MiCardia Corp.

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Summary:	Patients requiring mitral valve repair of the heart to reduce recurrent leakage of blood or residual regurgitation after initial implant can now avoid going under the knife for a second time. MiCardia's Dynaplasty platform has been designed to change the shape of an implantable medical device in response to fluctuations in anatomical conditions. For mitral valve repair, MiCardia's shape-memory nitinol device is similar to a standard annuloplasty ring, but when activated, pulls the two leaflets together in such a fashion as to significantly minimize regurgitation.

Further Analysis:

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MiCardia Corp.

Optimizing mitral valve repair

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Web Site: www.micardia.com

Contact: Donald Rohrbaugh, CEO

Industry Segment: Cardiovascular Devices

Business: Implantable devices for mitral valve repair

Founded: October 2004

Founders: Michael Henson (MedFocus Family of Funds), Chairman; Samuel Shaolian, CTO

Employees: 15

Financing to Date: $23 million

Investors: BioStar Ventures; HBM BioCapital; MedFocus Family of Funds; Wexford Capital LP; Japan Asia Investment Company

Board of Directors: Michael Henson; Donald Rohrbaugh; Samuel Shaolian; Maurice Buchbinder, MD (Foundation for Cardiovascular Medicine); Thomas Thaler, PhD (HBM BioCapital)

Scientific Advisory Board: Maurice Buchbinder; Francis Shannon, MD (William Beaumont Hospital, Royal Park, MI); Ottavio Alfieri, MD (San Raffaele University, Milan, Italy); Patrick McCarthy, MD (Northwestern University); Steven Almany, MD (William Beaumont Hospital, Royal Park, MI), Nicholas Lembo, MD (Piedmont Hospital, Atlanta); Stefan Verheye, MD, PhD (Antwerp Cardiovascular Institute, Antwerp, Belgium)

Patients requiring mitral valve repair of the heart to reduce recurrent leakage of blood or residual regurgitation after initial implant can now be effectively treated without having to go under the knife for a second time. **MiCardia Corp.** has designed its *Dynaplasty* platform to change the shape of an implantable medical device in response to fluctuations in anatomical conditions. For mitral valve repair, MiCardia's shape-memory nitinol (nickel titanium) device is similar to a standard annuloplasty ring, but when activated, it pulls the two leaflets together in such a fashion as to significantly minimize regurgitation. The company employs its Dynaplasty technology to address both the surgical and transcatheter markets.

Today, only 20% of diagnosed mitral valve disease patients are treated with either a repair or replacement of their heart valve. The valve repair option represents about 35,000 cases annually in the US and another roughly 17,000 cases in Europe, adding up to a combined yearly monetary opportunity of about $120 million.

This compares to the much larger transcatheter market, which is estimated to be in the range of $1 billion to $2 billion annually because it can address the 80% of patients currently not treated.

MiCardia's *enCor* and *enCorSQ* mitral valve repair systems mend a regurgitant mitral valve with standard surgical implant techniques. However, the shape of the enCor can only be changed immediately after surgery while in the operating room to a reduced ring size to decrease the amount of residual regurgitation. The second-generation enCorSQ can be activated either at time of surgery or at a later date in a less-invasive manner, typically six months to one year after initial implanting since this is the time frame where 15 to 20% of patients experience significant recurrent mitral valve regurgitation.

CE mark for the enCor was obtained in October 2010; CE mark for enCorSQ is anticipated the second quarter of 2011. However, FDA PMA will likely not occur until 2014.

Since 2000, MiCardia's two co-founders – Michael Henson of MedFocus Family of Funds and Chief Technology Officer Samuel Shaolian – have started three other enterprises, including Vertelink Corp. (minimally invasive spinal surgery), which was sold to **Medtronic Inc.** in 2003. [W#200310187] After starting Vertelink, the two entrepreneurs founded Onset Medical Corp. (an expandable sheath introducer for cardiology) in 2002 and Ellipse Technologies Inc. (spinal rods capable of being lengthened or shortened) in 2005. "I've always had the dream to develop products that can be used for less-invasive procedures," Shaolian says. "Many patients have only one chance to undergo open-heart surgery. So having the ability to change the shape of their implant after surgery is extremely beneficial."

Prior to becoming CEO of MiCardia in July 2010, Donald Rohrbaugh was with the Baxter Healthcare Corp. division of Baxter International Inc. from 1977 to 1996, both as a division general manager and as a research and development vice president. Subsequently, Rohrbaugh served as CEO and consultant to multiple start-ups, including founding CEO at Acorn Cardiovascular Inc. (a cardiac support device for heart failure) from 1997 to 2001 and CEO of an Australian company, Sunshine Heart Co. Pty. Ltd. (another device for heart failure) from 2002 to 2009.

MiCardia has roughly 40 patents applications (14 issued) and does not share royalties and/or revenues with another entity.

The steps to implant the enCor and enCorSQ are the same and employ the existing methodologies of standard annuloplasty rings. Both devices have an electrical lead that connects to a generator, which provides radiofrequency energy to the ring for 30 to 60 seconds. "The slight amount of heat introduced to the ring allows the ring to change to a predetermined shape," Rohrbaugh explains. The dimensions of the device, which comes in five different sizes, can be reduced by approximately one ring-size to more effectively pull the leaflets closer together (the anterior-posterior dimension), but without reducing the cross-sectional area of the valve, so that the valve still maintains good blood-flow characteristics.

A follow-up, outpatient procedure under local anesthesia for activating the enCorSQ is scheduled after completing an imaging of the heart (echocardiogram) to determine the degree of regurgitation. The product is called SQ because the lead to activate the device is implanted subcutaneously.

Two human clinical studies of the enCor (one in the US, the other in Europe) comprising 40 patients found that the device functions as a normal annuloplasty ring for mitral valve repair and can change shape to effectively reduce mitral valve regurgitation. "Regurgitation was either totally reduced or reduced to merely traces," Shaolian reports. European studies of the enCorSQ will begin in early 2011.

Within the surgical arena for conventional rings, three competitors dominate with nearly 90% of the market: **Edwards Lifesciences Corp.**, Medtronic and **St. Jude Medical Inc.** "But none of these rings allow for shape readjustment. They are fixed and cannot be changed," Rohrbaugh states. "These other rings are also unable to

be activated either in the operating room or at a later date. So these companies are unable to address the substantial number of patients who have significant recurrent mitral valve regurgitation." The only option for these competing rings is for the patient to undergo another open-chest procedure, with the associated costs and risks, he says. "However, most patients prefer not to undergo another surgery."

To address the growing interventional cardiology market, the catheter-based *enCorTC* will allow for the implanting of the device without the need for cardiac surgery. CE mark is expected in 2012.

Both Edwards and Medronic offer transcatheter procedures for aortic valve replacement. In addition, **Abbott Laboratories Inc.** has the *MitraClip* System, a catheter-based device in clinical trials that essentially clips together the leaflets of the mitral valve. Two start-ups, **Guided Delivery Systems Inc.** and **Valtech Cardio Ltd.**, also have devices that squeeze together the annulus of the mitral valve at the time of implant. "We also can change the shape of the annulus at implant, but we believe our ability to change the shape of the annulus months to years later to address recurrent regurgitation is a significant differentiating feature," Rohrbaugh says.

The enCor began selling in Europe in December at a price ranging from $2,000 to $2,500 (not including nominal disposables), depending on country, through a distribution network. The implantation of the ring falls under existing reimbursement codes. Sales of enCorSQ are expected to begin mid-2011, likely as the same price of the enCor and again through distributors. And although the implantation code is the same, a new code will need to be generated for the activation portion.

Initially, the first-generation enCor will establish MiCardia in the repair business. Then, the second-generation enCorSQ will become the standard product because of physician flexibility as to when the device is activated to reduce regurgitation.

Launch of the enCorTC is still three to four years away, at an unknown price. "Only about 20% of today's patients with mitral valve disease are referred to a device therapy to reduce the regurgitation. This leaves 80% of the market that is not being effectively treated," Rohrbaugh notes. "A transcatheter approach will make people more receptive to having the repair procedure."

MiCardia has raised $23 million to date: a Series A round of $4.5 million in 2004, a Series B of $9 million in 2006, and a $4.8 million convertible note. [W#200630525] [W#200930486] [W#201030100] A $25 million Series C round targeting VC firms and strategic partners should close in April 2011. The company is also actively seeking a strategic partner, ideally a large, international cardiovascular medical device player for both validation of the technology and assistance with clinical trials and marketing.

The future bodes well for the company. Over the years, three major players have acquired transcatheter technologies to treat the aortic valve: Edwards Lifesciences purchased Percutaneous Valve Technologies Inc. in 2003, followed by Medtronic's 2009 acquisition of CoreValve Inc. (now **Medtronic CoreValve LLC**) and the 2010 buyout of **Sadra Medical Inc.** by **Boston Scientific Corp.** [W#200310215] [W#200910024] [W#201010151] **Evalve Inc.**, purchased by Abbott in 2009, has been the only transcatheter mitral valve technology acquired to date. [W#200910100]

"I expect additional mitral valve transcatheter companies to be acquired because I believe the market potential for mitral valve repair/replacement is $1 billion to $2 billion a year, which is two to three times greater than the transcatheter aortic valve repair/replacement market," Rohrbaugh points out. – Bob Kronemyer