



Stereotaxis Receives FDA Clearance of Vdrive(TM) with V-Sono(TM) System

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Strengthens Niobe(R) Adoption and Opens Growing ICE Catheter Market to Company

ST. LOUIS, July 29, 2013 (GLOBE NEWSWIRE) -- Stereotaxis, Inc. (Nasdaq:STXS) announced today that it has been granted 510(k) clearance by the Food and Drug Administration (FDA) to market its Vdrive™ Robotic Navigation System with V-Sono™ Intracardiac Echocardiography (ICE) catheter manipulator in the U.S. This represents the first FDA clearance for the Vdrive family of products, which has been utilized in Europe since 2011.

"This is an exciting milestone for Stereotaxis," said William Mills, Stereotaxis Board Chairman and Interim Chief Executive Officer. "The Vdrive platform has added significant clinical value to a growing number of Niobe® ES labs in Europe, and this V-Sono clearance should accelerate procedure growth in our U.S. installed base as well as open up an untapped, expanding electrophysiology (EP) market where ICE catheters are widely utilized.

"More than 68,000 ICE catheters are used in U.S. EP labs each year, a number that is growing at an annual rate of 15%," Mr. Mills added.

The Vdrive with V-Sono system is indicated for the remote control of compatible ICE (or ultrasound) catheters inserted into the right atrium. For a Niobe ES remote magnetic navigation procedure, the Vdrive with V-Sono system can improve efficiency by enabling a single-operator workflow through eliminating the need for manual ICE manipulation inside the sterile and radiation field. In addition, procedural outcomes can be improved with more precise, stable ultrasound imaging, and radiation exposure to the clinical team can be further reduced. Based on preliminary clinical input received, the Company believes that the Vdrive with V-Sono system can bring similar benefits to additional types of procedures (beyond Niobe) that utilize ICE catheters.

First released in Europe in 2011, the Vdrive system has been utilized in over 2,000 clinical cases to date, of which 100 have utilized the V-Sono disposable, which was launched in Europe in 2012. The Company's Vdrive with V-Loop™ circular catheter manipulator is undergoing a five-center Investigational Device Exemption (IDE) study as part of a 510(k) submission to the FDA. This 120-patient IDE study has completed 60% of enrollment.

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 technologies are 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 is currently in clinical trials in order to obtain clearance 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, our continued access to capital and financial resources on a timely basis and on terms that are acceptable, our continued listing on the Nasdaq Global Market, 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 our systems and the timing of such purchases, the outcome of various shareholder litigation recently filed against us, 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.

CONTACT: Investor Contact:

Marty Stammer
Chief Financial Officer
314-678-6155

Investor Contact:

Todd Kehrli / Jim Byers
MKR Group, Inc.
323-468-2300

Stereotaxis, Inc.