

## HeartWare falls further behind with next-gen device pause



[Madeleine Armstrong](#)

A setback for its next-generation heart pump has put HeartWare International even further behind arch-rival Thoratec. And with Thoratec now part of medtech giant St. Jude Medical, HeartWare looks increasingly at risk of becoming an also-ran.

The company had been pinning its hopes on its miniature MVAD pump, less than half the size of its already approved HVAD, to expand its franchise. But those hopes have been dashed after adverse events forced it to further delay a study of the MVAD.

HeartWare had already stopped enrolment in the CE mark trial in September due to manufacturing and software issues. But then it started investigating the adverse events and now is not sure if the trial can resume in November as planned.

The company's stock fell 12% on Monday and another 20% yesterday to a five-year low of \$35.21.

HeartWare did not give further details of the adverse events except to say they "are typical of those seen in other clinical trials for ventricular assist devices". It also did not say when it might be able to restart the trial, but added that it "remains confident in the MVAD system". So far, 11 out of 60 patients have been enrolled.

The company is promising more information when it reports Q3 results on October 29.

### Check mate

The news is all the more disheartening for HeartWare as it comes at the same time as St. Jude's announcement of a European CE mark for the next-generation HeartMate 3 - which also has a head start in the US, where patients are already being recruited for a 1,000-strong pivotal study.

HeartMate 3's smaller size and lower rate of thrombosis should help recapture some of the market share Thoratec has lost to HeartWare, and St. Jude's marketing might will not hurt either.

Of course, HeartWare still has its HVAD pump, but again it is at a disadvantage: the HVAD is only approved in the US as a bridge to heart transplant, while Thoratec's older HeartMate II is also indicated as a destination therapy.

And the HVAD might never get the green light for destination use - earlier this year, a head-to-head study found a higher-than-expected rate of stroke, despite showing that the HVAD was non-inferior to HeartMate II on the primary endpoint of two-year survival ([Investors in HeartWare wary of stroke rates, April 17, 2015](#)).

**Selected left ventricular assist devices**

Device	Company	Status
HeartMate II	Thoratec/St Jude	CE marked; FDA approved as bridge-to-transplantation and destination therapy
HVAD	HeartWare	CE marked; FDA approved as bridge-to-transplantation
HeartMate 3	Thoratec/St Jude	CE marked
MVAD	HeartWare	CE mark trial suspended

At the time of the St. Jude-Thoratec deal, HeartWare was mooted as a potential acquisition target. It now looks a lot less attractive, but there is always a chance that one of St. Jude's cardiology rivals could attempt to bag a bargain while its valuation is low.

Credit Suisse analysts have suggested that Medtronic, Boston Scientific and Edwards Lifesciences might be potential suitors, and Abbott could also be interested. However, the analysts added that any deal is unlikely to happen before data on the MVAD emerge.

### **Mitral valves**

HeartWare is also striking deals of its own as it tries to expand out of its core heart pump business, agreeing to buy transcatheter mitral valve repair/replacement specialist Valtech Cardio last month ([Mitralmania continues as HeartWare buys Valtech, September 03, 2015](#)).

Valtech's repair device Cardioband just received the CE mark, but it is probably not going to be a huge seller: Wells Fargo analysts predict revenues of \$20m and \$40m in 2016 and 2017 respectively.

The potentially more lucrative mitral valve replacement product Cardiovalve has not yet been implanted in humans, so is unlikely to provide any relief to HeartWare in the near future.

And even the Valtech deal is not going smoothly, with activist investor Engaged Capital publicly opposing the acquisition, a stance that HeartWare "respectfully disagrees" with.

HeartWare is beset on all sides, and while it might hope for a white knight to rescue it, potential acquirers are probably waiting for the MVAD to prove its worth. HeartWare needs to restart its trial as soon as possible before it sinks further into the doldrums.

<b>Device</b>	<b>Trial</b>	<b>ID</b>
MVAD	MVAdvantage	NCT01831544
HeartMate 3	Momentum 3	NCT02224755

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