# Stereotaxis Receives FDA Clearance of Vdrive(TM) With V-Loop(TM) System

September 4, 2014

ST. LOUIS, Sept. 4, 2014 (GLOBE NEWSWIRE) -- Stereotaxis, Inc. (Nasdaq:STXS) announced today that it has received 510(k) clearance by the Food and Drug Administration (FDA) to market its Vdrive™ Robotic Navigation System with V-Loop™ Variable Loop Catheter Manipulator in the U.S The Company submitted a 510(k) Premarket Notification for the *Vdrive* with *V-Loop* system in March, following completion of a 120-patient, multi-center clinical study.

The *Vdrive* with *V-Loop* system is the Company's second *Vdrive* product to receive FDA clearance for use in the U.S. In July 2013, Stereotaxis was granted FDA clearance of its *Vdrive* with V-Sono™ ICE Catheter Manipulator. This past June, the Company submitted a 510(k) application to the FDA for its *Vdrive* with V-CAS™ Catheter Advancement System.

"This is another key step in our efforts to bring our full suite of *Vdrive* products to market in the U.S.," said William C. Mills, Stereotaxis Chief Executive Officer. "Our work to continually evolve the *Vdrive* platform and expand its availability reflects our commitment to achieving greater safety, operator efficiencies and patient outcomes in the electrophysiology (EP) lab through advanced robotic technologies."

Employed in conjunction with the Company's Niobe® ES magnetic navigation system, the *Vdrive* with *V-Loop* system is designed to remotely control the advancement, retraction, rotation, tip deflection and loop size of a compatible circular mapping catheter, which is used in approximately 60,000 complex EP procedures worldwide each year. With the launch of this new product in the U.S., the *Vdrive* Duo Robotic Navigation system can eliminate manual manipulation of the two most commonly repositioned diagnostic tools utilized during ablation procedures (variable loop and ICE catheters), enabling single user workflow and greater catheter stability.

***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. Over 100 issued patents support the Stereotaxis platform, which helps physicians around the world provide unsurpassed patient care with robotic precision and safety, improved lab efficiency and productivity, and enhanced integration of procedural 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 Navigation system and consumables.

The core components of Stereotaxis systems have received regulatory clearance in the U.S., European Union, Canada, China, Japan and elsewhere. The *V-Sono* ™ ICE catheter manipulator and *V-Loop* ™ variable loop catheter manipulator have received U.S. clearance, and the *V-CAS* ™ catheter advancement system 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, 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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