# Stereotaxis Submits 510(k) Application to FDA for Vdrive(TM) with V-Loop(TM) System

April 1, 2014

**Announces First Vdrive Duo System Installation in North America**

ST. LOUIS, April 1, 2014 (GLOBE NEWSWIRE) -- Stereotaxis, Inc. (Nasdaq:STXS) announced today that it has submitted a 510(k) Premarket Notification with the Food and Drug Administration (FDA) for the Company's Vdrive™ Robotic Navigation System with V-Loop™ Variable Loop Catheter Manipulator. This submission includes both the single arm system (Vdrive) and the two arm system (Vdrive Duo). If cleared by the FDA, the *Vdrive* with *V-Loop* system will be the Company's second *Vdrive* product to be cleared for use in the U.S. Its *Vdrive* with V-Sono™ Intracardiac Echocardiography Catheter Manipulator received FDA clearance in July 2013 and has been utilized in more than 75 cardiac ablation procedures to date in North America.

In addition, the company announced today that Sunnybrook Health Sciences Centre in Toronto, Canada has installed its Vdrive™ Duo System, representing the first installation of the Duo System in North America. An expansion of the *Vdrive* family of products, the *Vdrive* Duo System includes a second robotic arm offering remote control and manipulation of two compatible devices at the same time.

"Adding this technology to our minimally invasive arrhythmia lab, which is already cutting-edge with its use of robotic imaging-guided technology, is further enhancing the precision and safety of heart procedures," says Dr. Eugene Crystal, cardiologist and Director of Arrhythmia Services at Sunnybrook's Schulich Heart Centre. "We can now access really challenging areas of the heart chambers, which results in greater accuracy during ablation and a reduced risk of complications for patients."

The *Vdrive* with *V-Loop* system, already part of the clinical routine of several European electrophysiology (EP) labs, is indicated for remotely controlling the advancement, retraction, rotation, tip deflection, and loop size of a compatible catheter. In conjunction with the Company's Niobe® ES magnetic navigation system, the Vdrive with V-Loop system can improve efficiency and accuracy of loop catheter management during EP procedures. In the U.S., an estimated 60,000 loop catheters are used each year in complex EP procedures.

***About Stereotaxis***

Stereotaxis is a healthcare technology and innovation leader in the development of robotic cardiology instrument navigation systems designed to enhance the treatment of arrhythmias and coronary disease, as well as information management solutions for the interventional lab. With over 100 patents for use in a hospital's interventional surgical suite, Stereotaxis helps physicians around the world provide unsurpassed patient care with robotic precision and safety, improved lab efficiency and productivity, and enhanced collaboration of life-saving information. Stereotaxis' core Epoch™ Solution includes the Niobe® ES Remote Magnetic Navigation system, the Odyssey® portfolio of lab optimization, networking and patient information management systems and the Vdrive™ Robotic Mechanical Navigation system and consumables.

The core components of Stereotaxis systems have received regulatory clearance in the U.S., Europe, Canada and elsewhere. The V-Sono™ ICE catheter manipulator has received U.S. clearance, and the V-Loop™ circular catheter manipulator has been submitted for review by the U.S. Food and Drug Administration. For more information, please visit www.stereotaxis.com

*This press release includes statements that may constitute "forward-looking" statements, usually containing the words "believe," "estimate," "project," "expect" or similar expressions. Forward-looking statements inherently involve risks and uncertainties that could cause actual results to differ materially from the forward-looking statements. Factors that would cause or contribute to such differences include, but are not limited to, the Company's ability to raise additional capital on a timely basis and on terms that are acceptable, its ability to continue to manage expenses and cash burn rate at sustainable levels, its ability to continue to work with lenders to extend, repay or refinance indebtedness on acceptable terms, continued acceptance of the Company's products in the marketplace, the effect of global economic conditions on the ability and willingness of customers to purchase its systems and the timing of such purchases, the outcome of various shareholder litigation filed against Stereotaxis, competitive factors, changes resulting from the recently enacted healthcare reform in the U.S., including changes in government reimbursement procedures, dependence upon third-party vendors, timing of regulatory approvals, and other risks discussed in the Company's periodic and other filings with the Securities and Exchange Commission. By making these forward-looking statements, the Company undertakes no obligation to update these statements for revisions or changes after the date of this release. There can be no assurance that the Company will recognize revenue related to its purchase orders and other commitments in any particular period or at all because some of these purchase orders and other commitments are subject to contingencies that are outside of the Company's control. In addition, these orders and commitments may be revised, modified, delayed or canceled, either by their express terms, as a result of negotiations, or by overall project changes or delays.*

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