procedures include:

Ventricular Tachycardia. Ventricular tachycardia is a malignant, potentially lethal arrhythmia that is extremely difficult and time consuming to treat. The magnetic catheter has been characterized as the ideal tool for this application. These arrhythmias can often be modified or interrupted by the pressure of a conventional catheter making it very difficult to identify the appropriate location for the ablation, whereas magnetic catheters produce fewer extra beats and provide for easier and more efficient mapping of the diseased tissue. Successful ablation of ventricular tachycardia can extend the useful life of an implantable defibrillator, reduce shocks to the patient, reduce the need for antiarrhythmic drugs or, in some cases, obviate the need for an expensive implantable device and its associated follow-up.

Atrial Fibrillation. The most commonly diagnosed abnormal heart rhythm, atrial fibrillation, is a particular type of arrhythmia characterized by rapid, disorganized contractions of the heart s upper chambers, the atria, which lead to ineffective heart pumping and blood flow and can be a major risk factor for stroke. This chaotic electrical activity of the top chambers of the heart is estimated to be present in three million people in the United States and over seven million people worldwide. The number of potential patients for manual catheter-based procedures for atrial fibrillation has been limited because the procedures are extremely complex and are performed by only the most highly skilled electrophysiologists. They also typically have much longer procedure times than general ablation cases and the success rates have been lower and more variable. We believe that our system can allow these procedures to be performed by a broader range of electrophysiologists and, by automating some of the more complex catheter maneuvers, can standardize and reduce procedure times and significantly improve outcomes.

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.

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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 *Niobe* system also has a range of potential applications in minimally invasive neurosurgery, including biopsies and the treatment of tumors, treatment of vascular malformations and fetal interventions.

STRATEGIC RELATIONSHIPS

We have entered into business arrangements with technology leaders in the global interventional market, including two multinational fluoroscopy system manufacturers and one provider of catheters and electrophysiology mapping systems, that we believe aid us in commercializing our *Niobe* system. We believe the two imaging companies have a significant percentage of the installed base of imaging systems worldwide. We believe our arrangement with the provider of catheters and electrophysiology mapping systems is favorable to us because it provides for the integration of our system with market leading digital imaging and 3D catheter location sensing technology, as well as catheters compatible with our system.

Imaging

We have successfully integrated our *Niobe* 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 both currently compatible digital imaging fluoroscopy systems is unlikely to continue for multiple years 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 advanced Biosense Webster s 3D catheter location sensing technology, which we believe has the leading market position in this important field of visualization for electrophysiology

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procedures, with the *Niobe* system. We have jointly developed associated location and non-location sensing electrophysiology mapping and ablation catheters that are navigable with the *Niobe* system. We believe that these integrated products provide physicians with the elements required for effective complex electrophysiology procedures: highly accurate information as to the exact location of the catheter in the body and highly precise control over the working tip of the catheter.

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% and 9% of revenue for the years ended December 31, 2017 and 2016, respectively. These royalties were used to make payments under the debt agreement with Healthcare Royalty Partners II, L.P. (formerly Cowen Healthcare Royalty Partners II, L.P.) as discussed in Item 7 prior to its extinguishment in September, 2016.

Biosense Webster s distribution rights for co-developed catheters were exclusive through December 31, 2015 and currently are nonexclusive until December 31, 2018. Biosense Webster s right to distribute such products in Japan is exclusive until March 22, 2018 and nonexclusive until March 22, 2021. 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 *Niobe* system s open architecture platform with key imaging, location sensing and information systems in the interventional lab.

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We have also collaborated with a number of highly regarded interventional physicians in key clinical areas and have entered into agreements with a number of universities and teaching hospitals, which serve to increase our access to world class physicians and to expand our name recognition in the medical community. Our research and development expenses for the years ending December 31, 2017, 2016, and 2015, were $4.7 million, $5.5 million, and $6.3 million, respectively.

CUSTOMER SERVICE AND SUPPORT

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

Our back-up technical support includes a combination of on-line, telephone and on-site technical assistance services 24 hours a day, seven days a week. We 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*, *Odyssey*, and *Vdrive* Systems**

Our manufacturing strategy for our *Niobe* system and *Odyssey* Solution is to sub-contract the manufacture of major subassemblies of our system to maximize manufacturing flexibility and lower fixed costs. Our current 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 *Niobe* system, the *Vdrive* system and *Odyssey* Solution, including control and application software, are developed both internally and with integrated modules we purchase or license. We perform final testing of software products in-house prior to their commercial release.

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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 *Niobe* 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 *Niobe* system.

In countries outside the United States, reimbursement is obtained from various sources, including governmental authorities, private health insurance plans, and labor unions. In most foreign countries, private insurance systems may also offer payments for some therapies. Additionally, health maintenance organizations are emerging in certain European countries. In the European Union, we believe that substantially all of the procedures, whether commercial or in clinical trials, conducted with the *Niobe* system or *Vdrive* system have been reimbursed to date. In Japan, the Ministry of Health, Labor and Welfare (MHLW) has classified the *Niobe* system as a C2 medical device (the highest reimbursement category), and has established a technical fee of Japanese Yen 50,000 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.

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

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and our 3D integration technology. As of December 31, 2017, we had 86 issued U.S. patents, 1 co-owned U.S. patent and no licensed-in U.S. patents. In addition, we had 7 pending U.S. patent applications and 1 co-owned U.S. patent application. As of December 31, 2017 we had 29 issued foreign patents and 8 owned foreign patent applications. The key patents that protect our *Niobe* system extend until 2022 and beyond. We also have a number of invention disclosures under consideration and several applications that are being prepared for filing. We cannot be certain that any patents will be issued from any of our pending patent applications, nor can we be certain that any of our existing patents or any patents that may be granted in the future will provide us with protection.

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

We have also developed substantial expertise in magnet design, magnet physics and magnetic instrument control that was developed in connection with the development of the *Niobe* system, which we maintain as trade secrets. This expertise centers around our proprietary magnet design, which is a critical aspect of our ability to design, manufacture and install a cost-effective magnetic navigation system that is small enough to be installed in 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 *Epoch* Solution to be traditional catheter-based electrophysiology ablation approaches including RF (radiofrequency) ablation and non-RF therapies. To our knowledge, we are the only company that has commercialized remote, digital and direct control of the working tip of catheters for use in RF ablation procedures. Our success depends in part on convincing hospitals and physicians to convert traditional interventional procedures to procedures using our *Epoch* Solution.

We face competition from companies that are developing and marketing new products for use in electrophysiology. These products include next generation mapping systems and RF ablation devices with which our *Epoch* Solution is not currently compatible, as well as 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 private companies that have commercialized endovascular catheter navigation systems which have

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been cleared by the FDA for mapping procedures only. In addition, we are aware of two private companies with an electromagnetic catheter navigation system that have received CE Mark approval in Europe. 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.

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).

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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 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 requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; and

- Reports of Corrections and Removals regulation, which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act.

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

International Regulation

In order for us to market our products in other countries, we must obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. These regulations, including the requirements for

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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

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government on a publicly searchable website. In addition, we are subject to similar state laws related to the tracking and reporting of certain payments and other transfers of value to healthcare professionals.

HIPAA and Other Privacy Laws

We are subject to laws and regulations protecting the privacy and integrity of patient medical information, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information, and the applicable Privacy and Security Standards of HITECH, the Health Information Technology for Economic and Clinical Health Act. HIPAA also prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. In addition to federal regulations issued under HIPAA, some states and foreign countries have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. In those cases, it may be necessary to modify our operations and procedures to comply with the more stringent state and foreign laws, which may entail significant and costly changes for us.

Certificate of Need Laws

In a number of states in the U.S., a certificate of need or similar regulatory approval is required prior to the acquisition of high-cost capital items or various types of advanced medical equipment, such as our *Niobe* system. Many of the states in which we sell *Niobe* systems have laws that require institutions located in those states to 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, 2017, we had 117 employees, 22 of whom were engaged directly in research and development, 55 in sales and marketing activities, 15 in manufacturing and service, and 25 in general administrative activities including accounting, regulatory, clinical affairs, quality and training. A significant majority of our employees is not covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

Availability of Information

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

Executive Officers

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

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ITEM 1A. RISK FACTORS

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

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

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

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

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

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 2018 expenses will exceed its 2018 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 *Niobe* ES systems 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.

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.

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

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

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

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

Decreases in our backlog have occurred in the past and could occur in the future, causing delays in revenue recognition or even removal of orders and other commitments from our backlog. Such events would have a negative effect on our revenue and results of operations.

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

We anticipate that our *Niobe* ES system will continue to have a lengthy sales cycle because it consists of a relatively expensive piece of capital equipment, the purchase of which requires the approval of senior management at hospitals, inclusion in the hospitals interventional lab budget process for capital expenditures, and, in some instances, a certificate of need from the state or other regulatory approval. In addition, historically the majority of our *Niobe* ES systems and *Odyssey* systems have been delivered less than one year after the receipt of a purchase order from a hospital, with the timing being dependent on the construction cycle for the new or replacement interventional suite in which the equipment will be installed. In some cases, this time frame has been extended further because the interventional suite construction is part of a larger construction project at the customer site (typically the construction of a new building), which may occur with our existing and future

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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.

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 crises may cause customers to delay purchasing or installation decisions or cancel existing orders. The *Niobe* ES system, *Odyssey* Solution and *Vdrive* system are typically purchased as part of a larger overall capital project and an economic downturn or the lack of a robust recovery might make it more difficult for our customers, including distributors, to obtain adequate financing to support the project or to obtain requisite approvals. Any delay in purchasing decisions or cancellation of purchasing commitments may result in a decrease in our revenues. Another credit crisis similar to the credit crisis that began in 2008 could further affect our business if key suppliers are unable to obtain financing to manufacture our products or become insolvent and we are unable to manufacture product to meet customer demand. If the United States and global economy 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 two multinational fluoroscopy system manufacturers and one provider 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 two multinational fluoroscopy system manufacturers and one provider of catheters and electrophysiology mapping systems and other parties to

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integrate our instrument control technology with their respective imaging products or disposable interventional devices and to co-develop additional disposable interventional devices for use with our *Niobe* system. A significant portion of our revenue from system sales is derived from these integrated products. The maintenance of these collaborations, or the establishment of equivalent alternatives, is critical to our commercialization efforts. The commercial availability of both currently compatible digital imaging fluoroscopy systems is unlikely to continue for multiple years 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 *Niobe* system;
- any of our collaboration partners fails to develop or commercialize the integrated products in a timely manner; or
- we become involved in disputes with one or more of our collaboration partners regarding our collaborations.

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.

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.

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

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

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

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

Customers may choose to purchase competing products and not ours.

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

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

We face competition from companies that are developing drugs, gene or cellular therapies or other medical devices or procedures to treat the conditions for which our products are intended. The medical device and pharmaceutical industries make significant investments in research and development, and innovation is rapid and continuous. Other companies in the medical device industry continue to develop new devices and technologies for traditional interventional methods.

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.

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

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

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

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

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

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

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

We have incurred substantial net losses since inception, and we expect to incur losses into 2018 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

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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 *Niobe* ES system and certain components of our *Odyssey* Solution and *Vdrive* system. In addition, some of the components necessary for the assembly of our products are currently provided to us by a single supplier, including the magnets for our *Niobe* ES system and certain components of our *Odyssey* Solution, and we generally do not maintain large volumes of inventory. Our reliance on these third parties involves a number of risks, including, among other things, the risk that:

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

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

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

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

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

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

We purchase the permanent magnets for our *Niobe* ES system from a manufacturer that uses material produced in Japan, and we anticipate that certain of the production work for these magnets will be performed for this manufacturer in China. In addition, our subcontractor purchases magnets for our disposable interventional devices directly from a manufacturer in Japan. Any event causing a significant increase in price or a disruption of imports, including the imposition of import restrictions, could adversely affect our business. The flow of components from our vendors could also be adversely affected by financial or political instability in any of the countries in which the goods we purchase are manufactured, if the instability affects the production or export of product components from those countries. Trade restrictions in the form of tariffs or quotas, or both, could also affect the importation of those product components and could increase the cost and reduce the supply of products available to us. In addition, decreases in the value of the U.S. dollar against foreign currencies could increase the cost of products we purchase from overseas vendors.

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

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

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

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

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

Our commercial success 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

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

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

Our trade secrets, nondisclosure agreements and other contractual provisions to protect unpatented technology provide only limited and possibly inadequate protection of our rights. As a result, third parties may be able to use our unpatented technology, and our ability to compete in the market would be reduced. In addition, employees, consultants and others who participate in developing our products or in commercial relationships with us may breach their agreements with us regarding our intellectual property, and we may not have adequate remedies for the breach.

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

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

Successfully commercializing our products 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

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infringe patents held by them. Moreover, as the number of competitors in our market grows the possibility of a patent infringement claim against us increases. If we were not successful in obtaining a license or redesigning our products, we could be subject to litigation. If we lose in this kind of litigation, a court could require us to pay substantial damages or prohibit us from using technologies essential to our products covered by third-party patents. An inability to use technologies essential to our products would have a material adverse effect on our financial condition, results of operations and cash flow and could undermine our ability to continue operating as a going concern.

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

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

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

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

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

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

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

Many of our employees were previously employed at hospitals, universities or other medical device companies, including our competitors or potential competitors. We could in the future be subject to claims that these employees or we have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we

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are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Incurring such costs could have a material adverse effect on our financial condition, results of operations and cash flow.

If we or the parties in our strategic 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.

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

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

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

In many foreign countries in which we market our products, we are subject to regulations affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. Many of these regulations are similar to those of the FDA or other U.S. regulations. In addition, in many countries the national health or social security organizations require our products to be qualified before procedures performed using our products become eligible for reimbursement. Failure to receive or delays in the receipt of, relevant foreign qualifications could have a material adverse effect on our business, financial condition and results of operations. Due to the movement toward harmonization of standards in the European Union, we expect a changing regulatory environment in Europe characterized by a shift from a country-by-country regulatory system to a European Union-wide single regulatory system. We cannot predict the timing of this harmonization and its effect on us. Adapting our business to changing regulatory systems could have a material adverse effect on our business, financial condition, and results of operations. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension, or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

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

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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.

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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;

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

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

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

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

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

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Healthcare policy changes, including legislation enacted in 2010 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, the President signed into law the Budget Control Act of 2011, which created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee was charged with identifying a reduction of at least $1.2 trillion for the years 2013 through 2021. The Committee did not achieve this target by the imposed deadline, triggering the legislation s automatic reduction to several government programs. Included in the automatic reduction are aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013.

Changes to, or repeal of, the PPACA, which the new 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 new 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 certifi