Stereotaxis Receives FDA Clearance of Vdrive(R) With V-CAS(TM) System Along With Regulatory Approval of Odyssey(R) System in Japan

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ST. LOUIS, Jan. 5, 2015 (GLOBE NEWSWIRE) -- Stereotaxis, Inc. (Nasdaq:STXS) announced today that it has received 510(k) clearance by the Food and Drug Administration (FDA) for its Vdrive® with V-CAS™ Catheter Advancement System in the U.S., representing the Company's third *Vdrive* system product to be cleared for market entry. The Company also announced that it has received regulatory approval of its Odyssey® product line by the Japan Pharmaceuticals and Medical Devices Agency, the country's equivalent to the U.S. FDA.

Stereotaxis' *Vdrive* with V-Loop™ Variable Loop Catheter Manipulator received U.S. clearance in September 2014 and its *Vdrive* with V-Sono™ Intracardiac Echocardiography Catheter Manipulator has been available since 2013.

"The *Vdrive* system and disposable suite provides flexibility in robotic catheter and sheath control, adaptable to a physician's individual workflow and product preferences," said William C. Mills, Stereotaxis Chief Executive Officer. "As additional *Vdrive* system accessories gain market approval in the U.S., we move closer to our vision of a fully remote electrophysiology procedure environment."

The *Vdrive* with *V-CAS* system, which was first released in Europe in 2011, allows physicians to remotely control the advancement, retraction and rotation of a compatible fixed curve transseptal sheath, in conjunction with a magnetic ablation catheter. Utilized in the majority of ablation procedures, the fixed curve transseptal sheath provides stability and support to the ablation catheter during therapy delivery.

Bruno Schwagten, M.D., Ph.D. at ZNA Middelheim Hospital in Belgium, who has performed Stereotaxis magnetic navigation procedures since 2008 and started using the *Vdrive* with *V-CAS* system in 2012, said, "The addition of robotic sheath control to a magnetic procedure has simplified the therapy process and enhanced patient safety, allowing me to efficiently access even the most challenging areas of the heart chambers."

In Japan, approval of the Stereotaxis Odyssey Vision™ system for use in conjunction with the Niobe® ES remote magnetic navigation system comes three months after the Company's first commercial order in that country. The *Odyssey Vision* system, together with the Odyssey Cinema™ solutions, provides a consolidated user interface of all lab information during a *Niobe* procedure, as well as real-time or recorded viewing of procedures across networks and institutions. The Company expects to submit its *Vdrive* system for regulatory review in Japan during the first quarter of 2015.

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, *V-Loop* ™ variable loop catheter manipulator and *V-CAS* ™ catheter advancement system have received U.S. clearance. 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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