Evaluate Vantage

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HeartWare loses heart for Valtech buy

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The heart pump developer HeartWare International had hoped to expand into a new area – mitral valve disease – by acquiring Valtech Cardio. But its investors had other ideas, and now they have got their way: the deal has been called off.

It seems that investors would prefer HeartWare to focus on its core left ventricular assist device (LVAD) market with the hope of attracting a buyer. But, after problems with HeartWare's next-gen technology, will anyone be interested?

At least, from a potential acquirer's perspective, HeartWare would be cheap. Its share price has slid from around $85 just before the Valtech deal was announced to around $38 currently.

And St. Jude Medical's recent purchase of the LVAD rival Thoratec shows that bigger players are interested in the sector (*St. Jude pumps up heart failure offering with $3.4bn Thoratec buy, July 22, 2015*).

MVAD delays

St. Jude's cardiology competitors Medtronic, Boston Scientific and Abbott could make a move for HeartWare. However, any buyer might want to wait until the company has cleared up the issues with its MVAD, a smaller version of its marketed HVAD.

A trial of the MVAD was halted in September on what seemed like minor problems, but in October came reports of adverse events, and earlier this month the company admitted that the device would have to be altered significantly to combat the side effect of pump thrombus (*HeartWare suffers from blocked pipeline, January 13, 2016*).

HeartWare is looking into software fixes, but in the worst-case scenario the device might have to be redesigned and a new trial would be needed, which would mean a delay of 12-18 months, say Barclays analysts.

Amid all this disruption HeartWare obviously did not have the stomach to press on with the Valtech buy in the face of fierce shareholder opposition. It is a victory for activist investors including Engaged Capital, which owns around 1.3% of the company and has sent various letters to HeartWare's board outlining why it should ditch the deal.

Silver linings

While HeartWare has had a rocky time of late, there are some reasons to be cheerful. The company plans to seek expanded US approval for its HVAD system as destination therapy in mid-2016, six months earlier than expected, setting it up to get the nod in the second half of 2017.

HeartWare still faces a battle to catch up with St. Jude, whose older pump HeartMate II has been approved as destination therapy since 2010, while its next-gen HeartMate 3 is already CE marked in Europe and in a US pivotal trial.

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

Even so, the HVAD is “not going out of business” and could compete effectively against HeartMate 3, the Barclays analysts believe. They note that results from the CE mark trial of the HVAD are roughly in line with the HeartMate 3 CE mark data and “compare favourably on stroke and infection”.

It is therefore possible that HeartWare’s underlying business is sound and its latest troubles are just a blip – which could tempt one of the big guns to snap it up at a bargain price, now that Valtech is off the scene. But any acquirer will want to keep an eye on how the MVAD saga plays out, so HeartWare could be waiting a little longer for a suitor to come calling.

Device	Study	Trial ID
MVAD	MVAdvantage	NCT01831544
HeartMate 3	Momentum 3	NCT02224755

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