Evaluate Vantage

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Interview – ReliantHeart relies on tech to lure buyer

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The heart pump space has been an active area for acquisitions recently, with the two main companies, Thoratec and HeartWare, both being bought in the last year or so. One of the few smaller groups left, ReliantHeart, has just CE marked its flagship aVAD device, which could help it attract the attention of the big players.

“Does my phone ring? Yes,” chief executive Rodger Ford tells *EP Vantage*. “There’s a lot of interest, but what I need to do is get my head down and concentrate on getting the job done.” That job is launching the aVAD in Europe in September, as well as preparing for a US trial slated to start in the first quarter of 2017. Further into the future, the company is developing a wireless device that Mr Ford believes could revolutionise the field.

For now, ReliantHeart is focused on the aVAD. The US study will enrol around 400 patients and pit the aVAD against Thoratec’s – soon to be Abbott’s – HeartMate II, the only such device approved in the US as a permanent implant. The study will test both short and long-term use of the aVAD; if all goes well approval in the former could come in 2019 and in the latter around a year later.

While Thoratec and HeartWare are left ventricular assist device (LVAD) success stories, other companies have not fared so well. Jarvik Heart and Berlin Heart have both had devices CE marked since the mid-2000s but have not managed to get FDA approval. Jarvik announced a US trial of its Jarvik 2000 pump in 2012, but has been quiet since then.

Selected implantable left ventricular assist devices

Company	Product	Status
Thoratec/St. Jude/ Abbott	HeartMate II	CE marked; FDA approved as bridge-to-transplantation and destination therapy
	HeartMate 3	CE marked
HeartWare/Medtronic	HVAD	CE marked; FDA approved as bridge-to-transplantation
	MVAD	CE mark trial suspended
Berlin Heart	Incor	CE marked
Jarvik Heart	Jarvik 2000	CE marked
ReliantHeart	aVAD	CE marked

Mr Ford is confident that ReliantHeart will not go the same way because of the company’s technology, initially developed by surgeon Michael DeBakey and MicroMed Technology, which ReliantHeart acquired in 2013. “Our pump is far superior to the HeartWare and Thoratec pumps,” he says.

No strokes

The aVAD uses an axial flow pump whereas newer rival products, Thoratec’s HeartMate 3 and HeartWare’s HVAD, employ centrifugal pumps, which have been linked with a higher incidence of stroke – particularly the latter (*Investors in HeartWare wary of stroke rates, April 17, 2015*).

“We haven’t had any strokes so far in 90 patients implanted with our devices,” Mr Ford says.

Thoratec’s older HeartMate II is also an axial flow device, but has its own problems, namely, a risk of blood

clots forming inside the pump.

Again, Mr Ford thinks the aVAD will sidestep this issue. “There’s evidence we don’t produce thrombi inside the pump, like HeartMate II does. HeartMate II has a big axle, small blades and a much bigger radial shear,” he says. Shear stress is thought to contribute to the formation of clots.

Meanwhile the aVAD “has a little axle and long blades, so there’s not much to occlude the flow. It’s like blowing through a big milkshake straw versus a bar straw.”

The aVAD is also much lighter at 84g, versus the HVAD’s 145g and HeartMate 3’s 220g. “If there’s a weight on the bottom of the heart it’s more difficult for it to carry out its natural function,” Mr Ford says.

Another feature unique to the aVAD, according to Mr Ford, is remote monitoring. “It’s the only remotely monitored VAD in the world – I mean real-time, all the time, from anywhere.” This can detect, for example, whether the pump has become occluded or whether the patient is dehydrated, which makes their blood more viscous and more difficult to pump.

Going wireless

ReliantHeart is working on a version of the aVAD with a disconnectable cable. This will prepare the ground for a fully implanted wireless device, called Liberty, which could be available in 2018.

Existing LVADs are connected, via a wire running from the device to the outside of the body, to an externally worn controller and battery pack. “Patients think twice about whether they want to live that way,” says Mr Ford.

Liberty, meanwhile, could be disconnected from an external power charging system for six to seven hours at a time. Even if other companies can develop wireless devices, they will not allow the same amount of freedom, he says.

“Power consumption is the barrier [to a wireless LVAD],” the chief exec explains. “Our system consumes one third the power of the HVAD and HeartMate 3. Patients using [wireless versions of] the competing systems – if they ever come to market – may enjoy just one or two hours of freedom.”

ReliantHeart has raised $22m so far and is looking for another $13m or so to fund the European launch and US study. If it clears the FDA hurdle, bigger companies could be interested.

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