Stereotaxis Submits 510(k) Application to FDA for Vdrive(TM) With V-CAS(TM) Catheter Advancement System

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ST. LOUIS, June 10, 2014 (GLOBE NEWSWIRE) -- Stereotaxis, Inc. (Nasdaq:STXS) announced today that it has submitted a 510(k) Premarket Notification to the Food and Drug Administration (FDA) for the Company's Vdrive™ Robotic Navigation System with V-CAS™ Catheter Advancement System. The submission, which follows the Company's 510(k) application for *Vdrive* with V-Loop™ Variable Loop Catheter Manipulator on March 31, includes both the single-arm system (Vdrive) and the two-arm system (Vdrive Duo).

The *Vdrive* with *V-CAS* system is currently available in the European Union and Canada and has been used in more than 1,100 procedures since its introduction in 2011. The system 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 greater stability and support to the ablation catheter during therapy delivery.

"We are excited about the prospect of bringing the *Vdrive* with *V-CAS* system to the U.S. market, where we believe it could have significant potential for streamlining physician workflow," said William C. Mills, Stereotaxis Chief Executive Officer. "With the addition of this system, physicians have reported improved maneuverability as well as efficient use of devices during remote magnetic 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. 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 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 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 has received U.S. clearance, and the *V-Loop* ™ variable loop catheter manipulator and V-CAS catheter advancement system have 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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