Edwards Grabs Option to Acquire Transcatheter Mitral Valve Replacement Startup

By Varun Saxena

Originally published on FierceMedicalDevices

December 9, 2015 – Just as the flurry of M&A activity in the transcatheter mitral valve repair arena appears to be dying down, with nearly all of the developers snapped up by industry bigwigs, TAVR pioneer Edwards Lifesciences is threatening to start a run on related minimally invasive mitral valve replacement players too, thanks to the announcement of its exclusive option to acquire Baltimore's Harpoon Medical.

In addition, Edwards made an upfront investment in the company for an undisclosed sum, according to a line in a release describing its Dec. 9 investor conference with Wall Street.

The takeover of transcatheter mitral valve repair companies by industry bigwigs was entirely predictable, although the timing of such an occurrence was not. The run on transcatheter mitral valve replacement companies was characterized by the expensive takeover of many early-stage companies, so it shouldn't be a great surprise that the next potential scramble for repair players is starting just a few months after the previous one for replacement companies is dying down.

The economic and clinical success of transaortic valve replacements (TAVRs) has made the transcatheter mitral valve arena enticing to Edwards, Medtronic, Boston Scientific, Abbott and others, who have dropped a combined $100 million on the replacement side in recent month. Once the run on replacement players began, they quickly purchased the limited number of early-stage companies in order to not miss the first boat to commercialization.

That's because of a simple lesson from their experience with TAVRs: speed matters. First-comers Medtronic and Edwards dominate the TAVR arena, and their entrenched position is making life difficult for latecomers St. Jude Medical and Boston Scientific, whose CE marked devices don't have much market share in Europe, and still await FDA approval in the U.S.

Harpoon Medical's Harpoon system boasts some strong clinical data, or at least as strong as can be for such an early stage technology, *FierceMedicalDevices* previously reported.

The company reported at the TCT conference in San Francisco that all 10 patients in a feasibility study of its investigational minimally invasive mitral valve repair technology experienced a reduction or elimination of mitral valve regurgitation (MR).

MR occurs when blood flows backward with every contraction of the heart through ruptures in degenerated mitral valves and into the left atrium. The Harpoon system installs sutures, known as ePTFE neochords to plug the rupture in the valve. But it accomplishes the task using a minimally invasive technique conducted on a beating heart, sparing the patient from risky open-heart surgery, which involves use of a heart-lung machine while the heart is temporarily prevented from beating.

The Harpoon system exhibited a strong safety profile, with no adverse events such as stroke, heart attack or renal failure occurring. Two of the patients needed a reoperation in the days following the procedure, and one needed a reoperation for recurrent MR after a neochord became untied, according to the presentation slides.

While the Harpoon system does not involve the use of a delivery catheter, it still operates on the beating heart in a minimally invasive way, thereby avoiding many of the risks of open heart surgery, and shifting the risk/benefit profile in favor of earlier stage MR patients, who may otherwise adopt a wait-and-see approach to the condition.

Until now, transcatheter mitral valve replacement companies have generated more interest from industry leaders in part because they are a closer analogy to TAVRs (which are on the replacement, not repair side of the equation), with which they are more familiar. But the mitral valve's odd shape (unlike the circular aortic valve) and anatomy make implanting and securing an artificial mitral valve more technically challenging.

It's generally believed that both transcatheter mitral valve repair and replacement will play a role in the future, as both procedures are performed today using open heart surgery, which limits their utility--something that the new players hope to change by expanding the market with less invasive techniques.

Harpoon Medical and its competitors were also buoyed by a recent study published in the *New England Journal of Medicine*, which found that compared to mitral valve repair, mitral valve replacement results in a lower rate of heart failure and fewer

hospitalizations for cardiovascular complications at two years after surgery. But additional studies will be needed to determine if the *NEJM* findings related to devices that are surgically implanted using open heart surgery extend to transcatheter ones.

The only approved transcatheter devices for the mitral valve are in the repair arena, led by Abbott's FDA-approved Mitraclip, which earns about $250 million per year. The device was acquired by the takeover of Evalve for $410 million in 2009. Meanwhile Cardiac Dimension's Carillon device and Valtech's Cardioband have CE marks.

The latter is scheduled to soon become part of HeartWare, which seeks to join the arena, making it the only smaller company to join the wave of M&A related to transcatheter mitral valves.

Edwards has covered its bases on both sides of the mitral valve arena thanks to the option to acquire Harpoon Medical, combined with its acquisition of replacement player CardiAQ Valve Technologies for $350 million in cash, with an additional $50 million payable based on achieving a European regulatory milestone.

Edwards hopes the mitral valve market grows similarly to that for TAVRs, from which the company expects to earn $1.2 billion to $1.4 billion in 2016, representing a 10% to 18% underlying growth rate, according to the investor conference release.