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Edwards' \$350m CardiAQ buy ups mitral valve stakes



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Edwards Lifesciences' acquisition of transcatheter mitral valve replacement specialist CardiAQ Valve Technologies could be good news for the other smaller firms in the space if it spurs rival Medtronic to make a deal of its own.

Medtronic's mitral device is still in animal studies, but the company is no stranger to buying in innovation, and could look to the likes of Neovasc or Tendyne in a bid to keep up with – or overtake – Edwards. The latter is still ahead in the more established transcatheter aortic valve implantation (TAVI) market, and Medtronic is not used to playing second fiddle.

On top of the \$350m up front price of the deal, Edwards will pay CardiAQ's owners \$50m when it hits “a European regulatory milestone” – likely to be a CE mark for one or both of its valves. Edwards's shares were up 3% in early trade today.

The CardiAQ buy comes after a safety signal was seen with Edwards' own transcatheter mitral valve implantation (TMVI) contender, Fortis. The company halted a first-in-human trial in May after reports of thrombosis ([Edwards valve stumble makes Tiara sparkle, May 20, 2015](#)).

Edwards hasn't given up on its existing valve just yet, with a spokesperson telling *EP Vantage* that the company will continue with Fortis. It has recently reached agreement on protocol revisions to re-start enrollment. “We believe that Fortis and CardiAQ are complementary,” he said. “We plan to combine both companies' development programmes.”

Indeed, Edwards has had its eye on Irvine, California-based CardiAQ for some time, the spokesperson said. The company also claims to have the only device that uses a transvessel implantation approach to treat mitral regurgitation, which will allow transfemoral-transeptal delivery, via the femoral artery in the leg and then through the septum of the heart. One of the reasons catheter-mounted aortic valves have arrived sooner than mitral products is that owing to the heart's vasculature, mitral valves are trickier to deliver.

Last month, CardiAQ carried out the first human implant of its second-generation bioprosthetic mitral heart valve using this transfemoral-transeptal approach. Other TMVI devices in development are delivered transapically, through the chest and between the ribs, according to CardiAQ.

The company's valve can also be implanted transapically, and CardiAQ has already treated nine patients via this route. It is planning European trials to support CE marking of the device using both transapical and transfemoral access.

In addition, CardiAQ has the go-ahead from the US FDA to conduct a feasibility study of the second-generation device in up to 20 patients using both delivery methods.

Neovasc next?

With CardiAQ already taken, Medtronic might consider buying Neovasc, whose Tiara valve is the next most advanced TMVI product in development after Edwards' Fortis. However, doing so would involve taking on another legal battle with Edwards only a year after the companies settled their long-running TAVI spat, as CardiAQ is currently suing Neovasc for alleged fraud and misappropriation of trade secrets over the Tiara valve.

Another possible takeover target is Tendyne, which announced the first implant of its mitral valve in December, and its first US patient in April.

With the TMVI market expected to eventually outgrow the TAVI sector, it seems likely that Medtronic will buy into the field sooner or later.

Company	Device	Trial name	Trial description	Trial ID
Edwards Lifesciences	Fortis	-	European, 20 implants confirmed, full enrolment and completion date unknown	-
Neovasc	Tiara	Tiara-I	US and European, 30 patients, primary completion date December 2015	NCT02276547
Tendyne	Tendyne	Tendyne	US and Australian, 30 patients, primary completion date July 2015	NCT02321514
CardiaQ Valve Technologies	CardiaQ transapical	-	European, 60 patients, not yet recruiting, primary completion date December 2016	NCT02478008
CardiaQ Valve Technologies	CardiaQ transfemoral and transapical	-	US, 20 patients, completion date unknown	-

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