



MiCardia Corporation Receives US FDA Market Clearance For Dynaplasty™ Annuloplasty Devices

Irvine, CA – September 9, 2008 – MiCardia Corporation announced today that the U.S. Food and Drug Administration (“FDA”) has granted 510(k) marketing clearance for its Dynaplasty™ Annuloplasty Band DR™ and Annuloplasty Ring DR. These are the first of MiCardia’s innovative *Dynaplasty Technology* products to receive clearance.

Commenting on this approval MiCardia Chief Executive Officer, Paul Molloy said, “This is a key regulatory milestone for MiCardia which involved extensive technical validation of the Company’s first generation annuloplasty system. It prepares the way for the progression of this highly unique and innovative *Dynaplasty Technology* and pairs with the commencement of the Company’s DYANA Phase I human study in Europe. To our knowledge, MiCardia is the only company developing intra-operative, percutaneous and completely non-invasive dynamically adjustable implantable devices for the \$15 billion annual CHF market.”

Dynaplasty Technology

MiCardia is an emerging company developing the novel *Dynaplasty Technology* for the percutaneous and non-invasive treatment of structural heart disease including Mitral Valve Regurgitation (“MVR”), Tricuspid Valve Regurgitation and Congestive Heart Failure (“CHF”). *Dynaplasty Technology* provides devices that can be implanted into the heart and then dynamically adjusted either during a procedure or post-operatively for the proper shape and size to produce the optimal clinical outcome both at the time of the procedure or at subsequent post-operative intervals.

Heart valve annuloplasty bands are used for the process of remodeling the fibrous tissue at the base of the valve, the annulus, thereby returning the valve to a state of leaflet coaptation and competency. Ischemic or degenerative conditions lead to the enlargement of the heart ventricle, causing the mitral valve annulus to distort and enlarge, which in turn renders the valve incompetent, allowing blood to reverse and leak back through the valve, clinically referred to as Mitral Valve Regurgitation. In order to repair the incompetent valve, annuloplasty rings are commonly used in mitral valve repair operations. The rings are implanted around the base of the valve to help maintain the natural shape, motion and flexibility of the annulus. Incomplete or inaccurate repair, or change in the anatomical conditions of the annulus, may result in post

operative residual or recurrent regurgitation, requiring high-risk repeat surgical intervention and often valve replacement with significant morbidity and mortality.

Among the numerous currently emerging technologies for achieving *Minimally Invasive* mitral valve repair, *Dynaplasty* is the only technology able to optimize mitral valve repair clinical outcomes intra-operatively, immediately post-operatively, and at later intervals as the disease condition continues to recur. Such long term mitral valve competency management is performed today through re-intervention, rendering the aged and advanced stage patient at high risk of complications and death associated with repeat surgery.

Ultimately, MiCardia's *Dynaplast Technology* will provide a reduced-risk alternative for MVR patients via intra-operative percutaneous or completely non-invasive mitral valve optimization.

MiCardia is a development-stage company located in Irvine, California. MiCardia is developing dynamically activated implantable devices for the treatment of heart disease. For more information about MiCardia, please visit the Company's website at www.micardia.com.

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