FDA Clears Stereotaxis Magnetic Radio Frequency Guidewire for Peripheral Chronic Total Occlusions

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Revolutionary RF Guidewire Adds Large New Market Opportunity to Stereotaxis' Niobe(R) Platform

ST. LOUIS, Aug. 27 /PRNewswire-FirstCall/ -- Stereotaxis, Inc. (Nasdaq: STXS), announced today that it has received regulatory clearance from the U.S. Food and Drug Administration for its magnetically tipped, PowerAssert(TM) radiofrequency (RF) guidewire to cross chronic total occlusions in the peripheral vasculature.

Occluded or blocked arteries occur in patients with advanced peripheral arterial disease (PAD), and if left untreated can result in ulcerations and gangrene as well as significantly increased risk of limb loss and death. Eight to twelve million people have PAD, according to the American Heart Association. Stereotaxis' magnetically steerable RF guidewire is designed to ablate through chronic total occlusions (CTOs) in peripheral arteries. Its Niobe Magnetic Navigation System directs the guidewire's distal tip very precisely, allowing for accurate and efficient navigation through difficult to treat regions of the peripheral vasculature and CTOs.

"The safety and accuracy of the Stereotaxis system has been well documented in electrophysiology procedures, as have its ergonomic advantages and reduction of fluoro exposure," said John Young, MD, Director, Cardiovascular Innovation Program, The Ohio State University Medical Center, Columbus, Ohio. "With a growing diabetic population and increased prevalence of PAD, I am eager to use the magnetic RF guidewire. This will be the first CTO crossing device that can enable true intra-lesion steering, and I expect it to substantially improve the range of options for CTO treatment."

"Traditional, manual guidewires used for CTO crossing have little or no steering ability and therefore can only be used with great difficulty in tortuous vasculature, requiring a high level of operator skill and carrying a risk of vessel perforation," said Bevil J. Hogg, CEO of Stereotaxis. "Just as the safety, accuracy and efficacy of our Niobe Magnetic Navigation System have contributed significantly to the treatment of patients with cardiac arrhythmias in the field of electrophysiology, we believe that our PowerAssert RF guidewire will improve the prospects for treating patients with peripheral arterial disease. PowerAssert opens a significant new market opportunity for Stereotaxis, underscoring the Niobe system's capabilities as a platform for a broad and growing array of interventional procedures."

Stereotaxis is planning a limited clinical introduction of the guidewire to begin later this year, with a broader commercial launch to follow.

About Stereotaxis

Stereotaxis designs, manufactures and markets an advanced cardiology instrument control system for use in a hospital's interventional surgical suite to enhance the treatment of coronary artery disease and arrhythmias. The Stereotaxis System is designed to enable physicians to complete more complex interventional procedures by providing image guided delivery of catheters and guidewires through the blood vessels and chambers of the heart to treatment sites. This is achieved using computer-controlled, externally applied magnetic fields that govern the motion of the working tip of the catheter or guidewire, resulting in improved navigation, shorter procedure time and reduced x-ray exposure. The core components of the Stereotaxis system have received regulatory clearance in the U.S., Europe, Canada, China and Australia.

Safe Harbor

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, continued acceptance for the Company's products in the marketplace, competitive factors, the actual timing of regulatory approvals with respect to the magnetic irrigated catheter and otherwise, the timing of the re-introduction of the magnetic irrigated catheter in Europe and in the U.S., changes in government reimbursement procedures, dependence upon third-party vendors, 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 or canceled, either by their express terms, as a result of negotiations, or by project changes or delays.

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