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, 2023

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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2023) was approximately $100.9 million.

The number of outstanding shares of the registrant's common stock on February 29, 2024, was 82,128,762.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2024 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™, Cardiodrive®, and MAGiC ™ 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;
- 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 macroeconomic 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 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, and we are investing in research and development in these areas.

Our primary products include the *Genesis RMN* System, the *Odyssey* Solution, and other related devices. Through our strategic relationships with fluoroscopy system manufacturers, providers of catheters and electrophysiology mapping systems, and other parties, we offer our customers x-ray systems 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 have arrangements with fluoroscopy system manufacturers to provide such systems in a bundled purchase offer for hospitals establishing robotic interventional operating rooms. These are single-plane, full-power x-ray systems and include the c-arm and powered table. The combination of RMN Systems with our partnered x-ray systems reduces the cost of acquisition, the ongoing cost of ownership, and the complexity of installation of a robotic electrophysiology practice.

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 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, our prior generation robotic magnetic navigation system, the *Odyssey* Solution, *Cardiodrive*, e-Contact, and various disposable interventional devices have received regulatory clearances and approvals in the U.S., Europe, Canada, China, Japan and various other countries. We have received the regulatory clearances and approvals that allow us to market the *Vdrive* and *Vdrive Duo* Systems with the *V-CAS* device in the U.S. and Canada. We are pursuing regulatory approvals for the Stereotaxis MAGiC catheter, a robotically-navigated magnetic ablation catheter designed to perform minimally invasive cardiac ablation procedures, in various global geographies. Approval processes can be lengthy and uncertain, submissions may require revised or additional non-clinical and clinical data, and regulatory applications could be denied.

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, 2023, we had approximately $14.7 million of backlog, consisting of outstanding purchase orders and other commitments for these systems. Of the December 31, 2023 backlog, we expect approximately 81% to be recognized as revenue over the course of 2024. We had backlog of approximately $14.8 million as of December 31, 2022. 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, x-ray systems, 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 compatible 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.

X-ray systems

We have arrangements with fluoroscopy system manufacturers to provide such systems in a bundled purchase offer for hospitals establishing robotic interventional operating rooms. These are single-plane, full-power x-ray systems and include the c-arm and powered table. The combination of RMN Systems with our partnered x-ray systems reduces 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 associated disposable interventional devices. Within this toolkit, we manufacture and distribute:

- the *QuikCAS, an* automated catheter advancement disposable device designed to provide precise remote advancement of magnetically enabled electrophysiology catheters,
- the iCONNECT, a module designed to provide impedance data from a catheter while also allowing for the connection of a variety of catheters and systems, and
- the *V-CAS* 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 used with our robotic magnetic navigation systems and in traditional, manual procedures.

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.

With our partners, 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.

Additionally, we have other broad strategic collaborations, including the development of the Stereotaxis MAGiC catheter, our next-generation robotically-navigated magnetic ablation catheter designed to perform cardiac ablation procedures. Stereotaxis is the owner of the catheter and we are pursuing regulatory approvals for the MAGiC catheter in various global geographies. Approval processes can be lengthy and uncertain, submissions may require revised or additional non-clinical and clinical data, and regulatory applications could be denied.

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 compatible systems and devices and/or equivalent alternatives. We cannot provide any 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.

Other Recurring Revenue

Other recurring revenue includes revenue from product maintenance plans, service-type warranties, 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 product maintenance plans and software enhancements, service-type warranties, and the implied obligation to provide software enhancements are 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 approvals necessary for us to market the Genesis System with Cardiodrive, iCONNECT, Navigant, Odyssey and QuikCAS 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 approvals necessary for us to market the Niobe System with Cardiodrive, e-Contact, Navigant, Odyssey and QuikCAS in the U.S., Canada, China, Japan, and various other countries.

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

FINANCIAL INFORMATION ABOUT CUSTOMERS

No single customer accounted for more than 10% of total revenue for the years ended December 31, 2023 and 2022. No single country, other than the U.S., accounted for more than 10% of total revenue for the years ended December 31, 2023 and 2022.

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.

We have arrangements with fluoroscopy system manufacturers to provide such systems in a bundled purchase offer for hospitals establishing robotic interventional operating rooms.

We have entered into strategic relationships and successfully integrated with diagnostic mapping and imaging technologies to provide an ecosystem where physicians and patients benefit from the integration of procedure data.

With our partners, 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 contributed to the resources required for their development. Biosense Webster's distribution rights for co-developed catheters were nonexclusive until December 31, 2022. We received royalty payments from Biosense Webster during the term of the agreement. The agreement expired in December, 2022, and provides for a continuation of supply by Biosense Webster of the co-developed catheters to us or our customers for three years following the termination. The royalty payments were payable quarterly based on net revenues from sales of the co-developed catheters. Royalty revenue from the co-developed catheters represented 7% of revenue for the year ended December 31, 2022.

Additionally, we have other broad strategic collaborations, including the development of the Stereotaxis MAGiC catheter, our next-generation robotically-navigated magnetic ablation catheter designed to perform cardiac ablation procedures. Stereotaxis is the owner of the catheter and we are pursuing regulatory approvals for the MAGiC catheter in various global geographies. Approval processes can be lengthy and uncertain, submissions may require revised or additional non-clinical and clinical data, and regulatory applications could be denied.

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 compatible 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.

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 compatible 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 many of 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 2022 and are valid through September 2025.

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.

Our sales and marketing efforts include two important elements: (1) selling robotic magnetic systems, *Odyssey* Solutions, and magnetically compatible x-ray 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 robotic magnetic navigation systems 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 robotic magnetic navigation systems have been reimbursed to date. 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, 2023, we had 44 issued U.S. patents and 2 pending U.S. patent application. In addition, we had 15 issued foreign patents and 2 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 four 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 in catheter robotics 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 are pursuing regulatory approvals for the Stereotaxis MAGiC catheter, a robotically-navigated magnetic ablation catheter designed to perform minimally invasive cardiac ablation procedures, in various global geographies. We are aware of two other companies that also produce and sell magnetically enabled catheters. Approval processes can be lengthy and uncertain, submissions may require revised or additional non-clinical and clinical data, and regulatory applications could be denied.

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 (EU), which encompasses most of the major countries in Europe. The EU, 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 Regulation (MDR), 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. The MDR establishes a uniform, transparent, predictable, and sustainable regulatory framework across the EU for medical devices and ensures a high level of safety and health while supporting innovation. Regulations are directly applicable in EU member states without the need for member states to implement into national law. This aims at increasing harmonization across the EU. The MDR became effective on May 26, 2021. Devices lawfully placed on the market pursuant to the EU Medical Device Directive (MDD) prior to May 26, 2021, may generally continue to be made available on the market or put into service until and including May 26, 2025, provided that the requirements of the transitional provisions are fulfilled (referred to as the “sell-off” provision). In particular, the certificate in question must still be valid. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the MDR. If it is adopted by the European Parliament and Council, under draft legislation proposed by the European Commission, the sell-off provision would be removed.

We are subject to additional regulations in other foreign countries, including, but not limited to Canada, Taiwan, China, Japan, 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 €20 million or 4% of the total worldwide annual turnover of the preceding financial year, whichever is greater, 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 U.S. 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. Further, the California Consumer Privacy Rights Act ("CPRA"), which took effect on January 1, 2023, revised and expanded the CCPA, adding new data protection obligations to covered business and rights for consumers. Similar data protection laws have also been enacted by other states, including Virginia, Colorado, Connecticut, and Utah.

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.

Anti-Corruption Laws

Our operations outside the U.S. require us to comply with a number of U.S. and international regulations, including the Foreign Corrupt Practices Act ("FCPA"). The FCPA prohibits U.S. corporations from offering, promising, authorizing, or making payments to foreign government officials for the purpose of obtaining or retaining business. In many countries, the scope of the FCPA could include interactions with certain healthcare professionals. Other countries have enacted similar anti-corruption laws.

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, 2023, we had 122 employees, 35 of whom were engaged directly in research and development, 53 in sales and marketing activities, 16 in manufacturing and service, and 18 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, 2023, our employees were based in 11 different countries around the world, including the U.S. 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

The health, safety, and wellness of our employees is a priority in which we continue to invest. We provide our employees and their families with access to health and wellness programs that support employee wellbeing, time away from work, family care, mental health, and financial well-being. We also conduct on-site engagement activities that facilitate cross-team networking, collaboration, and innovation.

We continue to evolve our programs to respond to the best interest of our changing workforce, as well as the communities in which we operate, in compliance with government regulations. We manage overall safety with guidance based on regional, country, and local regulations and best practices. In the ongoing response to the COVID-19 pandemic, we continue to evaluate and adapt our protocols as necessary to support our employees as well as external physician customers and patients.

Compensation and Benefits

We strive to provide our employees with what we believe is a 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.
- Macroeconomic and geopolitical factors, as well as pandemics, epidemics or outbreaks of infectious disease could have an adverse effect our supply chain, our hospital customer buying patterns, and our ability to raise capital and could otherwise disrupt our normal business operations.

- 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 maintain our cash at financial institutions, often in balances that exceed federally insured limits.
- 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; or
- respond to competitive pressures.

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

Macroeconomic and geopolitical factors, as well as pandemics, epidemics or outbreaks of infectious disease could have an adverse effect our supply chain, our hospital customer buying patterns, and our ability to raise capital and could otherwise disrupt our normal business operations.

Future results of operations could be materially adversely impacted by macroeconomic and geopolitical factors. The Company continues to experience difficulties with periodic worldwide supply chain disruptions, including shortages and inflationary pressures, and logistics delays which make it difficult for us to source parts and ship our products. We have generally been able to conduct normal business activities albeit in a more deliberate manner than prior to the pandemic, including taking action to increase inventory levels and engaging in discussions with our vendors on contractual obligations, but we cannot guarantee that they will not be impacted more severely in the future. Our suppliers and contract manufacturers have experienced, and may continue to experience, similar difficulties. If our manufacturing operations or supply chains are materially interrupted, it may not be possible for us to timely manufacture or service our 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 in 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.

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. Hospitals continue to experience challenges with staffing and cost pressures as supply chain constraints and inflation drive up operating costs. 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. Our hospital customers have also experienced challenges in sourcing supplies, such as catheters, needed to perform procedures. Such shortages have, and may continue to, put pressure on procedures and our disposable revenue.

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. 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 system installations, service contracts and disposable products.

In addition to the aforementioned macroeconomic factors, the COVID-19 pandemic negatively affected demand for both our systems and our disposable products, and future similar occurrences may do so in the future. During the COVID-19 pandemic, we experienced business disruptions, including travel restrictions on us and our third-party distributors, which negatively affected our complex sales, marketing, installation, distribution and service network relating to our products and services, and that may occur again in the future. We also experienced reductions in demand for our disposable products as our healthcare customers (physicians and hospitals) re-prioritized the treatment of patients and diverted resources away from non-coronavirus areas, leading to the performance of fewer procedures in which our disposable products are used. Significant decreases to our capital or recurring revenues could have a material adverse effect on our business, operating results, and financial condition. While we cannot reliably estimate the ultimate duration of the impact or the severity of ongoing periodic resurgences of pandemic-related issues, we continue to anticipate periodic disruptions to our manufacturing operations, supply chains, procedures volumes, service activities, and capital system orders and placements, any of which could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

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 2024 operating expenses will exceed its 2024 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 systems. 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. While we have partnered with fluoroscopy manufacturers to reduce the cost of acquisition, the ongoing cost of ownership, and the complexity of installation of a robotic electrophysiology practice, this strategy may not be successful. If hospitals do not widely adopt our systems or partnered products or if they decide that our systems 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, as noted above, the global macroeconomic and geopolitical factors, including those related to the COVID-19 pandemic, have caused, and may continue to cause, our customers to 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 compatible products. The maintenance of these collaborations, or the establishment of equivalent alternatives, is critical to our commercialization efforts.

In the past, we have experienced disruptions and changes in our strategic relationships. There are no guarantees that any existing strategic relationships will continue and efforts are ongoing to ensure the availability of compatible 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, commercialize or support compatible products in a timely manner;
- any of our collaboration partners fails to maintain required regulatory approvals for their own products and such failure impacts our ability to deliver compatible systems in a timely manner or at all; or
- we become involved in disputes with one or more of our collaboration partners regarding our collaborations or contractual rights and obligations related thereto.

For example, supply chain disruptions have led to vendor discussions regarding contractual performance which we intend to resolve through continued negotiations but may require us to assert performance issues under our vendor agreements; in such event, we may not be successful in our claims, and even if we are successful, we may experience supply disruptions. Our collaborators range from small and midsized organizations which may have limited resources to 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. For example, our agreement with Biosense Webster expired by its terms on December 31, 2022. While the agreement provides for a continuation of supply by Biosense Webster of the co-developed catheters to us or our customers for three years following the termination, we no longer receive royalty payments from Biosense Webster. Although we are in the process of establishing alternative catheter supply arrangements, including the development of a fully owned magnetically enabled ablation catheter, we cannot guarantee that those arrangements will be successful. Failure to establish alternatives may reduce the likelihood that physician users will continue to use our technology which will have a negative impact on our future revenue, cash flow and operations. Even if we are successful in establishing one or more alternatives, we cannot guarantee that those arrangements will replace the royalty revenue stream previously received from the sale of the Biosense Webster catheter.

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 four 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 in catheter robotics 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 are pursuing regulatory approvals for the Stereotaxis MAGiC catheter, a robotically-navigated magnetic ablation catheter designed to perform minimally invasive cardiac ablation procedures, in various global geographies. We are aware of two other companies that also produce and sell magnetically enabled catheters. Approval processes can be lengthy and uncertain, submissions may require revised or additional non-clinical and clinical data, and regulatory applications could be denied.

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 537.7 million as of December 31, 2023, 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 rely on other parties to manufacture, and in some cases to service, magnetically compatible x-ray systems, catheter sensing technology, and a number of disposable interventional devices for use with our robotic magnetic navigation system. If these parties cannot or do not manufacture sufficient quantities to meet customer demand, or if their manufacturing processes are disrupted, or if they are not able to service or warrant their products, 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 sought 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, previous administrations implemented, or considered 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 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 workforce. 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. We also have arrangements with fluoroscopy system manufacturers to provide a complete solution for a robotic interventional operating room and these manufacturers have the obligation maintain appropriate regulatory clearance or approval to market and sell these systems. If these clearances or approvals are not received or are substantially delayed or if we are not able to offer either a sufficient array of approved disposable interventional devices or a fully integrated robotic magnetic navigation system, 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 revise or 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 China and 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. Additionally, we rely on the warranty provided by our third-party suppliers, including our fluoroscopy system providers. If product returns or warranty claims increase, or if our third-party suppliers do not honor their warranty obligations to us or certain claims are not covered thereunder, 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, 2023, we had 49.4 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. We filed a universal shelf registration statement on Form S-3 with the SEC in May 2023, which was declared effective by the SEC on June 6, 2023, registering the sale up to $100.0 million of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine. 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, the conversion of any convertible securities outstanding now or in the future, including the Series A Convertible Preferred Stock, or under our universal shelf registration statement), 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 Stock have received the stated value of $1,000 per share plus any accrued and unpaid dividends. Until all Series A Convertible Preferred Stock 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 Stock. 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 Stock 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.

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 expenses 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 or revenue streams related thereto.

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 2023, our common stock traded between $1.33 and $2.75 per share, on trading volume ranging from approximately 44,500 to 5.0 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, the Company 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 $7.1 million for the year ended December 31, 2023. As of December 31, 2023, the Company had approximately $37.0 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, *Odyssey* Solution, and compatible x-ray systems 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 products 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 maintain our cash at financial institutions, often in balances that exceed federally insured limits.

Adverse developments that affect financial institutions, transactional counterparties, or other third parties, or concerns or rumors about these events, have in the past and may in the future lead to market-wide liquidity problems. The majority of our cash is held in accounts at U.S. banking institutions that we believe are of high quality. Cash held in depository accounts may exceed the $250,000 Federal Deposit Insurance Corporation ("FDIC") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. On March 10, 2023, Silicon Valley Bank ("SVB"), where the Company maintained accounts with a cash balance of less than 6% of the Company's total cash, cash equivalents and marketable securities, was closed by the California Department of Financial Protection and Innovation and the FDIC was appointed as receiver. On March 12, 2023, the U.S. Department of the Treasury, Federal Reserve Board, and FDIC released a joint statement announcing that the FDIC would complete its resolution of SVB in a manner that fully protected all depositors at SVB and that depositors would have access to all of their money starting March 13, 2023. On March 26, 2023, it was announced that First-Citizens Bank & Trust Company would assume all of SVB's deposits and loans as of March 27, 2023. During the periods presented, the Company has not experienced any losses on its deposits of cash, cash equivalents or marketable securities. However, in the future, our access to our cash in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. Any material loss that we may experience in the future could have a material adverse effect on our business and our financial condition.

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 on-going 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 2023 fiscal year and that remain unresolved.

ITEM 1C. CYBERSECURITY

Cybersecurity risk management and strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes a cybersecurity incident response plan.

We design and assess our program based on various cybersecurity frameworks, such as the National Institute of Standards and Technology ("NIST") and the System and Organizational Controls ("SOC2"), as well as information security standards issued by the International Organization for Standardization, including ISO 27001 and ISO 27002. We use these cybersecurity frameworks and information security standards as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

We also maintain third party security procedures to identify, prioritize, assess, mitigate and remediate third party risks; however, we rely on the third parties we use to implement security programs commensurate with their risk, and we cannot ensure in all circumstances that their efforts will be successful.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program and shares common methodologies, reporting channels, and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise information technology ("IT") environment;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test, or otherwise assist with aspects of our security controls;
- cybersecurity awareness training for our employees, incident response personnel, and senior management; and
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents.

We have not identified any risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition.

Cybersecurity governance

Our management team, including our IT management team, is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants.

Our management team has certifications from various organizations, such as ISC2 (Certified Information Security Systems Professional or "CISSP"), Global Information Assurance ("GIAC"), and the EC-Council.

Our management team oversees efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel, threat intelligence and other information obtained from governmental, public, or private sources, including external consultants engaged by us, and alerts and reports produced by security tools deployed in the information technology environment.

The Board oversees our enterprise risk management processes, which includes cybersecurity risk, directly and through its audit committee. The audit committee of the Board assesses with management the Company's major risk exposures and the steps management has taken to monitor and control such exposures. The audit committee reviews management's risk assessment and risk management programs and reports on such matters to the full Board.

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 leases 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 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 leased approximately 2,200 square feet of office space in Maple Grove, Minnesota, under a lease agreement that ended August 31, 2022.

The Company also has leased office space in Amsterdam, The Netherlands through June 30, 2024. In addition, we lease an office space in Beijing, China under a lease agreement through November 29, 2026.

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.

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 29, 2024, there were approximately 419 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 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, and we are investing in research and development in these areas.

Our primary products include the *Genesis RMN* System, the *Odyssey* Solution, and other related devices. Through our strategic relationships with fluoroscopy system manufacturers, providers of catheters and electrophysiology mapping systems, and other parties, we offer our customers magnetically compatible x-ray systems 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 have arrangements with fluoroscopy system manufacturers to provide such systems in a bundled purchase offer for hospitals establishing robotic interventional operating rooms. These are single-plane, full-power x-ray systems and include the c-arm and powered table. The combination of RMN Systems with our partnered x-ray systems reduces the cost of acquisition, the ongoing cost of ownership, and the complexity of installation of a robotic electrophysiology practice.

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 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, our prior generation robotic magnetic navigation system, the *Odyssey* Solution, *Cardiodrive*, e-Contact, and various disposable interventional devices have received regulatory clearances and approvals in the U.S., Europe, Canada, China, Japan and various other countries. We have received the regulatory clearances and approvals that allow us to market the *Vdrive* and *Vdrive Duo* Systems with the *V-CAS* device in the U.S. and Canada. We are pursuing regulatory approvals for the Stereotaxis MAGiC catheter, a robotically-navigated magnetic ablation catheter designed to perform minimally invasive cardiac ablation procedures, in various global geographies. Approval processes can be lengthy and uncertain, submissions may require revised or additional non-clinical and clinical data, and regulatory applications could be denied.

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, 2023, we had approximately $14.7 million of backlog, consisting of outstanding purchase orders and other commitments for these systems. Of the December 31, 2023 backlog, we expect approximately 81% to be recognized as revenue over the course of 2024. We had backlog of approximately $14.8 million as of December 31, 2022. 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, x-ray systems, 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 compatible systems and devices and/or equivalent alternatives. For example, prior to the expiration of our agreement Biosense Webster on December 31. 2022, we received quarterly royalty payments based on net revenues from sales of co-developed catheters with Biosense Webster. Such royalty payments represented 7% of revenue for the year ended December 31, 2022. 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.

Risks and Uncertainties

Future results of operations could be materially adversely impacted by macroeconomic and geopolitical factors. The Company continues to experience difficulties with periodic worldwide supply chain disruptions, including shortages and inflationary pressures, and logistics delays which make it difficult for us to source parts and ship our products. We have generally been able to conduct normal business activities albeit in a more deliberate manner than prior to the pandemic, including taking action to increase inventory levels and engaging in discussions with our vendors on contractual obligations, but we cannot guarantee that they will not be impacted more severely in the future. Our suppliers and contract manufacturers have experienced, and may continue to experience, similar difficulties. If our manufacturing operations or supply chains are materially interrupted, it may not be possible for us to timely manufacture or service our 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 in 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.

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. Hospitals continue to experience challenges with staffing and cost pressures as supply chain constraints and inflation drive up operating costs. 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. Our hospital customers have also experienced challenges in sourcing supplies, such as catheters, needed to perform procedures. Such shortages have, and may continue to, put pressure on procedures and our disposable revenue.

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. 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 system installations, service contracts and disposable products.

In addition to the aforementioned macroeconomic factors, the COVID-19 pandemic or similar occurrences may continue to negatively affect demand for both our systems and our disposable products. In the past, we have experienced business disruptions, including travel restrictions on us and our third-party distributors, which negatively affected our complex sales, marketing, installation, distribution and service network relating to our products and services. We also experienced reductions in demand for our disposable products as our healthcare customers (physicians and hospitals) re-prioritized the treatment of patients and diverted resources away from non-coronavirus areas, leading to the performance of fewer procedures in which our disposable products are used. Significant decreases to our capital or recurring revenues could have a material adverse effect on our business, operating results, and financial condition. While we cannot reliably estimate the ultimate duration of the impact or the severity of ongoing periodic resurgences of pandemic-related issues, we continue to anticipate periodic disruptions to our manufacturing operations, supply chains, procedures volumes, service activities, and capital system orders and placements, any of which could have a material adverse effect on our business, financial condition, results of operations, or cash flows. The impact has varied widely over time by individual geography. In 2022, procedure volumes were challenged by periodic resurgences of COVID-19, ongoing hospital staffing issues and other factors. In the first quarter of 2023, the most recent COVID-19 resurgences in China continued to negatively impact our procedure volumes in that region, but as infections and hospitalization decreased, we saw a recovery of procedure volumes.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash, cash equivalents and marketable securities. Our investments may include, at any time, a diversified portfolio of cash equivalents and short- and long-term investments in a variety of high-quality securities, including money market funds, U.S. treasury and U.S. government agency securities, corporate notes and bonds, commercial paper, non-U.S. government agency securities, and municipal notes. The Company's exposure to any individual corporate entity is limited by policy. Deposits may exceed federally insured limits, and the Company is exposed to credit risk on deposits in the event of default by the financial institutions to the extent account balances exceed the amount insured by the Federal Deposit Insurance Corporation (FDIC). The Company closely monitors events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, including Silicon Valley Bank. On March 10, 2023, Silicon Valley Bank ("SVB"), where the Company maintained accounts with a cash balance of less than 6% of the Company's total cash, cash equivalents and marketable securities, was closed by the California Department of Financial Protection and Innovation and the FDIC was appointed as receiver. On March 12, 2023, the U.S. Department of the Treasury, Federal Reserve Board, and FDIC released a joint statement announcing that the FDIC would complete its resolution of SVB in a manner that fully protected all depositors at SVB and that depositors would have access to all of their money starting March 13, 2023. On March 26, 2023, it was announced that First-Citizens Bank & Trust Company would assume all of SVB's deposits and loans as of March 27, 2023. During the periods presented, the Company has not experienced any losses on its deposits of cash, cash equivalents or marketable securities.

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.

Investments Valuation

Our investments may include, at any time, a diversified portfolio of cash equivalents and short- and long-term investments in a variety of high-quality securities, including money market funds, U.S. treasury and U.S. government agency securities, corporate notes and bonds, commercial paper, non-U.S. government agency securities, and municipal notes. The assessment of the fair value of investments can be difficult and subjective. Generally accepted accounting principles for fair value measurement establishes 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.

Each level of input has different levels of subjectivity and difficulty involved in determining fair value. Valuation of Level 1 and 2 instruments generally do not require significant management judgment, and the estimation is not difficult. Level 3 instruments include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The determination of fair value for Level 3 instruments requires the most management judgment and subjectivity. There were no Level 3 securities for the periods presented.

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 of various devices as provided by co-development and co-placement arrangements, 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, service-type warranty, 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 service-type warranties and the implied obligation to deliver software enhancements if and when available is included in Other Recurring Revenue and is recognized ratably typically over the first year following installation of the system as the customer receives the service-type warranty and right to software updates throughout the period. The Company's system contracts generally do not provide a right of return. Systems are generally covered by a one-year service-type warranty or a one-year assurance-type warranty. Warranty costs for assurance-type warranty arrangements were approximately $0.5 million and $0.1 million for the years ended December 31, 2023 and 2022, 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 receives royalties on the sale of various devices as provided by co-development and co-placement arrangements with various manufacturers. The Company was entitled to royalty payments from Biosense Webster, payable quarterly based on net revenues from sales of the co-developed catheters, during the term of the agreement, which expired December 31, 2022.

Other Recurring Revenue:

Other recurring revenue includes revenue from product maintenance plans, service-type warranties, 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, service-type warranties, and the implied obligation to provide software enhancements are 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.

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. See Note 2 to the financial statements for additional details 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 $0.1 million and $0.2 million as of December 31, 2023 and 2022, respectively. The Company did not incur any impairment losses during any of the periods presented.

Cost of Contracts

Costs of systems revenue include direct product costs, installation labor and other costs, estimated warranty costs, initial training costs 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.

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 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, 2023 and 2022

Revenue. Revenue decreased from $28.1 million for the year ended December 31, 2022, to $26.8 million for the year ended December 31, 2023, a decrease of approximately 5%. Revenue from sales of systems increased from $6.8 million for the year ended December 31, 2022, to $8.7 million for the year ended December 31, 2023, an increase of approximately 28%, driven by increased system sales volumes in the current year period. Revenue from sales of disposable interventional devices, service and accessories decreased to $18.0 million for the year ended December 31, 2023, from $21.3 million for the year ended December 31, 2022, a decrease of approximately 15%. The decrease was primarily driven by prior period royalties paid to the Company by

Biosense Webster on the sale of co-developed catheters during the term of the agreement and by lower procedure volumes related to Biosense Webster catheter shortages.

Cost of Revenue. Cost of revenue increased from $9.7 million for the year ended December 31, 2022, to $11.9 million for the year ended December 31, 2023, an increase of approximately 23%. As a percentage of our total revenue, overall gross margin was 56% and 66% for the years ended December 31, 2023, and December 31, 2022, respectively. The decrease was primarily due to changes in product mix. Cost of revenue for systems sold increased from $5.8 million for the year ended December 31, 2022, to $8.1 million for the year ended December 31, 2023, primarily due to increased system sales volumes and period costs in the current year period. Gross margin for systems decreased from $1.0 million for the year ended December 31, 2022, to $0.7 million for the year ended December 31, 2023. Cost of revenue for disposables, service, and accessories remained consistent at $3.9 million for years ended December 31, 2022, and 2023. Gross margin for disposables, service and accessories was 79% for the current year period compared to 82% for the year ended December 31, 2022, driven by changes in product mix and higher costs under service contracts in the current year period.

Research and Development Expense. Research and development expenses decreased from $10.6 million for the year ended December 31, 2022, to $10.3 million for the year ended December 31, 2023, a decrease of approximately 3%. This decrease was primarily due to project timing in the current year period.

Sales and Marketing Expense. Sales and marketing expenses remained consistent with $12.4 million for the year ended December 31, 2023, as compared to $12.3 million for the year ended December 31, 2022, an increase of less than 1%.

General and Administrative Expense. General and administrative expenses include finance, information systems, legal, and general management expenses. General and administrative expenses decreased from $14.4 million for the year ended December 31, 2022, to $14.1 million for the year ended December 31, 2023, a decrease of approximately 2%. This decrease was primarily driven by lower administrative expenses, professional service fees and reduced currency loss in the current year period.

Interest Income. Net interest income was $1.1 million for the year ended December 31, 2023, and $0.5 million for the year ended December 31, 2022. The increase was driven by increased interest rates and higher return on invested balances in the current year period.

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, 2023, and December 31, 2022, to reflect these uncertainties. As of December 31, 2023, we had gross federal net operating loss carryforwards of approximately $127.4 million. The federal net operating loss carryforwards reflect accumulated book losses reduced for the 2013 IRC Section 382 ownership change limitation of $213.7 million, book/tax differences and expiration of unused carryforwards. The federal net operating loss carryforwards generated prior to the 2018 tax year of approximately $98.8 million will expire between 2030 and 2037. The federal net operating losses generated in 2018 and thereafter will be carried forward indefinitely as a result to changes in the tax law following the Tax Cuts and Jobs Act. As of December 31, 2023, we had gross state net operating loss carryforward of approximately $40.2 million which will expire at various dates between 2024 and 2042 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, cash equivalents, and investments.

As of December 31, 2023, our accumulated deficit was $537.7 million with cash and cash equivalents of $20.6 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, 2023 and 2022, the Company did not have any debt.

Liquidity

The following table summarizes our cash flow by operating, investing and financing activities for years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	2022
Cash flow used in operating activities	$ (9,139)	$ (8,415)
Cash flow provided by (used in) investing activities	19,765	(22,094)
Cash flow provided by financing activities	81	220

Net cash used in operating activities. We used approximately $9.1 million and $8.4 million of cash in operating activities during the years ended December 31, 2023 and 2022, respectively. The increase in cash used in operating activities was driven by the increased operating loss offset by changes in working capital in the current year period.

Net cash provided by (used in) investing activities. Cash provided by investing activities for the year ended December 31, 2023, consisted of $19.8 million. The cash generated during the year ended December 31, 2023, was from proceeds received from the maturity of short-term investments of $20.1 million, partially offset by $0.4 million of cash paid for equipment, construction and design costs associated with our new facility. Cash used in investing activities for the year ended December 31, 2022, consisted primarily of purchases of investments of $19.7 million and $2.4 million paid for equipment, design and construction costs associated with our new facility.

Net cash provided by financing activities. We generated approximately $0.1 million and $0.2 million of cash for the years ended December 31, 2023 and 2022, respectively. The cash generated in both periods was driven by the exercise of stock options and our employee stock purchase program.

At December 31, 2023, we had working capital of approximately $20.0 million, compared to a working capital of approximately $29.0 million at December 31, 2022. The decrease in working capital was primarily driven by the net loss incurred during the year ended December 31, 2023.

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. In addition, the Company filed a universal shelf registration statement on Form S-3 with the SEC in May 2023, which was declared effective by the SEC on June 6, 2023, registering for sale up to $100.0 million of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine. The net proceeds of any securities we sell under our shelf registration statement may be used for general corporate purposes, including among other possible uses, the acquisition of companies or businesses, repayment and refinancing of debt, working capital and capital expenditures. At this time, we have no plans to sell any such securities under our shelf registration statement.

The Company believes the cash, and cash equivalents on hand as of December 31, 2023, 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, 2023 and 2022, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, 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 Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Systems Revenue Recognition

Description of the Matter

As discussed in Note 2 to the financial statements, the Company generates revenue from initial sales of systems as well as recurring revenue from the sale of proprietary disposable devices, 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 and cost and margin analyses. We also tested management's assertion that control was transferred to the customer by inspecting documentation supporting the transfer of control on contracts.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2002.
St. Louis, Missouri
March 8, 2024

STEREOTAXIS, INC.
BALANCE SHEETS

(in thousands, except share amounts)	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 19,818	$ 8,586
Restricted cash - current	525	525
Short-term investments	-	19,844
Accounts receivable, net of allowance of $672 and $235 at 2023 and 2022, respectively	3,822	5,090
Inventories, net	8,426	7,876
Prepaid expenses and other current assets	676	1,325
Total current assets	33,267	43,246
Property and equipment, net	3,304	3,831
Restricted cash	219	744
Operating lease right-of-use assets	4,982	5,384
Prepaid and other non-current assets	137	208
Total assets	$ 41,909	$ 53,413
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,190	$ 3,270
Accrued liabilities	2,972	3,306
Deferred revenue	6,657	7,342
Current portion of operating lease liabilities	428	373
Total current liabilities	13,247	14,291
Long-term deferred revenue	1,637	1,654
Operating lease liabilities	5,062	5,488
Other liabilities	43	51
Total liabilities	19,989	21,484
Series A - Convertible preferred stock:		
Convertible preferred stock, Series A, par value $0.001; 22,358 and 22,383 shares outstanding at 2023 and 2022, respectively	5,577	5,583
Stockholders' equity:		
Convertible preferred stock, Series B, par value $0.001; 10,000,000 shares authorized, 5,610,121 shares outstanding at 2022	-	6
Common stock, par value $0.001; 300,000,000 shares authorized, 80,949,697 and 74,874,459 shares issued at 2023 and 2022, respectively	81	75
Additional paid in capital	554,148	543,438
Treasury stock, 4,015 shares at 2023 and 2022	(206)	(206)
Accumulated deficit	(537,680)	(516,967)
Total stockholders' equity	16,343	26,346
Total liabilities and stockholders' equity	$ 41,909	$ 53,413

See accompanying notes.

STEREOTAXIS, INC.
STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)	Year Ended December 31, 2023	2022
Revenue:		
Systems	$ 8,739	$ 6,845
Disposables, service and accessories	18,032	21,302
Total revenue	26,771	28,147
Cost of revenue:		
Systems	8,058	5,802
Disposables, service and accessories	3,853	3,875
Total cost of revenue	11,911	9,677
Gross margin	14,860	18,470
Operating expenses:		
Research and development	10,273	10,558
Sales and marketing	12,376	12,325
General and administrative	14,050	14,363
Total operating expenses	36,699	37,246
Operating loss	(21,839)	(18,776)
Other income	30	-
Interest income, net	1,096	484
Net loss	$ (20,713)	$ (18,292)
Cumulative dividend on convertible preferred stock	(1,343)	(1,343)
Net loss attributable to common stockholders	$ (22,056)	$ (19,635)
Net loss per share attributable to common stockholders:		
Basic	$ (0.27)	$ (0.26)
Diluted	$ (0.27)	$ (0.26)
Weighted average number of common shares and equivalents:		
Basic	80,702,358	76,061,183
Diluted	80,702,358	76,061,183

See accompanying notes.

STEREOTAXIS, INC
STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

Year Ended December 31, 2022

(in thousands, except share amounts)	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, 2021	22,387	$ 5,584	5,610,121	$ 6	74,618,240	$ 75	$ 532,641	$ (206)	$ (498,675)	$ 33,841
Stock issued for the exercise of stock options and stock appreciation rights					92,377		102			102
Stock-based compensation					110,726		10,576			10,576
Components of net loss									(18,292)	(18,292)
Employee stock purchase plan					44,783		118			118
Preferred stock conversion	(4)	(1)			8,333		1			1
Balance at December 31, 2022	22,383	$ 5,583	5,610,121	$ 6	74,874,459	$ 75	$ 543,438	$ (206)	$ (516,967)	$ 26,346

Year Ended December 31, 2023

(in thousands, except share amounts)	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, 2022	22,383	$ 5,583	5,610,121	$ 6	74,874,459	$ 75	$ 543,438	$ (206)	$ (516,967)	$ 26,346
Stock issued for the exercise of stock options					34,125		(15)			(15)
Stock-based compensation					319,019		10,623			10,623
Components of net loss									(20,713)	(20,713)
Employee stock purchase plan					56,966		96			96
Preferred stock conversion	(25)	(6)	(5,610,121)	(6)	5,665,128	6	6			6
Balance at December 31, 2023	22,358	$ 5,577	-	$ -	80,949,697	$ 81	$ 554,148	$ (206)	$ (537,680)	$ 16,343

See accompanying notes.

STEREOTAXIS, INC.
STATEMENTS OF CASH FLOWS

(in thousands)	Year Ended December 31, 2023	2022
Cash flows from operating activities		
Net loss	$ (20,713)	$ (18,292)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	595	429
Non-cash lease expense	31	103
Stock-based compensation	10,623	10,576
Accretion and short-term investment discount	(287)	(128)
Changes in operating assets and liabilities:		
Accounts receivable	1,268	316
Inventories	(550)	(2,906)
Prepaid expenses and other current assets	649	1,031
Other assets	71	70
Accounts payable	218	(169)
Accrued liabilities	(334)	(267)
Deferred revenue	(702)	989
Other liabilities	(8)	(167)
Net cash used in operating activities	(9,139)	(8,415)
Cash flows from investing activities		
Purchase of property and equipment	(366)	(2,378)
Purchases of short-term investments	-	(19,716)
Proceeds from maturity of short-term investments	20,131	-
Net cash provided by (used in) investing activities	19,765	(22,094)
Cash flows from financing activities		
Proceeds from issuance of stock, net of issuance costs	81	220
Net cash provided by financing activities	81	220
Net increase (decrease) in cash, cash equivalents, and restricted cash	10,707	(30,289)
Cash, cash equivalents, and restricted cash at beginning of period	9,855	40,144
Cash, cash equivalents, and restricted cash at end of period	$ 20,562	$ 9,855
Supplemental disclosure of cash flow information:		
Purchase of property and equipment included in accounts payable	$ -	$ 313
Reconciliation of cash, cash equivalents, and restricted cash to balance sheet as of December 31st:		
Cash and cash equivalents	$ 19,818	$ 8,586
Restricted cash - current	525	525
Restricted cash	219	744
Total cash, cash equivalents, and restricted cash	$ 20,562	$ 9,855

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. Through our strategic relationships with fluoroscopy system manufacturers, providers of catheters and electrophysiology mapping systems, and other parties, we offer our customers x-ray systems 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 have arrangements with fluoroscopy system manufacturers to provide such systems in a bundled purchase offer for hospitals establishing robotic interventional operating rooms. These are single-plane, full-power x-ray systems and include the c-arm and powered table. The combination of RMN Systems with our partnered x-ray systems reduces the cost of acquisition, the ongoing cost of ownership, and the complexity of installation of a robotic electrophysiology practice.

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 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, our prior generation robotic magnetic navigation system, the *Odyssey* Solution, *Cardiodrive*, e-Contact, and various disposable interventional devices have received regulatory clearances and approvals in the U.S., Europe, Canada, China, Japan and various other countries. We have received the regulatory clearances and approvals that allow us to market the *Vdrive* and *Vdrive Duo* Systems with the *V-CAS* device in the U.S. and Canada. We are pursuing regulatory approvals for the Stereotaxis MAGiC catheter, a robotically-navigated magnetic ablation catheter designed to perform minimally invasive cardiac ablation procedures, in various global geographies. Approval processes can be lengthy and uncertain, submissions may require revised or additional non-clinical and clinical data, and regulatory applications could be denied.

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, x-ray systems, 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 compatible 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").

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash, cash equivalents and marketable securities. Our investments may include, at any time, a diversified portfolio of cash equivalents and short-term and long-term investments in a variety of high-quality securities, including money market funds, U.S. treasury and U.S. government agency securities, corporate notes and bonds, commercial paper, non-U.S. government agency securities, and municipal notes. The Company's exposure to any individual corporate entity is limited by policy. Deposits may exceed federally insured limits, and the Company is exposed to credit risk on deposits in the event of default by the financial institutions to the extent account balances exceed the amount insured by the Federal Deposit Insurance Corporation (FDIC). The Company closely monitors events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, including Silicon Valley Bank. On March 10, 2023, Silicon Valley Bank ("SVB"), where the Company maintained accounts with a cash balance of less than 6% of the Company's total cash, cash equivalents and marketable securities, was closed by the California Department of Financial Protection and Innovation and the FDIC was appointed as receiver. On March 12, 2023, the U.S. Department of the Treasury, Federal Reserve Board, and FDIC released a joint statement announcing that the FDIC would complete its resolution of SVB in a manner that fully protected all depositors at SVB and that depositors would have access to all of their money starting March 13, 2023. On March 26, 2023, it was announced that First-Citizens Bank & Trust Company would assume all of SVB's deposits and loans as of March 27, 2023. During the periods presented, the Company has not experienced any losses on its deposits of cash, cash equivalents or marketable securities.

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand, money market instruments, and other highly liquid investments with original maturities of three months or less from the date of purchase.

Restricted Cash

Restricted cash primarily consists of cash that the Company is obligated to maintain in accordance with contractual obligations.

Investments

Our investments may include, at any time, a diversified portfolio of cash equivalents and short-and long-term investments in a variety of high-quality securities, including money market funds, U.S. treasury and U.S. government agency securities, corporate notes and bonds, commercial paper, non-U.S. government agency securities, and municipal notes. As of December 31, 2023, the Company had no short-term investments.

Amortized cost of U.S. treasury securities and marketable debt securities are based on the Company's purchase price adjusted for accrual of discount, or amortization of premium, and recognition of impairment charges, if any. The amortized cost of securities the Company purchases at a discount or premium will equal the face or par value at maturity or the call date, if applicable. Stated interest on investments is reported as income when earned and is adjusted for amortization or accretion of any premium or discount. Accrued interest receivable on investments, included in other current assets was less than $0.1 million as of December 31, 2023, and December 31, 2022.

Effective January 1, 2023, the Company reports held to maturity investments net of an allowance for expected credit losses in accordance with Accounting Standards Codification Topic 326, Financial Instruments – Credit Losses ("ASC 326"). The adoption of ASC 326 had no material impact on the Company's financial results for any prior periods, therefore no cumulative adjustment to beginning retained earnings was recorded. The Company segments its portfolio based on the underlying risk profiles of the securities and has a zero-loss expectation for U.S. treasury and U.S. government agency securities. The Company regularly reviews the securities using the probability of default method and analyzes the unrealized loss positions and evaluates the current expected credit loss by considering factors such as credit ratings, issuer-specific factors, current economic conditions, and reasonable and supportable forecasts. The Company did not have any material expected credit losses on investments or material expected credit losses on accrued interest related to investments during the years ended December 31, 2023, or December 31, 2022.

Fair Value Measurements

Financial instruments consist of cash and cash equivalents, restricted cash, investments, accounts receivable, and accounts payable.

The Company measures certain financial assets and liabilities at fair value on a recurring basis. General accounting principles for fair value measurement establishes 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.

As of December 31, 2023, financial assets classified as Level 2 consisted of money market funds. As of December 31, 2022, financial assets classified as Level 2 consisted of money market funds, U.S. treasury securities and corporate debt securities. The Company reviews trading activity and pricing for these investments as of the measurement date. When sufficient quoted pricing for identical securities is not available, the Company uses market pricing and other observable market inputs for similar securities. These inputs either represent quoted prices for similar assets in active markets or have been derived from observable market data. This approach results in the Level 2 classification of these securities within the fair value hierarchy.

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, net of allowances for expected credit losses. Credit is granted on a limited basis, with balances due generally within 30 days of billing. 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. Effective January 1, 2023, the Company reports accounts receivable and contract assets net of an allowance for expected credit losses in accordance with Accounting Standards Codification Topic 326, Financial Instruments – Credit Losses ("ASC 326"). The adoption of ASC 326 had no material impact on the Company's financial results for any prior periods, therefore no cumulative adjustment to beginning retained earnings was recorded. The provision for credit loss is based upon management's assessment of historical and expected net collections considering business and economic conditions and other collection indicators. We assess collectability by reviewing the accounts receivable aging schedule on an aggregated basis where similar characteristics exist and on an individual basis when we identify specific customers with known disputes or collectability issues. Amounts deemed uncollectible are recorded as an allowance for expected credit losses.

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.

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 of various devices as provided by co-development and co-placement arrangements, 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, service-type warranty, 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 service-type warranties and the implied obligation to deliver software enhancements if and when available is included in Other Recurring Revenue and is recognized ratably typically over the first year following installation of the system as the customer receives the service-type warranty and right to software updates throughout the period. The Company's system contracts generally do not provide a right of return. Systems are generally covered by a one-year service-type warranty or a one-year assurance-type warranty. Warranty costs for assurance-type warranty arrangements were approximately $0.5 million and $0.1 million for the years ended December 31, 2023 and 2022, respectively. Revenue from system delivery and installation represented 33% and 24% of revenue for the years ended December 31, 2023 and 2022, 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, 2023 and 2022, respectively.

Royalty:

The Company receives royalties on the sale of various devices as provided by co-development and co-placement arrangements with various manufacturers. The Company was entitled to royalty payments from Biosense Webster, payable quarterly based on net revenues from sales of the co-developed catheters, during the term of the agreement, which expired December 31, 2022. Royalty revenue from co-development and co-placement arrangements represented less than 1% and approximately 7% of revenue for the years ended December 31, 2023 and 2022, respectively.

Other Recurring Revenue:

Other recurring revenue includes revenue from product maintenance plans, service-type warranties, 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 43% and 41% of revenue for the years ended December 31, 2023 and 2022, respectively.

The following table summarizes the Company's revenue for systems and disposables, service and accessories for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	2022
Systems	$ 8,739	$ 6,845
Disposables, service and accessories	18,032	21,302
Total revenue	$ 26,771	$ 28,147

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 $14.7 million as of December 31, 2023. Performance obligations arising from contracts for disposables 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 (in thousands):

	December 31, 2023	December 31, 2022
Contract Assets - unbilled receivables	$ 72	$ 539
Customer deposits	$ 2,105	$ 2,339
Product shipped, revenue deferred	1,413	1,389
Deferred service and license fees	4,776	5,268
Total deferred revenue	$ 8,294	$ 8,996
Less: Long-term deferred revenue	(1,637)	(1,654)
Total current deferred revenue	$ 6,657	$ 7,342

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, 2023 and 2022, that was included in the deferred revenue balance at the beginning of each reporting period was $6.1 million and $5.9 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 $0.1 million and $0.2 million as of December 31, 2023 and 2022, 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, initial training costs 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.

Leasing Arrangements

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.

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.

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.

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, 2023 or 2022, 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, non-qualified 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 stock-based compensation at the grant date and the recognition of the related expense over the period in which the stock-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 weighted average assumptions and fair value for options granted during the year ended December 31, 2023, were 1) expected dividend rate of 0%; 2) expected volatility of 76% based on the Company's historical volatility; 3) risk-free interest rate based on the Treasury yield on the date of grant; and 4) expected term of 6.25 years. The resulting compensation expense is recognized over the requisite service period, which is generally four years, net of actual forfeitures. Restricted shares and units granted to employees and non-employee directors 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 2022 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, 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, 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, 2023, the Company had 3,650,115 shares of common stock issuable upon the exercise of outstanding options and stock appreciation rights at a weighted average exercise price of $3.93 per share, 49,375,135 shares of our common stock issuable upon conversion of our Series A Convertible Preferred Stock, and 1,502,131 shares of unvested restricted share units. The Company had no unearned restricted shares outstanding for the period ended December 31, 2023.

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 products against defects in material or workmanship for one year following sale or installation. Contracts related to the sale of systems typically contain a service-type warranty which is accounted for as a separate performance obligation in ASC 606, *Revenue from Contracts with Customers*. For assurance-type warranties, 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

No single customer accounted for more than 10% of total revenue for the years ended December 31, 2023 and 2022. No single country, other than the U.S., accounted for more than 10% of total revenue for the years ended December 31, 2023 and 2022.

Recently Issued Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 Company adopted the standard in the first quarter of 2023. The adoption of ASC 326 had no material impact on the Company's financial results for any prior periods, therefore no cumulative adjustment to beginning retained earnings was recorded.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"), which requires enhanced income tax disclosures, primarily related to the effective tax rate reconciliation and income taxes paid. The Company does not expect a significant impact on its income tax disclosures upon adoption of the ASU which will be effective in the Company's year ending December 31, 2025.

3. Financial Instruments

The following table summarizes the Company's cash and held to maturity securities' amortized cost, gross unrealized gains, gross unrealized losses, and fair value by significant investment category reported as cash and cash equivalents, restricted cash and investments as of December 31, 2023 and 2022:

	December 31, 2023							
	Valuation				Balance Sheet Classification			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Cash and Cash Equivalents	Restricted Cash-current	Short-term Investments	Restricted Cash
Cash	$ 2,122	$ -	$ -	$ 2,122	$ 2,122	$ -	$ -	$ -
Level 2								
Money market funds	18,440	-	-	18,440	17,696	525	-	219
US treasury securities	-	-	-	-	-	-	-	-
Corporate debt securities	-	-	-	-	-	-	-	-
Subtotal	18,440	-	-	18,440	17,696	525	-	219
Total assets measured at fair value	**$ 20,562**	**$ -**	**$ -**	**$ 20,562**	**$ 19,818**	**$ 525**	**$ -**	**$ 219**

	December 31, 2022							
	Valuation				Balance Sheet Classification			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Cash and Cash Equivalents	Restricted Cash-current	Short-term Investments	Restricted Cash
Cash	$ 3,258	$ -	$ -	$ 3,258	$ 3,258	$ -	$ -	$ -
Level 2								
Money market funds	1,615	-	-	1,615	346	525	-	744
US treasury securities	14,833	2	(2)	14,833	4,982	-	9,851	-
Corporate debt securities	9,993	-	(6)	9,987	-	-	9,993	-
Subtotal	26,441	2	(8)	26,435	5,328	525	19,844	744
Total assets measured at fair value	**$ 29,699**	**$ 2**	**$ (8)**	**$ 29,693**	**$ 8,586**	**$ 525**	**$ 19,844**	**$ 744**

Interest income recorded for these cash and investments was $1.1 million and $0.5 million during the years ended December 31, 2023, and December 31, 2022, respectively.

As of December 31, 2023 and 2022, the Company did not have any financial assets classified as Level 1 or Level 3 nor did the Company have financial liabilities valued at fair value on a recurring basis.

4. Inventory

Inventory consists of the following (in thousands):

	December 31, 2023	December 31, 2022
Raw materials	$ 5,918	$ 6,556
Work in process	1,034	530
Finished goods	3,413	2,697
Reserve for excess and obsolescence	(1,939)	(1,907)
Total inventory	$ 8,426	$ 7,876

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other assets consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Prepaid expenses	$ 181	$ 605
Prepaid commissions	110	187
Deposits	424	669
Other assets	98	72
Total prepaid expenses and other assets	813	1,533
Less: Noncurrent prepaid expenses and other assets	(137)	(208)
Total current prepaid expenses and other assets	$ 676	$ 1,325

6. Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Equipment	$ 4,269	$ 4,393
Leasehold improvements	2,911	2,692

Construction in process	-	204
	7,180	7,289
Less: Accumulated depreciation	(3,876)	(3,458)
Net property and equipment	$ 3,304	$ 3,831

The Company retired approximately $0.2 million of fully depreciated assets during the years ended December 31, 2023 and 2022. The Company had less than $0.1 million and approximately $1.2 million of property and equipment additions during the year ended December 31, 2023 and 2022, respectively, associated with the buildout of the new leased space in St. Louis, Missouri.

7. Leases

On March 1, 2021, the Company entered into an office lease agreement (the "Lease") with Globe Building Company (the "Landlord"), under which the Company leases 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.

As of December 31, 2023, the weighted average discount rate for operating leases was 9% and the weighted average remaining lease term for operating lease term is 7.99 years.

The following table represents lease costs and other lease information (in thousands):

	Year Ended December 31,	
	2023	**2022**
Operating lease cost	$ 908	$ 909
Short-term lease cost	17	28
Total net lease cost	$ 925	$ 937
Cash paid within operating cash flows	$ 1,000	$ 1,126

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, 2023, were as follows (in thousands):

	December 31, 2023
2024	$ 898
2025	919
2026	935
2027	956
2028	976
2029 and thereafter	3,054
Total lease payments	$ 7,738
Less: Interest	(2,248)
Present value of lease liabilities	$ 5,490

8. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2023	**December 31, 2022**
Accrued salaries, bonus, and benefits	$ 1,222	$ 1,381
Accrued licenses and maintenance fees	484	484
Accrued warranties	107	163
Accrued professional services	138	129
Deferred contract obligation	1,045	1,045
Other	19	155
Total accrued liabilities	3,015	3,357
Less: Long term accrued liabilities	(43)	(51)
Total current accrued liabilities	$ 2,972	$ 3,306

Certain prior year amounts have been reclassified to conform to the 2023 presentation.

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, 2023.

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 (the "Series B Preferred Stock"), $0.001 par value per share which were convertible into shares of the Company's common stock, at a price of $2.05 per share. In April 2023, all of the outstanding shares of Series B Convertible Preferred Stock were converted into shares of common stock on a one-for-one basis by the holder. The Series B Preferred Stock, which was a common stock equivalent but non-voting and with a blocker on conversion if the holder exceeded a specified threshold of voting security ownership, was 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 Preferred Stock was 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 $7.1 million for the years ended December 31, 2023 and 2022. The Company had approximately $37.0 million and $44.1 million of total unrecognized stock-based compensation expense remaining as of December 31, 2023 and 2022, respectively, under the CEO Performance Award assuming the grantee’s continued employment as CEO of the Company, or in a similar capacity, through 2030. As of December 31, 2023, none of the performance milestones established by the 2021 CEO Incentive Program have been achieved and no awards have been earned.

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 February 2022, the Compensation Committee of the Board of Directors adopted the 2022 Stock Incentive Plan (the “Plan”) which was subsequently approved by the Company’s shareholders. This plan replaced the 2012 Stock Incentive Plan which expired on May 19, 2022.

As of December 31, 2023, the Company had 2,690,393 remaining shares of the Company’s common stock to provide for current and future grants under its various equity plans.

The 2022 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 2022 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 2022 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.

The fair value of the grants of restricted shares and units is determined based on the closing price of our stock on the date of grant. Restricted stock unit grants are time-based and generally vest over a period of four years except for grants to directors which are generally earned over a period of six months.

As of December 31, 2023, 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 $3.2 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, 2023, is as follows:

	Number of Options/SARs	Range of Exercise Price	Weighted Average Exercise Price per Share
Outstanding, December 31, 2022	3,208,065	$0.74 - $9.87	$ 4.21
Granted	724,000	$1.51 - $2.57	$ 2.53
Exercised	(33,929)	$0.74 - $2.03	$ 1.09
Forfeited	(248,021)	$0.74 - $9.20	$ 3.96
Outstanding, December 31, 2023	3,650,115	$0.74 - $9.87	$ 3.93

As of December 31, 2023, the weighted average remaining contractual life of the options and stock appreciation rights outstanding was 6.88 years. Of the 3,650,115 options and stock appreciation rights that were outstanding as of December 31, 2023, 2,364,166 were vested and exercisable with a weighted average exercise price of $3.93 per share and a weighted average remaining term of 6.0 years.

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

	Year Ended December 31, 2023				
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	314,887	4.16	$ 0.74	314,887	$ 0.74
$1.01 - $2.00	80,516	8.52	$ 1.57	22,771	$ 1.47
$2.01 - $4.00	1,241,853	7.12	$ 2.33	600,481	$ 2.07
$4.01 - $10.00	2,012,859	7.08	$ 5.50	1,426,027	$ 5.45
	3,650,115	6.88	$ 3.93	2,364,166	$ 3.93

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 as of December 31, 2023. The intrinsic value of the options and stock appreciation rights outstanding as of December 31, 2023, was approximately $0.3 million based on a closing share price of $1.75 on December 31, 2023. There were 337,408 fully vested options or stock appreciation rights outstanding as of December 31, 2023, with an exercise price lower than the closing stock price on December 31, 2023. During the year ended December 31, 2023, the aggregate intrinsic value of options and stock appreciation rights exercised under the Company's stock option plans was less than $0.1 million.

The intrinsic value of the options and stock appreciation rights outstanding at December 31, 2022, was approximately $0.5 million based on a closing share price of $2.07 on December 31, 2022. There were 881,207 fully vested options or stock appreciation rights outstanding as of December 31, 2022, with an exercise price less than the closing stock price on December 31, 2022. During the year ended December 31, 2022, the aggregate intrinsic value of options and stock appreciation rights exercised under the Company's stock option plans was $0.1 million.

The weighted average grant date fair value of options granted during the years ended December 31, 2023 and 2022, was $2.53 per share and $4.49 per share, respectively.

A summary of the restricted stock unit activity for the year ended December 31, 2023, is as follows:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value per Unit
Outstanding, December 31, 2022	1,208,739	$ 4.21
Granted	610,038	$ 1.97
Vested	(316,646)	$ 1.17
Outstanding, December 31, 2023	1,502,131	$ 3.94

The intrinsic value of restricted stock units outstanding as of December 31, 2023, was $2.6 million based on a closing share price of $1.75 as of December 31, 2023. The intrinsic value of restricted stock units outstanding as of December 31, 2022, was $2.5 million based on a closing share price of $2.07 as of December 31, 2022. During the year ended December 31, 2023, the aggregate intrinsic value of restricted stock units vested was $0.6 million determined at the date of vesting.

2022 Employee Stock Purchase Plan

In 2022, the Company adopted its 2022 Employee Stock Purchase Plan ("ESPP"). 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, 2023, there were 107,688 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, and the issuance of options granted under the Company's stock option plan and its stock purchase plan as follows:

	December 31, 2023	December 31, 2022
Series A Convertible Preferred Stock	54,704,831	45,023,612
Series B Convertible Preferred Stock	-	5,610,121
Performance Share Unit Plan	13,000,000	13,000,000
Stock award plans	2,690,393	3,930,952
Employee Stock Purchase Plan	107,688	164,654
	70,502,912	67,729,339

10. Income Taxes

The provision for income taxes consists of the following (in thousands):

	Year Ended December 31,	
	2023	2022
Deferred:		
Federal	$ (2,108)	$ (1,990)
State and local	(773)	(93)
	(2,881)	(2,083)
Valuation allowance	2,881	2,083
	$ —	$ —

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,	
	2023	2022
U.S. statutory income tax rate	21.0%	21.0%
State and local taxes, net of federal tax benefit	1.7%	1.1%
Stock compensation permanent differences between book and tax	(7.2)%	(7.1)%
Other permanent differences between book and tax	(2.4)%	(3.0)%
State rate adjustments	2.1%	(0.6)%
Other adjustments	(1.3)%	-%
Valuation allowance	(13.9)%	(11.4)%
Effective income tax rate	—%	—%

The stock compensation permanent difference relates to the February 3, 2021, Board approved grant of 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 $7.1 million in each of the years ended December 31, 2023 and 2022, respectively, of which only a portion was allowed as a tax deduction in those years due to Internal Revenue Code Section 162(m) limitations. Included in other permanent differences between book and tax in the table above 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 (in thousands):

	Year Ended December 31,	
	2023	2022
Current accruals	$ 1,041	$ 859
Operating lease liabilities	1,330	1,360
Deferred revenue	68	96
Depreciation and amortization	3,172	2,007
Deferred compensation	1,570	1,525
Net operating loss carryovers	29,118	27,629
Deferred tax assets	36,299	33,476
Valuation allowance	(35,066)	(32,184)
Net deferred tax assets before deferred tax liabilities	1,233	1,292
Operating lease right-of-use assets	(1,207)	(1,249)
Capitalized compensation costs	(26)	(43)
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 deferred tax assets.

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

As of December 31, 2023, the Company had gross federal net operating loss carryforwards of approximately $127.4 million. The federal net operating loss carryforwards reflect accumulated book losses reduced for the 2013 IRC Section 382 ownership change limitation of $213.7 million, book/tax differences and expiration of unused carryforwards. The federal net operating loss carryforwards generated prior to the 2018 tax year of approximately $98.8 million will expire between 2030 and 2037. The federal net operating losses generated in 2018 and thereafter will be carried forward indefinitely as a result to changes in the tax law following the Tax Cuts and Jobs Act. As of December 31, 2023, we had gross state net operating loss carryforward of approximately $40.2 million which will expire at various dates between 2024 and 2042 if not utilized.

On December 31, 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 funded the federal government to the end of the fiscal 2020 year and provided 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 Payroll Protection Program funds. The Company will continue to monitor additional legislation related to COVID-19 and its impact on our operations.

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, 2003, forward, all tax years from 2003 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.

As of December 31, 2023 and 2022, the Company had less than $0.1 million in reserves for uncertain tax positions. The Company recognizes interest accrued, if any, net of tax and penalties, related to unrecognized tax benefits as components of the income tax provision, as applicable. As of December 31, 2023 and 2022, accrued interest and penalties were less than $0.1 million.

11. 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 (in thousands):

	Year Ended December 31,	
	2023	**2022**
Net loss	$ (20,713)	$ (18,292)
Cumulative dividend on convertible preferred stock	(1,343)	(1,343)
Net loss attributable to common stockholders	$ (22,056)	$ (19,635)
Weighted average number of common shares and equivalents:	80,702,358	76,061,183
Basic EPS	$ (0.27)	$ (0.26)
Diluted EPS	$ (0.27)	$ (0.26)

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

	December 31,	
	2023	**2022**
Shares issuable upon vesting/exercise of:		
Options to purchase common stock	3,650,115	3,208,065
Series A Convertible Preferred Stock and Accumulated Dividends	49,375,135	47,364,216
Series B Convertible Preferred Stock	-	5,610,121
Restricted stock units	1,502,131	1,208,739
	54,527,381	57,391,141

12. 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, 2023 and 2022.

13. 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 (in thousands):

	December 31, 2023	**December 31, 2022**
Warranty accrual, beginning of the fiscal period	$ 163	$ 242
Accrual adjustment for product warranty	547	113
Payments made	(603)	(192)
Warranty accrual, end of the fiscal period	$ 107	$ 163

14. 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. Subsequent to year end, security agreements have been executed under the provisions of the Uniform Commercial Code ("UCC"), and UCC financing statements have been filed by a vendor on underlying inventory for approximately $0.6 million. We believe the financing statements have been filed without merit, and we fully intend on contesting the propriety of such actions.

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, the third was delivered in October 2021, and the fourth was delivered in January 2022. The amount available under this letter of credit automatically reduces by one fortieth at the end of each month during the lease term.

15. 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, 2023 and 2022 were as follows (in thousands):

	Year Ended December 31,	
	2023	**2022**
United States	$ 18,199	$ 19,708
International	8,572	8,439
Total	$ 26,771	$ 28,147

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.

16. 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, 2023, 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, 2023. 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, 2023.

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"), within 120 days after December 31, 2023, 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, 37, 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. 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. Mr. Fischel's extensive understanding of our business, operations and strategy, as well as financial and medical device industry experience, enable him to make valuable contributions to the Board of Directors.

Kimberly R. Peery
Chief Financial Officer

Officer since October 2019

Ms. Peery, 55, 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 66 herein.

SCHEDULE II
VALUATION AND QUALIFYING ACCOUNTS
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022

	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, 2023	$ 235	554	(117)	$ 672
Year ended December 31, 2022	$ 180	118	(63)	$ 235
Allowance for inventories valuation:				
Year ended December 31, 2023	$ 1,907	83	(51)	$ 1,939
Year ended December 31, 2022	$ 2,165	112	(370)	$ 1,907

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	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#	Stereotaxis, Inc. 2022 Stock Incentive Plan, incorporated by reference to Exhibit 10.1 of Registrant's Form 10-Q (File No. 001-36159) for the fiscal quarter ended June 30, 2022.
10.1b#	Form of Restricted Share Unit Terms of Award Under Stereotaxis, Inc. 2022 Stock Incentive Plan, Director Award, incorporated by reference to Exhibit 10.1b of the Registrant's 10-K (File No. 001-36159) for the fiscal year ended December 31, 2022.
10.1c#	Form of Incentive Stock Option Award Agreement under the 2022 Stock Incentive Plan, incorporated by reference to Exhibit 10.1c of the Registrant's 10-K (File No. 001-36159) for the fiscal year ended December 31, 2022.
10.1d#	Form of Non-Qualified Stock Option Award Agreement under the 2022 Stock Incentive Plan, incorporated by reference to Exhibit 10.1d of the Registrant's 10-K (File No. 001-36159) for the fiscal year ended December 31, 2022.
10.1e#	2022 Employee Stock Purchase Plan, 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, 2022.
10.1f#	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.
10.1g#	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.
10.1h#	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.
10.1i#	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.
10.1j#	Form of Restricted Share Unit Terms of Award Under Stereotaxis, Inc. 2012 Stock Incentive Plan, Director Award, incorporated by reference to Exhibit 10.2 of the Registrant's Form 10-Q (File No. 001-36159) for the fiscal quarter ended March 31, 2017.
10.1k#	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.
10.1l#	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.
10.1m#	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#	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.
10.3#	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.

10.4#	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.
10.5#	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.
10.6a†	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.
10.6b†	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.
10.6c	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.
10.7	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.
10.8a	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.
10.8b	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.
10.8c	Second Amendment to Office Lease dated November 05, 2021, between Registrant and Globe Building Company, GP incorporated by reference to Exhibit 10.12i of the Registrant's Form 10-K (File No. 001-36159) filed on March 10, 2022.
10.9	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.
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.
22.1	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).
97.1	Policy for Recovery of Erroneously Awarded Compensation (filed herewith).

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 8, 2024

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 8, 2024
/s/ Kimberly R. Peery **Kimberly R. Peery**	Chief Financial Officer (principal financial officer and principal accounting officer)	March 8, 2024
/s/ David W. Benfer **David W. Benfer**	Director	March 8, 2024
/s/ Nathan Fischel **Nathan Fischel**	Director	March 8, 2024
/s/ Myriam J. Curet Myriam J. Curet	Director	March 8, 2024
/s/ Arun Menawat **Arun Menawat**	Director	March 8, 2024
/s/ Robert J. Messey **Robert J. Messey**	Director	March 8, 2024
/s/ Ross B. Levin **Ross B. Levin**	Director	March 8, 2024

Exhibit 22.1

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-3 No. 333-233846) of Stereotaxis, Inc. pertaining to the registration of 12,195,121 of shares of common stock of Stereotaxis, Inc.

4) Registration Statement (Form S-8 No. 333-258751) of Stereotaxis, Inc. pertaining to Stereotaxis, Inc. 2012 Stock Incentive Plan, as Amended and Restated, and David L. Fischel CEO Performance Share Unit Award

5) Registration Statement (Form S-8 No. 333-266776) of Stereotaxis, Inc. pertaining to Stereotaxis, Inc. 2022 Stock Incentive Plan and 2022 Employee Stock Purchase Plan

6) Registration Statement (Form S-3 No. 333-272101) of Stereotaxis, Inc., pertaining to registration of 91,221,439 shares of common stock of Stereotaxis, Inc.

7) Registration Statement (Form S-3 No. 333-272102) of Stereotaxis, Inc. pertaining to registration of 100,000,000 of debt securities, common stock, preferred stock, warrants, rights, or units of Stereotaxis, Inc.

of our reports dated March 8, 2024 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, 2023.

/s/ Ernst & Young LLP

St. Louis, Missouri
March 8, 2024

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 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 8, 2024

/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 8, 2024

/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, 2023 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 8, 2024

/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, 2023 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 8, 2024

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

STEREOTAXIS, INC.

INCENTIVE COMPENSATION RECOVERY POLICY

I. Introduction

The Board of Directors (the "**Board**") of Stereotaxis, Inc. (the "**Company**") has adopted this Incentive Compensation Recovery Policy (this "**Policy**") to provide for the recovery of certain executive compensation in the event of an Accounting Restatement resulting from material noncompliance with financial reporting requirements under the U.S. federal securities laws. This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 811 of the NYSE American Company Guide ("**Company Guide**"), which implements Rule 10D-1 under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**") (as promulgated pursuant to Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010).

II. Administration

This Policy shall be administered by the Compensation Committee of the Board (the "**Committee**"). Any determinations made by the Committee shall be final and binding on all affected individuals.

III. Definitions

For purposes of this Policy, the following capitalized terms shall have the meanings set forth below:

(a) "**Accounting Restatement**" means an accounting restatement (i) due to the material noncompliance of the Company with any financial reporting requirement under the U.S. federal securities laws, including any required accounting restatement to correct an error in previously issued financial restatements that is material to the previously issued financial statements (a "Big R" restatement), or (ii) that corrects an error that is not material to previously issued financial statements, but would result in a material misstatement if the error were not corrected the current period or left uncorrected in the current period (a "little r" restatement). Changes to the Company's financial statements that do not represent error corrections are not an Accounting Restatement, including: (A) retrospective application of a change in accounting principle; (B) retrospective revision to reportable segment information due to a change in the structure of the Company's internal organization; (C) retrospective reclassification due to a discontinued operation; (D) retrospective application of a change in reporting entity, such as from a reorganization of entities under common control; and (E) retrospective revision for stock splits, reverse stock splits, stock dividends or other changes in capital structure.

(b) "**Covered Executives**" means the Company's current and former Executive Officers, as determined by the Committee in accordance with Section 10D of the Exchange Act, Rule 811 and any other applicable NYSE American listing rules or standards.

(c) "**Erroneously Awarded Compensation**" means, with respect to each Covered Executive in connection with an Accounting Restatement, the amount of Recovery Eligible Incentive-based Compensation that exceeds the amount of Incentive-based Compensation that otherwise would have been Received had it been determined based on the restated amounts, computed without regard to any taxes paid.

(d) "**Executive Officer**" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person (including any executive officer of the Company's affiliates) who performs similar policy-making functions for the Company. Executive officers of the Company's subsidiaries are deemed executive officers of the Company if they perform such policy making functions for the Company. The term "Executive Officer" includes, without limitation, those officers identified by the Company in any disclosure made pursuant to the requirements of Regulation S-K Item 401(b).

(e) "**Financial Reporting Measures**" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return (and any measures that are derived wholly or in part from stock price or total shareholder return) shall for purposes of this Policy be considered Financial Reporting Measures. For the avoidance of doubt, a Financial Reporting Measure need not be presented in the Company's financial statements or included in a filing with the SEC.

(f) "**Incentive-based Compensation**" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure. Incentive-Based Compensation does not include base salary, bonus awards that are discretionary or based on subjective goals or goals unrelated to Financial Reporting Measures, equity awards that vest exclusively upon completion of a specified employment period, without any performance condition, and equity awards that vest based on milestones or performance conditions that are unrelated to Financial Reporting Measures.

(g) "**NYSE American**" means NYSE American LLC.

(h) "**Received**" - Incentive-based Compensation shall be deemed "received" in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-based Compensation award is attained, even if payment or grant of the Incentive-based Compensation occurs after the end of that period or is subject to additional time-based vesting requirements.

(i) "**Recovery Eligible Incentive-based Compensation**" means, in connection with an Accounting Restatement and with respect to each individual who served as a Covered Executive at any time during the applicable performance period for any Incentive-based Compensation (whether or not such Covered Executive is serving at the time the Erroneously Awarded Compensation is required to be repaid to the Company), all Incentive-based Compensation Received by such Covered Executive (i) on or after October 2, 2023, (ii) after beginning service as a Covered Executive, (iii) while the Company has a class of securities listed on a national securities exchange or a national securities association, and (iv) during the applicable Recovery Period.

(j) "**Recovery Period**" means, with respect to any Accounting Restatement, the three completed fiscal years of the Company immediately preceding the Restatement Date and any

transition period (that results from a change in the Company's fiscal year) of less than nine months within or immediately following those three completed fiscal years.

(k) "**Restatement Date**" means the earlier to occur of (i) the date that any of the Board, a committee of the Board or the officers of the Company authorized to take such action (if Board action is not required), concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, and (ii) the date a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

(l) "**SEC**" means the U.S. Securities and Exchange Commission.

IV. Repayment of Erroneously Awarded Compensation; Method of Recovery

(a) In the event of an Accounting Restatement, the Committee shall take reasonably prompt action after the Restatement Date to determine the amount of any Erroneously Awarded Compensation for each Covered Executive in connection with such Accounting Restatement and, thereafter, shall promptly provide each Covered Executive with a written notice containing the amount of Erroneously Awarded Compensation and a demand for repayment or return, as applicable. For Incentive-based Compensation based on (or derived from) stock price or total shareholder return where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in the applicable Accounting Restatement, the amount shall be determined by the Committee based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return upon which the Incentive-based Compensation was Received (in which case the Company shall maintain documentation of such determination of that reasonable estimate and provide such documentation to NYSE American).

(b) The Committee shall have broad discretion to determine the appropriate means of recovery of Erroneously Awarded Compensation based on all applicable facts and circumstances and taking into account the time value of money and the cost to shareholders of delaying recovery, including without limitation: (i) requiring reimbursement of cash Incentive-based Compensation previously paid; (ii) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards; (iii) offsetting the amount of any Erroneously Awarded Compensation from any compensation otherwise owed by the Company to the Covered Executive; (iv) cancelling outstanding vested or unvested equity awards; and/or (v) taking any other remedial and recovery action permitted by law. For the avoidance of doubt, except as set forth in Section IV(d) below, in no event may the Company accept an amount that is less than the amount of Erroneously Awarded Compensation in satisfaction of a Covered Executive's obligations hereunder.

(c) To the extent that a Covered Executive fails to repay all Erroneously Awarded Compensation to the Company when due (as determined in accordance with Section IV(b) above), the Company shall take all actions reasonable and appropriate to recover such Erroneously Awarded Compensation from the applicable Covered Executive. The applicable Covered Executive shall be required to reimburse the Company for any and all expenses reasonably incurred (including legal fees) by the Company in recovering such Erroneously Awarded Compensation in accordance with the immediately preceding sentence.

(d) Notwithstanding anything herein to the contrary, the Company shall not be required to take the actions contemplated by Section IV(b) above if the following conditions are met and the Committee determines that recovery would be impracticable:

(i) the direct expenses paid to a third party to assist in enforcing this Policy against a Covered Executive would exceed the amount to be recovered, after the Company has made a reasonable attempt to recover the applicable Erroneously Awarded Compensation, documented such attempts and provided such documentation to NYSE American;

(ii) recovery would violate home country law where that law was adopted prior to November 28, 2022; provided that, before determining that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on violation of home country law, the Company has obtained an opinion of home country counsel (acceptable to NYSE American) that recovery would result in such a violation and a copy of the opinion is provided to NYSE American; or

(iii) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder.

V. Acknowledgement by Covered Executives

The Committee shall provide notice of this Policy to, and seek written acknowledgement of this Policy from, each Covered Executive in the form attached hereto as Exhibit A; provided that the failure to provide such notice or obtain such acknowledgement shall have no impact on the applicability or enforceability of this Policy.

VI. Reporting and Disclosure.

The Company shall file all disclosures with respect to this Policy in accordance with the requirement of the U.S. federal securities laws, including the disclosure required by applicable SEC filings.

VII. No Indemnification

Notwithstanding the terms of any of the Company's organizational documents, any corporate policy or any contract, the Company shall not indemnify any Covered Executive against the loss of any Erroneously Awarded Compensation or any claims relating to the Company's enforcement of its rights under this Policy nor shall the Company pay or reimburse any Covered executive for any insurance premium to cover the loss of any Erroneously Awarded Compensation.

VIII. Interpretation

The Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act and any applicable rules or standards adopted by the SEC or any national securities exchange or national securities association on which the Company's securities are listed.

IX. Amendment; Termination

The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary to reflect final regulations adopted by the SEC under Section 10D of the Exchange Act and to comply with the Company Guide or any rules or standards adopted by the NYSE American or any other national securities exchange or national securities association on which the Company's securities are listed. The Board may terminate this Policy at any time. Notwithstanding the foregoing, no amendment or termination of this Policy shall be effective if such amendment or termination would (after taking into account any actions taken by the Company contemporaneously with such amendment or termination) cause the Company to violate any U.S. federal securities laws, SEC rule, the Company Guide or the rules of NYSE American or any other national securities exchange or national securities association on which the Company's securities are listed.

X. Other Recovery Rights

The Board intends that this Policy will be applied to the fullest extent of the law. The Committee may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the effective date of this Policy shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. Any right of recovery under this Policy is in addition to, and not in lieu of, any other remedies or rights of recovery that may be available to the Company under applicable law, regulation or rule or pursuant to the terms of any similar policy, whether or not included in any employment agreement, equity award agreement, or similar agreement, and any other legal remedies or rights available to the Company.

XI. Successors

This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives.

Exhibit A

STEREOTAXIS, INC.

INCENTIVE COMPENSATION RECOVERY POLICY ACKNOWLEDGEMENT FORM

By signing below, the undersigned (i) acknowledges and confirms that the undersigned has received and reviewed a copy of the Incentive Compensation Recovery Policy (the "**Policy**") of Stereotaxis, Inc. (the "**Company**") and (ii) acknowledges and agrees that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by returning any Erroneously Awarded Compensation (as defined in the Policy) to the Company to the extent required by, and in a manner permitted by, the Policy.

_____

Signature
Print Name:
Date: