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, 2021

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)**

710 North Tucker Boulevard, Suite 110
St. Louis, MO 63101
(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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**STXS**	**NYSE American**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T "See 232.405 of this Chapter" during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 ☒ 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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 NYSE American on June 30, 2021) was approximately $577.9 million.

The number of outstanding shares of the registrant's common stock on February 28, 2022 was 74,638,306.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2022 Annual Meeting of Shareholders are incorporated by reference in Part III, Items 10, 11, 12, 13 and 14.

STEREOTAXIS, INC.

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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. Genesis RMN®, Niobe®, Navigant®, Odyssey®, Odyssey Cinema™, Vdrive®, Vdrive Duo™, V-CAS™, V-Loop™, V-Sono™, 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, operating, sales and marketing, and regulatory strategies;
- our value proposition;
- the impact of the coronavirus ("COVID-19") pandemic and our responses to it;
- our overall liquidity and 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 industry generally, and overall economic conditions;
- our estimates regarding our capital requirements;
- our plans for hiring additional personnel; and
- any of our other plans, objectives, expectations and intentions contained in this annual report that are not historical facts.

These statements relate to future events or future financial performance, and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "could", "expects", "plans", "intends", "anticipates", "believes", "estimates", "predicts", "potential", or "continue", or the negative of such terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. These statements are only predictions.

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

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

OVERVIEW

Stereotaxis is a pioneer and global leader in surgical robotics for minimally invasive endovascular intervention. We design, manufacture and market robotic systems, instruments and information systems for the interventional laboratory. Our proprietary robotic technology, Robotic Magnetic Navigation, fundamentally transforms endovascular interventions using precise computer-controlled magnetic fields to directly control the tip of flexible interventional catheters or devices. Direct control of the tip of an interventional device, in contrast to all manual hand-held devices that are controlled from their handle, can improve the precision, stability, reach and safety of these devices during procedures.

Our primary clinical focus has been electrophysiology, specifically cardiac ablation procedures for the treatment of arrhythmias. Cardiac ablation has become a well-accepted therapy for arrhythmias and a multi-billion-dollar medical device market with expectations for substantial long-term growth. We have shared our aspiration and a product strategy to expand the clinical focus of our technology to several additional endovascular indications including coronary, neuro, and peripheral interventions.

There is substantial real-world evidence and clinical literature for Robotic Magnetic Navigation in electrophysiology. Hundreds of electrophysiologists at over one hundred hospitals globally have treated over 100,000 arrhythmia patients with our robotic technology. Clinical use of our technology has been documented in over 400 clinical publications. Robotic Magnetic Navigation is designed to enable physicians to complete more complex interventional procedures with greater success and safety by providing image-guided delivery of catheters through the blood vessels and chambers of the heart to treatment sites. This is achieved using externally applied computer-controlled magnetic fields that govern the motion of the working tip of the catheter, resulting in improved navigation. The more flexible atraumatic design of catheters driven using magnetic fields may reduce the risk of patient harm and other adverse events. Performing the procedure from a control cockpit enables physicians to complete procedures in a safe location protected from x-ray exposure, with greater ergonomics, and improved efficiency. We believe these benefits can be applicable in other endovascular indications where navigation through complex vasculature is often challenging or unsuccessful and generates significant x-ray exposure.

Our primary products include the *Genesis RMN* System, the *Odyssey* Solution, and other related devices. We also offer to our customers the Stereotaxis Imaging Model S x-ray System and other accessory devices.

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

The *Odyssey Solution* consolidates lab information onto one large integrated display, enabling physicians to view and control all the key information in the operating room. This is designed to improve lab layout and procedure efficiency. The system also features a remote viewing and recording capability called *Odyssey Cinema*, which is an innovative solution that delivers synchronized content for optimized workflow, advanced care, and improved productivity. This tool includes an archiving capability that allows clinicians to store and replay entire procedures or segments of procedures. This information can be accessed from locations throughout the hospital local area network and over the global Odyssey Network providing physicians with a tool for clinical collaboration, remote consultation, and training.

We promote our full suite of products in a typical hospital implementation, subject to regulatory approvals or clearances. This 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 the warranty period, and ongoing software updates. In hospitals where our full suite of products has not been implemented, equipment upgrade or expansion can be implemented upon purchasing of the necessary upgrade or expansion.

We have received regulatory clearances and registration necessary for us to market the *Genesis RMN* System in the U.S. and Europe, and we are in the process of obtaining necessary registrations for extending our markets in other countries. Our prior generation robotic magnetic navigation system, the *Niobe* System, and the *Odyssey* Solution, *Cardiodrive*, and various disposable interventional devices have received regulatory clearance in the U.S., Europe, Canada, China, Japan and various other countries. We have received the regulatory clearance, licensing and/or CE Mark approvals that allow us to market the *Vdrive* and *Vdrive Duo* Systems with the *V-CAS*, *V-Loop* and *V-Sono* devices in the U.S., Canada and Europe. The Stereotaxis Imaging Model S x-ray System is CE marked and cleared by the FDA.

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 the regulatory clearance, licensing, and/or approvals we currently have or are pursuing.

As of December 31, 2021, we had approximately $10.1 million of backlog, consisting of outstanding purchase orders and other commitments for these systems. Of the December 31, 2021 backlog, we expect approximately 78% to be recognized as revenue over the course of 2022. We had backlog of approximately $6.9 million as of December 31, 2020. There can be no assurance that we will recognize such revenue in any particular period or at all because some of our purchase orders and other commitments are subject to contingencies that are outside our control. These orders and commitments may be revised, modified or canceled, either by their express terms, as a result of negotiations or by project changes or delays. In addition, the sales cycle for the robotic magnetic navigation system is lengthy and generally involves construction or renovation activities at customer sites. Consequently, revenues and/or orders resulting from sales of our robotic magnetic navigation system can vary significantly from one reporting period to the next.

We have strategic relationships with technology leaders and innovators in the global interventional market. Through these strategic relationships we provide compatibility between our robotic magnetic navigation system and digital imaging and 3D catheter location sensing technology, as well as disposable interventional devices. The maintenance of these strategic relationships, or the establishment of equivalent alternatives, is critical to our commercialization efforts. There are no guarantees that any existing strategic relationships will continue, and efforts are ongoing to ensure the availability of integrated systems and devices and/or equivalent alternatives. 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.

We were incorporated in Delaware in June, 1990 as Stereotaxis, Inc. Our principal executive offices are located at 710 North Tucker Boulevard, Suite 110, St. Louis, Missouri 63101, and our telephone number is (314) 678-6100.

THE STEREOTAXIS VALUE PROPOSITION

Although great strides have been made in manual interventional devices and 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 procedures are still performed as invasive surgeries rather than as minimally invasive endovascular interventions.

Our systems address the current challenges in the interventional lab by providing precise computerized control of the working tip of the interventional instrument and by integrating this control with the visualization technology and information systems used during electrophysiology and endovascular interventional procedures, on a cost-justified basis.

We believe that our technology can:

- *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 and other endovascular 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. For endovascular navigation, precise and safe navigation through complex vasculature may also have a significant impact on procedure outcomes, efficiency, and cost. We believe our robotic technology can enhance procedure results by improving navigation of disposable interventional devices to treatment sites, and by affecting more precise and safe treatments once these sites are reached.

- *Expand the market by enabling minimally invasive endovascular intervention.* Treatment of a number of major diseases, including ventricular tachycardia, atrial fibrillation, congenital heart diseases, stroke, peripheral vascular disease, and coronary vascular disease, is highly challenging using conventional wire and/or catheter-based techniques. These patients may therefore be referred to 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 diseases to be treated interventionally on a much broader scale than today.

- *Enhance patient and physician safety.* The clinical value of our technology has been demonstrated in over 400 publications and in the real-world experience of more than 100,000 procedures. The clinical literature as well as other available data suggests meaningful reductions in major complications and patient exposure to radiation during procedures utilizing our robotic technology. This may be driven by the softer a-traumatic design of an interventional device navigated using magnetic fields. These safety benefits to patients are complemented by improved occupational safety for the physicians and nursing staff who are performing the procedures. Healthcare professionals face significant orthopedic and radiation exposure risks. Studies have documented that 49% of interventional cardiologists suffer orthopedic injury and 85% of brain tumors in these physicians present on the left side of the brain which is the side typically exposed to radiation when performing a manual procedure. Our robotic technology improves physician safety and reduces physician fatigue by enabling them to conduct procedures remotely from an adjacent control room, which reduces their exposure to harmful radiation, and the orthopedic burden of wearing lead.

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

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

- *Improve physician skill levels in order to improve the efficacy of complex cardiology procedures.* Training required for physicians to safely and effectively carry out manual interventional procedures typically takes years, over and above the training required to become a specialist in cardiology. This has led to a shortage of physicians who are skilled in performing more complex procedures. We believe that our robotic technology can allow procedures that previously required the highest levels of manual dexterity and skill to be performed effectively by a broader range of interventional physicians, with more standardized outcomes. In addition, interventional physicians can learn to use robotic systems in a relatively short period of time. The robotic magnetic navigation 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 our products, we believe hospitals will realize significant operational benefits when recruiting physicians to work in a safer procedure environment, while attracting patients who desire to have safer procedures that lead to better long-term outcomes.

PRODUCTS

Robotic Magnetic Navigation

Our proprietary robotic magnetic navigation systems ("RMN") include the Genesis *RMN* and the prior generation *Niobe* Systems. These systems are designed to enable physicians to complete more complex interventional procedures by providing image-guided delivery of catheters and guidewires through the blood vessels and chambers of the heart to treatment sites. This is achieved using externally applied magnetic fields that govern the motion of the working tip of the catheter or guidewire, resulting in improved navigation, efficient procedures and reduced x-ray exposure. Our systems provide physicians with precise remote digital instrument control in combination with sophisticated image integration. 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 RMN system allows the operator to navigate disposable interventional devices to the treatment site through complex paths in the blood vessels and chambers of the heart to deliver treatment by using computer controlled, externally applied magnetic fields to directly govern the motion of the working tip of these devices, each of which has a magnetically sensitive tip that predictably responds to magnetic fields generated by our system. Because the working tip of the disposable interventional device is directly controlled by these external magnetic fields, the physician has the same degree of control regardless of the number or type of turns, or the distance traveled by the working tip to arrive at its position in the blood vessels or chambers of the heart. This results in highly precise digital control of the working tip of the disposable interventional device while still giving the physician the option to manually advance the device.

Through our arrangements with fluoroscopy system manufacturers and providers of catheters and electrophysiology mapping systems, we provide compatibility between the robotic magnetic navigation system and the visualization and information systems used during electrophysiology and endovascular procedures in order to provide the physician with a comprehensive information and instrument control system. In addition, we have integrated the robotic magnetic navigation 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 robotic magnetic navigation system are identified and described below:

Robotic Magnetic Navigation System. Our robotic magnetic navigation systems utilize two permanent magnets mounted on articulating and pivoting arms with one magnet on either side of the patient table. These magnets generate magnetic navigation fields that are less than the strength of fields typically generated by MRI equipment and therefore require significantly less shielding, and cause significantly less interference, than MRI equipment. The robotic magnetic navigation system is indicated for use in cardiac, peripheral and neurovascular applications.

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

Odyssey® Solution

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

Stereotaxis Imaging Model S X-ray System

Developed in collaboration with Omega Medical Imaging, and designed to be specifically available with RMN Systems, the Stereotaxis Imaging Model S provides an integrated complete solution for a robotic interventional operating room. It is a single-plane, full-power x-ray system and includes the c-arm, powered table, motorized boom, and large high-definition monitors. Stereotaxis Imaging Model S incorporates modern fluoroscopy technology to support high quality imaging while minimizing radiation exposure for patients and physicians. The combination of RMN Systems with Stereotaxis Imaging Model S is designed to reduce the cost of acquisition, the ongoing cost of ownership, and the complexity of installation of a robotic electrophysiology practice.

Disposables and Other Accessories

Our robotic magnetic navigation systems are 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.

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

We also manufacture and market various disposable (the *V-Loop*, *V-Sono*, and *V-CAS*) components which can be manipulated by our Vdrive™ Robotic Navigation System a complimentary product that provides navigation and stability for diagnostic and therapeutic devices designed to improve interventional procedures. In addition, we also market and distribute other disposable and related devices that can be use with our robotic magnetic navigation systems.

Other Recurring Revenue

Other recurring revenue includes revenue from product maintenance plans, other post warranty maintenance, and the implied obligation to provide software enhancements if and when available for a specified period, typically one year following installation of our systems. Revenue from services and software enhancements is deferred and amortized over the service or update period, which is typically one year. Revenue related to services performed on a time-and-materials basis is recognized when performed.

Regulatory Approval

We have received regulatory clearance, licensing and/or CE Mark approvals necessary for us to market the *Genesis RMN* System in the U.S. and Europe, and we are in the process of obtaining necessary registrations for extending our markets in other countries.

We have received regulatory clearance, licensing and/or CE Mark approvals necessary for us to market the *Niobe* System, *Cardiodrive*, and various disposable devices in the U.S., Canada, Europe, China, Japan, and various other countries.

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

Biosense Webster has received FDA approval, and CE Mark for the CARTO® RMT navigation system for use with the *Niobe* System, the 4mm CELSIUS® RMT Diagnostic/Ablation Steerable Tip Catheter, the 4mm NAVISTAR® RMT Diagnostic/Ablation Steerable Tip Catheter, the 8mm Navistar RMT DS Diagnostic/Ablation Steerable Tip Catheter, and the 3.5mm NAVISTAR® RMT THERMOCOOL® Irrigated Tip Catheter. In addition, Biosense Webster has received FDA approval and CE Mark for the 3.5mm CELSIUS® RMT THERMOCOOL® Irrigated Tip Catheter. Biosense Webster also received China CFDA approval and Japan PMDA approval for the CARTO® RMT navigation system for use with the *Niobe* System, and the 3.5mm NAVISTAR® RMT THERMOCOOL® Irrigated Tip Catheter. Our strategic relationship with Biosense Webster provides for co-development of catheters that can be navigated with our system, both with and without Biosense Webster's 3D catheter location sensing technology. In addition, we can utilize technology which allows our system to recognize specific disposable interventional devices in order to prevent unauthorized use of our system. See "Strategic Relationships" below for a description of our arrangements with Biosense Webster.

FINANCIAL INFORMATION ABOUT CUSTOMERS

No single customer accounted for more than 10% of total revenue for the years ended December 31, 2021 and 2020. Revenue from customers in China accounted for $3.7 million, or 10% of total revenue for the year ended December 31, 2021 and revenue from customers in Finland accounted for $2.7 million, or 10%, of total revenue for the year ended December 31, 2020. No other single country, other than the U.S., accounted for more than 10% of total revenue for the years ended December 31, 2021 and 2020.

CLINICAL APPLICATIONS

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

Electrophysiology

The rhythmic beating of the heart results from the transmission of electrical impulses. When these electrical impulses are mistimed or uncoordinated, the heart fails to function properly, resulting in symptoms that can range from fatigue to stroke or death. Over 5.0 million people in the U.S. currently suffer from abnormal heart rhythms, which are known as arrhythmias. The prevalence of arrhythmias is expected to continue to rise as the population ages, life expectancy increases, and lifestyle factors such as obesity become more prevalent. Arrhythmias are a major physical and economic burden and are associated with stroke, heart failure, and adverse symptoms causing patients to be motivated to seek treatment. The combination of symptoms, prevalence and comorbidities make arrhythmias a major economic factor in healthcare.

Drug therapies for arrhythmias often have limited efficacy, poor compliance, and side effects. Consequently, physicians have increasingly sought more permanent, non-pharmacological, solutions for arrhythmias. The most common interventional treatment for arrhythmias 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, the physician may then use an ablation catheter to eliminate the aberrant signal or signal path, restoring the heart to its normal rhythm. These procedures may be performed separately but are more commonly performed at the same time.

We believe more than 5,000 interventional labs around the world are currently conducting over one million cardiac ablation procedures annually. The market has grown rapidly over the last decade with annualized procedure growth of approximately 10%.

We believe that Robotic Magnetic Navigation is particularly well-suited for these electrophysiology procedures which are time consuming, or which can only be performed by highly experienced physicians. These procedures include:

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

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

- *General Mapping and Ablations*. For the more routine mapping and ablation procedures, our system offers the unique benefit of precise catheter movement and consistent heart wall contact. Additionally, the system can control the procedure and direct catheter movement from the control room, saving the physician time and helping to avoid unnecessary exposure to high doses of radiation.

We believe that our system can address the current challenges in electrophysiology by permitting the physician to remotely navigate disposable interventional devices from a control room outside the x-ray field. Additionally, we believe that our system allows for more predictable and efficient navigation of these devices to the treatment site and enables catheter contact to be consistently maintained to efficiently apply energy on the wall of the beating heart. We also believe that our system will significantly lower the skill barriers required for physicians to perform complex electrophysiology procedures and, additionally, improve interventional lab efficiency and reduce disposable interventional device utilization.

Interventional Cardiology

More than half a million people die annually from coronary artery disease, a condition in which the formation of plaque in the coronary arteries obstructs the supply of blood to the heart, making this the leading cause of death in the U.S. Despite various attempts to reduce risk factors, each year over one million patients undergo interventional procedures in an attempt to open blocked vessels and another one half million patients undergo open heart surgery to bypass blocked coronary arteries.

Blockages within a coronary artery, often called lesions, are categorized by degree of obstruction as partial occlusions, non-chronic total occlusions and chronic total occlusions. Lesions are also categorized by the degree of difficulty with which they can be opened as simple or complex. Complex lesions, such as chronic total occlusions, longer lesions, and lesions located within smaller diameter vessels, are often very difficult or time consuming to open with manual interventional techniques.

We believe approximately 11,000 interventional labs worldwide are currently capable of conducting interventional cardiology. Over 4 million interventional cardiology procedures are performed annually in the U.S. alone. We estimate that approximately 10-15% of these interventional cardiology procedures currently being performed are complex and therefore require longer procedure times and may have sub-optimal outcomes. We believe that our system can substantially benefit this subset of complex interventional cardiology procedures.

Interventional Neuroradiology, Neurosurgery and Other Interventional Applications

Physicians used a predecessor to our *Niobe* System to conduct a number of procedures for the treatment of brain aneurysms, a condition in which a portion of a blood vessel wall balloons and which can result in debilitating or fatal bleeding and strokes. We believe the robotic magnetic navigation 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 manufacturers of fluoroscopy systems, ablation catheters, and electrophysiology mapping systems, that we believe aid us in commercializing our robotic magnetic navigation system. These arrangements are important to us as they provide for the integration of our system with digital imaging and 3D catheter location sensing technology, as well as catheters compatible with our system.

Imaging

We have successfully integrated our robotic magnetic navigation 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. There are no guarantees that any existing strategic relationships will continue, and efforts are ongoing to ensure the availability of integrated next generation systems and/or equivalent alternatives. 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 entered into strategic relationships and successfully integrated with diagnostic mapping technologies to provide a robust open ecosystem where physicians and patients benefit from the broad integration of procedure data.

With Biosense Webster, we have jointly developed associated location and non-location sensing electrophysiology mapping and ablation catheters that are navigable with our robotic magnetic navigation system. We believe that these 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 7% and 8% of revenue for the years ended December 31, 2021 and 2020, respectively.

Biosense Webster's distribution rights for co-developed catheters are nonexclusive until December 31, 2022. Upon the expiration or termination of the agreement, other than due to a change of control of Stereotaxis, the agreement provides for a continuation of supply by Biosense Webster of the co-developed catheters to us or our customers for three years. The agreement provides an opportunity to expand the product offering covered by the agreement to include a next generation irrigated magnetic catheter, subject to mutually agreeable terms including exclusive distribution rights.

Under the agreements with Biosense Webster, we granted Biosense Webster certain notice and discussion rights for product development activities we undertake relating to localization of magnetically enabled interventional disposable devices in fields outside of electrophysiology and mapping.

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

Additionally, we have entered into a broad strategic collaboration with Osypka AG. This collaboration includes the development of a next-generation magnetic ablation catheter to be navigated using Stereotaxis' robotic technology. Stereotaxis is funding the development and will be the sole owner of the catheter.

The maintenance of these arrangements, or the establishment of equivalent alternatives, is critical to our commercialization efforts. There are no guarantees that any existing strategic relationships or collaborations will continue.

RESEARCH AND DEVELOPMENT

We have assembled an experienced group of engineers and physicists with recognized expertise in magnetics, software, control algorithms, mechanics, electronics, systems integration and disposable interventional device design.

Our research and development efforts are focused in the following areas:

- development and enhancement of Robotic Magnetic Navigation Systems;
- designing new proprietary disposable interventional devices for use in Electrophysiology and other clinical specialties with our robotic systems; and
- software and other engineering efforts to enhance imaging integrations, user interface, automated navigation, and operating room connectivity.

Our research and development team collaborates with strategic third parties to integrate our robotic magnetic navigation system's open architecture platform with key imaging, location sensing and information systems in the interventional lab. We have also collaborated with a number of highly regarded interventional physicians in key clinical areas and have entered into agreements with a number of universities and teaching hospitals, which serve to increase our access to world class physicians and to expand our name recognition in the medical community.

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, allowing 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

Robotic Magnetic Navigation Systems and *Odyssey* Solution

Our manufacturing strategy for our *Robotic Magnetic Navigation* Systems and *Odyssey* Solution is to sub-contract the manufacture of major subassemblies of our systems to maximize manufacturing flexibility and lower fixed costs. We maintain quality control for all of our systems by completing final system assembly and inspection in-house.

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

Disposable Interventional Devices

Our manufacturing strategy for disposable interventional devices is to outsource their manufacture through subcontracting and to expand partnerships for other interventional devices. We work closely with our contract manufacturers and have strong relationships with component suppliers. We have entered into manufacturing agreements to provide high volume capability for devices other than catheters.

Software

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

General

Our manufacturing facility operates under processes that meet the FDA's requirements under the Quality System Regulation (QSR). Our ISO registrar and European notified British Standard Institution (BSI) has audited our facility annually since 2001 and found the facility to be in compliance with relevant requirements. The most recent ISO 13485 and MDSAP Certificate of Registration were issued in 2019 and 2020, respectively and are valid through September 2022.

SALES AND MARKETING

We market our products in the U.S and internationally through a direct sales force of senior sales specialists, distributors and sales agents, supported by account managers and clinical specialists who provide training, clinical support, and other services to our customers. In addition, Biosense Webster distributes magnetically-enabled electrophysiology mapping and ablation catheters, co-developed pursuant to our agreement with them.

Our sales and marketing efforts include two important elements: (1) selling robotic magnetic systems, *Odyssey* Solutions, Stereotaxis Imaging Model S x-ray Systems, 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 have been reimbursed to date. We expect that third-party payors will reimburse, under existing billing codes, procedures in which compatible ablation catheters are used. We expect healthcare facilities in the U.S. to bill various third-party payors, such as Medicare, Medicaid, other government programs and private insurers, for services performed with our products. We believe that procedures performed using our products, or targeted for use by products that do not yet have regulatory clearance or approval, are generally already reimbursable under government programs and most private plans. Accordingly, we believe providers in the U.S. will generally not be required to obtain new billing authorizations or codes in order to be compensated for performing medically necessary procedures using our products on insured patients. We cannot guarantee that reimbursement policies of third-party payors will not change in the future with respect to some or all of the procedures using the robotic magnetic navigation system.

In countries outside the United States, reimbursement is obtained from various sources, including governmental authorities, private health insurance plans, and labor unions. In most foreign countries, private insurance systems may also offer payments for some therapies. Additionally, health maintenance organizations are emerging in certain European countries. In Europe, we believe that substantially all of the procedures, whether commercial or in clinical trials, conducted with the *Niobe* System 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 and systems, including our robotic magnetic technology, navigational methods, mapping system and procedural workflows, 3D integration technology, and disposable interventional devices. As of December 31, 2021, we had 80 issued U.S. patents and 4 pending U.S. patent applications. In addition, we had 54 issued foreign patents and 15 pending foreign patent applications. The key patents that protect our technology and systems extend until 2028 and beyond.

We also have a number of invention disclosures under consideration and several applications that are being prepared for filing. We cannot be certain that any patents will be issued from any of our pending patent applications, nor can we be certain that any of our existing patents or any patents that may be granted in the future will provide us with protection.

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

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

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

COMPETITION

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

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

We face competition from companies that are developing and marketing new products for use in electrophysiology. These products include next generation mapping systems and RF ablation devices with which our robotic magnetic navigation system is not currently compatible, as well as non-RF ablation devices including single-shot cryoablation devices and other new products, such as pulse field ablation, 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 robotic technologies for electrophysiology and non-electrophysiology interventional procedures. We are aware of three companies that commercialized endovascular catheter navigation systems which have been cleared by the FDA for electrophysiology procedures as well as two companies with electromagnetic catheter navigation systems that received CE Mark approval in Europe. None of these companies seem to be active with any current commercial activities. Outside of electrophysiology, there are at least two companies that have commercialized robotic systems for guidewire manipulation and can be viewed as potential competitors as we look to address additional clinical applications.

We face direct competition to certain products in our *Odyssey* Solution. 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 magnetic navigation system are Class III therapeutic devices and are subject to the PMA process.

If U.S. clinical data are needed to support clearance, approval or a marketing application for our devices, generally, an investigational device exemption, or IDE, is assembled and submitted to the FDA. The FDA reviews and must approve the IDE before the study can begin. In addition, the study must be approved by an Institutional Review Board covering each clinical site involved in the study. When all approvals are obtained, we initiate a clinical study to evaluate the device. Following completion of the study, we collect, analyze and present the data in an appropriate submission to the FDA (i.e., in support of a 510(k), de novo, or PMA).

When a 510(k) clearance is required, we must submit a pre-market notification demonstrating that our proposed device is substantially equivalent to a previously cleared and legally marketed 510(k) device, de novo approved device, or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of pre-market approval applications. To establish substantial equivalence, the applicant must show that the new device has the same intended use as the predicate device, and it either has the same technological characteristics or has been shown to be equally safe and effective and does not raise different questions of safety and effectiveness as compared to the predicate device. The FDA may require further information, including clinical trial results or product test data, to make a determination regarding substantial equivalence. The FDA’s 510(k) clearance process usually takes from four to 12 months but can take longer.

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

After a device receives 510(k) clearance or de novo approval, any modification that could significantly affect its safety or effectiveness, or that would constitute a significant change in its intended use, will require a new clearance. Modification to a PMA approved device or its labeling may require either a new PMA or PMA supplement approval, which could be a costly and lengthy process.

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

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

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

- Medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; and

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

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

International Regulation

In order for us to market our products in other countries, we must obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. These regulations, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries may differ from that required to obtain FDA clearance or approval.

The primary regulatory environment in Europe is that of the European Union, which encompasses most of the major countries in Europe. The European Union, along with other member countries of the European Economic Area, or EEA, requires that manufacturers of medical products obtain the right to affix the CE Mark to their products before selling them in member countries of the EEA. The CE Mark is an international symbol of adherence to quality assurance standards and compliance with applicable directives. In order to obtain the right to affix the CE Mark to products, a manufacturer must obtain certification that its processes meet certain quality standards. Compliance with the Medical Device Directive, as certified by a recognized European Notified Body, permits the medical device manufacturer to affix the CE Mark on its products and commercially distribute those products throughout the EEA. We are subject to annual surveillance audits and periodic re-certification audits in order to maintain our CE Mark permissions.

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

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

Anti-Kickback and False Claims Laws

We are subject to various federal and state laws relating to healthcare fraud and abuse, including anti-kickback and false claims laws. The U.S. federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The definition of "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash and waivers of payments, and providing anything of value at less than fair market value. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws.

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

Transparency Laws

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

HIPAA and Other Privacy Laws

We are subject to laws and regulations protecting the privacy and integrity of patient medical information, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information, and the applicable Privacy and Security Standards of HITECH, the Health Information Technology for Economic and Clinical Health Act. HIPAA also prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters.

In addition to federal regulations issued under HIPAA, some states and foreign countries have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. For example, the General Data Protection Regulation (the "GDPR"), which is in effect across the European Economic Area (the "EEA"), imposes several stringent requirements for controllers and processors of personal data and increased our obligations, for example, by imposing higher standards when obtaining consent from individuals to process their personal data, requiring more robust disclosures to individuals, strengthening individual data rights, shortening timelines for data breach notifications, limiting retention periods and secondary use of information, increasing requirements pertaining to health data as well as pseudonymised data, and imposing additional obligations when we contract third-party processors in connection with the processing of personal data. The GDPR provides that EU member states may make their own further laws and regulations limiting the processing of genetic, biometric, or health data. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EU member states may result in fines of up to 4% of the total worldwide annual turnover of the preceding financial year and other administrative penalties.

In addition, effective January 1, 2020, California passed the California Consumer Privacy Act (the "CCPA"), which is considered by many to be the most far-reaching data privacy law introduced in the US to date and which introduces new compliance burdens on many organizations doing business in California who collect Personal Information about California residents. The CCPA's definition of Personal Information is very broad and specifically includes biometric information. The CCPA took effect in 2020 and will allow for significant fines by the state attorney general, as well as a private right of action from individuals in relation to certain security breaches. The enactment of the CCPA is prompting a wave of similar legislative developments in other US states and creating the potential for a patchwork of overlapping but different state laws. Additionally, a new California ballot initiative, the California Privacy Rights Act (the "CPRA") recently passed in California. The CPRA will impose additional data protection obligations on companies doing business in California. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required.

As a result of any of the foregoing, 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 robotic magnetic navigation system. Many of the states in which we sell robotic magnetic navigation 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.

Human Capital

Given the highly competitive nature of the medical device industry, the future success of our company depends on our ability to attract, retain, and further develop top talent. We value the diversity of each of our employees and the contributions they make in helping us achieve our mission to discover, develop and deliver robotic systems, instruments, and information solutions for the interventional laboratory. We are committed to attracting, developing, and retaining the best talent reflecting a diversity of ideas, backgrounds, and perspectives.

As of December 31, 2021, we had 130 employees, 38 of whom were engaged directly in research and development, 52 in sales and marketing activities, 21 in manufacturing and service, and 19 in general administrative activities including finance, information systems, legal and general management. A significant majority of our employees are not covered by a collective bargaining agreement, and we consider our relationship with our employees to be positive. We also engage the services of independent contractors and consultants as needed for special or temporary projects or specific expertise.

As of December 31, 2021, our employees were based in 9 different countries around the world. Our global workforce consists of diverse, highly skilled talent at all levels.

Diversity, Equity & Inclusion

Diversity, equity and inclusion are integral parts of our culture. We strongly believe in a diverse workplace where all employees can thrive in an inclusive environment free from discrimination, harassment, bias and prejudice. We strive to foster a culture where mutual respect, inclusive behavior, and dignity are core to our individual expectations.

Our employees represent a broad range of backgrounds and bring a wide array of perspectives and experiences that have helped us achieve our global leadership in innovative robotic technologies designed to enhance the treatment of arrhythmias and perform endovascular procedures.

Health, Safety, and Wellness

Employee safety and well-being is of utmost importance to us and has been of particular focus due to the COVID-19 pandemic. In response to the pandemic, we implemented significant changes that we determined were in the best interest of our employees, as well as the communities in which we operate, in compliance with government regulations. This included having a significant portion of our employee base work from home, while implementing additional safety measures for operation-critical development and manufacturing employees that worked on-site. In addition, despite the challenges and disruptions inflicted by COVID-19, we continued to support patients and physicians that rely on our technology, while protecting our sales and service employees, with the broad deployment of TeleRobotic support, leveraging proprietary connectivity technology to enable remote clinical and technical support of robotic electrophysiology practices.

Compensation and Benefits

We strive to provide our employees with what we believe is a very competitive and comprehensive total rewards package of compensation, benefits and services. In addition to base compensation, these packages, which vary by country and region, can include annual bonuses, sales commissions, 401(k) and/or pension plans, healthcare and insurance benefits for employees and family members, health savings and flexible spending accounts, paid time off, family leave, and flexible work schedules. In addition, we offer employees the benefit of equity ownership in the company through stock option grants and/or restricted stock units. Eligible employees have the opportunity to participate in an employee stock purchase plan, which offers the opportunity to purchase our common stock at a discount of 5%.

Training and Development

We recognize the importance of furthering education and development of our employees through the various stages of their careers. We are dedicated to promoting individual, leader, team, and organizational development through a number of tools and services. We offer a variety of professional development courses for our employees and support employee continuing education. In addition, our employees are required to complete compliance training applicable to our industry. We also have an annual global performance review process for reviewing all employees' performance and pay.

Availability of Information

We make certain filings with the SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments and exhibits to those reports, available free of charge in the Investors section of our website, *http://www.stereotaxis.com*, as soon as reasonably practicable after they are filed with the SEC. Further, these filings are available on the Internet at http://www.sec.gov. Information contained on our website is not part of this report and such information is not incorporated by reference into this report.

Executive Officers

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

ITEM 1A. RISK FACTORS

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

RISK FACTORS SUMMARY

Risks Related to Our Business and Business Operations

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

- A pandemic, epidemic or outbreak of infectious disease could have an adverse effect our business, operating results or financial condition.
- We may not be able to fund our business operations in the same manner as we have done historically if we do not improve the operating performance of the Company or raise additional capital.
- Hospital decision-makers may not purchase our Robotic Magnetic Navigation Systems or related products or may think that such systems and products are too expensive.
- 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.
- We will likely experience long and variable sales and installation cycles, which could result in substantial fluctuations in our quarterly results of operations.
- Physicians may not use our products if they do not believe they are safe, efficient and effective.
- Our collaborations with fluoroscopy system manufacturers and providers of catheters and electrophysiology mapping systems or other parties may fail, or we may not be able to enter into additional collaborations in the future.
- The complexity associated with selling, marketing, and distributing products could impair our ability to increase revenue.
- Our marketing strategy is dependent on collaboration with physician "thought leaders."
- Physicians may not commit enough time to sufficiently learn our system.
- Customers may choose to purchase competing products and not ours.
- 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.
- 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.
- We have incurred substantial losses in the past and may not be profitable in the future.
- 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.
- 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 may encounter problems at our manufacturing facilities or those of our subcontractors or otherwise experience manufacturing delays that could result in lost revenue.
- Our growth may place a significant strain on our resources, and if we fail to manage our growth, our ability to develop, market, and sell our products will be harmed.

Risks Relating to Technology and Intellectual Property Matters

- The rate of technological innovation of our products might not keep pace with the rest of the market.
- 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.
- We may be unable to protect our technology from use by third parties.
- Third parties may assert that we are infringing their intellectual property rights.
- Expensive intellectual property litigation is frequent in the medical device industry.
- 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.
- Our products and related technologies can be applied in different medical applications, and we may fail to focus on the most profitable areas.
- 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.
- Software errors or other defects may be discovered in our products.

Risks Relating to Regulatory and Legal Matters

- 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.
- 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.
- 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.
- Our suppliers, subcontractors, or we may fail to comply with the FDA quality system regulation or other quality standards.
- 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.
- Healthcare policy changes, including the potential repeal or amendment of any existing legislation, may have a material adverse effect on us.
- 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.

- Hospitals or physicians may be unable to obtain reimbursement from third-party payors for procedures using our products, or reimbursement for procedures may be insufficient to recoup the costs of purchasing our products.
- Our costs could substantially increase if we receive a significant number of warranty claims or have other significant, uninsured liabilities.

Risks Related to Our Common Stock

- Our principal stockholders continue to own a large percentage of our voting stock, and they have the ability to substantially influence matters requiring stockholder approval.
- Future issuances of our securities could dilute current stockholders' ownership.
- We have never paid dividends on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future.
- Our certificate of incorporation and bylaws, Delaware law, and one of our collaboration agreements contain provisions that could discourage a takeover.
- Evolving regulation of corporate governance and public disclosure may result in additional expenses and continuing uncertainty.
- Our future operating results may be below securities analysts' or investors' expectations, which could cause our stock price to decline.
- We expect that the price of our common stock could fluctuate substantially, possibly resulting in class action securities litigation.
- If we fail to continue to meet all applicable NYSE American Market requirements and the NYSE American determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock, which would impair the value of your investment and ultimately harm our business by limiting our access to equity markets for capital raising.

Risks Related to the February 2021 CEO Performance Stock Unit Grant

- We will incur significant additional stock-based compensation expense over the term of the CEO Performance Award regardless of whether or not any of the milestones are achieved**.**
- Our stockholders may experience substantial dilution upon payout of shares under the CEO Performance Award.
- Certain provisions in the PSU Agreement may discourage a change in control of the Company even if such a transaction would otherwise be beneficial to our stockholders.
- We are highly dependent on the services of Mr. Fischel, and our compensation package, including the CEO Performance Award, may fail to retain him.

Summary of General Risk Factors

- General economic conditions could materially adversely impact us.
- We may lose key personnel or fail to attract and retain replacement or additional personnel.
- We face currency and other risks associated with international operations.

Risks Related to Our Business and Business Operations

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

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

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

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

A pandemic, epidemic or outbreak of infectious disease could have an adverse effect our business, operating results or financial condition.

The novel coronavirus COVID-19 ("COVID-19") pandemic has resulted, and is likely to continue to result, in significant disruptions to the economy, as well as business and capital markets around the world. The full extent of the impact of the COVID-19 pandemic on our business, results of operations and financial condition will depend on numerous evolving factors that we may not be able to accurately predict.

As a result of the COVID-19 outbreak, we have experienced business disruptions, including travel restrictions on us and our third-party distributors, which have negatively affected our complex sales, marketing, installation, distribution and service network relating to our products and services. The COVID-19 pandemic may continue to negatively affect demand for both our systems and our disposable products by limiting the ability of our sales personnel to maintain their customary contacts with customers as governmental authorities institute prolonged quarantines, travel restrictions, and shelter-in-place orders, or as our customers impose limitations on contacts and in-person meetings that go beyond those imposed by governmental authorities.

In addition, many of our hospital customers, for whom the purchase of our system involves a significant capital purchase which may be part of a larger construction project at the customer site (typically the construction of a new building), may themselves be under economic pressures. This may cause delays or cancellations of current purchase orders and other commitments, and may exacerbate the long and variable sales and installation cycles for our robotic magnetic navigation systems. We may also experience significant reductions in demand for our disposable products as our healthcare customers (physicians and hospitals) continue to re-prioritize the treatment of patients and divert resources away from non-coronavirus areas, which we anticipate will lead to the performance of fewer procedures in which our disposable products are used. In addition, patients may consider foregoing or deferring procedures utilizing our products, even if physicians and hospitals are willing to perform them, which could also reduce demand for, and sales of, our disposable products.

As of the date of the filing of this Annual Report on Form 10-K, we believe our manufacturing operations and supply chains have been manageably impacted, but we cannot guarantee that they will not be impacted more severely in the future. If our manufacturing operations or supply chains are materially interrupted, it may not be possible for us to timely manufacture relevant products at required levels, or at all. Changes in economic conditions and supply chain constraints could lead to higher inflation than previously experienced or expected, which could, in turn, lead to an increase in costs. We may be unable to raise the prices of our products sufficiently to keep up with the rate of inflation. A material reduction or interruption to any of our manufacturing processes or a substantial increase in costs would have a material adverse effect on our business, operating results, and financial condition.

As governmental authorities around the world continue to institute prolonged mandatory closures, social distancing protocols and shelter-in-place orders, or as private parties on whom we rely to operate our business put in place their own protocols that go beyond those instituted by relevant governmental authorities, our ability to adequately staff and maintain our operations or further our product development could be negatively impacted.

Any disruption to the capital markets could negatively impact our ability to raise capital. If the capital markets are disrupted for an extended period of time and we need to raise additional capital, such capital may not be available on acceptable terms, or at all. Continued disruptions to the capital markets and other financing sources could also negatively impact our hospital customers' ability to raise capital or otherwise obtain financing to fund their operations and capital projects. Such could result in delayed spending on current projects, a longer sales cycle for new projects where a large capital commitment is required, and decreased demand for our disposable products as well as an increased risk of customer defaults or delays in payments for our systems installation, service contracts and disposable products.

We continue to evaluate and, where appropriate, take actions to reduce costs and spending across our organization. We will continue to actively monitor the situation and may take further actions that alter our business operations that may be required by federal, state, or local governmental authorities that may be implemented by our vendors, supplier or customers, or that we determine are in the best interests of our employees, customers, suppliers and stockholders.

We may not be able to fund our business operations in the same manner as we have done historically 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 2022 operating expenses will exceed its 2022 gross margin. The Company expects to continue to incur operating losses and negative cash flows until revenues reach a level sufficient to support ongoing operations or expense reductions are in place. The Company's liquidity needs will be largely determined by the success of clinical adoption within the installed base of our robotic magnetic navigation system as well as by new placements of capital systems. The Company's plans for improving the liquidity conditions primarily include its ability to control the timing and spending of its operating expenses and raising additional funds through debt or equity financing.

There can be no assurance that any of our plans will be successful or that additional capital will be available to us on reasonable terms, or at all, when needed. If we are unable to improve the operating performance of the Company or if we are unable to obtain sufficient additional capital, it may impair our ability to obtain new customers or hire and retain employees, any of which could force us to substantially revise our business plan or cease operations, which may reduce or negate the value of your investment.

Hospital decision-makers may not purchase our Robotic Magnetic Navigation Systems or related products or may think that such systems and products are too expensive.

To achieve and grow sales, hospitals must purchase our products, and in particular, our robotic magnetic navigation system. The robotic magnetic navigation system is a novel device, and hospitals and physicians are traditionally slow to adopt new products and treatment practices. In addition, hospitals may delay their purchase or installation decision for the robotic magnetic navigation system based on the disposable interventional devices that have received regulatory clearance or approval. Moreover, the robotic magnetic navigation system is an expensive piece of capital equipment, representing a significant portion of the cost of a new or replacement interventional lab. Although priced significantly below a robotic magnetic navigation system, the *Odyssey* Solution is still an expensive product. 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, liquidity position, and cash flow.

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

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

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

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

We anticipate that our robotic magnetic navigation 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 products have been delivered less than one year after the receipt of a purchase order from a hospital, with the timing being dependent on the construction cycle for the new or replacement interventional suite in which the equipment will be installed. In some cases, this time frame has been extended further because the interventional suite construction is part of a larger construction project at the customer site (typically the construction of a new building), which may occur with our existing and future purchase orders. We cannot assure you that the time from purchase order to delivery for systems to be delivered in the future will be consistent with our historical experience. Moreover, a global economic slowdown may cause our customers to further delay construction or significant capital purchases, which could further lengthen our sales cycle. This may contribute to substantial fluctuations in our quarterly operating results. As a result, in future quarters our operating results could fall below the expectations of securities analysts or investors, in which event our stock price would likely decrease.

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 our products 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 fund company operations going forward.

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

We have collaborated with and are continuing to collaborate with fluoroscopy system manufacturers and providers of catheters and electrophysiology mapping systems and other parties to make our instrument control technology compatible with their respective imaging products or disposable interventional devices and to co-develop additional disposable interventional devices for use with our products. A significant portion of our revenue from system sales is derived from these integrated products. The maintenance of these collaborations, or the establishment of equivalent alternatives, is critical to our commercialization efforts.

There are no guarantees that any existing strategic relationships will continue, and efforts are ongoing to ensure the availability of integrated next generation systems and/or equivalent alternatives. 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.

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

- we fail to or are unable to maintain adequate compatibility of our products with the most prevalent imaging products or disposable interventional devices expected by our customers for their clinical practice;
- any of our collaboration partners delays or fails in the integration of its technology or new products with our robotic magnetic navigation 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 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. If we are unable to effectively utilize our existing sales force or increase our existing sales force in the foreseeable future, we may be unable to generate the revenue we have projected in our business plan. Factors that may inhibit our sales and marketing efforts include:

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

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

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

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

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

In order for physicians to learn to use the robotic magnetic navigation 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 also face competition from companies that are developing robotic technologies for electrophysiology and non-electrophysiology interventional procedures. We are aware of three companies that commercialized endovascular catheter navigation systems which have been cleared by the FDA for electrophysiology procedures as well as two companies with electromagnetic catheter navigation systems that received CE Mark approval in Europe. None of these companies seem to be active with any current commercial activities. Outside of electrophysiology, there are at least two companies that have commercialized robotic systems for guidewire manipulation and can be viewed as potential competitors as we look to address additional clinical applications.

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

If these or other new products or technologies emerge that provide the same or superior benefits as our products at equal or lesser cost, it could render our products obsolete or unmarketable. In addition, the presence of other competitors may cause potential customers to delay their purchasing decisions, resulting in a longer than expected sales cycle, even if they do not choose our competitors' products. We cannot be certain that physicians will use our products to replace or supplement established treatments or that our products will be competitive with current or future products and technologies.

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

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

Our robotic magnetic navigation 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.

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

We have incurred substantial net losses since inception, including incurring an accumulated deficit of $498.7 million as of December 31, 2021, and we expect to incur losses into the future as we continue the commercialization of our products. 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.

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 other disposable devices. We also depend on various third-party suppliers for the magnets we use in our robotic magnetic navigation system and certain components of our *Odyssey* Solution. In addition, some of the components necessary for the assembly of our products are currently provided to us by a single supplier, including the magnets for our robotic magnetic navigation 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, we, as well as our contract manufacturers, may have excess or inadequate inventory of materials and components.

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

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

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

We purchase the permanent magnets for our robotic magnetic system from a manufacturer that uses material produced in Japan, and we anticipate that a certain amount of the production work for these magnets will be performed for this manufacturer in China. Given the complex relationships between China and the U.S., political, diplomatic, military, or other events could result in business disruptions, including increased regulatory enforcement against companies, tariffs, trade embargoes, and export restrictions relating to this production work. For example, in 2020, the U.S. government amended the Entity List rules to expand the requirement to obtain a license prior to the export of certain technologies. In addition, in 2020, a new U.S. regulation seeks to prohibit the U.S. government from contracting with companies who use the products or services of certain Chinese companies. While we believe that these regulations do not materially impact our business at this time, we cannot predict the impact that additional regulatory changes may have on our business in the future, which could adversely affect our business operations in China, or may otherwise limit our ability to offer our products and services in China and other parts of the world. In addition, our subcontractor may purchase magnets for our disposable interventional devices directly from a manufacturer in Japan. The relationships with these manufacturers and suppliers are generally on a purchase order basis and do not provide a contractual obligation to provide adequate supply or acceptable pricing on a long-term basis. These vendors could discontinue sourcing or supplying these magnets at any time. If any of our significant vendors were to discontinue their relationship with us or with our subcontractor, or if the factories were to suffer a disruption in their production, we may be unable to replace the vendors in a timely manner, which could result in short-term disruption to our supply of magnets as we transition our orders to new vendors or factories which could, in turn, cause a significant increase in price or a disruption of imports, including the imposition of import restrictions, could adversely affect our business, financial condition and results of operations. The flow of components from our vendors could also be adversely affected by financial or political instability or travel restrictions or bans in any of the countries in which the goods we purchase are manufactured, if the instability or restriction 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. For example, the previous administration implemented, or was considering the imposition of, tariffs on certain foreign goods, and we cannot predict the ongoing status of tariffs or any further potential legislation or actions taken by the U.S. federal government that restrict trade, such as additional tariffs, trade barriers, and other protectionist or retaliatory measures taken by governments in Europe, Asia, and other countries, could adversely impact our ability to sell products and services, which could increase the cost of our products and the components and raw materials that go into making them. Countries may also adopt other protectionist measures that could limit our ability to offer our products and services. In addition, decreases in the value of the U.S. dollar against foreign currencies, or significant price increase from these suppliers, 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 products and 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.

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

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

Risks Relating to Technology and Intellectual Property Matters

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, our products, it could be difficult for us to maintain our advantages associated with being an early developer of this technology. Likewise, the innovation and development cycle of competitors may impact our research and development efforts and ultimately, commercial adoption of viable research and development efforts. 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.

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, use of user names and passwords for access to information technology systems, 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, war or other military conflicts, natural disasters, or other catastrophic events. We have programs in place to detect, contain, and respond to data security incidents, and we continually make improvements to our networks and systems in order to minimize or eliminate vulnerabilities. However, because the techniques used to exploit systems change frequently and can be difficult to detect, we may not be able to prevent these intrusions or mitigate them when and if they occur. Additionally, we rely on some information technology networks and systems managed by third parties, and we rely on these third parties to deploy appropriate measures to protect their systems and networks. Vulnerabilities in their systems could compromise the security of our own infrastructure. 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, which may allow them to compete with us and harm our business.

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

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

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

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, and any defense of such assertions may be unsuccessful and expensive, even if we are successful.

Successfully commercializing our products depends in part on not infringing patents held by third parties. It is possible that one or more of our products, including those that we have developed in conjunction with third parties, infringes existing patents. We may also be liable for patent infringement by third parties whose products we use or combine with our own and for which we have no right to indemnification. In addition, because patent applications are maintained under conditions of confidentiality and can take many years to issue, there may be applications now pending of which we are unaware and which may later result in issued patents that our products infringe. Determining whether a product infringes a patent involves complex legal and factual issues and may not become clear until finally determined by a court in litigation. Our competitors may assert that our products infringe patents held by them. Moreover, as the number of competitors in our market grows the possibility of a patent infringement claim against us increases. If we were unsuccessful 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 our current business operations.

Expensive intellectual property litigation is frequent in the medical device industry and may cause to incur substantial expenses to defend.

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.

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

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

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

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

Software errors or other defects may be discovered in our products and the resulting performance issues may damage our business and our reputation in the industry in which we operate.

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.

Risks Related to Regulatory and Legal Matters

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

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

Furthermore, obtaining 510(k) clearances, de novo approvals, PMAs or PMA supplement approvals, from the FDA could result in unexpected and significant costs for us and consume management's time and other resources. The FDA could ask us to supplement our submissions, collect non-clinical data, conduct clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain a 510(k) clearance, de novo approvals, or PMA or PMA supplement approval, the clearance or approval could be revoked or other restrictions imposed if post-market data demonstrates safety issues or lack of effectiveness. We cannot predict with certainty how, or when, the FDA will act on our marketing applications. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be adversely affected. Also, a failure to obtain approvals may limit our ability to grow domestically and internationally.

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

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

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

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

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

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

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

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. The European Union recently adopted new EN ISO 13485:2016 standards, and we have been certified to these standards. If we or our suppliers or subcontractors fail to comply with the FDA regulation or EN ISO 13485:2016 standards, we or they may be required to cease all or part of our operations for some period of time until we or they can demonstrate that appropriate steps have been taken to comply with such standards or face other enforcement action, such as a public warning letter, untitled letter, fines, injunctions, civil penalties, seizures, operating restrictions, partial suspension or total shutdown of production, refusing requests for 510(k) clearance, de novo petitions, or PMA approval of new products, withdrawing 510(k) clearance, de novo approvals, or PMA approvals already granted, and/or criminal prosecution. We cannot be certain that our facilities or those of our suppliers or subcontractors will comply with the FDA or EN 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 or 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 the FDA refusing requests for and/or delays in 510(k) clearance, de novo approval, or PMA approval of new products.

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, including the California Consumer Privacy Act, or CCPA, which is introduces new and far-reaching law data privacy compliance burdens on many organizations doing business in California who collect personal information about California residents;
- the General Data Protection Regulation, or GDPR, which imposes requirements for controllers and processors of personal data and is in effect across the European Economic Area, or EEA, such as imposing higher standards when obtaining consent from individuals to process their personal data, requiring more robust disclosures to individuals, strengthening individual data rights, shortening timelines for data breach notifications, limiting retention periods and secondary use of information, increasing requirements pertaining to health data as well as pseudonymised data, and imposing additional obligations when we contract third-party processors in connection with the processing of personal data;
- federal self-referral laws, such as the Stark Anti-Referral Law, which prohibits a physician from making a referral to a provider of certain health services with which the physician or the physician's family member has a financial interest;
- federal and state Sunshine laws, which require manufacturers of certain medical devices to collect and report information on payments or transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members; and
- regulations pertaining to receipt of CE mark for our products marketed outside of the United States and submission to periodic regulatory audits in order to maintain these regulatory approvals.

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

Healthcare policy changes, including the potential repeal or amendment of any existing 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 federal 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.

Decisions by both the federal and state governments on funding priorities for various healthcare programs impact the finances of our customers on an ongoing and recurring basis. Such decisions may impact purchasing decisions of a customer.

Changes to, or repeal of, the 2010 Patient Protection and Affordable Care Act (PPACA), which different administrations and certain members of Congress have affirmatively indicated that they will pursue, could materially and adversely affect our business and financial position, and results of operations. Even if the PPACA is not amended or repealed, the administration could propose changes impacting implementation of the PPACA, which could materially and adversely affect our financial position or operations. However, we cannot currently predict the content, timing or impact that any such future legislation will have on our business.

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

Some states require health care providers to obtain a certificate of need or similar regulatory approval prior to the acquisition of high-cost capital items such as our products. 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, the sales and installation cycle of our robotic magnetic navigation systems may be longer in certificate of need states due to the time it takes our customers to obtain the required approvals. In addition, our customers must meet various federal and state regulatory and/or accreditation requirements in order to receive payments from government-sponsored health care programs such as Medicare and Medicaid, receive full reimbursement from third party payors, and maintain their customers. Our international customers may be required to meet similar or other requirements. Any lapse by our customers in maintaining appropriate licensure, certification or accreditation, or the failure of our customers to satisfy the other necessary requirements under government-sponsored health care programs or other requirements could cause our sales to decline.

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

We expect that U.S. hospitals will continue to bill various third-party payors, such as Medicare, Medicaid and other government programs and private insurance plans, for procedures performed with our products, including the costs of the disposable interventional devices used in these procedures. If, in the future, our disposable interventional devices do not fall within U.S. reimbursement categories and our procedures are not reimbursed, or if the reimbursement is insufficient to cover the costs of purchasing our system and related disposable interventional devices, the adoption of our systems and products would be significantly slowed or halted, and we may be unable to generate sufficient sales to support our business. Our success in international markets also depends upon the eligibility of our products for reimbursement through government-sponsored health care payment systems and third-party payors. In both the U.S. and foreign markets, health care cost-containment efforts are prevalent and are expected to continue. These efforts could reduce levels of reimbursement available for procedures involving our products and, therefore, reduce overall demand for our products as well. A failure to generate sufficient sales could have a material adverse impact on our financial condition, results of operations and cash flow.

Our costs could substantially increase if we receive a significant number of warranty claims or have other significant, uninsured liabilities.

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.

Moreover, for certain risks, we do not maintain insurance coverage because of cost and/or availability. In addition, in the future, we may not continue to maintain certain existing insurance coverage or adequate levels of coverage. Premiums for many types of insurance have increased significantly in recent years and, depending on market conditions and our circumstances, in the future, certain types of insurance, such as directors' and officers' insurance, may not be available on acceptable terms or at all. Because we retain some portion of our insurable risks and, in some cases, we are entirely self-insured, unforeseen or catastrophic losses in excess of insurance coverage could require us to pay substantial amounts, which may have a material adverse impact on our business, financial condition, results of operations, or cash flows.

Risks Related to Our Common Stock

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

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

Future issuances of our securities could dilute current stockholders' ownership.

As of December 31, 2021, we had 5.6 million shares of our common stock issuable upon conversion of our Series B Convertible Preferred Stock and 45.3 million shares of our common stock issuable upon conversion of our Series A Convertible Preferred Stock. Our Series A Convertible Preferred Stock bears dividends at a rate of six percent (6.0%) per annum, which are cumulative and accrue daily from the date of issuance on the $1,000 stated value. Such dividends will not be paid in cash, except in connection with any liquidation, dissolution or winding up of the Company or any redemption of the Series A Convertible Preferred Stock. Instead, the value of the accrued dividends is added to the liquidation preference of the Series A Convertible Preferred Stock and will increase the number of shares of common stock issuable upon conversion, which will dilute the ownership of our common stockholders.

In addition, a significant number of shares of our common stock are subject to issuance under our existing stock incentive plans and we may request the ability to issue additional such securities. We may also decide to raise additional funds through public or private debt or equity financing to fund our operations. While we cannot predict the effect, if any, that future sales of debt, our common stock, other equity securities or securities exercisable for or convertible into our common stock or other equity securities or the availability of any of the foregoing for future sale, will have on the market price of our common stock, it is likely that sales of substantial amounts of our common stock (including shares issued upon the exercise of stock options and stock appreciation rights, the vesting of the CEO Performance Share Unit Award and restricted stock units, or the conversion of any convertible securities outstanding now or in the future, including the Series A and Series B Convertible Preferred Shares), will dilute the ownership of our existing stockholders and that the perception that such sales could occur, will adversely affect prevailing market prices for our common stock.

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

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

We have paid no cash dividends on any of our classes of common stock to date and we currently intend to retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be an investor's sole source of gain for the foreseeable future.

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

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

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

In addition, our collaboration agreement with Biosense Webster contains provisions that may similarly discourage a takeover and negatively affect our share price as described above under "Business-Strategic Relationships".

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

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

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

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

- demand for our products;
- the performance of third-party contract manufacturers and component suppliers;
- our ability to develop sales and marketing capabilities;
- the success of our strategic relationships with two multinational fluoroscopy system manufacturers and one provider of catheters and electrophysiology mapping systems;
- our ability to develop, introduce and market integrated next generation systems and/or alternatives to our current strategic relationships with fluoroscopy system manufacturers and the catheter and electrophysiology mapping system provider on a timely basis;
- our ability to develop, introduce and market new or enhanced versions of our products on a timely basis;
- our ability to obtain regulatory clearances or approvals for our new products; and
- our ability to obtain and protect proprietary rights.

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

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

While our common stock is traded on the NYSE American Market, trading volume may be limited or sporadic. The market price of our common stock has experienced, and may continue to experience, substantial volatility. During 2021, our common stock traded between $4.31 and $10.30 per share, on trading volume ranging from approximately 93,800 to 4.5 million shares per day. The market price of our common stock will be affected by a number of factors, including:

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

These factors, as well as general economic, credit, political and market conditions, may materially adversely affect the market price of our common stock. As with the stock of many other public companies, the market price of our common stock has been particularly volatile during the recent period of upheaval in the capital markets and world economy. This excessive volatility may continue for an extended period of time following the filing date of this report. Furthermore, the stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Volatility in the price of our common stock on the NYSE American Market may depress the trading price of our common stock, which could, among other things, allow a potential acquirer of the Company to purchase a significant amount of our common stock at low prices. In addition, the volatility of our stock price could lead to class action securities litigation being filed against us, which could result in substantial costs and a diversion of our management resources, which could significantly harm our business.

If we fail to continue to meet all applicable NYSE American Market requirements and the NYSE American determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock, which would impair the value of your investment and ultimately harm our business by limiting our access to equity markets for capital raising.

Our common stock is currently listed on the NYSE American Market. We currently meet the continued listing standards of NYSE American. However, we cannot guarantee that we will be able to continue to comply with the required standards in order to maintain a listing of our common stock on the NYSE American. If we fail to continue to meet all applicable NYSE American requirements in the future and the NYSE American determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock, which would adversely affect our ability to obtain financing for the continuation of our operations, as a result, harming our business. This delisting could also impair the value of your investment.

Risks Related to the February 2021 CEO Performance Stock Unit Grant

We will incur significant additional stock-based compensation expense over the term of the CEO Performance Award regardless of whether or not any of the milestones are achieved.

As described in Note 9 of the accompanying notes to the consolidated financial statements in Part II, Item 8 of this Form 10-K, on February 23, 2021, the Company`s Board of Directors, upon recommendation of the Compensation Committee, approved the grant of the Performance Share Unit Award ("CEO Performance Award") pursuant to the CEO Performance Share Unit Award Agreement (the "PSU Agreement"), to David L. Fischel, the Company's Chief Executive Officer. Under the terms of the PSU Agreement, we will incur significant additional stock-based compensation expense over the term of the award regardless of whether or not any of the milestones are achieved as the probability of meeting the ten market capitalization milestones is not considered in determining the timing of expense recognition. The expense will be recognized on an accelerated basis through 2030. Total stock-based compensation recorded as operating expense for the CEO Performance Award was $6.1 million for the year ended December 31, 2021. As of December 31, 2021, the Company had approximately $51.3 million of total unrecognized stock-based compensation expense remaining under the CEO Performance Award if Mr. Fischel continues to serve as CEO, or in a similar capacity, through 2030. This additional stock-based compensation expense, incurred regardless of whether or not any milestones are achieved, increases the difficulty for the Company to achieve a profitable position as measured by generally accepted accounting principles.

Our stockholders may experience substantial dilution upon payout of shares under the CEO Performance Award.

If Mr. Fischel achieves all the milestones specified in the CEO Performance Award, by increasing the Company's market capitalization to $5.5 billion for the specified period, he will receive 13,000,000 shares of common stock subject to the vesting requirements in the agreement. If (i) all 13,000,000 shares of common stock subject to the PSU Agreement were to become fully vested, outstanding and held by Mr. Fischel; (ii) all other shares of common stock and stock units held by Mr. Fischel were fully vested and were outstanding; (iii) estimated dilution as a result of potential exercises or conversions from existing grants to employees and non-employee directors and the outstanding convertible preferred stock were to be considered; and (iv) there were no other dilutive events of any kind, Mr. Fischel would beneficially own approximately 10% of the outstanding shares of Stereotaxis common stock after the dilutive events described above and without considering the impact of any other potential future dilutive events or the potential sale of stock required to pay taxes upon the vesting of the restricted stock units.

Certain provisions in the PSU Agreement may discourage a change in control of the Company even if such a transaction would otherwise be beneficial to our stockholders.

Under the terms of the CEO Performance Award, in the event of a change in control of the Company, the market capitalization formula will be modified to equal the total amount of consideration paid to all equity holders of the Company, with the number of shares to be issued pursuant to the CEO Performance Grant giving effect to such valuation. For all valuations above $1.0 billion in connection with a change in control, partial credit for the next following tranche shall be allocated pro rata based on the market capitalization in such change in control. Any vested shares upon such a change in control will vest and be paid at the time of the consummation of the change in control, and the service component of the CEO Performance Award will otherwise be disregarded. These terms may discourage potential business partners from pursuing a merger or acquisition, even if the merger or acquisition would be viewed favorably by, or be beneficial to, our other stockholders.

We are highly dependent on the services of Mr. Fischel, and our compensation package, including the CEO Performance Award, may fail to retain him.

Since assuming the role of CEO in February 2017, Mr. Fischel has revitalized the Company's commercial capabilities, strengthened its financial position, and led the development of a robust innovation strategy, and stockholders have benefited substantially, with Stereotaxis' stock appreciating substantially. However, between February 2017 and December 2020, Mr. Fischel served as CEO without drawing a salary or any other form of cash or equity compensation for his work as CEO, and currently his only compensation is an annual salary of $60,000, which is substantially below market. While the Board believes that the CEO Performance Award provides substantial future benefit to all its stockholders and incentivizes Mr. Fischel to serve as CEO for the long term, there is no assurance that Mr. Fischel will continue as CEO.

General Risk Factors

General economic conditions could materially adversely impact us.

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

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.

We face currency and other risks associated with international operations.

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

- currency fluctuations that could impact the demand for our products or result in currency exchange losses;
- export restrictions, tariff and trade regulations and foreign tax laws;
- customs duties, export quotas or other trade restrictions;
- travel restrictions or bans;
- economic and political instability;
- war or other military conflicts, such as the current hostilities between Russia and Ukraine, and any related impact on macroeconomic conditions as a result of such conflict; and
- shipping delays.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

We have not received any written comments regarding our periodic or current reports from the staff of the SEC that were issued 180 days or more preceding the end of our 2021 fiscal year and that remain unresolved.

ITEM 2. PROPERTIES

On March 1, 2021, the Company entered into an office lease agreement (the "Lease") with Globe Building Company (the "Landlord"), under which the Company will lease executive office space and manufacturing facilities of approximately 43,100 square feet of rentable space located at 710 N. Tucker Boulevard, St. Louis, Missouri (the "Premises") that will serve as the Company's new principal executive and administrative offices and manufacturing facility. Lease payments commenced January 1, 2022 and the lease has a term of ten years, with two renewal options of five years each. The new lease space includes approximately 23,000 square feet of office space and 20,100 square feet of demonstration and assembly space. The Company gained access to the Premises in the third quarter 2021 to begin constructing leasehold improvements. In the fourth quarter of 2021, the Company received an occupancy permit and relocated its operations to the new leased space.

The Company's previous primary facilities were also located in St. Louis, Missouri and the Company leased approximately 52,000 square feet of office space and 12,000 square feet of demonstration and assembly space under a lease agreement that ended December 31, 2021.

In August 2016, the Company entered into an agreement to sublease approximately 11,000 square feet of office space immediately and an additional 16,000 square feet of office space beginning in January of 2017. The sublease ended December 31, 2021.

We lease approximately 2,200 square feet of office space in Maple Grove, Minnesota, under a lease agreement through October 31, 2023, and have leased office space in Amsterdam, The Netherlands through August 31, 2022. In addition, we lease an office space in Beijing, China under a lease agreement through November 29, 2023.

ITEM 3. LEGAL PROCEEDINGS

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

As previously disclosed, on April 29, 2021, a putative class action complaint was filed in Delaware Chancery Court by Richard Barre, a purported shareholder, against the Company and its current directors, as defendants (the "Action"). The complaint alleged breaches of fiduciary duty against the defendants based on alleged disclosure deficiencies in the definitive proxy statement (the "Proxy Statement") filed by the Company on April 9, 2021 relative to the vote at the Company's 2021 Annual Meeting of Stockholders that was to be held on May 20, 2021 (the "2021 Stockholder Meeting") seeking stockholder approval of issuance of shares under the Performance Share Unit Award (the "CEO Performance Award") granted to David L. Fischel, the Company's chief executive officer. The complaint sought various remedies, including a preliminary injunction seeking to enjoin the vote at the 2021 Stockholder Meeting to approve the issuance of shares for the CEO Performance Award.

Although the Company believed that the claims were wholly without merit and that no further disclosure was required to supplement the Proxy Statement under applicable law, as previously disclosed, the Company filed a supplement to the Proxy Statement on May 10, 2021 (the "Proxy Supplement") addressing the alleged disclosure claims in order to eliminate the burden, expense, and uncertainties inherent in such litigation, and without admitting any liability or wrongdoing. On May 12, 2021, the plaintiff withdrew the motion for a preliminary injunction and voluntarily dismissed the Action, reserving the right to apply for an award of attorneys' fees and reimbursement of expenses.

On May 21, 2021, the Chancery Court approved a stipulation under which the plaintiff voluntarily dismissed the Action with prejudice as to itself only, but without prejudice as to any other putative class member. The Chancery Court retained jurisdiction solely for the purpose of adjudicating the anticipated application of plaintiff's counsel for an award of attorneys' fees and reimbursement of expenses in connection with the supplemental disclosures included in the Proxy Supplement.

The Company subsequently agreed to pay $675,000 to the plaintiff's counsel for attorneys' fees and expenses in full satisfaction of the claim for attorneys' fees and expenses in the Action. The Chancery Court has not been asked to review, and will pass no judgment on, the payment of the attorneys' fees and expenses or their reasonableness.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

PRICE RANGE OF COMMON STOCK

Our common stock began trading on the NASDAQ Global Market under the symbol "STXS" on August 12, 2004 and was transferred to the NASDAQ Capital Market effective August 19, 2013. On August 4, 2016 our common stock was transferred to the OTCQX® Best Market and on September 6, 2019 our common stock was transferred to the NYSE American Market.

As of February 28, 2022, there were approximately 417 stockholders of record of our common stock, although we believe that there is a significantly larger number of beneficial owners of our common stock.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

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

This report includes various forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results could differ materially from those anticipated in these forward looking statements as a result of various factors, including those set forth in Item 1A. "Risk Factors." Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include, but are not limited to, discussions regarding our operating strategy, sales and marketing strategy, regulatory strategy, our industry generally, overall economic conditions, our financial condition, liquidity and capital resources, our results of operations, and the impact of the ongoing coronavirus ("COVID-19") pandemic and our responses to it. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words "believes," "expects," "anticipates," "intends," "estimates," "projects," "can," "could," "may," "will," "would," or similar expressions. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You should not unduly rely on these forward-looking statements, which speak only as of the date on which they were made. They give our expectations regarding the future but are not guarantees. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Overview

Stereotaxis is a pioneer and global leader in surgical robotics for minimally invasive endovascular intervention. We design, manufacture and market robotic systems, instruments and information systems for the interventional laboratory. Our proprietary robotic technology, Robotic Magnetic Navigation, fundamentally transforms endovascular interventions using precise computer-controlled magnetic fields to directly control the tip of flexible interventional catheters or devices. Direct control of the tip of an interventional device, in contrast to all manual hand-held devices that are controlled from their handle, can improve the precision, stability, reach and safety of these devices during procedures.

Our primary clinical focus has been electrophysiology, specifically cardiac ablation procedures for the treatment of arrhythmias. Cardiac ablation has become a well-accepted therapy for arrhythmias and a multi-billion-dollar medical device market with expectations for substantial long-term growth. We have shared our aspiration and a product strategy to expand the clinical focus of our technology to several additional endovascular indications including coronary, neuro, and peripheral interventions.

There is substantial real-world evidence and clinical literature for Robotic Magnetic Navigation in electrophysiology. Hundreds of electrophysiologists at over one hundred hospitals globally have treated over 100,000 arrhythmia patients with our robotic technology. Clinical use of our technology has been documented in over 400 clinical publications. Robotic Magnetic Navigation is designed to enable physicians to complete more complex interventional procedures with greater success and safety by providing image-guided delivery of catheters through the blood vessels and chambers of the heart to treatment sites. This is achieved using externally applied computer-controlled magnetic fields that govern the motion of the working tip of the catheter, resulting in improved navigation. The more flexible atraumatic design of catheters driven using magnetic fields may reduce the risk of patient harm and other adverse events. Performing the procedure from a control cockpit enables physicians to complete procedures in a safe location protected from x-ray exposure, with greater ergonomics, and improved efficiency. We believe these benefits can be applicable in other endovascular indications where navigation through complex vasculature is often challenging or unsuccessful and generates significant x-ray exposure.

Our primary products include the *Genesis RMN* System, the *Odyssey* Solution, and other related devices. We also offer to our customers the Stereotaxis Imaging Model S x-ray System and other accessory devices.

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

The *Odyssey* Solution consolidates lab information onto one large integrated display, enabling physicians to view and control all the key information in the operating room. This is designed to improve lab layout and procedure efficiency. The system also features a remote viewing and recording capability called *Odyssey Cinema*, which is an innovative solution that delivers synchronized content for optimized workflow, advanced care, and improved productivity. This tool includes an archiving capability that allows clinicians to store and replay entire procedures or segments of procedures. This information can be accessed from locations throughout the hospital local area network and over the global Odyssey Network providing physicians with a tool for clinical collaboration, remote consultation, and training.

We promote our full suite of products in a typical hospital implementation, subject to regulatory approvals or clearances. This 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 the warranty period, and ongoing software updates. In hospitals where our full suite of products has not been implemented, equipment upgrade or expansion can be implemented upon purchasing of the necessary upgrade or expansion.

We have received regulatory clearances and registration necessary for us to market the *Genesis RMN* System in the U.S. and Europe, and we are in the process of obtaining necessary registrations for extending our markets in other countries. Our prior generation robotic magnetic navigation system, the *Niobe* System, and the *Odyssey* Solution, *Cardiodrive*, and various disposable interventional devices have received regulatory clearance in the U.S., Europe, Canada, China, Japan and various other countries. We have received the regulatory clearance, licensing and/or CE Mark approvals that allow us to market the *Vdrive* and *Vdrive Duo* Systems with the *V-CAS*, *V-Loop* and *V-Sono* devices in the U.S., Canada and Europe. Stereotaxis Imaging Model S x-ray System is CE marked and cleared by the FDA.

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 the regulatory clearance, licensing, and/or approvals we currently have or are pursuing.

As of December 31, 2021, we had approximately $10.1 million of backlog, consisting of outstanding purchase orders and other commitments for these systems. Of the December 31, 2021 backlog, we expect approximately 78% to be recognized as revenue over the course of 2022. We had backlog of approximately $6.9 million as of December 31, 2020. There can be no assurance that we will recognize such revenue in any particular period or at all because some of our purchase orders and other commitments are subject to contingencies that are outside our control. These orders and commitments may be revised, modified or canceled, either by their express terms, as a result of negotiations or by project changes or delays. In addition, the sales cycle for the robotic magnetic navigation system is lengthy and generally involves construction or renovation activities at customer sites. Consequently, revenues and/or orders resulting from sales of our robotic magnetic navigation system can vary significantly from one reporting period to the next.

We have strategic relationships with technology leaders in the global interventional market. Through these strategic relationships we provide compatibility between our robotic magnetic navigation system and digital imaging and 3D catheter location sensing technology, as well as disposable interventional devices. The maintenance of these strategic relationships, or the establishment of equivalent alternatives, is critical to our commercialization efforts. There are no guarantees that any existing strategic relationships will continue, and efforts are ongoing to ensure the availability of integrated systems and devices and/or equivalent alternatives. 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.

COVID-19 Pandemic

Prior to the spread of COVID-19, we were experiencing procedure trends consistent with the fourth quarter of 2019. We also saw strength in new capital orders. Beginning in January 2020, we saw a substantial reduction in robotic procedures in Asia Pacific, especially in China. By the height of the pandemic in that region, weekly procedures decreased to approximately 40% of the average rate experienced in the fourth quarter. As the COVID-19 pandemic subsided in China in March 2020, procedure volume began to recover and, by the end of the first quarter of 2020, we were seeing weekly procedures in the Asia Pacific region approach 70% of the fourth quarter average rates. Procedure disruption in other geographies was not significant until the middle of March 2020, when the worldwide impact of COVID-19 intensified. By the end of March, procedures in the U.S and Europe, which represent the majority of our procedures, declined to approximately 70% of the weekly procedure rate experienced in the fourth quarter of 2019. As the pandemic spread throughout the first quarter of 2020, various local restrictions on travel, mandatory closures, social distancing protocols and shelter-in-place orders negatively impacted our ability to complete installation and service activities, which resulted in declines in system and service revenue in the first quarter. Our supply-chain also experienced some impact as some suppliers struggled to source sub-components in February when most factories in China were seemingly closed. These issues were mostly alleviated by the end of the first quarter with the opening of the Chinese economy. During the first quarter, we also took proactive actions to reduce the risk that a prolonged future reduction in Chinese manufacturing might have on us. During the early portion of the second quarter, weekly procedures in the United States and Europe continued to decline, reaching approximately 40% of fourth quarter 2019 levels by the middle of April. In May, with the reopening of various regions, procedures in both geographies began to recover and by the end of June, procedures were approximating the level seen before the pandemic. During the second quarter of 2020, weekly procedure rates in Asia Pacific continued to improve, eventually reaching the pre-pandemic weekly procedure rate. During the third quarter of 2020, weekly procedures continued to recover and approached the levels seen before the pandemic. During the fourth quarter of 2020, periodic resurgence of COVID-19 caused hospitals and patients in some areas to again postpone procedures. Overall, weekly procedures during the fourth quarter remained generally consistent with the recovery seen in the third quarter.

During the first quarter of 2021, periodic resurgences of COVID-19 and the delayed rollout of vaccines in some geographies continued to impact our procedure volumes. Overall, procedure volumes improved slightly compared to the fourth quarter 2020 and were approximately 5% higher than the first quarter of 2020. While procedures in the Asia Pacific region had recovered to pre-pandemic levels, procedures in other geographies remained impacted with total procedures approximately 15% below those seen in the first quarter of 2019. During the second quarter of 2021, as the rollout of vaccines continued in the US and were varied in other geographies, overall procedure volumes for the second quarter 2021 remained fairly consistent with the first quarter of 2021 and were nearly 40% higher than the second quarter of 2020. During the third and fourth quarters of 2021, a resurgence of COVID and hospital staffing shortages depressed procedure volumes. Overall procedure volumes fell in the third quarter of 2021 by approximately 9% as compared to the third quarter of 2020 and overall procedure volumes in the fourth quarter of 2021 fell by approximately 8% as compared to the fourth quarter of 2020.

We have experienced some challenges and disruptions due to the pandemic such as worldwide supply chain disruptions, including shortages and inflationary pressures, and logistics delays which makes it difficult for us to source parts and ship our products. Our customers have also experienced similar supply chain issues as well as labor shortages, both of which have contributed to delayed hospital construction project timelines. While concerns remain, we are generally able to conduct normal business activities albeit in a more deliberate manner than prior to the pandemic.

Ongoing

Even with the rollout of effective vaccines, we do not expect all markets to recover at the same pace. The ongoing impact that the pandemic will have on our business will likely continue to vary by individual geography based on the extent of the outbreak in each area, the timing of vaccine distribution, specific governmental restrictions and the availability of testing capabilities, personal protective equipment, and hospital facilities, as well as decisions by our vendors, suppliers, customers and, ultimately, patients in response to the pandemic, none of which we are able to currently and accurately predict. While we cannot reliably estimate the depth or length of the impact, we continue to anticipate significant, periodic disruptions to our procedures volumes, service activities and system placements in 2022. In addition, we would expect that capital system orders will continue to experience some delay.

Capital markets and worldwide economies continue to be significantly impacted by the COVID-19 pandemic, and the outlook for 2022 depends on future developments, including but not limited to: the length and severity of ongoing outbreaks (including further new variants beyond Delta and Omicron, which may be more contagious, more severe or less responsive to treatment or vaccines), the effectiveness of containment actions, and the timing of vaccinations and achievement of herd immunity. The impact on local and/or global economies is uncertain, including ongoing risk of recession. Such economic disruptions, including a recession, could have a material adverse effect on our long-term business as hospitals continue to monitor and adjust capital and overall spending or redirect such spending to treatments related directly to the pandemic. To date, our manufacturing operations and supply chains have been manageably impacted, but we cannot guarantee that such will not be impacted further in the future. If our manufacturing operations or supply chains are materially interrupted, it may not be possible for us to timely manufacture relevant products at required levels, or at all. A material reduction or interruption to any of our manufacturing processes could have a material adverse effect on our business, operating results, and financial condition. Further, the COVID-19 pandemic and local actions, such as “shelter-in-place” orders and restrictions on our ability to travel and access our customers or temporary closures of our facilities or the facilities of our suppliers and their contract manufacturers, could also significantly impact our sales and our ability to ship our products and supply our customers. Any of these events could negatively impact the number of procedures performed and the number of system placements and have a material adverse effect on our business, financial condition, results of operations, or cash flows.

Critical Accounting Policies and Estimates

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

Revenue Recognition

The Company accounts for revenue in accordance with Accounting Standards Codification Topic 606 (“ASC 606”), *Revenue from Contracts with Customers*.

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

In accordance with Accounting Standards Codification Topic 606 (“ASC 606”), “Revenue from Contracts with Customers,” we account for a contract with a customer when there is a legally enforceable contract between the Company and the customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. We record our revenue based on consideration specified in the contract with each customer, net of any taxes collected from customers that are remitted to government authorities.

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

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

Our revenue recognition policy affects the following revenue streams in our business as follows:

Systems:

Contracts related to the sale of systems typically contain separate obligations for the delivery of system(s), installation and an implied obligation to provide software enhancements if and when available for one year following installation. Revenue is recognized when the Company transfers control to the customer, which is generally at the point when acceptance occurs that indicates customer acknowledgment of delivery or installation, depending on the terms of the arrangement. Revenue from the implied obligation to deliver software enhancements if and when available is recognized ratably typically over the first year following installation of the system as the customer receives the right to software updates throughout the period and is included in Other Recurring Revenue. The Company's system contracts generally do not provide a right of return. Systems are generally covered by a one-year assurance type warranty; warranty costs were approximately $0.2 million and less than $0.1 million for the years ended December 31, 2021 and 2020, respectively.

Disposables:

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

Royalty:

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

Other Recurring Revenue:

Other recurring revenue includes revenue from product maintenance plans, other post warranty maintenance, and the implied obligation to provide software enhancements if and when available for a specified period, typically one year following installation of our systems. Revenue from services and software enhancements is deferred and amortized over the service or update period, which is typically one year. Revenue related to services performed on a time-and-materials basis is recognized when performed.

Sublease Revenue:

A portion of our principal executive office was subleased to a third party through 2021. In accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2016-02, *Leases (Topic 842)*, the Company recorded sublease income as revenue.

The Company invoices its customers based on the billing schedules in its sales arrangements. Contract assets primarily represent the difference between the revenue that was recognized based on the relative selling price of the related performance obligations and the contractual billing terms in the arrangements. Customer deposits primarily relate to future system sales but can also include deposits on disposable sales. Deferred revenue is primarily related to service contracts, for which the service fees are billed up-front, generally quarterly or annually, and for amounts billed in advance for system contracts for which some performance obligations remain outstanding. For service contracts, the associated deferred revenue is generally recognized ratably over the service period. For system contracts, the associated deferred revenue is recognized when the remaining performance obligations are satisfied. See Note 2 to the financial statements for additional detail on deferred revenue. The Company did not have any impairment losses on its contract assets for the periods presented.

Assets Recognized from the Costs to Obtain a Contract with a Customer

The Company has determined that sales incentive programs for the Company's sales team meet the requirements to be capitalized as the Company expects to generate future economic benefits from the related revenue generating contracts after the initial capital sales transaction. The costs capitalized as contract acquisition costs included in prepaid expenses and other assets in the Company's balance sheets were $0.2 million and $0.3 million as of December 31, 2021 and 2020, respectively. The Company did not incur any impairment losses during any of the periods presented.

Leases

The Company accounts for leases in accordance with ASU No. 2016-02 "Leases" (Topic 842) and all subsequent ASUs that modified Topic 842. A lease is defined as a contract, or part of a contract, that conveys the right to control the use of identified property, plant or equipment for a period of time in exchange for consideration. The Company determines if a contract contains a lease at inception. For contracts where the Company is the lessee, operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liability on the Company's balance sheet. The Company currently does not have any finance leases.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as the Company's leases generally do not provide an implicit rate. Lease terms may include options to extend or terminate when the Company is reasonably certain that the option will be exercised. Lease expense is recognized on a straight-line basis over the lease term.

The Company also has lease arrangements with lease and non-lease components. The Company elected the practical expedient not to separate non-lease components from lease components for the Company's operating leases. Additionally, the Company applies the short-term lease measurement and recognition exemption in which right of use assets and lease liabilities are not recognized for leases less than twelve months.

As disclosed in Note 6, on March 1, 2021, the Company entered into an office lease agreement (the "Lease") with Globe Building Company (the "Landlord"), under which the Company is leasing executive office space and manufacturing facilities of approximately 43,100 square feet of rentable space located at 710 N. Tucker Boulevard, St. Louis, Missouri (the "Premises") that serves as the Company's new principal executive and administrative offices and manufacturing facility. Lease payments commenced on January 1, 2022 and the lease has a term of ten years, with two renewal options of five years each. The minimum annual rent under the terms of the Lease ranges from approximately $0.8 million in 2022 to $1.0 million in 2031.

The Company gained access to the Premises in the third quarter 2021 to begin constructing leasehold improvements. In accordance with ASC 842, the Company recorded a ROU asset and lease liability. The initial recognition of the ROU asset and lease liability was $5.9 million. In the fourth quarter of 2021, the Company received an occupancy permit and relocated its operations to the new leased space.

Cost of Contracts

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

Stock-based Compensation

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

For market-based awards, stock-based compensation expense is recognized over the minimum service period regardless of whether or not the market target is probable of being achieved. The fair value of such awards is estimated on the grant date using Monte Carlo simulations.

The amount of compensation expense to be recorded in future periods may increase if we make additional grants of options, stock appreciation rights or restricted shares. The amount of expense to be recorded in future periods may decrease if the requisite service periods are not completed.

Valuation of Inventory

We value our inventory at the lower of the actual cost of our inventory, as determined using the first-in, first-out (FIFO) method, or its current net realizable value. We periodically review our physical inventory for excess, obsolete, and potentially impaired items and reserve accordingly. Our reserve estimate for excess and obsolete is based on expected future use. Excess manufacturing overhead costs attributable to idle facility expenses or abnormally low production volumes are excluded from inventory and recorded as an expense in the period incurred.

Income Taxes

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

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

Results of Operations

Comparison of the Years ended December 31, 2021 and 2020

Revenue. Revenue increased from $26.6 million for the year ended December 31, 2020, to $35.0 million for the year ended December 31, 2021, an increase of approximately 32%. Revenue from sales of systems increased from $3.6 million for the year ended December 31, 2020, to $11.2 million for the year ended December 31, 2021, an increase of approximately 208%, driven by increased system sales volumes in the current year period. Revenue from sales of disposable interventional devices, service and accessories increased to $22.9 million for the year ended December 31, 2021, from $22.0 million for the year ended December 31, 2020, an increase of approximately 4%, driven by higher procedure volumes partially offset by slightly lower service revenue. Sublease revenue was $1.0 million for the years ended December 31, 2021 and 2020.

Cost of Revenue. Cost of revenue increased from $7.7 million for the year ended December 31, 2020, to $11.8 million for the year ended December 31, 2021, an increase of approximately 54%. As a percentage of our total revenue, overall gross margin decreased to 66% for the year ended December 31, 2021, from 71% for the year ended December 31, 2020 driven by changes in product mix. Cost of revenue for systems sold increased from $3.7 million for the year ended December 31, 2020 to $7.5 million for the year ended December 31, 2021, primarily due to increased system sales volumes in the current year period. Gross margin for systems increased from less than negative $0.1 million for the year ended December 31, 2020 to positive $3.6 million for the year ended December 31, 2021. Cost of revenue for disposables, service, and accessories increased to $3.3 million for the year ended December 31, 2021 from $3.0 million for year ended December 31, 2020 driven by increased disposable sales volumes and higher expenses incurred under service contracts in the current year period. Gross margin for disposables, service and accessories was 86% for the current year period compared to 87% for the year ended December 31, 2020. Cost of sublease revenue was $1.0 million for both the years ended December 31, 2021 and 2020.

Research and Development Expense. Research and development expense increased from $8.1 million for the year ended December 31, 2020, to $10.2 million for the year ended December 31, 2021, an increase of approximately 25%. This increase was primarily due to higher project spending and measured hiring in the current year period.

Sales and Marketing Expense. Sales and marketing expense increased from $11.2 million for the year ended December 31, 2020 to $11.9 million for the year ended December 31, 2021, an increase of approximately 7%. This increase was primarily due to increased sales and marketing activities as normal activities resume following the height of the pandemic as well as higher compensation related costs.

General and Administrative Expense. General and administrative expenses include finance, information systems, legal, and general management expenses. General and administrative expense increased from $6.4 million for the year ended December 31, 2020 to $14.0 million for the year ended December 31, 2021, an increase of approximately 120%. This increase was primarily driven by higher stock-based compensation expense for the previously announced CEO Performance Award and the appreciating stock price as well as higher professional service fees in the current year period.

Interest Income (Expense). Net interest expense was less than $0.1 million for the year ended December 31, 2021, and net interest income was less than $0.1 million for the year ended December 31. 2020.

Income Taxes

Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. Accordingly, net deferred tax assets have been fully offset by valuation allowances as of December 31, 2021, and December 31, 2020 to reflect these uncertainties. We may not be able to utilize all of these loss carryforwards prior to their expiration. As of December 31, 2021, we had gross federal net operating loss carryforwards of approximately $120.1 million. The federal net operating loss carryforwards reflect accumulated book losses reduced for the 2013 IRC Section 382 ownership change limitation of $255.6 million and approximately $123.3 million of book/tax differences and expiration of unused carryforwards. The federal net operating loss carryforwards generated prior to the 2018 tax year will expire between 2030 and 2037. The federal net operating loss generated during and beyond 2018 will be carried forward indefinitely as a result of changes in the tax law following the Tax Cuts and Jobs Act. As of December 31, 2021, we had gross state net operating loss carryforward of approximately $37.6 million which will expire at various dates between 2022 and 2041 if not utilized.

Liquidity and Capital Resources

Liquidity refers to the liquid financial assets available to fund our business operations and pay for near-term obligations. These liquid financial assets consist of cash and cash equivalents. We are continuously and critically reviewing our liquidity and anticipated capital requirements in light of the significant uncertainty created by the COVID-19 pandemic.

As of December 31, 2021, our accumulated deficit was $498.7 million with cash and cash equivalents of $40.1 million, inclusive of restricted cash. Since inception, we have financed our operations primarily through cash generated by operations and proceeds from our debt and stock offerings.

Capital Resources

As of December 31, 2021, the Company did not have any debt.

Revolving Line of Credit

The Company had a working capital line of credit with its primary lender, Silicon Valley Bank that matured on June 30, 2020 and was not renewed.

Paycheck Protection Program

The Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) was enacted on March 27, 2020 in the United States. Among the provisions contained in the CARES Act was the creation of the Paycheck Protection Program that provides for Small Business Administration (“SBA”) Section 7(a) loans for qualified small businesses. In general, the loan could be forgiven as long as the funds were used for payroll related expenses as well as rent and utilities paid during the twenty-four-week period from the date of the loan and as long as certain headcount and salary/wage levels were maintained. On April 10, 2020, the Company was informed by its lender, Midwest BankCentre (the “Bank”), that the Bank received approval from the SBA to fund the Company’s request for a loan under the SBA’s Paycheck Protection Program (“PPP Loan”). Per the terms of the PPP Loan, the Company received total proceeds of approximately $2.2 million from the Bank on April 20, 2020. In accordance with the loan forgiveness requirements of the CARES Act, the Company used the full proceeds from the PPP Loan primarily for payroll costs, rent and utilities. In March 2021, the Company applied for loan forgiveness and in June 2021, full loan forgiveness was granted by the SBA. The Company recognized a net gain from debt extinguishment of approximately $2.2 million upon forgiveness.

2020 Equity Financing

As disclosed in Note 9, on May 25, 2020, the Company entered into a Securities Purchase Agreement with certain accredited investors, whereby it, in a direct registered offering, agreed to issue and sell to the investors an aggregate of 3,658,537 shares of the Company’s common stock, $0.001 par value per share, at a price of $4.10 per share. The Company received net proceeds of approximately $15.0 million, after offering expenses.

Liquidity

The following table summarizes our cash flow by operating, investing and financing activities for years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,	
	2021	**2020**
Cash flow used in operating activities	$ (2,946)	$ (3,512)
Cash flow used in investing activities	(1,397)	(71)
Cash flow provided by financing activities	547	17,340

Net cash used in operating activities. We used approximately $2.9 million and $3.5 million of cash in operating activities during the years ended December 31, 2021 and 2020, respectively. The decrease in cash used in operating activities was driven by lower working capital requirements during the current year period.

Net cash used in investing activities. We used $1.4 million and less than $0.1 million of cash in investing activities during the years ended December 31, 2021 and 2020, respectively. The increase in cash used in investing activities was driven by the purchases of equipment and design and build-out costs associated with our new facility.

Net cash provided by financing activities. We generated approximately $0.5 million and 17.3 million of cash for the years ended December 31, 2021 and 2020, respectively. The cash generated in the current year period was driven by the proceeds from issuance of stock from exercises of stock options, net of issuance costs, and proceeds from our employee stock purchase program. The cash generated in the year ended December 31, 2020 was primarily driven by the net proceeds of $15.0 million received from the May 2020 Securities Purchase Agreement and $2.2 million of proceeds received from the Paycheck Protection Program loan.

At December 31, 2021, we had working capital of approximately $38.1 million, compared to a working capital of approximately $39.1 million at December 31, 2020. The decrease in working capital was primarily driven by the net loss incurred during the year ended December 31, 2021.

The Company had a working capital line of credit with its primary lender, Silicon Valley Bank that matured on June 30, 2020 and was not renewed.

Our principal source of liquidity is cash provided by operations and by the issuance of common stock through the exercise of stock options and our employee stock purchase program as well as cash received from past equity raises. The Company believes the cash and cash equivalents on hand as of December 31, 2021 will be sufficient to meet its obligations as they become due in the ordinary course of business for at least 12 months following the date of the financial statements included in this Annual Report on Form 10-K, as well as for periods beyond that 12-month period. Our cash requirements depend on numerous factors, including success of clinical adoption within the installed base of robotic magnetic systems, new placements of capital systems, the resources we devote to developing and supporting our products, and other factors. We expect to continue to fund our operations with cash resources primarily generated from the proceeds of our past equity raises and from our working capital. In the future, we may finance cash needs through the sale of other equity securities or non-core assets, strategic collaboration agreements, debt financings or through distribution rights.

Off-Balance Sheet Arrangements

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial Statements
Index To Financial Statements

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

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Stereotaxis, Inc. (the Company) as of December 31, 2021 and 2020, the related statements of operations, convertible preferred stock and stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2021, and the related notes and the financial statement schedule listed in the Index at Item 15(a) (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved especially challenging, subjective, or complex judgments. The communication of the critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Systems Revenue Recognition

Description of the Matter

As discussed in Note 2 to the financial statements, the Company generates revenue from initial capital sales of systems as well as recurring revenue from the sale of proprietary disposable devices, from royalties paid to the Company for co-developed catheters, and revenue from ongoing software updates and service contracts. The Company's contracts for system sales generally have multiple performance obligations.

Auditing the timing and amount of revenue recognized for system sales required significant auditor judgment because it involves several subjective management assumptions and estimates including the identification of performance obligations within the contracts, the estimation of the standalone selling price of each performance obligation, the allocation of transaction price to each performance obligation, and a determination of the timing of the satisfaction of the performance obligation.

How We Addressed the Matter in Our Audit

To test system revenue, our audit procedures included, among others, testing management's identification of the performance obligations and the allocation of the transaction price to each performance obligation by performing an independent assessment of customer contracts and comparing our assessment to that of management. We also tested management's estimated standalone selling prices for its identified performance obligations based on actual prices charged for similar products and services sold on a standalone basis. We also tested management's assertion that control was transferred to the customer by inspecting documentation supporting the transfer of control on contracts.

Valuation of CEO Performance Award

Description of the Matter

As discussed in Note 9 to the consolidated financial statements, the Company granted to David L. Fischel, the Company's Chief Executive Officer, a share-based compensation award, consisting of an aggregate of 13,000,000 performance share units of the Company's common stock. The award vests in ten tranches based on whether certain market capitalization milestones are met. The Company estimated the grant date fair value of the award using the Monte Carlo simulation model and recognized stock-based compensation expense of $6.1 million for the year ended December 31, 2021 related to this award.

Auditing the Company's valuation of the aforementioned award was challenging because of the subjective auditor judgment necessary in evaluating the propriety of the complex valuation methodologies and significant assumptions used in estimating the fair value of the award as of the grant date and estimating the vesting period of each tranche of the award. Such significant assumptions include volatility of the Company's common stock price, risk free interest rate and grant term.

How We Addressed the Matter in Our Audit	To test the valuation award, our procedures included, among others, involving our internal valuation specialists and evaluating and testing the valuation methodologies and significant assumptions stated above. For example, we performed independent comparative calculations to estimate volatility of the Company's common stock price and compared our estimates with those of the Company, assessed the appropriateness of the model utilized by the Company to calculate the grant term and correlated recognition of compensation expense.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2002.
St. Louis, Missouri
March 10, 2022

STEREOTAXIS, INC.
BALANCE SHEET

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 38,738,591	$ 43,939,512
Restricted cash - current	454,268	-
Compensating cash arrangement	-	250,620
Accounts receivable, net of allowance of $179,913 and $123,614 at 2021 and 2020, respectively	5,405,860	3,515,136
Inventories, net	4,433,394	3,295,457
Prepaid expenses and other current assets	2,356,190	1,716,014
Total current assets	51,388,303	52,716,739
Property and equipment, net	2,631,891	195,129
Restricted cash	951,563	-
Operating lease right-of-use assets	5,734,775	2,235,442
Other assets	278,154	308,515
Total assets	$ 60,984,686	$ 55,455,825
Liabilities and stockholders' equity		
Current liabilities:		
Short-term debt	$ -	$ 1,185,058
Accounts payable	4,188,471	1,608,636
Accrued liabilities	2,528,189	3,209,235
Deferred revenue	6,276,781	5,282,770
Current portion of operating lease liabilities	268,121	2,287,487
Total current liabilities	13,261,562	13,573,186
Long-term debt	-	973,252
Long-term deferred revenue	2,238,150	548,915
Operating lease liabilities	5,842,456	-
Other liabilities	218,582	131,231
Total liabilities	21,560,750	15,226,584
Series A - Convertible preferred stock:		
Convertible preferred stock, Series A, par value $0.001; 22,387 and 22,513 shares outstanding at 2021 and 2020, respectively	5,583,768	5,605,323
Stockholders' equity:		
Convertible preferred stock, Series B, par value $0.001; 10,000,000 shares authorized, 5,610,121 shares outstanding at 2021 and 2020	5,610	5,610
Common stock, par value $0.001; 300,000,000 shares authorized, 74,618,240 and 73,694,203 shares issued at 2021 and 2020, respectively	74,618	73,694
Additional paid in capital	532,640,795	522,709,846
Treasury stock, 4,015 shares at 2021 and 2020	(205,999)	(205,999)
Accumulated deficit	(498,674,856)	(487,959,233)
Total stockholders' equity	33,840,168	34,623,918
Total liabilities and stockholders' equity	$ 60,984,686	$ 55,455,825

See accompanying notes.

STEREOTAXIS, INC.
STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2021	**2020**
Revenue:		
Systems	$ 11,167,676	$ 3,626,284
Disposables, service and accessories	22,867,066	22,017,631
Sublease	986,120	986,120
Total revenue	35,020,862	26,630,035
Cost of revenue:		
Systems	7,526,575	3,715,416
Disposables, service and accessories	3,276,491	2,962,710
Sublease	986,120	986,120
Total cost of revenue	11,789,186	7,664,246
Gross margin	23,231,676	18,965,789
Operating expenses:		
Research and development	10,198,553	8,136,914
Sales and marketing	11,948,068	11,178,325
General and administrative	13,973,498	6,364,365
Total operating expenses	36,120,119	25,679,604
Operating loss	(12,888,443)	(6,713,815)
Interest (expense) income, net	(10,071)	67,356
Gain on extinguishment of debt	2,182,891	-
Net loss	$ (10,715,623)	$ (6,646,459)
Cumulative dividend on Series A convertible preferred stock	(1,345,031)	(1,369,421)
Loss attributable to common stockholders	$ (12,060,654)	$ (8,015,880)
Net loss per share attributable to common stockholders:		
Basic	$ (0.16)	$ (0.11)
Diluted	$ (0.16)	$ (0.11)
Weighted average number of common shares and equivalents:		
Basic	75,558,233	72,746,268
Diluted	75,558,233	72,746,268

See accompanying notes.

STEREOTAXIS, INC
STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
Year Ended December 31, 2020

	Convertible Preferred Stock Series A (Mezzanine)		Convertible Preferred Stock Series B		Common Stock		Additional Paid-In	Treasury	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	(Deficit)
Balance at December 31, 2019	23,110	$ 5,758,190	5,610,121	$ 5,610	68,529,623	$ 68,530	$ 504,211,040	$ (205,999)	$ (481,312,774)	$ 22,766,407
Issuance of common stock					3,863,314	3,863	15,057,950			15,061,813
Share-based compensation					147,989	149	3,169,199			3,169,348
Components of net loss									(6,646,459)	(6,646,459)
Employee stock purchase plan					32,467	32	119,910			119,942
Preferred stock conversion	(597)	(152,867)			1,120,810	1,120	151,747			152,867
Balance at December 31, 2020	22,513	$ 5,605,323	5,610,121	$ 5,610	73,694,203	$ 73,694	$ 522,709,846	$ (205,999)	$ (487,959,233)	$ 34,623,918

Year Ended December 31, 2021

	Convertible Preferred Stock Series A (Mezzanine)		Convertible Preferred Stock Series B		Common Stock		Additional Paid-In	Treasury	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	(Deficit)
Balance at December 31, 2020	22,513	$ 5,605,323	5,610,121	$ 5,610	73,694,203	$ 73,694	$ 522,709,846	$ (205,999)	$ (487,959,233)	$ 34,623,918
Issuance of common stock					332,232	333	429,473			429,806
Share-based compensation					325,954	325	9,362,582			9,362,907
Components of net loss									(10,715,623)	(10,715,623)
Employee stock purchase plan					19,699	20	117,585			117,605
Preferred stock conversion	(126)	(21,555)			246,152	246	21,309			21,555
Balance at December 31, 2021	22,387	$ 5,583,768	5,610,121	$ 5,610	74,618,240	$ 74,618	$ 532,640,795	$ (205,999)	$ (498,674,856)	$ 33,840,168

See accompanying notes.

STEREOTAXIS, INC.
STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (10,715,623)	$ (6,646,459)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	105,653	126,211
Non-cash lease expense	2,706,651	2,340,428
Share-based compensation	9,362,907	3,169,348
Loss on asset disposal	170	-
Gain on debt extinguishment	(2,182,891)	-
Non-cash interest	24,581	-
Changes in operating assets and liabilities:		
Accounts receivable	(1,890,724)	1,814,441
Inventories	(1,137,937)	(1,447,927)
Prepaid expenses and other current assets	(640,176)	(245,092)
Compensating cash arrangement	250,620	(250,620)
Other assets	30,361	(90,412)
Accounts payable	1,433,840	(490,461)
Accrued liabilities	(681,046)	488,131
Deferred revenue	2,683,246	184,972
Operating lease liability	(2,382,894)	(2,340,046)
Other liabilities	87,351	(124,286)
Net cash used in operating activities	(2,945,911)	(3,511,772)
Cash flows from investing activities		
Purchase of property and equipment	(1,396,590)	(70,896)
Net cash used in investing activities	(1,396,590)	(70,896)
Cash flows from financing activities		
Proceeds from Paycheck Protection Program loan	-	2,158,310
Proceeds from issuance of stock, net of issuance costs	547,411	15,181,755
Net cash provided by financing activities	547,411	17,340,065
Net (decrease) increase in cash and cash equivalents	(3,795,090)	13,757,397
Cash and cash equivalents at beginning of period	43,939,512	30,182,115
Cash and cash equivalents at end of period	$ 40,144,422	$ 43,939,512
Supplemental disclosure of cash flow information:		
Interest paid	$ -	$ -
Purchases of property and equipment included in accounts payable	$ 1,145,995	$ -
Reconciliation of cash, cash equivalents, and restricted cash to balance sheet as of December 31st:		
Cash and cash equivalents	$ 38,738,591	$ 43,939,512
Restricted cash - current	454,268	-
Restricted cash	951,563	-
Total cash, cash equivalents, and restricted cash	$ 40,144,422	$ 43,939,512

See accompanying notes.

Notes to Financial Statements

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

1. Description of Business

Stereotaxis designs, manufactures and markets robotic systems, instruments and information systems for the interventional laboratory. Our proprietary robotic technology, Robotic Magnetic Navigation, fundamentally transforms endovascular interventions using precise computer-controlled magnetic fields to directly control the tip of flexible interventional catheters or devices. Direct control of the tip of an interventional device, in contrast to all manual hand-held devices that are controlled from their handle, can improve the precision, stability, reach and safety of these devices during procedures.

Our primary clinical focus has been electrophysiology, specifically cardiac ablation procedures for the treatment of arrhythmias. Cardiac ablation has become a well-accepted therapy for arrhythmias and a multi-billion-dollar medical device market with expectations for substantial long-term growth. We have shared our aspiration and a product strategy to expand the clinical focus of our technology to several additional endovascular indications including coronary, neuro, and peripheral interventions.

There is substantial real-world evidence and clinical literature for Robotic Magnetic Navigation in electrophysiology. Hundreds of electrophysiologists at over one hundred hospitals globally have treated over 100,000 arrhythmia patients with our robotic technology. Clinical use of our technology has been documented in over 400 clinical publications. Robotic Magnetic Navigation is designed to enable physicians to complete more complex interventional procedures with greater success and safety by providing image-guided delivery of catheters through the blood vessels and chambers of the heart to treatment sites. This is achieved using externally applied computer-controlled magnetic fields that govern the motion of the working tip of the catheter, resulting in improved navigation. The more flexible atraumatic design of catheters driven using magnetic fields may reduce the risk of patient harm and other adverse events. Performing the procedure from a control cockpit enables physicians to complete procedures in a safe location protected from x-ray exposure, with greater ergonomics, and improved efficiency. We believe these benefits can be applicable in other endovascular indications where navigation through complex vasculature is often challenging or unsuccessful and generates significant x-ray exposure.

Our primary products include the *Genesis RMN* System, the *Odyssey* Solution, and other related devices. We also offer to our customers the Stereotaxis Imaging Model S x-ray System and other accessory devices.

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

The *Odyssey Solution* consolidates lab information onto one large integrated display, enabling physicians to view and control all the key information in the operating room. This is designed to improve lab layout and procedure efficiency. The system also features a remote viewing and recording capability called *Odyssey Cinema*, which is an innovative solution that delivers synchronized content for optimized workflow, advanced care, and improved productivity. This tool includes an archiving capability that allows clinicians to store and replay entire procedures or segments of procedures. This information can be accessed from locations throughout the hospital local area network and over the global Odyssey Network providing physicians with a tool for clinical collaboration, remote consultation, and training.

We promote our full suite of products in a typical hospital implementation, subject to regulatory approvals or clearances. This 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 ongoing software updates. In hospitals where our full suite of products has not been implemented, equipment upgrade or expansion can be implemented upon purchasing of the necessary upgrade or expansion.

We have received regulatory clearances and registration approvals necessary for us to market the *Genesis RMN* System in the U.S. and Europe, and we are in the process of obtaining necessary registrations for extending our markets in other countries. The *Niobe* System, *Odyssey* Solution, *Cardiodrive*, and various disposable interventional devices have received regulatory clearance in the U.S., Europe, Canada, China, Japan and various other countries. We have received the regulatory clearance, licensing and/or CE Mark approvals that allow us to market the *Vdrive* and *Vdrive Duo* Systems with the *V-CAS*, *V-Loop* and *V-Sono* devices in the U.S., Canada and Europe. Stereotaxis Imaging Model S x-ray System is CE marked and FDA cleared.

We have strategic relationships with technology leaders and innovators in the global interventional market. Through these strategic relationships we provide compatibility between our robotic magnetic navigation system and digital imaging and 3D catheter location sensing technology, as well as disposable interventional devices. The maintenance of these strategic relationships, or the establishment of equivalent alternatives, is critical to our commercialization efforts. There are no guarantees that any existing strategic relationships will continue, and efforts are ongoing to ensure the availability of integrated systems and devices and/or equivalent alternatives. 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.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").

Cash and Cash Equivalents

The Company considers all short-term investments purchased with original maturities of three months or less to be cash equivalents. The Company places its cash with high-credit-quality financial institutions and invests primarily in money market accounts.

Restricted Cash

Restricted cash primarily consists of cash that the Company is obligated to maintain in accordance with contractual obligations. The Company's restricted cash was $1.4 million at December 31, 2021. No cash was restricted at December 31, 2020.

Compensating Cash Arrangement

In July 2020, the Company entered into a letter of credit to support a commitment of less than $0.3 million. As a condition of the letter of credit, the Company was required to maintain a $0.3 million compensating balance until the expiration of the letter of credit. The letter of credit expired in the fourth quarter of 2021.

Accounts Receivable and Allowance for Uncollectible Accounts

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

Financial Instruments

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

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

The Company's financial assets consist of restricted cash and cash equivalents invested in money market funds which totaled $1.4 million as of December 31, 2021 and 2020. The financial assets consisting of cash equivalents invested in money market funds are classified as Level 2 as described above and total interest income recorded for these investments was insignificant for the years ended December 31, 2021 and 2020. As of December 31, 2021 and 2020, the Company did not have any financial liabilities valued at fair value on a recurring basis.

Inventory

The Company values its inventory at the lower of cost, as determined using the first-in, first-out (FIFO) method, or net realizable value. The Company periodically reviews its physical inventory and provides a reserve upon identification of potential excess or obsolete items. Excess manufacturing overhead costs attributable to idle facility expenses or abnormally low production volumes are excluded from inventory and recorded as an expense in the period incurred.

Property and Equipment

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

Long-Lived Assets

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

Intangible Assets

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

Use of Estimates

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

Revenue and Costs of Revenue

Revenue Recognition

The Company accounts for revenue in accordance with Accounting Standards Codification Topic 606 (“ASC 606”), *Revenue from Contracts with Customers*.

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

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

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

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

Our revenue recognition policy affects the following revenue streams in our business as follows:

Systems:

Contracts related to the sale of systems typically contain separate obligations for the delivery of system(s), installation and an implied obligation to provide software enhancements if and when available for one year following installation. Revenue is recognized when the Company transfers control to the customer, which is generally at the point when acceptance occurs that indicates customer acknowledgment of delivery or installation, depending on the terms of the arrangement. Revenue from the implied obligation to deliver software enhancements if and when available is recognized ratably over the first year following installation of the system as the customer receives the right to software updates throughout the period and is included in Other Recurring Revenue. The Company’s system contracts generally do not provide a right of return. Systems are generally covered by a one-year assurance type warranty; warranty costs were approximately $0.2 million and less than $0.1 million for the years ended December 31, 2021 and 2020, respectively. Revenue from system delivery and installation represented 32% and 14% of revenue for the years ended December 31, 2021 and 2020, respectively.

Disposables:

Revenue from sales of disposable products is recognized when control is transferred to the customers, which generally occurs at the time of shipment, but can also occur at the time of delivery depending on the customer arrangement. Disposable products are covered by an assurance type warranty that provides for the return of defective products. Warranty costs were not material for the periods presented. Disposable revenue represented 24% and 28% of revenue for the years ended December 31, 2021 and 2020, respectively.

Royalty:

The Company is entitled to royalty payments from Biosense Webster, payable quarterly based on net revenues from sales of the co-developed catheters. Royalty revenue from the co-developed catheters represented 7% and 8% of revenue for the years ended December 31, 2021 and 2020, respectively.

Other Recurring Revenue:

Other recurring revenue includes revenue from product maintenance plans, other post warranty maintenance, and the implied obligation to provide software enhancements if and when available for a specified period, typically one year following installation of our systems. Revenue from services and software enhancements is deferred and amortized over the service or update period, which is typically one year. Revenue related to services performed on a time-and-materials basis is recognized when performed. Other recurring revenue represented 34% and 46% of revenue for the years ended December 31, 2021 and 2020, respectively.

Sublease Revenue:

A portion of our principal executive office was subleased to a third party through 2021. In accordance with Accounting Standards Update (ASU) 2016-02, “Leases” (Topic 842), the Company recorded sublease income as revenue. Sublease revenue represented 3% and 4% of revenue for the years ended December 31, 2021 and 2020, respectively. The sublease ended December 31, 2021.

	Year Ended December 31,	
	2021	**2020**
Systems	$ 11,167,676	$ 3,626,284
Disposables, service and accessories	22,867,066	22,017,631
Sublease	986,120	986,120
Total revenue	$ 35,020,862	$ 26,630,035

Transaction price allocated to remaining performance obligations relates to amounts allocated to products and services for which the revenue has not yet been recognized. A significant portion of this amount relates to the Company’s systems contracts and obligations that will be recognized as revenue in future periods. These obligations are generally satisfied within two years after contract inception but may occasionally extend longer. Transaction price representing revenue to be earned on remaining performance obligations on system contracts was approximately $10.1 million as of December 31, 2021. Performance obligations arising from contracts for disposables, royalty and service are generally expected to be satisfied within one year after entering into the contract.

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

	December 31, 2021	**December 31, 2020**
Contract Assets - unbilled receivables	$ 178,354	$ 284,415
Customer deposits	$ 925,050	$ -
Product shipped, revenue deferred	1,794,374	645,200
Deferred service and license fees	5,795,507	5,186,485
Total deferred revenue	$ 8,514,931	$ 5,831,685
Less: Long-term deferred revenue	(2,238,150)	(548,915)
Total current deferred revenue	$ 6,276,781	$ 5,282,770

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

Revenue recognized for the years ended December 31, 2021 and 2020, that was included in the deferred revenue balance at the beginning of each reporting period was $5.1 million and $5.0 million, respectively.

The Company has determined that sales incentive programs for the Company's sales team meet the requirements to be capitalized as the Company expects to generate future economic benefits from the related revenue generating contracts after the initial capital sales transaction. The costs capitalized as contract acquisition costs included in prepaid expenses and other assets in the Company's balance sheets were $0.2 million and $0.3 million as of December 31, 2021 and 2020, respectively. The Company did not incur any impairment losses during any of the periods presented.

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

Research and Development Costs

Internal research and development costs are expensed in the period incurred. Amounts receivable from strategic relationships under research reimbursement agreements are recorded as a contra-research and development expense in the period reimbursable costs are incurred. There were no material receivables as of December 31, 2021 or 2020 under these types of agreements. Advance receipts or other unearned reimbursements are included in accrued liabilities on the accompanying balance sheet until earned.

Stock-Based Compensation

The Company accounts for its grants of stock options, stock appreciation rights, restricted shares, and restricted stock units and for its employee stock purchase plan in accordance with the provisions of general accounting principles for share-based payments. These accounting principles require the determination of the fair value of the share-based compensation at the grant date and the recognition of the related expense over the period in which the share-based compensation vests.

For time-based awards, the Company utilizes the Black-Scholes valuation model to determine the fair value of stock options and stock appreciation rights at the date of grant. The resulting compensation expense is recognized over the requisite service period, which is generally four years. Restricted shares and units granted to employees are valued at the fair market value at the date of grant. The Company amortizes the fair market value to expense over the service period. If the shares are subject to performance objectives, the resulting compensation expense is amortized over the anticipated vesting period and is subject to adjustment based on the actual achievement of objectives.

For market-based awards, stock-based compensation expense is recognized over the minimum service period regardless of whether or not the market target is probable of being achieved. The fair value of such awards is estimated on the grant date using Monte Carlo simulations.

Shares purchased by employees under the 2009 Employee Stock Purchase Plan are considered to be non-compensatory.

Net Loss per Common Share

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

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

As of December 31, 2021, the Company had 2,818,012 shares of common stock issuable upon the exercise of outstanding options and stock appreciation rights at a weighted average exercise price of $4.10 per share, 45,306,189 shares of our common stock issuable upon conversion of our Series A Convertible Preferred Stock, 5,610,121 shares of our common stock issuable upon conversion of our Series B Convertible Preferred Stock and 1,164,723 shares of unvested restricted share units. The Company had no unearned restricted shares outstanding for the period ended December 31, 2021.

Income Taxes

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

Product Warranty Provisions

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

Patent Costs

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

Concentrations of Risk

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

No single customer accounted for more than 10% of total revenue for the years ended December 31, 2021 and 2020. Revenue from customers in China accounted for $3.7 million, or 10% of total revenue, for the year ended December 31, 2021. Revenue from customers in Finland accounted for $2.7 million, or 10%, of total revenue, for the year ended December 31, 2020. No other single country, other than the U.S. accounted for more than 10% of total revenue for the years ended December 31, 2021 and 2020.

Recently Issued Accounting Pronouncements

In December 2019, the FASB issued ASU 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes" as part of its effort to reduce the complexity of accounting standards. The ASU is effective for fiscal years beginning after December 15, 2020. The Company adopted with no impact to the Company's financial statements.

In June 2016, the FASB issued ASU 2016-13, "Financial Instruments-Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments" and also issued subsequent amendments to the initial guidance under ASU 2018-19, ASU 2019-04 and ASU 2019-05. The standard modifies the measurement approach for credit losses on financial instruments, including trade receivables, from an incurred loss method to a current expected credit loss method, otherwise known as "CECL." The standard requires the measurement of expected credit losses to be based on relevant information, including historical experience, current conditions and a forecast that is supportable. The standard is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years; early adoption is permitted. The standard must be adopted by applying a cumulative adjustment to retained earnings. The Company anticipates adopting the standard in the first quarter of 2023, although it does not expect a significant impact to the Company's financial results.

3. Inventory

Inventory consists of the following:

	December 31, 2021	December 31, 2020
Raw materials	$ 3,641,785	$ 2,950,912
Work in process	133,576	433,026
Finished goods	2,822,808	2,987,039
Reserve for excess and obsolescence	(2,164,775)	(3,075,520)
Total inventory	$ 4,433,394	$ 3,295,457

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other assets consist of the following:

	December 31, 2021	December 31, 2020
Prepaid expenses	$ 1,011,647	$ 754,062
Prepaid commissions	229,150	271,174
Deposits	1,276,080	855,970
Other assets	117,467	143,323
Total prepaid expenses and other assets	2,634,344	2,024,529
Less: Noncurrent prepaid expenses and other assets	(278,154)	(308,515)
Total current prepaid expenses and other assets	$ 2,356,190	$ 1,716,014

5. Property and Equipment

Property and equipment consist of the following:

	December 31, 2021	December 31, 2020
Equipment	$ 3,670,081	$ 6,488,984
Leasehold improvements	17,653	2,338,441
Construction in process	2,155,740	-
	5,843,474	8,827,425
Less: Accumulated depreciation	(3,211,583)	(8,632,296)
Net property and equipment	$ 2,631,891	$ 195,129

The Company retired approximately $5.5 million of fully depreciated assets during the year ended December 31, 2021. The Company had approximately $2.5 million of property and equipment additions during the year ended December 31, 2021 associated with the buildout of the new leased space in St. Louis, Missouri.

6. Leases

A lease is defined as a contract, or part of a contract, that conveys the right to control the use of identified property, plant or equipment for a period of time in exchange for consideration. The Company accounts for leases in accordance with Accounting Standards Update No. 2016-02 “Leases” (Topic 842) and all subsequent ASUs that modified Topic 842 (“ASC 842”). The Company determines if an arrangement contains a lease at inception.

The Company leases its facilities under operating leases. In accordance with ASC 842, operating lease agreements are recognized on the balance sheet as a right-of-use (“ROU”) asset and a corresponding lease liability. These leases generally do not have significant rent escalation holidays, concessions, leasehold improvement incentives, or other build-out clauses. Further, the leases do not contain contingent rent provisions. Many of our leases include both lease (i.e., fixed payments including rent, taxes, and insurance costs) and non-lease components (i.e., common-area or other maintenance costs) which are accounted for as a single lease component as we have elected the practical expedient to group lease and non-lease components for all leases. A portion of our existing principal executive office was subleased to a third party through 2021. The sublease did not have significant rent escalation holidays, concessions, leasehold improvement incentives, or other build-out clauses. In addition, the sublease did not contain contingent rent provisions nor were there options to extend or terminate the sublease. The sublease ended December 31, 2021.

The Company’s lease agreements often include one or more options to renew at the Company’s discretion. If at lease inception, the Company considers the exercising of a renewal option to be reasonably certain, the Company will include the extended term in the calculation of the ROU asset and lease liability. The Company elected not to include short-term leases (i.e., leases with initial terms of twelve months or less) on the balance sheet.

On March 1, 2021, the Company entered into an office lease agreement (the “Lease”) with Globe Building Company (the “Landlord”), under which the Company will lease executive office space and manufacturing facilities of approximately 43,100 square feet of rentable space located at 710 N. Tucker Boulevard, St. Louis, Missouri (the “Premises”) that will serve as the Company’s new principal executive and administrative offices and manufacturing facility. Lease payments commenced on January 1, 2022, and the lease has a term of ten years, with two renewal options of five years each. The minimum annual rent under the terms of the Lease ranges from approximately $0.8 million in 2022 to $1.0 million in 2031. The Company gained access to the Premises in the third quarter 2021 to begin constructing leasehold improvements. In accordance with ASC 842, the Company recorded a ROU asset and lease liability. The initial recognition of the ROU asset and lease liability was $5.9 million. In the fourth quarter of 2021, the Company received an occupancy permit and relocated its operations to the new leased space.

The calculated amounts of the ROU assets and lease liabilities are impacted by the length of the lease term and the discount rate used to calculate the present value of the minimum lease payments. ASC 842 requires the use of the discount rate implicit in the lease whenever this rate is readily determinable. As this rate is rarely determinable, the Company utilizes its incremental borrowing rate at lease inception. At December 31, 2021, the weighted average discount rate for operating leases was 9% and the weighted average remaining lease term for operating lease term is 10.0 years.

The following table represents lease costs and other lease information:

	Year Ended December 31,	
	2021	2020
Operating lease cost	$ 2,706,651	$ 2,340,428
Short-term lease cost	57,350	66,865
Sublease income	(986,120)	(986,120)
Total net lease cost	$ 1,777,881	$ 1,421,173
Cash paid within operating cash flows	$ 2,223,111	$ 2,486,309

Variable lease costs consist primarily of taxes, insurance, and common area or other maintenance costs for our leased facilities and equipment which are paid based on actual costs incurred.

Future minimum payments for operating leases with initial or remaining terms of one year or more as of December 31, 2021, were as follows:

	December 31, 2021
2022	$ 801,183
2023	870,782
2024	891,596
2025	912,410
2026	933,224
2027 and thereafter	4,985,873
Total lease payments	$ 9,395,068
Less: Interest	(3,284,491)
Present value of lease liabilities	$ 6,110,577

7. Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2021	December 31, 2020
Accrued salaries, bonus, and benefits	$ 1,515,553	$ 2,044,826
Accrued licenses and maintenance fees	483,879	483,879
Accrued warranties	241,451	157,615
Accrued taxes	177,399	172,744
Accrued professional services	73,000	138,359
Accrued lease deposit payable	124,286	124,286
Other	131,203	218,757
Total accrued liabilities	2,746,771	3,340,466
Less: Long term accrued liabilities	(218,582)	(131,231)
Total current accrued liabilities	$ 2,528,189	$ 3,209,235

8. Debt and Credit Facilities

The Company had a working capital line of credit with its primary lender, Silicon Valley Bank that matured on June 30, 2020 and was not renewed.

The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted on March 27, 2020 in the United States. Among the provisions contained in the CARES Act was the creation of the Paycheck Protection Program that provides for Small Business Administration ("SBA") Section 7(a) loans for qualified small businesses. In general, the loan could be forgiven as long as the funds were used for payroll related expenses as well as rent and utilities paid during the twenty-four-week period from the date of the loan and as long as certain headcount and salary/wage levels were maintained. On April 10, 2020, the Company was informed by its lender, Midwest BankCentre (the "Bank"), that the Bank received approval from the SBA to fund the Company's request for a loan under the SBA's Paycheck Protection Program ("PPP Loan"). Per the terms of the PPP Loan, the Company received total proceeds of approximately $2.2 million from the Bank on April 20, 2020. In accordance with the loan forgiveness requirements of the CARES Act, the Company used the full proceeds from the PPP Loan primarily for payroll costs, rent and utilities. In March 2021, the Company applied for loan forgiveness and in June 2021, full loan forgiveness was granted by the SBA. The Company recognized a net gain from debt extinguishment of approximately $2.2 million.

In accordance with general accounting principles for fair value measurement, the Company's debt was measured at fair value (Level 2), which approximated the carrying value of the debt as of December 31, 2020.

9. Convertible Preferred Stock and Stockholders' Equity

The holders of common stock are entitled to one vote for each share held and to receive dividends whenever funds are legally available and when declared by the Board of Directors subject to the rights of holders of all classes of stock having priority rights as dividends. No dividends have been declared or paid as of December 31, 2021.

2020 Equity Financing

On May 25, 2020, the Company entered into a Securities Purchase Agreement with certain accredited investors, whereby it, in a direct registered offering, agreed to issue and sell to the investors an aggregate of 3,658,537 shares of the Company's common stock, $0.001 par value per share, at a price of $4.10 per share. The Company received net proceeds of approximately $15.0 million, after offering expenses.

Series B Convertible Preferred Stock

On August 7, 2019, the Company entered into a Securities Purchase Agreement with certain institutional and other accredited investors, whereby it, as part of a private placement, agreed to issue and sell to the investors 5,610,121 shares of the Company's Series B Convertible Preferred Stock, $0.001 par value per share which are convertible into shares of the Company's common stock, at a price of $2.05 per share. The Series B Preferred Stock, which is a common stock equivalent but non-voting and with a blocker on conversion if the holder would exceed a specified threshold of voting security ownership, is convertible into common stock on a one-for-one basis, subject to adjustment for events such as stock splits, combinations and the like as provided in the Purchase Agreement. The Series B Convertible Preferred Stock is reported in the stockholders' equity section of the Company's balance sheet.

Series A Convertible Preferred Stock and Warrants

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

The SPA Warrants were modified on February 28, 2018 to allow for a reduction in the exercise price from $0.70 per share to $0.28 per share for a period between March 1, 2018 and March 5, 2018 and to modify certain beneficial ownership limitations and to eliminate certain redemption rights, resulting in, among other things, the exercise of a substantial number of the SPA Warrants for cash. The remaining unexercised 15,385 Warrants expired on September 29, 2021.

2021 CEO Performance Award Unit Grant

On February 23, 2021, the Company`s Board of Directors, upon recommendation of the Compensation Committee, approved the grant of the CEO Performance Award to the Company's Chief Executive Officer. The CEO Performance award is a 10-year performance award of up to 13,000,000 shares, tied to the achievement of market capitalization milestones and subject to minimum service requirements.

As detailed in the table below, the CEO Performance Award consists of ten vesting tranches. The first market capitalization milestone is $1.0 billion, and each of the remaining nine market capitalization milestones are in additional $500 million increments, up to $5.5 billion.

Tranche #	No. of Shares Subject to PSU	Market Capitalization Milestones
1	1,000,000	$ 1,000,000,000
2	1,500,000	$ 1,500,000,000
3	1,500,000	$ 2,000,000,000
4	2,000,000	$ 2,500,000,000
5	1,000,000	$ 3,000,000,000
6	1,000,000	$ 3,500,000,000
7	1,000,000	$ 4,000,000,000
8	2,000,000	$ 4,500,000,000
9	1,000,000	$ 5,000,000,000
10	1,000,000	$ 5,500,000,000
Total:	**13,000,000**	

Each tranche represents a portion of the PSUs covering the number of shares outlined in the table above. Each tranche vests upon (i) satisfaction of the market capitalization milestones and (ii) continued employment as CEO of the Company from the grant date through December 31, 2030. Absent an earlier termination, the PSUs will expire on December 31, 2030. If our CEO ceases employment as CEO of the Company for any reason including death, disability, termination for cause or without cause (as defined in the award agreement), or if he voluntary terminates after service as CEO for at least five years, the remaining service period will be waived and he will retain any PSUs that have vested through the date of termination.

The Company received Shareholder approval at its annual meeting on May 20, 2021 for shares to be issued under the award.

The market capitalization requirement is considered a market condition under FASB Accounting Standards Codification Topic 718 “Compensation – Stock Compensation” and is estimated on the grant date using Monte Carlo simulations. Recognition of stock-based compensation expense of all the tranches commenced on February 23, 2021, the date of grant, as the probability of meeting the ten market capitalization milestones is not considered in determining the timing of expense recognition. The expense will be recognized on an accelerated basis through 2030. Key assumptions for estimating the performance-based awards fair value at the date of grant included share price on grant date, volatility of the Company’s common stock price, risk free interest rate, and grant term.

Total stock-based compensation recorded as operating expense for the CEO Performance Award was $6.1 million for the year ended December 31, 2021. As of December 31, 2021, the Company had approximately $51.3 million of total unrecognized stock-based compensation expense remaining under the CEO Performance Award assuming the grantee’s continued employment as CEO of the Company, or in a similar capacity, through 2030.

Stock Award Plans

The Company has various stock plans that permit the Company to provide incentives to employees, directors, and third-party consultants of the Company in the form of equity compensation. In July 2012, the Compensation Committee of the Board of Directors adopted the 2012 Stock Incentive Plan (the “Plan”) which was subsequently approved by the Company’s shareholders. This plan replaced the 2002 Stock Incentive Plan which expired on March 25, 2012.

On May 20, 2021, the shareholders approved an amendment to the Plan, which was previously approved and adopted by the Compensation Committee of the Board of Directors of the Company. Under the amendment on May 20, 2021, the number of shares authorized for issuance under the Plan was increased by four million shares. As of December 31, 2021, the Company had 4,909,848 remaining shares of the Company’s common stock to provide for current and future grants under its various equity plans.

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

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

The exercise price of options to non-employee directors shall not be less than 100% of the fair value of the stock subject to the option on the date the option is granted. Annual grants to directors generally vest between one and five years following grant.

As of December 31, 2021, the total compensation cost related to options, stock appreciation rights, and non-vested stock granted to employees and non-employees under the Company's stock award plans but not yet recognized was approximately $5.1 million, excluding compensation not yet recognized related to the CEO Performance Award discussed above. This cost will be amortized over a period of up to four years over the underlying estimated service periods and will be adjusted for subsequent changes in actual forfeitures and anticipated vesting periods.

A summary of the option and stock appreciation rights activity for the year ended December 31, 2021 is as follows:

	Number of Options/SARs	Range of Exercise Price	Weighted Average Exercise Price per Share
Outstanding, December 31, 2020	2,456,979	$0.74 - $35.20	$ 2.90
Granted	942,000	$6.09 - $9.87	7.10
Exercised	(358,613)	$0.74 - $4.52	1.93
Forfeited	(222,354)	$0.74 - $35.20	6.99
Outstanding, December 31, 2021	2,818,012	$0.74 - $9.87	$ 4.10

As of December 31, 2021, the weighted average remaining contractual life of the options and stock appreciation rights outstanding was 7.77 years. Of the 2,818,012 options and stock appreciation rights that were outstanding as of December 31, 2021, 1,229,610 were vested and exercisable with a weighted average exercise price of $2.33 per share and a weighted average remaining term of 6.7 years.

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

	Year Ended December 31, 2021				
Range of Exercise Prices	Options Outstanding	Weighted Average Remaining Life	Weighted Average Exercise Price	Number of Options Currently Exercisable	Weighted Average Exercise Price Per Vested Share
$0.00 - $1.00	397,306	6.17	$ 0.74	371,534	$ 0.74
$1.01 - $2.00	60,037	3.52	$ 1.76	57,312	$ 1.79
$2.01- $4.00	698,237	6.99	$ 2.10	458,847	$ 2.08
$4.01 - $10.00	1,662,432	8.63	$ 5.83	341,917	$ 4.48
	2,818,012	7.77	$ 4.10	1,229,610	$ 2.33

The intrinsic value of options and stock appreciation rights is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company's common stock for the options and stock appreciation rights that were in-the-money at December 31, 2021. The intrinsic value of the options and stock appreciation rights outstanding at December 31, 2021 was approximately $6.6 million based on a closing share price of $6.20 on December 31, 2021. There were 1,229,610 fully vested options or stock appreciation rights outstanding at December 31, 2021 with an exercise price less than the closing stock price on December 31, 2021. During the year ended December 31, 2021 the aggregate intrinsic value of options and stock appreciation rights exercised under the Company's stock option plans was $1.9 million.

The intrinsic value of the options and stock appreciation rights outstanding at December 31, 2020 was approximately $5.9 million based on a closing share price of $5.09 on December 31, 2020. There were 884,654 fully vested options or stock appreciation rights outstanding at December 31, 2020 with an exercise price less than the closing stock price on December 31, 2020. During the year ended December 31, 2020 the aggregate intrinsic value of options and stock appreciation rights exercised under the Company's stock option plans was $0.4 million.

The weighted average grant date fair value of options and stock appreciation rights granted during the years ended December 31, 2021 and 2020 was $7.10 per share and $4.49 per share, respectively.

A summary of the restricted stock unit activity for the year ended December 31, 2021 is as follows:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value per Unit
Outstanding, December 31, 2020	1,112,473	$ 2.46
Granted	378,204	$ 7.18
Vested	(325,954)	$ 3.97
Forfeited	-	-
Outstanding, December 31, 2021	1,164,723	$ 3.57

The intrinsic value of restricted stock units outstanding at December 31, 2021 was $7.2 million based on a closing share price of $6.20 as of December 31, 2021. During the year ended December 31, 2021, the aggregate intrinsic value of restricted stock units vested was $2.4 million determined at the date of vesting.

2009 Employee Stock Purchase Plan

In 2009, the Company adopted its 2009 Employee Stock Purchase Plan ("ESPP"). In June 2014 and again in May 2019, the Company's stockholders approved an amendment of the ESPP to increase the number of shares authorized for issuance under the ESPP by 250,000 shares. Eligible employees have the opportunity to participate in a new purchase period every 3 months. Under the terms of the plan, employees can purchase up to 15% of their compensation of the Company's common stock, subject to an annual maximum of $25,000, at 95% of the fair market value of the stock at the end of the purchase period, subject to certain plan limitations. As of December 31, 2021, there were 209,437 remaining shares available for issuance under the Employee Stock Purchase Plan.

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

	December 31, 2021	December 31, 2020
Warrants	-	15,385
Series A Convertible Preferred Stock	45,031,944	45,278,096
Series B Convertible Preferred Stock	5,610,121	5,610,121
Performance Share Unit Plan	13,000,000	-
Stock award plans	4,909,848	2,054,941
Employee Stock Purchase Plan	209,437	229,136
	68,761,350	53,187,679

The remaining unexercised 15,385 SPA Warrants expired on September 29, 2021 and no warrants were outstanding at December 31, 2021.

10. Fair Value Measurements

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

Level 1: Values are based on unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2: Values are based on quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or other model-based valuation techniques for which all significant assumptions are observable in the market.

Level 3: Values are generated from model-based techniques that use significant assumptions not observable in the market.

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

	Fair Value Measurement Using			
	Total	Quoted Prices in Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets at December 31, 2021:				
Cash invested in money market accounts	$ 1,405,831	$ —	$ 1,405,831	$ —
Total assets at fair value	$ 1,405,831	$ —	$ 1,405,831	$ —
Assets at December 31, 2020:				
Cash invested in money market accounts	$ 1,429,331	$ —	$ 1,429,331	$ —
Total assets at fair value	$ 1,429,331	$ —	$ 1,429,331	$ —

The Company did not have any financial liabilities valued at fair value on a recurring basis as of December 31, 2021 or December 31, 2020.

Level 1

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

Level 2

The Company's financial assets consist of restricted cash and cash equivalents invested in money market funds in the amount of $1,405,831 and $1,429,331 at December 31, 2021 and December 31, 2020, respectively. These assets are classified as Level 2, as described above, and total interest income recorded for these investments was insignificant during the years ended December 31, 2021 and December 31, 2020.

Level 3

The Company does not have any financial assets or liabilities classified as Level 3.

11. Income Taxes

The provision for income taxes consists of the following:

	Year Ended December 31,	
	2021	2020
Deferred:		
Federal	$ (1,723,223)	$ (1,172,382)
State and local	1,266	22,240
	(1,721,957)	(1,150,142)
Valuation allowance	1,721,957	1,150,142
	$ —	$ —

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

	Year Ended December 31,	
	2021	2020
U.S. statutory income tax rate	21.0%	21.0%
State and local taxes, net of federal tax benefit	1.4%	1.8%
Stock compensation permanent differences between book and tax	(10.1)%	-%
Other permanent differences between book and tax	5.3%	(3.5)%
State rate adjustments	(1.5)%	(2.2)%
Prior year return-to-provision adjustment	0.0%	0.2%
Valuation allowance	(16.1)%	(17.3)%
Effective income tax rate	—%	—%

The stock compensation permanent difference relates to the February 23, 2021 Board approved grant of the Performance Share Unit Award pursuant to the CEO Performance Share Unit Award Agreement (the "PSU Agreement") to David L. Fischel, the Company's Chief Executive Officer. Total stock-based compensation attributed to the PSU Agreement was $6.1 million for the year ended December 31, 2021 of which only a portion was allowed as a tax deduction due to Internal Revenue Code Section 162 (m) limitations. Included in other permanent differences between book and tax in the above table are differences such as incentive stock option expenses, nondeductible meals and entertainment and stock compensation shortfalls. The state rate adjustments are a result of changes in apportionment and various state rate law changes.

The components of the deferred tax asset are as follows:

	Year Ended December 31,	
	2021	2020
Current accruals	$ 1,068,263	$ 1,329,681
Operating lease liabilities	1,421,910	536,307
Deferred revenue	145,724	9,412
Depreciation and amortization	521,993	952,208
Deferred compensation	1,111,150	874,403
Net operating loss carryovers	27,219,641	25,264,611
Deferred tax assets	31,488,681	28,966,622
Valuation allowance	(30,100,904)	(28,378,947)
Net deferred tax assets before deferred tax liabilities	1,387,777	587,675
Operating lease right-of-use assets	(1,334,462)	(524,105)
Capitalized compensation costs	(53,315)	(63,570)
Net deferred tax assets	$ —	$ —

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

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. The Company considers projected future taxable income and tax planning strategies in making this assessment. Based upon the level of historical taxable losses, and projections for future periods over which the deferred tax assets are deductible, the Company determined that a 100% valuation allowance of net deferred tax assets was appropriate.

On December 21, 2020, Congress approved the Consolidations Appropriations Act, 2021 (the "Appropriations Act"), which was signed into law by the President on December 27, 2020. The Appropriations Act funds the federal government to the end of the fiscal year and provides further COVID-19 economic relief. One of the business provisions included in the Appropriations Act is clarification of the income tax deductibility of business expenses that were paid for with the Paycheck Protection Program funds. The Company will continue to monitor for additional legislation related to COVID-19 and its impact on our results of operations.

As of December 31, 2021, we had gross federal net operating loss carryforwards of approximately $120.1 million. The federal net operating loss carryforwards reflect accumulated book losses reduced for the 2013 IRC Section 382 ownership change limitation of $255.6 million and approximately $123.3 million of book/tax differences and expiration of unused carryforwards. The federal net operating loss carryforwards generated prior to the 2018 tax year will expire between 2030 and 2037. The federal net operating loss generated during and beyond 2018 will be carried forward indefinitely as a result of changes in the tax law following the Tax Cuts and Jobs Act. As of December 31, 2021, we had gross state net operating loss carryforward of approximately $37.6 million which will expire at various dates between 2022 and 2041 if not utilized.

The Company files income tax returns in the U.S. federal jurisdiction and various state and local jurisdictions. As the Company has a federal net operating loss carryforward from the year ended December 31, 2000 forward, all tax years from 2000 forward are subject to examination. As states have varying carryforward periods, and the Company has recently entered into additional states, the states are generally subject to examination for the previous 10 years or less.

At December 31, 2021 and 2020, the Company had approximately $0.1 million in reserves for uncertain tax positions. The Company recognizes interest accrued, if any, net of tax and penalties, related to unrecognized tax benefits as components of the income tax provision, as applicable. As of December 31, 2021, accrued interest and penalties were less than $0.1 million.

12. Net Loss per Share

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

	Year Ended December 31,	
	2021	**2020**
Net loss	$ (10,715,623)	$ (6,646,459)
Cumulative dividend on Series A Convertible Preferred Stock	(1,345,031)	(1,369,421)
Net loss attributable to common stockholders	$ (12,060,654)	$ (8,015,880)
Weighted average number of common shares and equivalents:	75,558,233	72,746,268
Basic EPS	$ (0.16)	$ (0.11)
Diluted EPS	$ (0.16)	$ (0.11)

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

	December 31,	
	2021	**2020**
Shares issuable upon vesting/exercise of:		
Options to purchase common stock	2,818,012	2,456,979
Series A Convertible Preferred Stock and Accumulated Dividends	45,306,189	43,483,062
Series B Convertible Preferred Stock	5,610,121	5,610,121
Restricted stock units	1,164,723	1,112,473
Warrants	-	15,385
	54,899,045	52,678,020

13. Employee Benefit Plan

The Company offers employees the opportunity to participate in a 401(k) plan and matches employee contributions up to 3% of each participating employee's compensation. The Company recognized expense of approximately $0.3 million for the years ended December 31, 2021 and 2020.

14. Product Warranty Provisions

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

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

	December 31, 2021	**December 31, 2020**
Warranty accrual, beginning of the fiscal period	$ 157,615	$ 141,697
Accrual adjustment for product warranty	198,595	49,974
Payments made	(114,759)	(34,056)
Warranty accrual, end of the fiscal period	$ 241,451	$ 157,615

15. Commitments and Contingencies

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

In April 2021, the Company entered into a letter of credit pursuant to the Lease agreement totaling approximately $1.8 million to be delivered in four equal installments of which the first was delivered in April 2021, the second was delivered in July 2021 and the third was delivered in October 2021, for approximately $0.4 million each. The amount available under this letter of credit will automatically reduce by one fortieth at the end of each month during the lease term.

As discussed further in Part I, Item 3, in response to an April 29, 2021 punitive class action complaint, in August 2021, the Company agreed to pay $675,000 to plaintiff's counsel for attorneys' fees and expenses in full satisfaction of the claims in the matter. The Chancery Court has not been asked to review, and will pass no judgment on, the payment of the attorneys' fees and expenses or their reasonableness.

16. Segment Information

The Company considers reporting segments in accordance with general accounting principles for disclosures about segments of an enterprise and related information. The Company's system and disposable devices are developed and marketed to a broad base of hospitals in the United States and internationally. The Company considers all such sales to be part of a single operating segment. Geographic revenues for the years ended December 31, 2021 and 2020 were as follows:

	Year Ended December 31,	
	2021	**2020**
United States	$ 20,359,558	$ 17,442,883
International	14,661,304	9,187,152
Total	$ 35,020,862	$ 26,630,035

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

17. Subsequent Events

None.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Report on Internal Control Over Financial Reporting

As of December 31, 2021, the Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, the Company's disclosure controls and procedures were effective.

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. The Company's management assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. In making the assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) in Internal Control—Integrated Framework. Based on our assessment, our management has concluded that our internal control over financial reporting is effective as of December 31, 2021.

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

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

ITEM 9B. OTHER INFORMATION

None.

PART III

Certain information required by Part III is omitted from this Report on Form 10-K since we intend to file our definitive Proxy Statement for our next Annual Meeting of Stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended (the "Proxy Statement"), no later than April 30, 2022, and certain information to be included in the Proxy Statement is incorporated herein by reference.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

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

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

Stereotaxis, Inc.
Attn: Kimberly R. Peery
710 North Tucker Boulevard, Suite 110
St. Louis, MO 63101
314-678-6100

We intend to promptly disclose any amendments to, or waivers from, any provision of the Code of Business Conduct and Ethics by posting the relevant material on our website (www.stereotaxis.com) in accordance with SEC rules.

The following is information with respect to our executive officers:

David L. Fischel
Chief Executive Officer and Chairman of the Board since February 2017
Director since September 2016

Mr. Fischel, 35, has served as Chief Executive Officer and Chairman of the Board since February 2017. He has served as a director of Stereotaxis since leading the equity investment and positive strategic initiatives announced in September 2016. He has served for over ten years as Principal and portfolio manager for medical device investments at DAFNA Capital Management, LLC. In addition to his research responsibilities, Mr. Fischel has been deeply involved in all aspects of DAFNA Capital's operations including legal, accounting, IT, compliance, human resources and marketing. Prior to joining DAFNA Capital, he was a research analyst at SCP Vitalife, a healthcare venture capital fund. Mr. Fischel completed his B.S. magna cum laude in Applied Mathematics with a minor in Accounting at the University of California at Los Angeles and received his MBA from Bar-Ilan University in Tel Aviv. He is a Certified Public Accountant, Chartered Financial Analyst and Chartered Alternative Investment Analyst.

Kimberly R. Peery
Chief Financial Officer
Officer since October 2019

Ms. Peery, 53, was appointed as the Chief Financial Officer in October 2019. She joined the Company in 2003 and has held various positions of increasing responsibilities including Vice President of Finance and Information Systems since November 2016 and Controller from April 2013 to November 2016. Prior to joining the Company, she served as a controller at various private companies. Ms. Peery is a Certified Public Accountant.

ITEM 11. EXECUTIVE COMPENSATION

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

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

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

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

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

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

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

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

— Schedule II: Valuation and Qualifying Accounts.

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

(3) Exhibits

See Exhibit Index appearing on page 68 herein.

SCHEDULE II
VALUATION AND QUALIFYING ACCOUNTS
FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020

	Balance at Beginning of Year	Additions Charged to Cost and Expenses	Deductions	Balance at the End of Year
Allowance for doubtful accounts and returns:				
Year ended December 31, 2021	$ 123,614	96,212	(39,913)	$ 179,913
Year ended December 31, 2020	$ 380,212	(29,411)	(227,187)	$ 123,614
Allowance for inventories valuation:				
Year ended December 31, 2021	$ 3,075,520	49,267	(960,012)	$ 2,164,775
Year ended December 31, 2020	$ 3,895,451	126,616	(946,547)	$ 3,075,520

EXHIBIT INDEX

Number	Description
3.1a	Restated Articles of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
3.1b	Certificate of Amendment to Amended and Restated Certificate of Incorporation, incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K (File No. 000-50884) filed on July 10, 2012.
3.2	Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on September 30, 2016.
3.3	Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2004.
3.4	Certificate of Designations, Preferences and Rights of Series B Convertible Preferred Stock, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on August 09, 2019.
4.1	Form of Specimen Stock Certificate, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 4.1.
4.2	Form of Warrant issued pursuant to that certain Securities Purchase Agreement, dated September 26, 2016, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K (file No. 001-36159) filed on September 28, 2016.
4.3	Form of Amended and Restated Warrant of Stereotaxis, Inc. issued pursuant to that certain Consent and Amendment, dated as of February 28, 2018, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on March 6, 2018.
4.4	Description of Registrant's securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, incorporated by reference to Exhibit 4.7 of the Registrant's Form 10-K/A (File No. 001-36159) filed on April 9, 2021.
10.1a#	Amended and Restated Stereotaxis, Inc. 2012 Stock Incentive Plan, effective February 9, 2016, incorporated by reference to Exhibit 10.2 of the Registrant's Form 10-Q (File No. 001-36159) for the fiscal quarter ended June 30, 2016.
10.1b#	Amended and Restated Stereotaxis, Inc. 2012 Stock Incentive Plan, effective February 22, 2017, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 001-36159) for the fiscal quarter ended June 30, 2017.
10.1c#	Amended and Restated Stereotaxis, Inc. 2012 Stock Incentive Plan, effective February 11, 2021, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q ((File No. 001-36159) for the fiscal quarter ended June 30, 2021.
10.1d#	Form of Restricted Share Unit Terms of Award Under Stereotaxis, Inc. 2012 Stock Incentive Plan, March 5, 2013, incorporated by reference to Exhibit 10.1d of the Registrant's Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2012.
10.1e#	Form of Restricted Share Unit Terms of Award Under Stereotaxis, Inc. 2012 Stock Incentive Plan, Director Award, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 001-36159) for the fiscal quarter ended March 31, 2017.
10.1f#	Form of Incentive Stock Option Terms of Award Under Stereotaxis, Inc. 2012 Stock Incentive Plan, incorporated by reference to Exhibit 10.1f of the Registrant's Form 10-K (File No. 001-36159) filed on March 20, 2018 for the fiscal year ended December 31, 2017.
10.1g#	Form of Non-Qualified Stock Option Terms of Award Under Stereotaxis, Inc. 2012 Stock Incentive Plan, incorporated by reference to Exhibit 10.1g of the Registrant's Form 10-K (File No. 001-36159) filed on March 20, 2018 for the fiscal year ended December 31, 2017.
10.1h#	Form of Restricted Share Unit Terms of Award Under Stereotaxis, Inc. 2012 Stock Incentive Plan, incorporated by reference to Exhibit 10.2 of Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2012.

10.2#	2002 Stock Incentive Plan, as amended and restated June 10, 2009, incorporated by reference to Exhibit 10.2 of the Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2009.
10.3#	Amended and Restated Stereotaxis, Inc. Employee Stock Purchase Plan, as adopted March 27, 2014, incorporated by reference to Exhibit 10.5 of the Registrant's Form 10-Q (File No. 001-36159) for the fiscal quarter ended June 30, 2014.
10.4#	Summary of Non-Employee Director Compensation Program effective January 1, 2017, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 001-36159) for the fiscal quarter ended March 31, 2017.
10.5#	Summary of Non-Employee Director Compensation Program effective July 1, 2021, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10Q (File No. 001-36159) for the fiscal quarter ended September 30, 2021.
10.6#	Executive Employment Agreement, dated December 17, 2020, by and between Stereotaxis, Inc. and David L. Fischel, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on December 18, 2020.
10.7#	Performance Share Unit Award Agreement, dated February 23, 2021, by and between Stereotaxis, Inc. and David L. Fischel, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on February 24, 2021.
10.8a†	Collaboration Agreement dated June 8, 2001, between the Registrant and Siemens AG, Medical Solutions, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.9.
10.8b†	Extended Collaboration Agreement dated May 27, 2003, between the Registrant and Siemens AG, Medical Solutions, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.10.
10.8c†	Amendment to Collaboration Agreement dated May 5, 2006, between the Company and Siemens Aktiengesellschaft, Medical Solutions, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2006.
10.9a†	Development and Supply Agreement dated May 7, 2002, between the Registrant and Biosense Webster, Inc., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.11.
10.9b†	Amendment to Development and Supply Agreement dated November 3, 2003, between the Registrant and Biosense Webster, Inc., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.12.
10.9c†	Alliance Expansion Agreement, dated as of May 4, 2007, between Biosense Webster, Inc. and the Registrant, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended June 30, 2007.
10.9d†	Second Amendment to Development Alliance and Supply Agreement, dated as of July 18, 2008, between the Registrant and Biosense Webster, Inc., incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended September 30, 2008.
10.9e	Third Amendment to Development Alliance and Supply Agreement with Biosense Webster, Inc. effective as of December 21, 2009, incorporated by reference to Exhibit 10.22 of the Registrant's Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2009.
10.9f	Fourth Amendment to Development Alliance and Supply Agreement with Biosense Webster, Inc., effective May 1, 2010, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 000-50884) for the fiscal quarter ended March 31, 2010.
10.9g	Fifth Amendment to Development Alliance and Supply Agreement with Biosense Webster, Inc., dated as of July 30, 2010, incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K/A (File No. 000-50884) filed on August 3, 2010.
10.9h†	Sixth Amendment and Catheter and Mapping System Extension to Development Alliance and Supply Agreement with Biosense Webster, Inc., dated January 3, 2011, effective as of December 17, 2010, incorporated by reference to Exhibit 10.13h of the Registrant's Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2010.

10.9i	Seventh Amendment to the Development Alliance and Supply Agreement with Biosense Webster, Inc., effective December 5, 2011, incorporated by reference to Exhibit 10.13i of the Registrant's Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2011.
10.9j	Eighth Amendment to the Development Alliance and Supply Agreement effective June 19, 2018, among the Company and Biosense Webster, Inc., incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K (File No. 001-36159) filed on June 25, 2018.
10.10	Form of Indemnification Agreement between the Registrant and its directors and executive officers, incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.14.
10.11†	Letter Agreement, effective October 6, 2003, between the Registrant and Philips Medizin Systeme G.m.b.H., incorporated by reference to the Registration Statement on Form S-1 (File No. 333-115253) originally filed with the Commission on May 7, 2004, as amended thereafter, at Exhibit 10.16.
10.12a†	Office Lease dated November 15, 2004, between the Registrant and Cortex West Development I, LLC, incorporated by reference to Exhibit 10.39 of the Registrant's Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2004.
10.12b	Amendment to Office Lease dated November 30, 2007, between the Registrant and Cortex West Development I, LLC, incorporated by reference to Exhibit 10.22 of the Registrant's Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2007.
10.12c	Second Amendment to Office Lease dated May 1, 2013, between Registrant and Wexford 4320 Forest Park, LLC, successor to Cortex West Development I, LLC, incorporated by reference to Exhibit 10.17c of the Registrant's Form 10-K (File No. 001-36159) for the fiscal year ending December 31, 2013.
10.12d	Third Amendment to Office Lease dated August 14, 2013, between Registrant and Wexford 4320 Forest Park, LLC, successor to Cortex West Development I, LLC, incorporated by reference to Exhibit 10.17d of the Registrant's Form 10-K (File No. 001-36159) for the fiscal year ending December 31, 2013.
10.12e	Fourth Amendment to Office Lease, effective October 1, 2015, between Registrant and Wexford 4320 Forest Park, LLC, successor to Cortex West Development I, LLC, incorporated by reference to Exhibit 10.13e of the Registrant's Form 10-K (File No. 001-36159) for the fiscal year ending December 31, 2015.
10.12f	Fifth Amendment to Office Lease, effective January 10, 2019, between Registrant and VTR LS 4320 FOREST PARK, LLC successor to Cortex West Development I, LLC, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on January 10, 2019.
10.12g	Office Lease dated February March 1, 2021, between the Registrant and Globe Building Company, GP, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on March 4, 2021.
10.12h	First Amendment to Office Lease dated March 30, 2021, between Registrant and Globe Building Company, GP incorporated by reference to Exhibit 10.1b of the Registrant's Form 10-Q (File No. 001-36159) filed on May 13, 2021.
10.12i	Second Amendment to Office Lease dated November 05, 2021, between Registrant and Globe Building Company filed herewith.
10.13a	Second Amended and Restated Loan and Security Agreement, effective November 30, 2011, by and among the Company, Stereotaxis International, Inc. and Silicon Valley Bank incorporated by reference to Exhibit 10.19f of the Registrant's Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2011.
10.13b	First Loan Modification Agreement (Domestic), between the Company, Stereotaxis International, Inc. and Silicon Valley Bank, dated March 30, 2012, incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K (File No. 000-50884) filed on April 2, 2012.
10.13c	Second Amendment to the Amended and Restated Loan and Security Agreement (Domestic) dated May 1, 2012, between the Company, Stereotaxis International, Inc. and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 000-50884) filed on May 2, 2012.
10.13d	Third Amendment to Amended and Restated Loan and Security Agreement (Domestic), dated May 7, 2012, between the Company, Stereotaxis International, Inc. and Silicon Valley Bank, incorporated by reference to Exhibit 10.75 of the Registrant's Registration Statement on Form S-1 (File No. 000-50884) filed May 23, 2012.

10.13e	Fourth Loan Modification Agreement (Domestic), dated December 28, 2012, between the Company, Stereotaxis International, Inc. and Silicon Valley Bank incorporated by reference to Exhibit 10.19f of the Registrant's Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2012.
10.13f	Fifth Loan Modification Agreement (Domestic) dated March 29, 2013 between the Company, Stereotaxis International, Inc. and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 000-50884) filed on April 1, 2013.
10.13g	Sixth Loan Modification and Waiver Agreement (Domestic), dated June 28, 2013, between the Company, Stereotaxis International, Inc., and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 000-50884) filed on July 1, 2013.
10.13h	Seventh Loan Modification and Waiver Agreement (Domestic), dated July 31, 2013, between the Company, Stereotaxis International, Inc. and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 000-50884) filed on August 2, 2013.
10.13i	Eighth Loan Modification Agreement (Domestic), dated August 30, 2013, between the Company, Stereotaxis International, Inc. and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 000-50884) filed on September 3, 2013.
10.13j	Ninth Loan Modification Agreement (Domestic), dated March 28, 2014, between the Company, Stereotaxis International, Inc. and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on March 31, 2014.
10.13k	Tenth Loan Modification Agreement (Domestic), dated March 27, 2015, between Silicon Valley Bank, the Company, and Stereotaxis International, Inc., incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on March 30, 2015.
10.13l	Eleventh Loan Modification Agreement (Domestic), dated May 10, 2016, between the Company, Stereotaxis International, Inc., and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 001-36159) filed on May 11, 2016.
10.13m	Third Amended and Restated Loan and Security Agreement, effective November 7, 2017, among the Company, Stereotaxis International, Inc., and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 001-36159) for the fiscal quarter ended September 30, 2017.
10.13n	First Amendment to Third Amended and Restated Loan and Security Agreement, dated April 26, 2018, between Silicon Valley Bank, the Company, and Stereotaxis International, Inc., incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on April 30, 2018.
10.13o	Second Amendment to and Reinstatement of Third Amended and Restated Loan and Security Agreement, dated June 27, 2019, between Silicon Valley Bank, the Company, and Stereotaxis International, Inc., incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on July 1, 2019.
10.14	Securities Purchase Agreement, dated September 26, 2016, between the Company and certain investors named therein, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on September 28, 2016.
10.15	Registration Rights Agreement, dated September 26, 2016, between the Company and certain purchasers named therein, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on September 28, 2016.
10.16	Consent and Amendment, dated as of February 28, 2018, by and between Stereotaxis, Inc. and the holders identified on the signature pages thereto, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8–K (File No. 001-36159) filed on March 6, 2018.
10.17	Securities Purchase Agreement dated as of August 7, 2019 by and among Stereotaxis, Inc. and the investors listed on the Schedule of Buyers attached thereto, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8–K (File No. 001-36159) filed on August 8, 2019.
10.18	Registration Rights Agreement dated as of August 7, 2019 by and among Stereotaxis, Inc. and the Buyers party thereto, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8–K (File No. 001-36159) filed on August 8, 2019.

10.19	Loan Agreement, dated April 20, 2020, between the Registrant and Midwest BankCentre, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q (File No. 001-36159) filed on May 11, 2020.
10.20	Securities Purchase Agreement between the Company and the Investors, dated as of May 25, 2020 incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-36159) filed on May 25, 2020.
21.1	List of Subsidiaries of the Registrant, incorporated by reference to Exhibit 21.1 of the Registrant's Form 10-K (File No. 000-50884) for the fiscal year ended December 31, 2009.
23.1	Consent of Ernst & Young LLP.
31.1	Rule 13a-14(a)/15d-14(a) Certification (pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, executed by Chief Executive Officer).
31.2	Rule 13a-14(a)/15d-14(a) Certification (pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, executed by Chief Financial Officer).
32.1	Section 1350 Certification (pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Chief Executive Officer).
32.2	Section 1350 Certification (pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Chief Financial Officer).
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
#	Indicates management contract or compensatory plan.
†	Confidential treatment granted as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission.
††	Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission.

SIGNATURES

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

STEREOTAXIS, INC. (Registrant)

Date: March 10, 2022 By: */s/ David L. Fischel*

David L. Fischel
Chief Executive Officer

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

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

Signature	Title	Date
/s/ David L. Fischel **David L. Fischel**	Chairman of the Board of Directors and Chief Executive Officer (principal executive officer)	March 10, 2022
/s/ Kimberly R. Peery **Kimberly R. Peery**	Chief Financial Officer (principal financial officer and principal accounting officer)	March 10, 2022
/s/ David W. Benfer **David W. Benfer**	Director	March 10, 2022
/s/ Nathan Fischel **Nathan Fischel**	Director	March 10, 2022
/s/ Myriam J. Curet Myriam J. Curet	Director	March 10, 2022
/s/ Arun Menawat **Arun Menawat**	Director	March 10, 2022
/s/ Robert J. Messey **Robert J. Messey**	Director	March 10, 2022
/s/ Ross B. Levin **Ross B. Levin**	Director	March 10, 2022

Exhibit 10.12i

SECOND AMENDMENT TO LEASE AGREEMENT

THIS SECOND AMENDMENT TO LEASE AGREEMENT (the **"Second Amendment")** is made as of the ___ day of October, 2021 ("Effective Date"), by and between Globe Building Company, a Missouri general partnership **("Landlord"),** and Stereotaxis, Inc., a Delaware corporation **("Tenant").**

WITNESSETH:

WHEREAS, Landlord and Tenant entered into that certain Lease Agreement dated March 1, 2021 (the **"Original Lease"),** for space on the ground floor of the building known as the Globe Building, located at 710 N. Tucker, St. Louis, Missouri; and

WHEREAS, the parties hereto modified the Original Lease by the First Amendment to Lease Agreement dated March 30, 2021 (as modified, the "**First Amended Lease**"); and

WHEREAS, the parties hereto have agreed to modify the First Amended Lease in the manner hereinafter described (the First Amended Lease as amended by this Second Amendment to Lease is referred to as the "**Lease**"); and

WHEREAS, words and phrases having defined meanings in the Lease shall have the same respective meanings when used herein, unless otherwise expressly defined herein.

NOW, THEREFORE, in consideration of the mutual covenants herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree as follows:

1. Creation of Final Tenant Improvement Bid and Final Tenant Improvement Plans. Exhibit E, Section A (iii) to the Lease describes the procedure for the modification of Approved Construction Document Tenant Improvement Plans and Preliminary MEP Plans into the final plans that will be used to construct the Tenant Improvements. Tenant and Landlord have followed that procedure and have agreed on "**Final Tenant Improvement Plans**" and a "**Final Tenant Improvement Bid**" (as both those terms are defined in the First Amended Lease).

2. Final Tenant Improvement Plans: Tenant and Landlord agree that **Exhibit 1** to this Second Amendment to Lease—consisting of the Remiger Design Stereotaxis DD Pricing Set dated 4/9/21, as amended by a CD Bid Set dated 4/30/21, as amended by Addendums 1 & 2 dated 5/21/21 and 5/31/21 respectively, and finally by the addendums made during the value engineering process which are described in the Addendum 5 dated 8/30/21—constitute the **Final Tenant Improvement Plans**. In the event of any conflict between the Addendum dated 8/30/21 and the earlier drawings, the Addendum dated 8/30/21 shall control.

3. Final Tenant Improvement Bid: Tenant and Landlord accept that **Exhibit 2** to this Second Amendment to Lease constitutes the **Final Tenant Improvement Bid**, which is based on the Final Tenant Improvement Plans as amended by the Addendum 5 dated 8/30/21.

4. Modifications to Final Tenant Improvement Plans and Final Tenant Improvement Bid: Tenant and Landlord acknowledge that they are still exploring methods of value engineering the design of the Tenant Improvements. Any changes in the **Final Tenant Improvement Plans** and/or **Final Tenant Improvement Bid** from Exhibits 1 and 2 (respectively) shall be handled as a Change Order pursuant to Exhibit E, Section E, to the Lease.

5. TI Shortfall: Per Section C of Exhibit E to the Lease and as of the Effective Date, the amount by which the TI Costs exceeds the Allowance Funds is the TI Shortfall. The Allowance Funds consist of the following:

$1,426,595 per the allowances provided for in the Lease; plus the following amounts from the Tenant Improvement Bid that the Parties agree should be included in Landlord Delivery Condition. Rather than rebid the project, the Parties agree to adjust the Allowance Funds as follows (all numbers below include general contractor's general conditions, profit and overhead totaling 18%, as applicable):

- $20,425.80 for upgrading the glass walls around the conference rooms and CEO office.
- $10,014.66 for installation of motorized and insulated garage door to the new loading dock.
- $6,490.00 for new doorway and lighting in the Storage Space.
- $3,750.00 for Landlord's agreed upon contribution to the fly-through created by Remiger.

$40,680.46 Total Additional Allowance FUNDS

Therefore, the Allowance Funds are: **$1,467,275.46.**

The Final Tenant Improvement Bid is **$3,220,399**.
The TI Shortfall is **($3,220,399-$1,467,275.46) = $1,753,123.54.**

The ratios of Allowance Funds and TI Shortfall to the Final Tenant Improvement Bid are as follows:

TI Shortfall:	54%
Allowance Funds:	46%

The Parties agree that if any modifications are made to the **Final Tenant Improvement Plans** and/or **Final Tenant Improvement Bid** following the Effective Date pursuant to Section 4 above, and such changes affect the costs of the above Tenant Improvements, TI Costs, Allowance Costs and/or TI Shortfall, Landlord shall account for such modified costs and adjust the above calculations within 30 days following final completion of the Tenant Improvements in accordance with Section C of Exhibit E.

6. Miscellaneous.

a. This Second Amendment may be executed in one or more counterparts, each of which shall be deemed an original and all such counterparts, taken together, shall constitute but one and the same instrument. Facsimile signatures on any counterpart shall be effective as an original signature, but the parties hereto agree to deliver to the other original signatures within thirty (30) days after the date of this Second Amendment.

b. Except as expressly amended and modified hereby, all of the terms and provisions of the Lease shall remain unchanged and in full force and effect and are hereby ratified and confirmed.

c. In the event of any conflict between the terms of this Second Amendment and the terms of the Lease, the terms of this Second Amendment shall govern and control.

d. This Second Amendment shall inure to the benefit of the parties hereto and their respective successors and assigns.

e. Tenant acknowledges that the First Amended Lease as amended by this Second Amendment contains the entire agreement between Landlord and Tenant relating to Tenant's lease of the Premises, and supersedes all prior discussions, representations, communications and agreements between them related to Tenant's lease of the Premises.

IN WITNESS WHEREOF, the parties have executed this Second Amendment as of the day and year set forth above.

TENANT:

STEREOTAXIS, INC., a Delaware corporation

By: */s/ Kimberly R. Peery*
Name: Kimberly R. Peery
Title: CFO

LANDLORD:

GLOBE BUILDING COMPANY, a Missouri general partnership

By: */s/ Steven M. Stone*
Steven M. Stone, Authorized Representative

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1) Registration Statement (Form S-8 No. 333-197930) of Stereotaxis, Inc. pertaining to the Stereotaxis, Inc. 2009 Employee Stock Purchase Plan

2) Registration Statements (Form S-8 Nos. 333-197929, 333-213052, 333-219860 and 333-233847) of Stereotaxis, Inc. pertaining to the Stereotaxis, Inc. 2012 Stock Incentive Plan

3) Registration Statement (Form S-1 No. 333-214255) of Stereotaxis, Inc. pertaining to the registration of 86,065,014 of shares of common stock of Stereotaxis, Inc.

4) Registration Statement (Form S-3 No. 333-233846) of Stereotaxis, Inc. pertaining to the registration of 12,195,121 of shares of common stock of Stereotaxis, Inc.

5) Registration Statement (Form S-3 No. 333-237194) of Stereotaxis, Inc. pertaining to the registration of up to $100,000,000 of debt securities, common stock, preferred stock, warrants, rights, or units of Stereotaxis, Inc.

6) Registration Statement (Form S-3 No. 333-258751) of Stereotaxis, Inc. pertaining to Stereotaxis, Inc. 2021 Stock Incentive Plan, as Amended and Restated, and David L. Fischel CEO Performance Share Unit Award

of our reports dated March 10, 2022 with respect to the financial statements and schedule of Stereotaxis, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2021.

/s/ Ernst & Young LLP
St. Louis, Missouri
March 10, 2022

Exhibit 31.1

Certification of Principal Executive Officer

I, David L. Fischel, certify that:

1. I have reviewed this annual report on Form 10-K of Stereotaxis, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2022

/s/ David L. Fischel

David L. Fischel
Chief Executive Officer
Stereotaxis, Inc.
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer

I, Kimberly R. Peery, certify that:

1. I have reviewed this annual report on Form 10-K of Stereotaxis, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2022

/s/ Kimberly R. Peery

Kimberly R. Peery
Chief Financial Officer
Stereotaxis, Inc.
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Stereotaxis, Inc. (the "Company") on Form 10-K for the period ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David L. Fischel, Chief Executive Officer of the Company, certify, pursuant to Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 10, 2022

/s/ David L. Fischel
David L. Fischel
Chief Executive Officer
Stereotaxis, Inc.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Stereotaxis, Inc. (the "Company") on Form 10-K for the period ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kimberly R. Peery, Chief Financial Officer of the Company, certify, pursuant to Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 10, 2022

/s/ Kimberly R. Peery
Kimberly R. Peery
Chief Financial Officer
Stereotaxis, Inc.